



Methodology

This document was approved by ACOEM's Board of Directors on November 5, 2022.

1. Introduction

The American College of Occupational and Environmental Medicine (ACOEM) first published its *Occupational Medicine Practice Guidelines (Guidelines)* for common health disorders of workers in 1997 (1). In 2004, ACOEM released the second edition of the *Guidelines*, based on an updated search and evaluation of the literature (2). The methodology used for those editions was described in the introduction to each volume, and in other publications (3,4).

In early 2006, the President of ACOEM announced a schedule to produce updates of the *Guidelines*, and the formation of an updated Guideline development structure, including the Evidence-Based Practice Committee (EBPC), the Guideline Methodology Committee (GMC), and Evidence-Based Practice Panels (EBPPs). The GMC was asked to update and describe in depth the methodology to be used for all ACOEM evidence-based products and services. That document was approved by the ACOEM Board of Directors on November 13, 2006 and published in 2008 (5).

In 2007, the first guideline using the updated methodology was published. Additional ACOEM guidelines were produced over the next several years (6,7). In 2011, the entire second edition had been updated and published as the third edition of the *Guidelines* (7). Subsequently, there were additional advances in the science of developing quality Guidelines, and a new document from the Institute of Medicine (*Clinical Practice Guidelines We Can Trust*) was published (8). The 2017 ACOEM Guidelines Methodology document was updated to include those and other advances in guidelines development. Summary charts comparing ACOEM's methodology to the standards set in AGREE II, AMSTAR, GRADE, and IOM are available in [Appendices 1-4](#).

This 2022 Methodology includes further advancements in the science of evidence-based practice guidelines development. These include incorporation of scoring epidemiological articles using Ottawa-Newcastle scales (9,10) for those questions that are primarily addressed by epidemiological studies instead of randomized controlled trials.

Following are examples of how ACOEM's methodology has been improved to address the more detailed criteria for AGREE II additionally developed in AGREE-REX (**A**ppraisal of **G**uidelines **RE**search and **E**valuation - **RE**commendations **EX**cellence) (11). These examples include:

- (a) consistency of results among included studies;
- (b) addressing precision of point estimates;
- (c) providing quantified harms and benefits when known;
- (d) addressing directness of the evidence to the PICO(T) question;
- (e) assessing risk(s) of bias;
- (f) balancing strengths of recommendations against harms and benefits;
- (g) including assessment of potential confounding;
- (h) dose-response relationships when known;
- (i) including patient and/or provider flexibility where appropriate;
- (j) referring to algorithms, screening tools and other tools to facilitate adoption and implementation;

- (k) consideration of access to various interventions especially based on geographic limitations;
- (l) including economic analyses when available;
- (m) addressing barriers to adoption and implementation; and
- (n) monitoring data required.

In all cases, the PICO(T) questions addressed in the ACOEM Guidelines are of relevance and interest to affected populations. Guidelines end user's scopes of practice are necessarily broad, therefore, some PICO(T) questions will naturally not apply to all providers. Stakeholder inputs are sought from numerous sources (see below). The ACOEM Guidelines overall goals are in all cases to facilitate the earliest diagnosis and treatment to effect the earliest return to occupational and non-occupational function; in those cases where full recovery is not possible, then the goals are to facilitate the best function possible. Thus, ACOEM Guideline adoption can be reasonably projected to result in improved clinical outcomes.

2. Purpose and Scope

Purpose

The purpose of the *Guidelines* is to define evidence-based best practices for key areas of occupational health care and disability management in order to:

- Improve the accuracy and efficiency with which the diagnostic process is conducted;
- Identify the effectiveness and risks of treatments in resolving a disease process, structural pathology, or relieving symptoms and achieving functional improvement and return to work;
- Improve or restore the health of workers with occupationally related illnesses or injuries by using proven effective tests and treatments with net benefit;
- Improve the quality of occupational health care and disability management;
- Identify care pathways that facilitate the earliest return and/or preservation of function, and
- Enhance patient autonomy (12).

Scope

The *Guidelines* address the key domains of occupational medicine practice including:

- Diagnosing health problems likely to be work-related;
- Determining work-relatedness individually and collectively;
- Managing medical care;
- Treating work-related health problems efficiently and effectively;
- Managing associated disability and preventing work loss;
- Preventing work-related health problems; and
- Promoting health.

Examples of the broad clinical questions (13) that the *Guidelines* may address in these areas are listed in [Attachment 1](#).

The *Guidelines* contain “Foundations of Occupational Medicine Practice” and “Disorders.” The Foundation guidelines review prevention; initial assessment and documentation; initial approaches to treatment; work-relatedness; disability prevention/management; pain, suffering, and restoration of function; and independent medical examinations/consultations. The Disorders guidelines include complaints related to the neck and upper back; shoulder; elbow; forearm, wrist, and hand; low back; hip/groin; knee; ankle and foot; chronic pain; eye; traumatic brain injury; COVID-19; occupational asthma and interstitial lung disease; and workplace mental health (posttraumatic stress disorder, anxiety disorders, and depressive disorders).* The primary content of the Foundation guidelines include principles that are generally timeless and rarely need updating. However, the Disorders

guidelines require updating to include advancements in diagnosis and/or treatment by identifying new clinical questions to address for each clinical entity or diagnostic group. Questions are framed in PICO(T) format: population of interest, intervention, comparison group, and outcome (time or type) (14). The questions for etiology, diagnosis, and prognosis are framed in a modified PICO(T) format, emphasizing such factors as specific exposures or trauma for etiology or prevention, natural history for prognosis, and the reproducibility and performance of diagnostic tests compared to accepted reference standards for clinical assessment. (See [Attachment 2](#) for criteria considered when developing the questions to address for the updates to the *Guidelines*.)

**Additional topics may be included in the update of the Guidelines.*

Patient Population

The *Guidelines* apply to working age adults with medical conditions related to work or that affect the ability to work. In general, we consider working age adults to be individuals ages 18 to 65, although the Guidelines also apply to those workers over age 65. As a practical matter, many studies relevant to the Guidelines evaluate general adult populations (i.e., age 18 and older) that include adults over 65 who may or may not be working. Those studies are incorporated in the evidence-base for consideration unless there is a clear rationale for exclusion (e.g., highly unlikely to apply to the general population of working age adults). Such exclusions are rare. Thus, while the ACOEM guidelines are targeted towards working age adults, the evidence used is often found in studies of general adult populations that have a preponderance of working age adults.

Target Audience

The target users of the *Guidelines* are:

- Physicians and other health care providers;
- Healthcare organizations;
- Patients and consumers;
- Clinical case managers;
- Insurers and third party administrators;
- Insurance claims managers and utilization reviewers;
- Attorneys and judges;
- Workers' compensation regulators and policy makers; and
- All others with responsibility for or involvement in worker health, safety and productivity and workers' compensation systems.

3. Organizational Structure

The ACOEM Board of Directors has approved the following organizational structure and methods for the development of recommendations for evidence-based practice contained in this update. The Board also has the opportunity to review and comment on all evidence-based guidelines prior to publication. Comments from the Board are reviewed in the same way as external review comments. However, in order to maintain editorial independence required of quality guidelines, the Board does not officially approve the Guidelines. Below are the function, responsibility, and objective (FRO) statements for the committees and panels involved with ACOEM's Guideline-related activities (see Attachment 3 for a detailed description of the selection and training of Guidelines development groups described below).

Evidence-based Practice Committee (EBPC)

The EBPC is comprised of the chairs of each of the Expert Panels. Meetings may be attended by others who have been involved with previous ACOEM Guideline activities (e.g., panel members and

similar individuals). The EBPC is charged with coordinating the updates of the ACOEM evidence-based practice Guidelines. The EBPC:

1. Assists with determining the priority of individual guidelines and advises regarding the timetable for review of guideline topics.
2. Assists with identification of additional guideline topics and clinical questions to be considered in the *Guidelines*.
3. Addresses challenging questions, typically regarding methodology

Research Team(s)

Trained research teams:

1. Draft preliminary clinical questions in PICO(T) format for each guideline.
2. Develop and document search strategies and methods for each guideline topic.
3. Conduct systematic literature searches for each guideline topic.
4. Critically appraise, grade and critique each study to determine which articles are to be included vs. excluded.
5. Summarize studies in evidence tables.
6. Draft background text, rationale statements, and recommendations for each guideline topic.
7. Compile, format, and update relevant references for guideline topic.

Evidence-based Practice Panels (EBPPs or “Panels”)

Multidisciplinary panels are appointed and trained to develop and/or update evidence-based practice recommendations. Separate panels are appointed for each organ system, topic, musculoskeletal body part, or skill area covered by the Guidelines.* The Panels:

1. Discuss and approve draft clinical questions to frame the literature search
2. Review critical analyses of the literature based on this approved methodology.
3. Develop, review and approve new or updated evidence-based recommendations for clinical practice, care management, and disability management.

Panels are often subdivided into areas of practice or research interest at the discretion of the Panel Chair in discussion with the Editor-in-Chief (e.g., medical management, other therapies, tests, harms, screening) particularly when the Panel has a large scope of work.

*Currently, these areas are asthma, interstitial lung disease, low back, neck/upper back, hand/wrist/forearm, elbow, shoulder, hip/groin, knee, foot/ankle, eye, chronic pain, opioids, traumatic brain injury, COVID-19, PTSD, anxiety, depression, and disability prevention/management.

Guideline Methodology Committee (GMC)

The GMC establishes the methodology and quality review process for the development and revision of the Guidelines and all evidence-based products and services produced or endorsed by ACOEM. The GMC:

1. Develops the methodology for the development and revision of the *Guidelines* and other evidence-based products.
2. Refines, clarifies, and updates the methodology based on state-of-the-art, internationally accepted methods.
3. Ensures adherence to these state-of-the-art methods by assigning methodologists to each panel.
4. Approves Panel members after reviewing applications, curriculum vitae, and conflict of interest (COI) information of individuals interested in participating on one of the Panels.
5. Trains Panel members in this methodology and the guideline development process.

6. Publishes documents that describe and explain the methodology used for ACOEM evidence-based materials and products (5).
7. Works with ACOEM's Education department to assure consideration and evaluation of evidence in ACOEM educational offerings.

4. Process for Development and Revision of the Guidelines and Other ACOEM Evidence-based Products

Background and Introduction

The process for development of ACOEM Guidelines and evidence-based products was developed by the GMC and includes participation of the EBPC, review and formulation of recommendations by the Panels, stakeholder input, external peer review, and review by the ACOEM Board of Directors. Members of the Guideline development groups are selected from applications of ACOEM members and nominees from relevant interest groups and professional organizations. All panel members are required to complete an application and an online questionnaire to i) outline qualifications and interests; ii) disclose potential conflicts of interest; and iii) indicate their willingness to adhere to confidentiality procedures (see [Attachments 4](#) and [5](#)). Summaries of disclosures for all panel members are made available online. All members of the Guideline development groups are required to complete training in ACOEM's evidence-based medicine methodology (5). For further discussion of the selection of participants in the Guideline development groups and the training in the ACOEM methodology, see [Attachments 3](#) and [6](#).

Oversight by the Editor and Evidence-based Practice Committee (EBPC)

The ACOEM Board of Directors appoints one physician to chair the entire updating process and act as Editor-in-Chief of the Guideline. This physician also serves as chair of the EBPC.

Prioritization of Topics for Review and Recommendation

To identify and guide the work of the Panel for each topic (i.e., disorder or body system), the Editor-in-Chief and Research Team, in collaboration with the EBPC, work with each panel to identify clinical questions about diagnosis and treatment to consider to be addressed. Clinical questions may also be suggested by Board members, peer reviewers, external shareholders and others.

The following procedures are then followed:

1. The Research Team preliminarily identifies the most common occupational health problems, tests and treatments in terms of frequency, cost, time off work, apparent benefits, apparent harms, and rapid increases in utilization.*
2. Diagnoses are grouped by organ system, topic, musculoskeletal body part, or skill area into homogeneous diagnostic groups. Tests and treatments are identified.
3. The Guidelines Editor-in-Chief and his/her designees provide preliminary PICO(T) questions for review and solicit suggestions for inclusion of health conditions, diagnostic measures, and treatment to members of each panel for the area of interest covered by the panel. The health conditions, diagnostic measures, and treatment include common and emerging diagnoses, and commonly used (but not necessarily safe or effective) tests and treatment (medications, physical and psychological modalities, or procedures) from Panel members. The Editor-in-Chief and his/her designees seeks input from other stakeholders.
4. The PICO(T) questions are finalized for a given guideline by the Expert Panel.

*At present, diagnosis- and procedure-specific data are available from workers' compensation claims. Representative data may be available from large workers' compensation carriers, large self-insured employers, or existing research organizations that aggregate insurance claim data such as the Workers' Compensation Research Institute or the California Workers' Compensation Institute.

Review and Formulation of Recommendations by the Evidence-based Practice Panels

Panel members for each subject area are queried for diagnostic and treatment measures to potentially include in the updated guidelines. For guideline updates, previous diagnostic and treatment measures and their associated literature are included along with new material from literature searches. Panel and research team members, and the Editor-in-Chief collaborate to determine contents and formulate recommendations. The Panels, with assistance from the Research Team, formulate recommendations for guidelines in the following manner:

1. Literature Evaluation: Literature Search and Study Selection (13)

The Research Team conducts systematic literature reviews for each guideline topic assigned. In order to identify all high- and moderate-quality original research studies, the literature search is broad and comprehensive. Medical Subject Heading (MeSH) Terms are used to identify studies relevant to the tests, treatments and diagnoses in question. A combination of MeSH terms and other terms are used in order to determine the method that will yield the most relevant studies in the search process.

Treatment-related study searches

For treatment-related study searches, randomized controlled trials (RCTs), and randomized crossover trials, quality guidelines, meta-analyses and systematic reviews are the primary foci of these exhaustive literature searches to obtain original study reports. Prospective and retrospective cohort studies are searched if there are no RCTs and systematic reviews identified. Cohort studies are also solicited for adverse effects of medical devices. High-quality guidelines, meta-analyses and systematic reviews are sought primarily for verification of search completeness; they are independently assessed for reproducibility of conclusions.

RCTs and randomized crossover trials are all selected for critical appraisal (when available) and quality grading (see [Attachment 7](#)). For evidence of harms, retrospective cohort studies, harms reported from RCTs, large database studies (aka, big data), case reports, and case series are sought. In some instances, there are no available RCTs and available quality data may be only or largely derived from epidemiological studies (e.g., adverse events). Epidemiological studies may also be the only option when it is unethical and/or impractical to perform RCTs due to inherent harms. Possible examples include dose limits, tapering and discontinuation, and traffic safety in the Opioids Guideline and the utility of disability screening in Work Disability Prevention and Management Guideline. (see Table C-2). For risk factor assessments, prospective cohort studies are preferentially sought, with retrospective cohort, case control or cross-sectional studies sequentially selected where prospective cohort studies are absent. In some cases, studies with lower grades of evidence may be selected to examine current practice patterns or for other reasons. In order to ensure that all relevant, higher-quality studies are identified, researchers also perform hand searches of reference lists in related articles.

Diagnostic or screening searches

For diagnostic study searches, all study design types are searched. Searches for these topics primarily focus on large, comparative trials looking at two or more diagnostic tests that are being compared. Ideally, one is the “gold standard” test for that condition. Key terms (such as “Sensitivity and Specificity” [MeSH] OR “Predictive Value of Tests” [MeSH] OR “Gold-standard” OR accurate OR accuracy OR precision OR precise OR test) are used to identify the accuracy of the new test. Delimiters are used to narrow the search results and include: “Humans” and “English.”

Diagnostic studies are then summarized in evidence tables (see [Attachment 8](#)). Quality grading of these studies is done by following a grading procedure which is different from the procedure used for RCTs (see [Table C-1](#)). Emphasis is placed on what the test being studied is compared to. Another criterion is data to calculate test specificity and sensitivity are provided, allowing for those calculations. Studies that compare the new test to an established Gold Standard test are evaluated

first. Studies that compare the new test to another test, but not the Gold Standard are also evaluated. To ensure all relevant studies are included in the review, researchers consult with panel members and screen the references from the previously identified studies.

Search Term Documentation

Search strategies and methods, including specific databases, search terms, number of studies found (e.g., regarding treatment efficacy searches including RCTs and crossover trials) are documented. A search results section (in paragraph form) is included in each recommendation. This section includes the databases searched, limits on publication dates and languages, the search terms used, the number of studies found from all the databases searched, the total number of articles screened, the number meeting inclusion and exclusion criteria, the number critically appraised, and the total number of studies included. See [Attachment 9](#) for an example of a bibliographic search criteria table and [Attachment 10](#) for a list of the databases that are searched. The tracking logs that document the search process, search terms, limitations, etc., are also published in order to maintain transparency.

The Research Team reviews the abstracts of all citations found in the bibliographic search and identifies studies relevant to the topic that might meet the inclusion criteria (e.g., in English, RCTs that address treatment questions, relevant literature for adverse effects, relevant systematic reviews and clinical studies that address treatment or diagnostic study question, and comparative studies for diagnostic or screening tests) as adequate evidence and that could be used as the basis for evidence-based guidance statements. Researchers then retrieve the full text of these articles and perform a second screening process of the study in order to determine which studies meet the inclusion criteria to be considered as adequate evidence for these purposes (as shown in [Table A-1](#) and [Table A-2](#)). For those studies accepted as providing adequate evidence, individual article quality ratings are included in the evidence tables (see [Attachment 11](#)).

2. Literature Evaluation: Critical Review of Studies (13)

The Research Team reviews in detail each study that meets inclusion criteria. They summarize important information from each article in an evidence table (see [Attachment 11](#)). Evidence tables include first author’s last name, year of publication, study design, quality rating score, population sample, treatment comparison, results, conclusions and any comments relevant to the study. In addition, potential conflict of interest (COI) and study sponsorship are reported.*

The evidence presented in the evidence tables is limited to primary studies. In most cases, quality systematic reviews, meta-analyses and professional guidelines are reviewed for comparison and assessment of reproducibility. The relative ranking of study designs for theoretical robustness of design is shown in [Attachment 7](#). The below table summarizes the level of confidence levels for the different study designs. While study design should confer various levels of confidence in the reproducibility of the results, how the studies are conducted and analyzed is quite variable and must be specifically appraised.

| Study Design | Level of Confidence |
|--|---------------------|
| Randomized controlled trials (score of 0-11, with 8-11 high quality, 4-7.5 moderate quality, and <4 low quality) | I |
| Prospective cohort study | II |
| Prospective comparative study | II |

| | |
|-------------------------------|-----|
| Case-crossover study | II |
| Large, population-based study | II |
| Retrospective study | III |
| Case-control study | III |
| Cross-sectional study | III |

Therefore, the Research Team critically appraises, grades and critiques each study. Reviewers grade each study using the numerical quality score shown in [Table B](#) (Quality Scoring of Treatment Studies) and [Table C-1](#) (Scoring for Diagnostic Studies). These scores are grouped into designations of high, moderate or low quality evidence and report the scoring in the combined quality assessment table (see [Attachment 11](#)) (e.g., quality scores of 4.0 or higher are moderate or high quality). Where major flaws are present despite this scoring, then the study will also be excluded.

Guidance may be developed based on evidence for treatment of a related diagnosis or another body part. When the pathophysiology and treatment of the condition is identical, guidance may be developed using the entire body of evidence on that topic (e.g., "A,B,C letter-grade evidence" for medications for treatment of osteonecrosis elsewhere in the body including the hip is used to infer treatment of osteonecrosis of the shoulder). Whether A,B,C,I grade is used depends on specific factors including the degree of similarity of the pathophysiology and intervention.

When the disorder with quality evidence is similar, but not identical to another disorder without quality evidence, "I-rated guidance" (i.e., expert consensus) may be developed based on expert opinion (e.g., generalized anxiety disorder evidence used for guidance to treat panic disorder). When the pathophysiology of the disorder is identical but the intervention is substantially different, then the body of evidence from treatment of another body part may be used for expert opinion recommendations (e.g., "I-rated guidance" for arthroplasty treatment of osteonecrosis of the hip used to infer arthroplasty treatment of osteonecrosis of the shoulder).

Epidemiological studies may be used when there is no available quality RCT (e.g., opioid dose limit fatalities are best studied in large population-based cohort studies, as it is both feasibly impractical and unethical to test dose limits with an RCT design; or where there is an important question for which RCTs have yet to be produced). In these instances, other available types of studies such as cohorts and potentially case-control studies may be utilized to assess the association(s) between exposure and outcome. The scoring system used for these studies is the Ottawa-Newcastle system (see [Table C-2](#)). Studies with scores of 0-3 are low quality, 4-6 moderate quality, and 7-9 are deemed high quality provided there are no major flaws to alter the quality assessment based on the score.

For diagnostic studies, the appraisals and critiques are different from those used for treatment studies. The highest scores are given to studies that compare the new test to a Gold Standard (if one exists). The timing of the testing in relation to the progression of the disease state is also evaluated. The score for diagnostic studies is also a proportion of a possible total of 11. The categorization of high, moderate, and low quality studies is the same as in treatment-related studies.

Researchers with graduate-level education (i.e., Master's, PhD, MD) score each study for quality. The study is critiqued for methodological strengths and weaknesses, and assessed for the robustness and validity of the conclusions derived from the presented data.

After studies are scored for quality, the research team then synthesizes data from each study in a summary evidence table. An evidence table is developed for each research question. Articles are presented in score order with the highest-scored study listed first. Evidence scored as low quality does not receive a full summary. Only the first and last column in the evidence table are filled for these studies as low quality evidence does not significantly impact the strength of a recommendation. Articles with moderate/high quality scores may also be excluded because of failure to meet important criteria and/or a potentially fatal study flaw (e.g., randomization failure, high dropout rate).

After the body of quality evidence is assembled, scored, and critiqued on a given subject, the included body of quality evidence is graded. Draft recommendations are then formulated to be sent to the EBPP. In all cases, a Research Team physician performs a secondary review for clinical relevance and logic. The Panels may also perform an additional quality review.

3. Development of Guidelines and Recommendation Statements (13)

The Panels review and modify draft recommendations formulated by the Research Team. The Panels (and/or sub-Panels) review the evidence tables, evidence summaries, draft recommendations, and the original studies. After review, the Panels conduct discussions and agree on the strength of evidence ratings for each topic ([Table D](#)) and finalize recommendations for all clinical questions. The table below illustrates the minimum thresholds ACOEM uses for its evidence-based recommendations. If sub-Panels are employed, the recommendations of the sub-Panel are forwarded to the entire Panel in aggregate for additional discussion. Each recommendation is reviewed, edited (if necessary), and clearly labeled as “strongly recommended,” “moderately recommended,” “recommended,” “consensus-recommended,” “consensus-no recommendation,” “consensus -not recommended,” “not recommended,” “moderately not recommended,” and “strongly not recommended” ([Table E](#)).

| Minimum Thresholds for Evidence-based Recommendations (A, B, C-Level Evidence) | | |
|---|--|---|
| Class of Intervention | Minimum Study Design | Comments |
| Medications | Randomized, controlled trial (RCT) with placebo treatment arm. Randomized comparative trial is an alternative when there is both an effective treatment that is widely accepted and has a known level of efficacy. | Highest quality study(ies) as rated. Evidence of fatalities or severe adverse effects may reduce the rating. |
| Exercise, Behavioral | Sham-controlled RCT when possible, or randomized controlled comparative trial (RCCT) when sham-control not possible. Discrete exercise (or other) regimen specified.* | Highest quality study(ies) as rated. Substantial adherence to the CONTENT scale (19) and/or the CONSORT extension for pragmatic trials (20) supports inclusion. |
| Heat Therapies, Electrical Therapies, Manipulation, Acupuncture | RCT with sham-control when possible, or RCCT when not possible.* | Highest quality study(ies) as rated. Evidence of fatalities or severe adverse effects may reduce the |

| | | |
|---|---|--|
| | | rating. |
| Injections; radiofrequency ablation and other procedures | RCT with sham control. | Highest quality study(ies) as rated. Evidence of fatalities or severe adverse effects may reduce the rating. |
| Surgery | RCT with sham-control. Or, evidence of overwhelming benefit with >95% resolution of problem and return to normal function in nearly all cases (e.g., Total Hip Replacement, Hernia Repair). | Highest quality study(ies) as rated. Evidence of fatalities or severe adverse effects may reduce the rating. |

*Pragmatic RCTs which include clinical decision making with a limited intervention set and a clear decision making process that is reproducible are eligible for inclusion.

Panel unanimity is sought. Failing attainment of unanimity, consensus is sought for all recommendations and rationales in each guideline. There may be multiple communications (e.g., teleconferences, e-mail, in-person meetings) utilized to reach a unanimous opinion (or consensus) on both the recommendation and the wording of the recommendation for any individual topic. When unanimity is not achieved, a vote is taken (see [Attachment 12](#) for a voting process example). Consensus is met if the vote among the panel is 80% or greater in favor of a recommendation. If the vote among the panel is less than 80%, the percentages in favor of, and against the recommendation are recorded and published with the guideline. Minority statements may be included in such cases. As an example of a minority statement, indications for the intervention may be published although the overall recommendation is against that intervention.

The health benefits, adverse effects, risks and relative costs of each recommended test or treatment are explicitly considered and discussed in formulating the recommendations (13). Benefits should significantly exceed risks. Each recommendation specifies to which condition it applies. For tests and treatment recommendations, the recommendations will state the:

- Diagnoses or problems for which the test or treatment is indicated;
- Specific indications for the test or treatment, including:
 - Prior treatments or tests that might be appropriate, and how many would be appropriate prior to application of the additional treatment or tests;
- Point in the time course of the problem for which the test or treatment is appropriate;
- Conservative treatment that should be carried out prior to use of the test and treatment;
- Reasonable or necessary concurrent treatments;
- Relative and absolute contraindications to the test or procedure;
- Number of tests or procedures that are appropriate at a given time in the time course of the problem;
- Potential benefits of the test or procedure;
- Potential harms, including effects on disability and return to work;
- Relative costs [low (<\$100), medium (\$100-500), or high (>\$500)]; and
- Level of confidence (certainty regarding) in the evidence supporting the recommendations [low, moderate, or high]. A high strength of evidence (A) generally, but not always coincides with high confidence, moderate evidence (B) with moderate confidence, and low evidence (C and I) with low confidence. The Panel adjusts these up or down based on additional information (e.g., longstanding strongly supported practice

without likelihood of ever undergoing testing; urine drug screening for opioids compliance do not undergo RCTs so this recommendation could be upgraded to high confidence).

As funding/sponsorship of pharmaceuticals and devices or appliances is almost universally commercial, evidence tables will include information about potential conflicts of interest beginning in 2014 ("No mention of industry sponsorship or conflict of interest," "No industry sponsorship or conflict of interest," "Industry sponsored (who was the sponsor)," and/or "Industry conflict of interests (what/was/were the conflict of interests)"). It is also problematic that there are studies of expensive interventions conducted in clinical settings where there is significant bias to support the organization's business; currently, there is no clear method to address this potentially significant source of funding bias. In certain areas, this may have made little difference as the comparisons were between the medication and placebo and the results may be consistent and considerable. However, in other studies, the comparison groups may have been sub-optimally treated (e.g., a low dose of ibuprofen; not conducting either sham-controlled or comparative trial against a gold standard) and produced a bias in favor of the medication or device. In addition, industry-sponsored studies have been shown to frequently have better results and lower complication rates than studies conducted by independent investigators (21,22,23).

Studies that include the general population of adults are necessarily used to develop most recommendations in the guidelines as there are few trials conducted solely on the target working population. However, thoughtful consideration is given to the extent to which the findings may or may not be applicable to employed populations.

ACOEM's "**First principles**" of clinical logic and ethics should be observed in formulating guidelines and clinical recommendations. These principles are:

Ethics

- Clinicians/Panelists should adhere to ACOEM's Code of Ethics.
- Clinicians/Panelists should disclose any financial, intellectual, or other conflicts of interest (including ownership or other financial arrangements) they may have with any testing or treatment methods or companies.

Diagnostic Testing

- Tests should be performed when the results are likely to affect the course of treatment.
- Imaging or testing should generally be done to confirm a clinical impression prior to surgery or other major, invasive treatment, not purely for information purposes.

Treatment

Relative Effectiveness

- Treatments should improve on the natural history of the disorder, which in many cases is recovery without treatment.
- When there are options for testing or treatment available, the clinician should choose the option associated with improved and meaningful clinical outcomes as well as statistical significance.
- Treatment should be in accordance with evidence-based practice as described in this methodology, particularly with respect to prioritization of treatment modalities.

Use of High-Quality Evidence

- Recommendations should be based on high quality evidence rather than simply study design, with evidence of efficacy balanced with evidence of risks and harms.

Management

- Invasive treatment, outside of emergencies, should in almost all cases be preceded by adequate conservative treatment.
- Treatment should have specific, objective goals and should be monitored for achievement of those goals within a reasonable time.
- Failure to achieve a functional goal does not change the risk/benefit calculation for a subsequent treatment.

Invasive Treatment

- Invasive treatment may be recommended if evidence-based conservative treatment does not improve health and function and there is evidence of effectiveness for a specific diagnosis, indication, and situation.
- The more invasive and permanent, the more caution should be exercised in considering invasive tests or treatments and the stronger the evidence of efficacy should be.

Disability Management

- Treatment should not create dependence or functional disability.

Shared Decision Making

- Testing and treatment decisions should be the result of collaboration between the clinician and the patient with full disclosure of benefits and risks.
- The best treatment strategy should be preferentially recommended. The best strategy, or optimal approach is generally that which demonstrates the greatest magnitude of difference in comparing with placebo/sham, is superior when comparing with other approaches, has the least risk of adverse effects and is low cost. Of these items, the magnitude of treatment benefit is the most important and the cost is the least of the considerations, but at times cost may be the key distinguishing factor between treatment or diagnostic options.
- In cases where the patient cedes that judgment to the clinician, the clinician's analysis as to the best treatment strategy should be implemented.

Cost-effectiveness

- The more costly the test or intervention, discretion should be generally exercised prior to ordering the test or treatment and the stronger the evidence of efficacy should be.
- When two treatment methods appear equivalent regarding magnitude of benefits and speed of recovery, cost-effectiveness should be an integral part of the clinician's synopsis and analysis of treatment modalities, in conjunction with assessing the patient's current medical status.

Rationale Statements

An explicit link between each recommendation and the supporting evidence is provided. Each recommendation includes an evidence table and list of references (13). Each recommendation is accompanied by a paragraph that describes the Panel's conclusion about the evidence found on that question, known as the rationale for the specific recommendation. These paragraph(s) explain how the Panel interpreted and weighed the evidence and how they balanced evidence of effectiveness or accuracy against potential harms and relative cost-effectiveness in formulating the recommendations. For example, if the quality of the synthesized evidence was inconsistent, then the Panel may comment on how they interpreted and weighed the evidence in a logical and fair way and adhered to the "First Principles" listed above (13). The final recommendations are then drafted and approved (see [Table F](#) for characteristics of the recommendations). [Attachment 13](#) summarizes the process described above (the literature search, review of studies, and development of recommendations) and which individuals are responsible for each task.

External Peer Review

ACOEM conducts external peer review of the *Guidelines* to: 1) assure that all relevant high quality scientific literature related to the topics has been found; 2) assure that the important evidence from the scientific literature relevant to the *Guidelines* has been accurately interpreted; 3) solicit opinions on whether the findings and recommendation statements are appropriate and consistent with the evidence; and 4) obtain general information on the *Guidelines'* conclusions and presentation from external topic experts. A more detailed explanation of the external peer review process is included in [Attachments 14](#) and [15](#). These experts may also review the methodology used as well as summaries of the critically appraised evidence and the recommendations in each area. The *Guidelines* list the names of all peer reviewers, along with their affiliations for those not desiring anonymity. The Panels review the comments received from the external peer reviewers and make any final modifications to the *Guidelines*. In addition, a pre-publication version of all guidelines will be shared for a period of two weeks for public comment.

Stakeholder Input

In order to understand the needs and preferences of those individuals and organizations who use or are affected by the use of clinical practice guidelines in workplace settings and in the workers' compensation system, ACOEM solicits broad inputs from anyone interested in the *Guidelines*, including the following stakeholders: clinicians, health-care systems, labor representatives, workers/patients, employers, utilization reviewers, case managers, insurers and third-party administrators, attorneys, regulators and policy makers. ACOEM solicits input from these stakeholders by inviting them to submit comments to us through our [website](#) (see [Attachment 16](#) for further details). State agencies also provide the ACOEM *Guidelines* link to their stakeholders and anyone else interested in input to the ACOEM *Guidelines*.

ACOEM also seeks input from stakeholders into the scoping of the guidelines by inviting them to submit comments to us through our [website](#) on the list of clinical questions we research for each guideline.

Pilot Testing

The *Guidelines* are pilot tested by having clinicians, utilization review managers, case managers, state workers' compensation systems, etc., use or comment on use of the *Guidelines* in their daily practice or management activities to determine if they are clear, easy to use and generally useful. The *Guidelines* may be modified based on the feedback received from pilot testing, if the suggestions increase usability. In 2014, the Reed Group conducted a pilot test and redesigned their website to address the input received during this process. For example, tools (e.g., DART [Diagnosis and Related Treatments]) have been developed to help users get to the recommendations, evidence, and rationale more easily.

Review by the GMC and the ACOEM Board of Directors

During the entire evidence-based development process, a designated methodologist from the GMC works with the Panels, editors and Research Team to ensure that this evidence-based methodology is being followed, both in the literature evaluation process and in the development of conclusion, rationale, and recommendation statements. The ACOEM Board of Directors may comment on the guidelines during the external review period. Their comments are reviewed by the Panel and included in the same manner as the of external peer reviewers' comments. The Panels and the Research Team have complete editorial independence from ACOEM and Reed Group, neither of which influences the *Guidelines*.

5. Updating Process

ACOEM reviews the literature periodically to identify any major changes in the evidence base by content area. Subsequent updates of the *Guidelines* include a full review of previous

recommendations. Comprehensive updates will involve the Panels and will review new evidence and revise recommendations at least every 3-5 years. Major changes in literature may necessitate more frequent updates, resulting in focused updates.

6. Applicability/Tools for Putting it Into Practice

MDGuidelines®

The ACOEM *Guidelines* are available as part of the Reed Group's *MDGuidelines®* which are available at www.MDGuidelines.com. The Reed Group has released a new tool, DART (Diagnosis and Related Treatments), which provides instant access to ACOEM diagnostic and treatment recommendations and the evidence behind the recommendations.

Monitoring/Auditing Criteria

ACOEM has developed monitoring and auditing criteria for each guideline (see [Attachment 17](#)).

7. Appendices

7.1. Appendix 1: Methods by Which ACOEM Adheres to the AGREE II Criteria

| AGREE II ITEM | ACOEM PRACTICE GUIDELINE PROCESS |
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| Domain 1. Scope and Purpose | |
| Overall objectives of the guideline is (are) specifically described. | <p>The purposes of the ACOEM <i>Practice Guidelines</i> are to improve efficiency and accuracy of diagnoses, improve effectiveness of treatment, maximize relief of symptoms and improve function, and facilitate return to work in workers with occupationally related illnesses or injuries. The <i>Guidelines</i> address the key domains of occupational medicine practice including: diagnosing health problems likely to be work-related; determining work-relatedness individually and collectively; managing medical care; treating work-related health problems efficiently and effectively; managing associated disability and work loss; preventing work-related health problems; and promoting health.</p> <p>Each guideline includes a list of specific objectives for that guideline.</p> |
| Health question(s) covered by the guideline is (are) specifically described. | <p>The Evidence-based Practice Panels and research team compile dozens of health questions for each of the guidelines that results in hundreds of recommendations. An example of some of these health questions include, (1) Among patients or workers with hip osteoarthritis, what is the evidence that NSAIDs result in reduced pain and improved function compared with placebo or no treatment?, (2) Among patients of workers with hip osteoarthritis, what is the evidence that tricyclic antidepressants result in reduced pain and improved function compared with placebo or no treatment, (3) What evidence supports the use of opioids for treatment of acute, subacute, chronic and post-operative non-malignant pain?, and (4) Are opioid treatment agreements (opioid contract, doctor/patient agreement, or informed consent) effective?</p> <p>If there is no evidence for treatment of employed populations of workers with that disorder, then the Panels and research team examines and analyzes the evidence for the general population with that disorder. Our “Foundation” Guidelines will include the identification of questions that should be addressed regarding best practices for general management of clinical conditions, disability, and medico-legal matters. Our “Disorder” Guidelines will identify clinical questions to address for each clinical entity or diagnostic group. These questions will be framed in PICO(T) format (population of interest, intervention, comparison group, and outcome).</p> <p>Each guideline includes a list of specific questions covered by that guideline.</p> |
| Population (patients, public, etc.) to whom the guideline | Working age adults (~18-65 years) with health conditions related to work or that affect the ability to work. However, many workers are |

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| <p>is meant to apply is specifically described.</p> | <p>now older than 65, so guidance has been expanded to include all workers. As a practical matter, many studies include older adults. Those studies are incorporated in the evidence-base for consideration unless there is a clear rationale for exclusion (e.g., highly unlikely to apply to a working age population). Such exclusions are rare. Thus, while the ACOEM Guidelines are targeted towards working age adults, the evidence used may include the general adult population, resulting in guidelines that likely have substantially wider applicability than the target population.</p> |
| <p>Domain 2. Stakeholder Involvement</p> | |
| <p>Guideline development group includes individuals from all relevant professional groups.</p> | <p>The ACOEM Guidelines Methodology Committee is comprised of ACOEM members with not only expertise in occupational and environmental medicine but also internal medicine, physical medicine and rehabilitation, and a representative from the American Physical Therapy Association. Evidence-based Practice Panels and external reviewers also include professionals from all involved specialties (e.g., occupational medicine, physical therapy, occupational therapy, neurosurgery, orthopedic surgery, pain specialists, psychology, psychiatry, chiropractic medicine, podiatry, preventive medicine, sports medicine, osteopathy, disability, acupuncture, neuromuscular electrodiagnostic medicine, physical medicine and rehabilitation, family medicine, etc.).</p> <p>ACOEM also seeks input from stakeholders, including professional societies, unions, insurers, into the scoping of the guidelines by inviting them to submit comments to us through our website (https://form.jotform.com/202114643550141) on the list of clinical questions we research for each guideline.</p> |
| <p>Views and preferences of the target population (patients, public, etc.) have been sought.</p> | <p>ACOEM has a webpage (https://form.jotform.com/202114270486044) that provides workers, businesses, insurers, union representatives, occupational health professionals, patients, and other stakeholders in evaluation and treatment of work-related health issues a means to provide input into the <i>Practice Guidelines</i>.</p> <p>The Reed Group also has a feedback process to provide feedback on the guidelines.</p> <p>ACOEM also seeks input from unions and patient groups into the scoping of the guidelines by inviting them to submit comments to us through our website (https://form.jotform.com/202114643550141) on the list of clinical questions we research for each guideline.</p> |
| <p>Target users of the guideline are clearly defined.</p> | <p>Target users include physicians and other healthcare providers, healthcare organizations, patients and consumers, clinical case managers, insurance and third-party administrators, claims adjusters, utilization reviewers, attorneys, judges, regulators, and workers' compensation regulators and policy makers.</p> |

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| <p>Domain 3. Rigor of Development</p> | |
| <p>Systematic methods were used to search for evidence.</p> | <p>Research Team staff conduct exhaustive systematic literature reviews for each guideline topic assigned. In order to identify all high- and moderate-quality original research studies, the literature search is broad and comprehensive. Medical Terms (MeSH Terms) are used to identify studies relevant to the treatments and diagnoses in question. A combination of MeSH terms and other terms are used in order to determine the method that will yield the most relevant studies in the search process. ACOEM searches PubMed, CINAHL, Cochrane Central Register of Controlled Trials, and Scopus for primary sources of original research. It also searches other databases likely to contain references of high-quality medical literature, including Google Scholar to identify potential quality, impactful literature that includes the gray literature. Additional literature may be reviewed brought to the research team’s attention from interested parties.</p> <p>Search strategies and methods, including specific databases, search terms, number of studies found (e.g., regarding treatment efficacy searches including RCTs and crossover trials) are documented. A search results section (in paragraph form) is included as a footnote for each evidence table. This section includes the databases searched, that there were no limits on publication dates, limited to English language, the search terms used, the number of studies found from all the databases searched, the total number of articles screened, the number meeting inclusion and exclusion criteria, the number critically appraised, and the total number of studies included of high or moderate quality. Those of low quality are also clearly identified in tables.</p> |
| <p>Criteria for selecting the evidence are clearly described.</p> | <p>Criteria for inclusion in study rating and critical analysis of studies of diagnosis/clinical assessment methods are: (1) evaluate the efficacy of the assessment method (i.e., the “test”) in a group that contains subjects both with and without the condition the test is intended to assess, (2) be a prospective cohort study or an arm of a Randomized Controlled Trial (RCT), and (3) compare the findings of the assessment method to an adequate reference standard for all subjects. All trials potentially selected for inclusion are abstracted into tables of evidence and then formally scored. Those that score moderate or high quality are included. All included studies are also critically appraised and critiqued.</p> <p>Criteria for inclusion in study rating and critical analysis of studies of treatment efficacy are: (1) evaluate a group of subjects with a representative spectrum of the clinical condition of interest, (2) be an RCT or randomized crossover trial evaluating clinical outcomes in a group receiving the intervention compared to a comparison group receiving either no intervention or a different intervention, and (3) evaluate functional outcomes that are important to a patient’s overall health or well-being or are important to society. Each article</p> |

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| | is both scored and critically appraised. They are compiled into evidence tables. Those of low quality are kept in separate evidence tables and thus also clearly identifiable. |
| Strengths and limitations of the body of evidence are clearly described. | Each included article is critically appraised. Comments from that appraisal process are recorded in the tables of evidence. Strengths and limitations of the body of evidence is discussed in the rationale section for all recommendations. |
| Methods used for formulating recommendations are clearly described. | <p>Each article that meets inclusion criteria is reviewed and critically appraised and scored on 11 criteria (i.e., randomization, concealment, baseline comparability, patient/provider/evaluator blinding, co-interventions, compliance rate, dropout rate, timing and intention-to-treat analysis). Each criterion is scored 0.0, 0.5 or 1.0. These individual ratings are summed up, resulting in an overall rating that ranges from 0 to 11. The rating for each article is then converted into a quality grade – low quality (scores 0-3.5), moderate quality (4.0-7.5), or high quality (8.0-11.0). High and moderate quality studies are abstracted into evidence tables that include details of study methods, outcomes, and statistical analyses. Low-quality studies are not utilized for guidance, but are also compiled into evidence tables and included in appendices to help clearly denote and separate the included from the excluded studies. All RCTs and randomized crossover trials are considered to have an intrinsic level of confidence in the results of “I”.</p> <p>For observational studies, a design level of “II” includes prospective cohort studies, prospective comparative studies, case-crossover and large, population-based studies. A level of confidence of “III” is used for retrospective, case control or cross-sectional studies. While study design should confer various levels of confidence in the reproducibility of the results, how the studies are conducted and analyzed is quite variable and must be specifically appraised.</p> <p>Another comparable but somewhat different tool is used to score diagnostic studies. Rarely, a study has fatal flaw (e.g., high dropout rate) that negates that study’s quality score and is noted in the comments/critique. This ACOEM scoring tool includes metrics used in most other major scoring tools, but includes more metrics than most tools. It has proven durable and reproducible</p> <p>Research staff then use the tables to grade the strength of evidence in order to draft specific clinical practice recommendations. The Evidence-based Practice Panels then review the draft strength of moderate and high quality studies, study critiques, evidence ratings and recommendations, modify them as per the methodology, and develop final recommendations. In reviewing or revising recommendations, the expert Panels review the articles, evidence tables, and strength-of-evidence ratings (A, B, C, or I). Panels discuss recommendations for diagnosis or treatment based on the critically appraised body of evidence using a “best evidence” approach. In addition to critically appraised evidence, “First Principles” of medical logic and ethics are observed in formulating recommendations. The</p> |

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| | <p>ACOEM evidence-based recommendations are classified as follows: Strongly Recommended (A) (i.e., at least 2 high-quality studies); Moderately Recommended (B) (at least 1 high-quality and/or multiple moderate quality); Recommended (C) (at least one moderate quality study); Recommended, Insufficient Evidence (I); No Recommendation, Insufficient Evidence (I); Not Recommended, Insufficient Evidence (I); Not Recommended (C); Moderately Not Recommended (B); and Strongly Not Recommended (A). The insufficient evidence recommendations are used to clearly denote these are expert consensus recommendations.</p> |
| <p>Health benefits, side effects and risks have been considered in formulating the recommendations.</p> | <p>Each diagnostic test or treatment option states whether it is invasive or non-invasive, has low-moderate-or high adverse effects, and whether it is low-moderate-or high cost. Counter treatments are discussed to address adverse effects when appropriate (e.g., treatments to prevent NSAID-induced gastropathy).</p> |
| <p>There is an explicit link between the recommendations and the supporting evidence.</p> | <p>Each recommendation has an evidence table indicating the high and moderate quality studies used to develop that recommendation. Specific reference citations are also included in the rationale for recommendations to provide an explicit link between recommendations and evidence, and where appropriate, the specific citation(s) to develop the indications section are also noted. If there are no quality studies available (insufficient evidence), it is stated in the text, and the evidence rating is automatically “I, Insufficient Evidence.” This is labeled insufficient evidence in part to clearly mark those recommendations as consensus recommendations of the Evidence-based Practice Panel. In cases where the highest quality study has specific dose, frequency, etc. information that is also referenced in the recommendations to assist providers in identifying the specific intervention and schedule used to effect those results.</p> |
| <p>Guideline has been externally reviewed by experts prior to publication.</p> | <p>Each guideline is sent out for extensive external peer reviews. We invite the relevant other professional societies to review (e.g., American Physical Therapy Association, American College of Preventive Medicine, The American Occupational Therapy Association, American Academy of Physical Medicine & Rehabilitation, Academy of Organizational & Occupational Psychiatry, American Association of Occupational Health Nurses, American Academy of Disability Evaluating Physicians, American Academy of Neurology, American Association of Neuromuscular & Electrodiagnostic Medicine, American Board of Independent Medical Examiners, American Psychological Association, California Orthopaedic Association’s Workers’ Compensation Committee, Society for Industrial and Organizational Psychology, American College of Physicians, American Osteopathic College of Occupational and Preventive Medicine, Association for Applied Psychophysiology and Biofeedback, and Society for Behavioral Medicine). Some external peer-reviewers choose to remain anonymous, and ACOEM respects those wishes. Those who choose not to remain anonymous are acknowledged in the specific guideline they reviewed. ACOEM wishes to thank all external peer reviewers for their services that are</p> |

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| | viewed as important to the development of high-quality evidence-based treatment guidelines for the care of injured workers. |
| Procedure for updating the guideline is provided. | A 3 year rolling update process is in place. However, ACOEM does a yearly review of the literature and will make immediate changes to the guidelines if new high and moderate quality RCTs become available that require a significant change in the recommendations. This will occur as quickly as a couple weeks to complete the through process if there is a major study produced that changes existing guidance. |
| Domain 4. Clarity and Presentation | |
| Recommendations are specific and unambiguous. | All recommendations are clearly stated. For those that are recommended, we also include indications, dose/frequency, discontinuation as appropriate, and harms/benefits. |
| Different options for management of the condition or health issue are clearly presented. | Each guideline lists a variety of diagnostic tests and treatment options (medications, exercise, skilled medical therapies, injections, or surgery) that might be beneficial to the patient based on their disorder. Where there are quality comparative trials, the comparisons between different treatment or testing options are noted. When a recommendation between two different testing or treatment options is able to be concluded, that information is also incorporated into the guideline. Issues of competing interventions are also noted in the algorithms that typically list a few options at each step in a preferred sequence; where there is no clearly preferred strategy, then multiple options are listed at that step. |
| Key recommendations are easily identifiable. | Recommendations are easily searchable through their online publication in <i>MDGuidelines</i> .® |
| Domain 5. Applicability | |
| Guideline provides advice and/or tools on how the recommendations can be put into practice. | The ACOEM <i>Practice Guidelines</i> are available as part of the Reed Group's <i>MDGuidelines</i> ® which are available at www.MDGuidelines.com . The Guidelines include relatively thorough algorithms to assist in suggested sequential strategies to treat simple to complex problems. The Guidelines have developed many other tools including a comprehensive, combined opioid consent and contractual agreement document. |
| Guideline describes facilitators and barriers to its application. | Issues including lack of geographic access to certain technologies have been incorporated into the guidelines (e.g., access to MRI may be limited, which may necessitate CT scanning for certain disorders). Lack of access to certain specialties has also been noted, with alternate procedures provided (e.g., individual components of a multidisciplinary rehabilitation program). |
| The potential resource implications of applying the | Cost criteria are noted and included in the guidance. This is considered by the Evidence-based Practice Panels when developing |

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| recommendations have been considered. | the recommendations. The costs are included in the “Rationale for Recommendations” section. Low cost is defined as <\$100, moderate cost is \$100-500, and high cost is >\$500. |
| Guideline presents monitoring and/or auditing criteria. | ACOEM monitoring/auditing criteria have been developed for key evaluation or outcomes methods. |
| Domain 6. Editorial Independence | |
| Views of the funding body have not influenced the content of the guideline. | The <i>Guidelines</i> are editorially independent from Reed Group, Ltd. and ACOEM’s Board of Directors. The <i>ACOEM Practice Guidelines</i> are published by Reed Group, Ltd. but with strict editorial independence for all guidance. |
| Competing interests of guideline development group members have been recorded and addressed. | The <i>ACOEM Practice Guidelines</i> includes an application process for all panel members. The application process includes each panel member completing an online confidentiality/conflict of interest form. Each guideline contains a list of the panel members and a brief summary of their place(s) of employment; national, regional, and local committee affiliations; guidelines related professional activities; research grants/other support they are receiving; and any financial/non-financial conflict of interests are listed. |

7.2. Appendix 2: Methods by Which ACOEM Adheres to the AMSTAR Criteria

| AMSTAR | ACOEM PRACTICE GUIDELINE PROCESS |
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| 1. Was an ‘a priori’ design provided? | Yes, see ACOEM Guideline methodology documents. Each guideline includes a list of objectives for that specific guideline. A list of specific clinical questions is also compiled and available at https://form.jotform.com/202114643550141 . |
| 2. Was there duplicate study selection and data extraction? | Yes. All ACOEM Guidelines have at least two systematic literature searches performed, and nearly all have had many more than two. There are at least two different people who perform study selection. There are at least two who perform data extraction. Also, the core research team discuss appropriateness (or not) of inclusion of some of the studies (e.g., unclear study design, short reports, etc.). If questions arise, the core team come to consensus. |
| 3. Was a comprehensive literature search performed? | <p>Yes. Research Team staff conduct systematic literature reviews for each guideline topic/question. In order to identify all high- and moderate-quality original research studies, the literature search is broad and comprehensive. Medical Terms (MeSH Terms) are used to identify studies relevant to answer the questions regarding the treatments and diagnostic procedures. A combination of MeSH terms and other terms are typically used in order to determine the method that will yield the most relevant studies in the search process.</p> <p>ACOEM searches PubMed, CINAHL, Cochrane Central Registry of Controlled Trials, and Scopus for primary sources of original research. ACOEM conducts extensive supplementary searches using review articles, systematic reviews, and reference lists of the included and excluded studies. We also search other databases likely to contain references of high-quality medical literature, including Google Scholar to identify potential quality, impactful literature that includes the grey literature. Additional literature is reviewed that is brought to the research team’s attention from interested parties (e.g., panel members, public).</p> <p>Search strategies and methods are recorded in detail, including specific databases, search terms, number of studies found (e.g., regarding treatment efficacy searches including RCTs and crossover trials) are documented. A search results section in paragraph form is also included as a footnote for each evidence table. This section includes the databases searched, that there were no limits on publication dates, limited to English language (although we also have used citations of foreign language articles that suggest results for a potentially quality study, we do not use them for guidance), the search terms used, the number of studies found from all the databases searched, the total number of articles screened, the number meeting inclusion and exclusion criteria, the number critically appraised, and the total number of studies included of high or moderate quality. Those of low quality are</p> |

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| | also clearly identified in tables. |
| 4 Was the status of publication (i.e. grey literature) used as inclusion criterion? | Yes. As noted above, searches include Google Scholar to attempt to capture relevant studies both in the peer-reviewed and in the grey literature. Searches and references also include conference proceedings and trial registries. |
| 5. Was a list of studies (included and excluded) provided? | Yes. The high- and moderate-quality studies are listed in a table of included studies. The low-quality studies are also listed in a table. These also include abstracted information, study design, COI, study quality score, assignment groups, results, author's conclusion and critique. |
| 6. Were the characteristics of the included studies provided? | Yes. The rules for included studies are clearly specified in the methodology documents. These rules include study design, quality metrics to be scored. Additionally, summary tables include study characteristics such as population, disease status, disease severity, as well as type of study such as RCT, crossover trial, pilot study, etc. |
| 7. Was the scientific quality of the included studies assessed and documented? | <p>Yes. The criteria for scoring the studies were all developed a priori. The criteria for the scientific quality of the included studies is clearly specified in the methodology documents. This includes 2 specific scoring tools. Each study is individually scored. This scoring system includes 11 specific, well-defined, measurable quality metrics. Naturally, it does not include merely study design. Each criterion is scored 0, 0.5 or 1.0 based on the degree to which the criterion is met. There are 'anchors' or scoring guides for applying the tool. The sum of the scores determines the quality rating. Low quality is a score of 0-3.5, moderate of 4.0-7.5 and high of 8.0+. All RCTs and randomized crossover trials are considered to have an intrinsic level of confidence in the results of "I."</p> <p>For observational studies, a design level of "II" includes prospective cohort studies, prospective comparative studies, case-crossover and large, population-based studies. A level of confidence of "III" is used for retrospective, case control or cross-sectional studies. While study design should confer various levels of confidence in the reproducibility of the results, how the studies are conducted and analyzed is quite variable and must be specifically appraised.</p> <p>Another comparable but somewhat different tool is used to score diagnostic studies. Rarely, a study has fatal flaw (e.g., high dropout rate) that negates that study's quality score and is noted in the comments/critique. This ACOEM scoring tool includes metrics used in most other major scoring tools but includes more metrics than most tools. It has proven durable and reproducible. Those of low as well as high quality are clearly identified in tables and both high- and low-quality studies are evaluated such that the comments and scores reflect the quality of the study.</p> |
| 8. Was the scientific quality of the included studies used appropriately in | Yes. The methodological rigor and scientific quality of individual studies are including in the individual study scores are then summed into 'letter-grade' recommendations, or A, B, C recommendations in favor or against a treatment or diagnostic test based upon the numbers and quality of studies in favor/against the intervention or test. This too is clearly |

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| <p>formulating conclusions?</p> | <p>spelled out in the methodology documents.</p> <p>In cases where evidence is either absent or substantially conflicting, a 4th category, Insufficient Evidence, is used to clearly demarcate consensus-based recommendations.</p> <p>In formulating the final recommendations, the numbers of studies, the strength of those studies, are all included in summary statements in the clearly defined, “Rationale for Recommendation” section of each guidelines statement.</p> |
| <p>9. Were the methods used to combine the findings of studies appropriate?</p> | <p>Yes. There are cases where it is sensible to perform combined analyses, and pooled analyses are performed. In those cases, test for homogeneity (I^2), and/or random effects models are used are performed. These are reported in the guidelines. Additionally, many pooled analyses are performed by Cochrane reviews. Those are used provided they are reasonable to perform the summary estimates (these would rarely be disagreed with). However, there are many guidelines recommendations for which summary measures would be inappropriate due to differing attributes across the studies on that given topic including: population heterogeneity, use of different outcome measures, substantially varying time intervals, etc.</p> |
| <p>10. Was the likelihood of publication bias assessed?</p> | <p>For all Cochrane reviews, all funnel plots are reviewed. Results suggesting publication bias are noted and those results are included in the guidelines. The ACOEM Guidelines also attempts to identify sources and types of publication bias through grey literature searches, conference proceedings, and trial registries. Through systematic capture of studies’ results, it is hoped that this source of bias is reduced.</p> |
| <p>11. Was the conflict of interest included?</p> | <p>Yes. New/updated guidelines track all reported sources of conflicts of interest for RCTs. These are detailed in the first column of the included as well as excluded studies tables.</p> |

7.3. Appendix 3: Methods by Which ACOEM Adheres to GRADE Criteria

| GRADE CRITERIA | ACOEM PRACTICE GUIDELINE PROCESS |
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| 1. Quality of Evidence Consistency | |
| <p>“Quality of evidence” should be defined consistently with one of the two definitions (for guidelines or for systematic reviews) used by the GRADE Working Group.</p> | <p>The ACOEM Guidelines systematic reviews evaluate evidence using a GRADE-based system that is a more detailed adaptation of GRADE. The ACOEM Guidelines also separate between evidence evaluation and construction of recommendations, also in keeping with GRADE.</p> <p>The ACOEM Guidelines relies on systematic reviews conducted in accordance with the highest standards to provide current guidance on the relevant clinical questions. ACOEM evidence reviews utilize both prior systematic reviews and ACOEM also conducts its own systematic reviews. In accordance with GRADE, the systematic reviews particularly sought are Cochrane and other high-quality systematic reviews, in addition to other scientific reviews. In ACOEM’s systematic reviews, the ACOEM overall strength of evidence ratings of the quality of evidence correlate with the extent to which ACOEM has confidence that effect estimates are correct.</p> <p>The Research Team staff conducts systematic literature reviews for each guideline topic/question (PICO(T)). The team develop tables of evidence containing the particular topic/question such as (e.g., treatment for a particular condition). In order to identify all high- and moderate-quality original research studies, the literature search is broad and comprehensive. Medical Terms (MeSH Terms) are used to identify studies relevant to answer the questions regarding the treatments and diagnostic procedures. A combination of MeSH terms and other terms are typically used in order to determine the method that will yield the most relevant studies in the search process.</p> <p>ACOEM searches PubMed, CINAHL, Cochrane Central Registry of Controlled Trials, and Scopus for primary sources of original research. ACOEM conducts extensive supplementary searches using review articles, systematic reviews, and reference lists of the included and excluded studies. It also searches other databases likely to contain references of high quality medical literature, including Google Scholar to identify potential quality, impactful literature that also includes the grey literature. Additional literature is reviewed that is brought to the research team’s attention from interested parties (e.g., panel members, public).</p> <p>Search strategies and methods are recorded in detail per each PICO(T) question, including specific databases, search</p> |

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| | <p>terms, number of studies found (e.g., regarding treatment efficacy searches including RCTs and crossover trials) are documented. A search results section in paragraph form is also included as a footnote for each evidence table. This section includes the databases searched, that there were no limits on publication dates (or with updates from original searches without limits), limited to English language (although we also have used citations of foreign language articles that suggest results for a potential quality study, we do not use them for guidance), the search terms used, the number of studies found from all the databases searched, the total number of articles screened, the number meeting inclusion and exclusion criteria, the number critically appraised, and the total number of studies included of high or moderate quality. Those of low quality are also clearly identified in the table and/or listed. Also in keeping with GRADE, fatally flawed studies are excluded and the reasons for exclusion are noted in the “Comments” column of the evidence table; this is provided to further transparency.</p> |
| <p>2. Explicit Consideration of Evidence</p> | |
| <p>Explicit consideration should be given to each of the GRADE criteria for assessing the quality of evidence (risk of bias/study limitations, directness, consistency of results, precision, publication bias, magnitude of the effect, dose-response gradient, influence of residual plausible confounding and bias “antagonistic bias” although different terminology may be used.</p> | <p>Each article that meets inclusion criteria is reviewed and critically appraised.</p> <p>For randomized controlled clinical trials and randomized crossover trials, each article is scored on 11 criteria (i.e., randomization, concealment, baseline comparability, patient/provider/evaluator blinding, co-interventions, compliance rate, dropout rate, timing and intention-to-treat analysis). Each of the 11 criterion is scored 0.0, 0.5 or 1.0. These individual ratings are summed up, resulting in an overall rating that ranges from 0 to 11. The rating for each article is then converted into a quality grade for that specific study (which is different than that for the entire body of quality evidence on that topic/PICO(T) question) – low quality (scores 0-3.5), moderate quality (4.0-7.5), or high quality (8.0-11.0). High and moderate quality studies are abstracted into evidence tables that include details of study methods, outcomes, and statistical analyses. Low quality studies are not utilized for guidance but are also compiled into tables and included in appendices to help clearly denote and separate the included from the excluded studies. All RCTs and randomized crossover trials are considered to have an intrinsic level of confidence in the results of “I.”</p> <p>For observational studies, a design level of “II” includes prospective cohort studies, prospective comparative studies, case-crossover and large, population-based studies. A level of confidence of “III” is used for retrospective, case control or cross-sectional studies.</p> |

While study design should confer various levels of confidence in the reproducibility of the results, how the studies are conducted and analyzed is quite variable and must be specifically appraised.

Another comparable but somewhat different tool is used to score diagnostic studies. Rarely, a study has fatal flaw (e.g., high dropout rate) that negates that study's quality score and is noted in the comments/critique. This ACOEM scoring tool includes metrics used in most other major scoring tools but includes more metrics than most tools. It has proven durable and reproducible.

A risk of bias is also evaluated. For example, a significant loss to follow up can bias the interpretation of results in any study. Consideration of study elements such as this are reviewed to seek to avoid inclusion or (over)reliance on biased results. A separate risk of bias score (beyond the 0-11 score above) is also provided.

Each study is critically appraised and includes a thorough evaluation of sources of bias and study limitations. The critical appraisal process also includes searching for evidence of magnitude of effect, dose-response gradient(s), directness, precision (residual), confounding, and publication bias. The overall body of evidence is also analyzed for these factors in aggregate as well as for consistency of results across the quality studies.

These study designs flaws include potential for confounding. Careful consideration of the study's methods, any published tables, text and data are scrutinized for such concerns.

There may be limited high quality studies available on any given topic and randomized trials may not exist. ACOEM examines the directness of evidence for consideration in guidelines by determining the level of interest, for example, a particular intervention leading to a particular outcome has, particularly in terms of applicability to employed populations.

ACOEM carefully considers all elements of reported results but puts greater emphasis on studies with outcome measures with the greatest precision. Emphasis is also placed on where there are stronger, unbiased, central point estimates (i.e., magnitude of the effect). These are further emphasized where there are such findings that are also consistent across studies.

Dose response relationships are rarely addressed in most trials. However, when they are addressed it is typically interpretable as a strong indicator suggesting true effects versus spurious results. Thus, in most cases it would improve the likelihood of a stronger recommendation.

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| | <p>Additionally, dose response relationship information would likely be included in both the specific dose/frequency/duration of the recommendation as well as being highlighted in the rationale for recommendation section (e.g., frequency and/or intensity of bouts of exercise).</p> <p>Methods for addressing Conflicts of Interest (COI): This includes an extensive COI form that must be completed by all individuals of the Guideline Development Group (GDG) (i.e., panels). The process includes disclosure of current and potential future activities relevant to clinical practice guideline development. Financial compensation must be disclosed. There are provisions for someone not to participate in guideline development if they are viewed as of major importance for other areas, but then abstain from guideline development in the area where there is/are COI(s).</p> <p>The ACOEM <i>Practice Guidelines</i> includes an application process for all panel members. The application process includes each panel member completing an on online confidentiality conflict of interest form. Each guideline contains a list of panel members and a brief summary of their place(s) of employment, national, regional and local committee affiliations, guidelines related to professional activities, research grants/other support they are receiving; and any financial/nonfinancial conflicts of interest are listed. These are vetted by the ACOEM Guidelines Methodology Committee when someone has a significant COI(s) that requires further addressing and/or implementation of the management plan briefly noted above.</p> |
| <p>3. Quality of Evidence Outcome(s)</p> | |
| <p>The overall quality of evidence should be assessed for each important outcome and expressed using four (e.g. high, moderate, low, very low) or, if justified, three (e.g. high, moderate, and very low and low combined into low) categories based on definitions for each category that are consistent with the definitions used by the GRADE Working Group.</p> | <p>The ACOEM Guidelines process has 4 overall categories of evidence. The categories are High, Moderate, Low, and Insufficient evidence. The latter category may be considered equivalent to the GRADE “very low” category.</p> <p>High and moderate quality studies are abstracted into evidence tables that include details of study methods, outcomes, and statistical analyses (See above 2. Quality of Evidence). Low quality studies are not utilized for guidance but are compiled and included in appendices to help clearly denote and separate the included (high and moderate), from the excluded studies.</p> <p>Additionally, sparse data, such as in the case of a small sample size are evaluated differently than those studies with ample-sized samples. Also, if confidence intervals of a particular study are too wide, judgments regarding risks and benefits may result in a reduced recommendation</p> |

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| | rating, as such data must be considered sparse or imprecise. |
| 4. Judgments of Evidence Summaries | |
| <p>Evidence summaries (narrative or in table format) should be used as the basis for judgments about the quality of evidence and the strength of recommendations. Ideally, full evidence profiles suggested by the GRADE Working Group should be used and these should be based on systematic reviews. At a minimum, the evidence that was assessed and the methods that were used to identify and appraise that evidence should be clearly described. In particular, reasons for up and downgrading should be described transparently.</p> | <p>Evidence summaries are included for all topics. These are supplied in tabular form (see above), as well as in a summary paragraph form in the Rationale for Recommendation sections. All recommendations are also clearly stated in bold type. There is also a table at the beginning of each Guideline that lists all of the recommendations.</p> <p>For those that are recommended, also include indications, which are in detail to provide sufficient information to clarify the circumstances under which the intervention or procedures should be considered.</p> <p>Also recorded are the dose/frequency, discontinuation as appropriate, and harms/benefits. In cases where the higher quality study(ies) has(have) specific dose, frequency etc. information, that is preferentially referenced in the recommendation’s dose/frequency section to assist providers in identifying the specific intervention and schedule used to effect those superior results</p> <p>Strong recommendations are clearly stated as, “Strongly Recommended, Evidence A” in bold type. Each recommendation has an evidence table indicating the high and moderate quality studies used to develop that recommendation. Specific reference citations are also included in the rationale for recommendations to provide an explicit link between recommendations and evidence, and where appropriate, the specific citation(s) to develop the indications section are also noted.</p> <p>References for specific recommendations, dose, frequency, etc. are also cited to improve clarity and understanding of the sources of recommendations.</p> |
| 5. Balance | |
| <p>Explicit consideration should be given to each of the GRADE criteria for assessing the strength of a recommendation (the balance of desirable and undesirable consequences, quality of evidence, values and preferences, and resource use) and a general approach should be reported (e.g. if and how costs were considered, whose values and preferences were assumed, etc.).</p> | <p>Each strength of recommendation includes assessments and descriptions of benefits and harms; the guidelines include a succinct discussion regarding balancing desirable and undesirable consequences that emphasizes the quality of the evidence. Costs are also specifically included (low <\$100, moderate \$100-500, high >\$500), although in keeping with GRADE recommendations that are generally not included as affecting recommendations (accepting, for example, where there is equivalency but costs substantially differ). The trade-offs between risks and benefits are carefully considered before implementation into the ACOEM Guidelines. ACOEM Guidelines reflect the</p> |

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| | <p>overall strengths and weaknesses of the particular study in the comments section of the tables. If, for example, there are found to be usually high adverse events associated with the study, the table comments and rationale for recommendation will reflect this. Conversely, if there is apparent value in a particular study and body of evidence, the comments will contain the particular information. Additionally, bias is also evaluated in both RCTs and diagnostic studies in the ACOEM Guidelines.</p> |
| <p>6. Expression of Strength of Recommendations</p> | |
| <p>The strength of recommendations should be expressed using two categories (weak/conditional and strong) for or against a management option and the definitions for each category should be consistent with those used by the GRADE Working Group. Different terminology to express weak/conditional and strong recommendations may be used, although the interpretation and implications should be preserved</p> | <p>Each included article is critically appraised. The comments from the appraisal process are recorded in in the tables of evidence. The strengths and limitations of the body of evidence is in the rationale section for all recommendations.</p> <p>GRADE-style recommendations are used for all recommendations. Each strength of recommendation that has supportive quality evidence is clearly labeled as Strongly Recommended (A), Moderately Recommended (B), Recommended (C). For those with quality evidence against, they are similarly labeled Strongly Not Recommended (A), Moderately Not Recommended (B), Not Recommended (C). To attain a Strong (A) recommendation requires at least 2 high-quality, supportive/consistent studies. To attain Moderate (B) recommendations requires at least 1 high and/or multiple moderate quality, supportive/consistent studies. To attain a “C” letter recommendation requires at least one moderate-quality study. There are circumstances when strengths of recommendations may be downgraded and these are specified in the Rationale for Recommendation section whenever they occur (e.g., studies substantially conflict, severe adverse effects, elevated mortality rates, and lack of replication of prior results despite passage of at least 5 years).</p> <p>For those recommendations without quality evidence, they are also clearly designated as: (i) Recommended, Insufficient Evidence (I), (ii) No Recommendation (I), and (iii) Not Recommended, Insufficient Evidence (I). Insufficient evidence recommendations are based on either an absence of quality evidence, conflicting evidence, and/or expert panel consensus and are clearly designated as “I” as yet another example of thoughtful and deliberate transparency regarding the lack of quality supportive data and/or “very low” quality data used by GRADE.</p> |
| <p>7. Transparency</p> | |

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| <p>Decisions about the strength of the recommendations</p> | <p>ACOEM uses highly detailed criteria to develop strength of recommendations. This is accomplished to provide as transparent a set of processes as available anywhere in Guidelines. These transparent methods are more explicit than GRADE requires. The details for determination of strength of ratings are noted above and in the Methodology document.</p> <p>Briefly, research staff use the tables to grade the strength of evidence in order to draft specific clinical practice recommendations. The Evidence-based Practice Panels then review the draft strength of moderate and high-quality studies, study critiques, evidence ratings and recommendations, modify them as per the methodology, and develop final recommendations. In reviewing or revising recommendations, the expert Panels review the articles, evidence tables, and preliminary strength-of-evidence ratings (A, B, C, or I) that could be downgraded based on specific factors noted (e.g., studies substantially conflict, severe adverse effects, elevated mortality rates, and lack of replication of prior results despite passage of at least 5 years). Any downgrading is always specified in the Rationale for Recommendations section explicitly to assure transparency. Evidence tables are sequenced from high- to lower quality studies to assure that the replication of the strength of evidence ratings is also transparent and in keeping with the Rational for Recommendation section to further ability of others to test the results, update results with new studies and thus further Guidelines transparency.</p> <p>Panels discuss recommendations for diagnosis or treatment based on the critically appraised body of evidence using a “best evidence” approach. In addition to critically appraised evidence, “First Principles” of medical logic and ethics are observed in formulating recommendations. The ACOEM evidence-based recommendations are classified as follows: Strongly Recommended (A) (i.e., at least 2 high-quality studies); Moderately Recommended (B) (at least 1 high-quality and/or multiple moderate quality); Recommended (C) (at least one moderate quality study); Recommended, Insufficient Evidence (I); No Recommendation, Insufficient Evidence (I); Not Recommended, Insufficient Evidence (I); Not Recommended (C); Moderately Not Recommended (B); and Strongly Not Recommended (A). The Insufficient evidence recommendations are used to clearly denote these are expert consensus recommendations.</p> |
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7.4. Appendix 4: Methods by Which ACOEM Adheres to the IOM Criteria

| IOM CRITERIA | ACOEM PRACTICE GUIDELINE PROCESS |
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| STANDARD 1: Establishing Transparency | |
| 1.1 The processes by which a CPG is developed and funded should be detailed explicitly and publicly accessible. | The ACOEM Guidelines have longstanding methodology documents available on ACOEM’s website that are highly detailed regarding how the Guidelines are developed and produced. |
| STANDARD 2: Management of Conflict of Interest (COI) | |
| <p>2.1 Prior to selection of the Guideline Development Group (GDG), individuals being considered for membership should declare all interests and activities potentially resulting in COI with development group activity, by written disclosure to those convening the GDG.</p> <ul style="list-style-type: none"> · Disclosure should reflect all current and planned commercial (including services from which a clinician derives a substantial proportion of income), non-commercial, intellectual, institutional, and patient/public activities pertinent to the potential scope of the CPG. <p>2.2 Disclosure of COIs within GDG</p> <ul style="list-style-type: none"> · All COI of each GDG member should be reported and discussed by the prospective development group prior to the onset of their work. · Each panel member should explain how their COI could influence the CPG | <p>Methods for addressing Conflicts of Interest (COI) are detailed in the methodology documents. This includes an extensive COI form that must be completed by all individuals of Guidelines Development Group (i.e., panels). Process include disclosing current and potential future activities relevant to CPG development. Financial compensation must be disclosed as well. There are provisions for someone to not participate in guideline development if they are viewed as of major importance for other areas, but then abstain from guideline development in the area where there is/are COI(s).</p> <p>The ACOEM <i>Practice Guidelines</i> includes an application process for all panel members. The application process includes each panel member completing an online confidentiality/conflict of interest form. Each guideline contains a list of the panel members and a brief summary of their place(s) of employment; national, regional, and local committee affiliations; guidelines related professional activities; research grants/other support they are receiving; and any financial/non-financial conflict of interests are listed. These are vetted by the ACOEM Guidelines Methodology Committee when someone has a significant COI(s) that requires further addressing and/or implementation of the management plan briefly noted above.</p> <p>ACOEM works to limit COIs. ACOEM’s Guidelines Methodology Committee selects those with fewer or no COI rather than those with larger COI(s). A few members have national recognition and expertise in a select area. If these members of the Guidelines Development Group have any involvement of COI, these members are not allowed to comment on the particular subject. They are utilized for their expertise on subject matter and guidelines topics for which they do not have COI(s). ACOEM Guidelines never use a majority of panel members who have COIs. Chairs are never chosen who have COIs. Funders have no role in the clinical practice guideline development.</p> |

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| <p>development process or specific recommendations.</p> <p>2.3 Divestment</p> <ul style="list-style-type: none"> Members of the GDG should divest themselves of financial investments they or their family members have in, and not participate in marketing activities or advisory boards of, entities whose interests could be affected by CPG recommendations. <p>2.4 Exclusions</p> <ul style="list-style-type: none"> Whenever possible GDG members should not have COI. In some circumstances, a GDG may not be able to perform its work without members who have COIs, such as relevant clinical specialists who receive a substantial portion of their incomes from services pertinent to the CPG. Members with COIs should represent not more than a minority of the GDG. The chair or co-chairs should not be a person(s) with COI. Funders should have no role in CPG development. | |
| <p>STANDARD 3: Guideline Development Group Composition</p> | |
| <p>3.1 The GDG should be multidisciplinary and balanced, comprising a variety of methodological experts and clinicians, and populations expected to be</p> | <p>The ACOEM empanels a group of multidisciplinary experts for each panel. Panels include relevant experts (e.g., for Low Back Pain, including expertise in occupational medicine, orthopedics, neurosurgery, pain medicine, chiropractic, physical therapy, psychology, and methodologists). ACOEM further seeks to balance panels based on emphases. For example, chronic pain includes more</p> |

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| <p>affected by the CPG.</p> <p>3.2 Patient and public involvement should be facilitated by including (at least at the time of clinical question formulation and draft CPG review) a current or former patient and a patient advocate or patient/consumer organization representative in the GDG.</p> <p>3.3 Strategies to increase effective participation of patient and consumer representatives, including training in appraisal of evidence, should be adopted by GDGs.</p> | <p>psychologists than other body parts due to the predisposing mental health factors plus comorbid conditions of depression and anxiety.</p> <p>Patient and public involvement is sought at multiple steps in the process. Involvement of patient advocates has been included, including 501c3 patient-advocacy organizations and legal representatives. Involvement of labor/worker/union physicians has been included.</p> <p>ACOEM seeks input from stakeholders, including patients, consumer advocates, professional societies, unions, insurers, into the scoping of the guidelines by inviting them to submit comments to us through our website (https://form.jotform.com/202114643550141) on the list of clinical questions we research for each guideline.</p> <p>ACOEM also has a webpage (https://form.jotform.com/202114270486044) that provides workers, businesses, insurers, union representatives, occupational health professionals, patients, and other stakeholders in evaluation and treatment of work-related health issues a means to provide input into the <i>Practice Guidelines</i>.</p> <p>The Reed Group also has a feedback process to provide feedback on the ACOEM guidelines.</p> |
| <p>STANDARD 4: Clinical Practice Guideline-Systematic Review Intersection</p> | |
| <p>4.1 CPG developers should use systematic reviews that meet standards set by the Institute of Medicine’s Committee on Standards for Systematic Reviews of Comparative Effectiveness Research.</p> <p>4.2 When systematic reviews are conducted specifically to inform particular guidelines, the GDG and systematic review team should interact regarding the scope, approach, and output of both processes.</p> | <p>ACOEM utilizes Cochrane systematic reviews, in addition to other scientific systematic reviews that meet or exceed the IOM’s Committee on Standards for Systematic Reviews of Comparative Effectiveness Research. However, the ACOEM Guidelines relies on systematic reviews conducted in accordance with the highest standards to provide current guidance on the relevant clinical questions.</p> <p>The Research Team staff conduct exhaustive systematic literature reviews for each guideline topic/question. In order to identify all high- and moderate-quality original research studies, the literature search is broad and comprehensive. Medical Terms (MeSH Terms) are used to identify studies relevant to answer the questions regarding the treatments and diagnostic procedures. A combination of MeSH terms and other terms are typically used in order to determine the method that will yield the most relevant studies in the search process.</p> <p>ACOEM searches PubMed, CINAHL, Cochrane Central Registry of Controlled Trials, and Scopus for primary sources of original research. ACOEM conducts extensive supplementary searches using review articles, systematic reviews, and reference lists of the included and excluded studies. It also searches other databases likely to contain references of high quality medical literature, including Google Scholar to identify potential quality, impactful</p> |

literature that includes the grey literature. Additional literature is reviewed that is brought to the research team's attention from interested parties (e.g., panel members, public).

Search strategies and methods are recorded in detail, including specific databases, search terms, number of studies found (e.g., regarding treatment efficacy searches including RCTs and crossover trials) are documented. A search results section in paragraph form is also included as a footnote for each evidence table. This section includes the databases searched, that there were no limits on publication dates, limited to English language (although we also have used citations of foreign language articles that suggest results for a potentially quality study, we do not use them for guidance), the search terms used, the number of studies found from all the databases searched, the total number of articles screened, the number meeting inclusion and exclusion criteria, the number critically appraised, and the total number of studies included of high or moderate quality. Those of low quality are also clearly identified in tables.

The criteria for scoring the studies were all developed a priori. The criteria for the scientific quality of the included studies is clearly specified in the methodology documents. This includes 2 specific scoring tools. Each study is individually scored. This scoring system includes 11 specific, well-defined, measureable quality metrics. Naturally, it does not include merely study design. Each criterion is scored 0, 0.5 or 1.0 based on the degree to which the criterion is met. There are 'anchors' or scoring guides for applying the tool. The sum of the scores determines the quality rating. Low quality is a score of 0-3.5, moderate of 4.0-7.5, and high of 8.0+. All RCTs and randomized crossover trials are considered to have an intrinsic level of confidence in the results of "I."

For observational studies, a design level of "II" includes prospective cohort studies, prospective comparative studies, case-crossover and large, population-based studies. A level of confidence of "III" is used for retrospective, case control or cross-sectional studies. While study design should confer various levels of confidence in the reproducibility of the results, how the studies are conducted and analyzed is quite variable and must be specifically appraised. Another comparable but somewhat different tool is used to score diagnostic studies. Rarely, a study has fatal flaw (e.g., high dropout rate) that negates that study's quality score and is noted in the comments/critique. This ACOEM scoring tool includes metrics used in most other major scoring tools but includes more metrics than most tools. It has proven durable and reproducible. Those of low as well as high quality are clearly identified in tables and both high- and low-quality studies are evaluated such that the comments and scores reflect the quality of the study.

The methodological rigor and scientific quality of individual studies are including in the individual study scores are then summed into 'letter-grade' recommendations, or A, B, C recommendations in favor or against a treatment or diagnostic test based upon the

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| | <p>numbers and quality of studies in favor/against the intervention or test. This too is clearly spelled out in the methodology documents.</p> <p>The ACOEM evidence-based recommendations are classified as follows: Strongly Recommended (A) (i.e., at least 2 high-quality studies); Moderately Recommended (B) (at least 1 high-quality and/or multiple moderate quality); Recommended (C) (at least one moderate quality study); Recommended, Insufficient Evidence (I); No Recommendation, Insufficient Evidence (I); Not Recommended, Insufficient Evidence (I); Not Recommended (C); Moderately Not Recommended (B); and Strongly Not Recommended (A). The Insufficient evidence recommendations are used to clearly denote these are expert consensus recommendations.</p> <p>In cases where evidence is either absent or substantially conflicting, Insufficient Evidence, is used to clearly demarcate consensus-based recommendations.</p> <p>In formulating the final recommendations, the numbers of studies, the strength of those studies, are all included in summary statements in the clearly defined, “Rationale for Recommendation” section of each guidelines statement.</p> <p>There are cases where it is sensible to perform combined analyses, and pooled analyses are performed. In those cases, test for homogeneity (I^2), and/or random effects models are used are performed. These are reported in the guidelines. Additionally, many pooled analyses are performed by Cochrane reviews. Those are used provided they are reasonable to perform the summary estimates (these would rarely be disagreed with). However, there are many guideline recommendations for which summary measures would be inappropriate due to differing attributes across the studies on that given topic including: population heterogeneity, use of different outcome measures, substantially varying time intervals, etc.</p> <p>After performing the systematic review for the ACOEM Guidelines, any discrepancies with prior quality systematic reviews are addressed first in the Guideline development group and then in the panel deliberation processes.</p> |
| <p>STANDARD 5: Establishing Evidence Foundations for and Rating Strength of Recommendations</p> | |
| <p>5.1 For each recommendation, the following should be provided:</p> <ul style="list-style-type: none"> · An explanation of the reasoning underlying the recommendation, including: -A clear description of | <p>Each recommendation has a description of the benefits and the harms.</p> <p>There is a summary of all relevant available evidence. This is provided in tables of included studies, as well as excluded studies. The quality evidence is then summarized in the Rationale for Recommendation section. This includes a succinct discussion of the limitations of the quality and quantity of the literature base. Consistency is addressed in this summary. Conflicts are highlighted and if significant, Insufficient Evidence (aka consensus)</p> |

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| <p>potential benefits and harms.</p> <p>-A summary of relevant available evidence (and evidentiary gaps), description of the quality (including applicability), -quantity (including completeness), and consistency of the aggregate available evidence.</p> <p>-An explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendation.</p> <ul style="list-style-type: none"> · A rating of the level of confidence in (certainty regarding) the evidence underpinning the recommendation. · A rating of the strength of the recommendation in light of the preceding bullets. · A description and explanation of any differences of opinion regarding the recommendation. | <p>recommendations may be provided to clearly demarcate the limits of quality studies.</p> <p>Where there are no quality studies, or substantially conflicting studies, only consensus of Insufficient Evidence recommendations are possible. This is intentionally done to provide a clear mark for expert opinion and clinical experience. Where relevant, theories are also often mentioned, including relevant citations.</p> <p>A rating of the level of confidence is included for all recommendations in updated/new guidelines.</p> <p>A rating of the strength of the recommendation is provided in bold type for all recommendations (see above discussion and methodology documents).</p> <p>In rare cases, there is a split opinion on a panel. This is reported as a percentage of votes. The rationale for the dissension is briefly discussed.</p> |
| <p>STANDARD 6: Articulation of Recommendations</p> | |
| <p>6.1 Recommendations should be articulated in a standardized form detailing precisely what the recommended action is and under what circumstances it should be performed.</p> <p>6.2 Strong recommendations should be worded so that compliance with the recommendation(s) can be evaluated.</p> | <p>All recommendations are clearly stated and are in bold type.</p> <p>For those that are recommended, we also include indications, which are in detail to provide sufficient information to clarify the circumstances under which the intervention or procedures should be considered.</p> <p>Also recorded are the dose/frequency, discontinuation as appropriate, and harms/benefits. In cases where the highest quality study has specific dose, frequency, etc., information, that is preferentially referenced in the recommendation’s dose/frequency section to assist providers in identifying the specific intervention and schedule used to effect those results.</p> <p>Strong recommendations are clearly stated as, “Strongly Recommended, Evidence A” in bold type. Each recommendation has an evidence table indicating the high and moderate quality studies used to develop that recommendation. Specific reference citations are also included in the rationale for recommendations to provide an explicit link between recommendations and evidence, and where</p> |

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| | appropriate, the specific citation(s) to develop the indications section are also noted. |
| STANDARD 7: External Review | |
| <p>7.1 External reviewers should comprise a full spectrum of relevant stakeholders, including scientific and clinical experts, organizations (e.g., health care, specialty societies), agencies (e.g., federal government), patients, and representatives of the public.</p> <p>7.2 The authorship of external reviews submitted by individuals and/or organizations should be kept confidential unless that protection has been waived by the reviewer(s).</p> <p>7.3 The GDG should consider all external reviewer comments and keep a written record of the rationale for modifying or not modifying a CPG in response to reviewers' comments.</p> <p>7.4 A draft of the CPG at the external review stage or immediately following it (i.e., prior to the final draft) should be made available to the general public for comment. Reasonable notice of impending publication should be provided to interested public stakeholders.</p> | <p>Extensive, independent external peer-reviewers are sought for each guideline. These may number as many as 40 identified individuals per guideline (many times, the total number is unclear as the society or organization provides one summary opinion). External reviewers are comprised of national as well as international experts on the particular subject matter. We invite the relevant other professional societies to review (e.g., American Physical Therapy Association, American College of Preventive Medicine, The American Occupational Therapy Association, American Academy of Physical Medicine & Rehabilitation, Academy of Organizational & Occupational Psychiatry, American Association of Occupational Health Nurses, American Academy of Disability Evaluating Physicians, American Academy of Neurology, American Association of Neuromuscular & Electrodiagnostic Medicine, American Board of Independent Medical Examiners, American Psychological Association, California Orthopaedic Association's Workers' Compensation Committee, Society for Industrial and Organizational Psychology, American College of Physicians, American Osteopathic College of Occupational and Preventive Medicine, Association for Applied Psychophysiology and Biofeedback, and Society for Behavioral Medicine). Target users for reviews also include appropriate healthcare organizations, patients and consumers, clinical case managers, insurance and third-party administrators, claims adjusters, utilization reviewers, attorneys, judges, regulators, and workers' compensation regulators and policy makers. The federal government is largely uninvolved in workers' compensation.</p> <p>ACOEM maintains records of external reviews. It maintains confidentiality of the reviews. Some external peer-reviewers choose to remain anonymous, and ACOEM respects those wishes. Those who choose to not remain anonymous are acknowledged in the specific guideline they reviewed. ACOEM wishes to thank all external peer reviewers for their services that are viewed as important to the development of high-quality evidence-based treatment guidelines for the care of injured workers.</p> <p>All comments from external reviewers are maintained and considered prior to final clinical practice guideline publication. Individualized responses are sent for every comment received to the reviewer(s) to note the inclusion, and in some cases, lack of inclusion of the suggestion in the final document. Changes in the language are provided to the reviewers in response to their concerns. In rare cases, additional clarification to a revision has been sent by the reviewer and generally has been incorporated.</p> <p>A pre-publication version of all guidelines will be posted at the <i>MDGuidelines</i> site for a period of two weeks for public comment.</p> |

| STANDARD 8: Updating | |
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| <p>8.1 The CPG publication date, date of pertinent systematic evidence review and proposed date for future CPG review should be documented in the CPG.</p> <p>8.2 Literature should be monitored regularly following CPG publication to identify the emergence of new, potentially relevant evidence and to evaluate the continued validity of the CPG.</p> <p>8.3 CPGs should be updated when new evidence suggests the need for modification of clinically important recommendations. For example, a CPG should be updated if new evidence shows that a recommended intervention causes previously unknown substantial harm, that a new intervention is significantly superior to a previously recommended intervention from an efficacy or harms perspective, or that a recommendation can be applied to new populations.</p> | <p>ACOEM guidelines have comprehensive reviews at least every 3-5 years and more frequently as salient and pertinent articles potentially affect the guidance and recommendations.</p> <p>The publication date, systematic review dates and proposed updating dates are all documented.</p> <p>The literature is continuously monitored for new scientific publications by the research team as well as the CPG and GDP as new articles are published.</p> <p>ACOEM does a yearly review of the literature and makes immediate changes to the guidelines if new high and moderate quality RCTs become available that require a significant change in the recommendations. This will occur as quickly as a couple weeks to complete the through process if there is a major study produced that changes existing guidance.</p> |

8. Attachments

8.1. Attachment 1: Clinical Questions in the Key Domains of Occupational Medicine Practice

The *Guidelines* may answer the following clinical questions about variably diagnosed or treated, disabling, costly (individually or in the aggregate), controversial or common conditions:

Diagnosis

- What are the unique diagnostic criteria for a given condition?
 - What is the diagnostic test performance (+/- predictive value, likelihood ratios)?
- What are the most effective methods and approaches for the (early) identification or diagnosis of the condition?
 - At what time in the course of the disorder are the methods and approaches appropriate? Why?
 - What is the relationship, if any, between a patient's age, gender, socioeconomic status and/or racial or ethnic grouping and specific treatment outcomes for the condition?

Treatment

- What are the most effective methods and approaches for treating the condition that improve on the untreated/natural course of recovery?
 - At what time in the course of the disorder are the methods or approaches most effective? Why?
 - Are there any individual factors that quality evidence indicates would result in superior outcomes if they are included in the treatment selection(s), e.g., age, sex, gender, job physical demands, psychosocial factors, etc.?
 - Are there contraindications to the methods or approaches?
- What are the specific diagnoses and indications, if any, for surgery as a means of treating the condition?
 - What prior conservative treatment is appropriate?
 - At what time in the course of the disorder is surgery appropriate and effective, with benefits exceeding harms? Why?
 - What are the relative and absolute contraindications for surgical procedures?
 - What are the relative benefits and harms of the various surgical and non-surgical interventions that may be used to treat the condition?

8.2. Attachment 2: Problem Formulation Example

| | |
|--|--|
| Clinical Question | What are the most appropriate, necessary, efficient and effective [etiologic analyses] [tests/methods] [treatments] to ... |
| Intended Use of Guideline | To assist clinicians with the management of ... |
| Population | Workers |
| Health Problem | [Symptom] [Diagnosis, defined by...] |
| Health Intervention[s] | History Risks Physical exam Tests Medications Physical medicine Procedures |
| Practitioners | Occupational health nurses, occupational medicine physicians, chiropractors, physical therapists, etc. |
| Setting | Outpatient? Inpatient? |
| Intermediate biological or statistical outcomes | Health service use Sensitivity, specificity, FP, FN, predictive value, OR, NNT Iatrogenic problems, NNH Symptom frequency and severity Time loss Reduced work capacity |
| Important health and economic outcomes | Function Disability, productivity/work capacity, and time lost from work Impairment Quality of work or personal life Costs of prevention or treatment vs. benefits Health service use, efficiency |

8.3. Attachment 3: Procedures for the Selection and Training of Guidelines Development Groups

1. Selection of Guidelines' Development Groups

ACOEM invites individuals to apply to serve on an Evidence-based Practice Panel by completing an application and confidentiality/disclosure form and sending a copy of their CV. All applications are reviewed by the GMC who then appoints the panel members. Information provided in CV may be verified for accuracy. Initially, committee and panel members will serve for one three year revision cycle unless reappointed using the procedures below. ACOEM maintains documentation of these applications, invitations to external organizations, qualifications, selection, acceptances and membership for committees, panels and external reviewers. Clinicians with vested interests in promoting their clinical practice patterns are identified as also having potential conflicts of interest and individuals with experience in workers' compensation claims administration have significant value in identifying potential topics, difficulties with guidelines interpretations, etc. Thus, the membership of these panels has been broadened to incorporate greater diversity and thus strengthen the processes. In some cases, ACOEM invites individuals to serve as consultants to the panel to serve as an "expert" on a particular area in that guideline. Therefore, they will only be responsible for reviewing and assisting the panel on a particular topic.

Ongoing Selection Process

As committee and panel members finish their terms or leave the committees or panels for other reasons, ACOEM will invite members to apply for one or more of the committees and panels described above. Interested individuals will submit a current CV, completed application (Attachment 4), and confidentiality and disclosure forms ([Attachment 5](#)). The GMC reviews the applications and assigns interested individuals to the appropriate committee/panel. Appointments are based on the expressed interest of the applicant, education, and experience in evidence-based medicine.

The ACOEM President will also invite selected medical specialty societies to nominate individuals to serve on appropriate committees or panels. Nominations will be sought from relevant clinical specialty organizations, as well as from other sources. All individuals interested in serving as a Panel member will follow the same application process as ACOEM members. ACOEM will inform the professional societies that their nominees may or may not be selected for a particular Panel. The GMC assures that all Panels have adequate representation from the appropriate medical and non-medical specialties relevant to the topic. However, selected Panel members will serve as individuals bringing the perspective of their discipline, and not as formal representatives of their professional societies. All applicants that are not selected as Panel members will be invited to participate in the external peer review process.

2. Training Guideline Development Groups

The GMC trains the Panels on the approved methodology as described herein. A sample training curriculum is presented in [Attachment 6](#). Training is available online so that Panel members can download and view the training materials at their convenience. All members involved in the update of the Guidelines and the production of other evidence-based products and educational efforts will be required to view the training.

8.4. Attachment 4: ACOEM Evidence-based Practice Committee Appointments Application Form

I (please print your name here) would like to be considered for membership on the (please check all that apply):

- The **Methodology Committee** which is charged with developing, maintaining, and ensuring adherence to state-of-the-art methods.
- The **Evidence-based Practice Committee (EBPC)** which is charged with oversight of the operations of the guidelines. The ACOEM Guidelines Editor-in-Chief will chair this Committee.
- An **Evidence-based Practice Panel** which is a subgroup of the EBPC and will focus on developing body part/system specific evidence-based guideline recommendations. As there are multiple subgroups appointed, please specify the body part or specific system that you are most interested in (e.g., shoulder, hand, mental health, respiratory, etc.). The EBPP is responsible for oversight of the acquisition of quality evidence, evaluation of the evidence, as well as with development of evidence-based practice recommendations.

Body Part/System _____

To assist ACOEM in evaluating your committee preference(s), please provide the following information. (Be concise and attach any additional supporting information as necessary.)

1) ABMS certification(s) you hold (check all that apply):

Occupational Medicine

Preventive Medicine (e.g., General Preventive Medicine or Aerospace Medicine)

Orthopedic Surgery

Physical Medicine & Rehabilitation

Family Medicine

Internal Medicine

Other (please specify): _____

2) Graduate degrees you hold (check all that apply):

MD

DO

PhD

MPH/MSPH

MS

DrPH

DC

Other _____

3) Describe your formal training in clinical epidemiology and biostatistics. (List schools and degrees and/or courses, and any training received in non-degree programs.)

Number of graduate credits you have had in:

Epidemiology: ____ credits

Biostatistics: ____ credits

4) Briefly describe your experience in conducting formal reviews of the medical literature. (For example, for which journals have you provided review services and how often? How many reviews have you conducted to date? What other types of reviews have you performed?)

5) Describe any contributions you have made, especially to the medical literature, and identify the subject. (For example, how many epidemiological research articles have you published? How many clinical research articles? How many meta-analyses/structured review papers? How many other systematic reviews have you completed, including technical reports, and on what subjects?)

- 6) Describe any experience you have had in serving on guideline creation panels and/or consensus panels.
- 7) What relevant national, regional, or local committees have you served on?
- 8) What are your primary reasons for wanting to participate on the committee/panel you selected?
- 9) What do you see as your primary strengths?
- 10) What biases might you bring to the process (and we all have some)?
- 11) Do you have any potential financial or non-financial conflicts of interest? Are you currently involved in developing treatment guidelines for other organizations? If yes, please explain.
- 12) Is there any particular clinical expertise that you bring to this project? If so, please elaborate.
- 13) Is there any particular technical expertise (e.g., statistics, analyzing the medical literature, or creating guidelines) that you bring to this project? If so, please explain.

8.5. Attachment 5: Panel Member Confidentiality Agreement / Statement of Disclosures

Name:

Company:

Which panel(s) are you on or being considered for?

Panel 1:

Panel 2:

Date:

In serving as an Evidence-based Practice Panel Member for the updates to the American College of Occupational and Environmental Medicine's (ACOEM) Occupational Medicine Practice Guidelines, I agree to participate in all calls, conferences and meetings as possible and (check each to indicate my understanding):

Confidentiality: I will keep all information, emails, discussions and notes pertaining to the guideline under development confidential.

Drafts: I will not copy or distribute any version or portions of the guideline to which I contribute to non-panel members at any time.

Copyright Ownership: I understand that the ACOEM Guidelines are owned by the Reed Group and nothing in my panel participation can be considered a transfer of copyright.

Acknowledgement: I understand that my participation is voluntary and published acknowledgement online or in print is to be expected but may be withheld if my participation was limited or I withdraw from the panel.

Methodology: I understand and will abide by the ACOEM Guideline Methodology and principles of evidence-based medicine and am prepared to participate in panel activities.

Conflict of Interest: I understand that the ACOEM Guidelines are developed in a transparent manner and I will fully disclose potential conflicts of interest consistent with the CMSS standards of disclosure.

Conflict of Interest: In keeping with IOM standards, I will disclose any potential financial or intellectual relationships that a user of the ACOEM Guidelines might construe as bias and will update ACOEM as to any changes during my panel tenure.

Conflict of Interest: I understand that ACOEM will have the right to limit my panel participation in some or all areas to achieve the balance required to produce guidelines of the highest quality.

Transparency: I understand that these disclosures are in keeping with the IOM standards and are for the intention of managing conflict of interest. As part of a transparent process, these disclosures may be published, released or electronically posted. In addition to sending a copy of your CV, please specify the names and nature of the relationship for the questions below (only include relationships that are or potentially could be worth more than \$10,000 during the course of panel participation). When appropriate, you may indicate "see CV" but please be specific (e.g., "see CV," page 4).

Financial

Employment (list organizations/employers):

Organization/Employer 1 _____

Organization/Employer 2 _____

Organization/Employer 3 _____

List those who contract for your services:

Contractor 1 _____

Contractor 2 _____

Contractor 3 _____

Clinical Practice Focus (list clinical activities that contribute more than 10% of annual income – e.g., surgical or pain-control procedures, diagnostic studies, etc.):

Clinical Activity 1 _____

Clinical Activity 2 _____

Clinical Activity 3 _____

Clinical Activity 4 _____

Business Ownership (list health-related businesses where you have more than a 10% equity position):

Business 1 _____ Description _____

Business 2 _____ Description _____

Institutions (list institutions that contract for your services):

Institution 1 _____

Institution 2 _____

Consultancy (list consulting projects or activities within the last year that have contributed more than 10% of annual income):

Client 1 _____

Client 2 _____

Client 3 _____

Honoraria/Speakers Bureau (list any advisory or speaking relationships where drugs might be related to possible interventions addressed by the guidelines):

Client 1 _____ Topic _____

Client 2 _____ Topic _____

Client 3 _____ Topic _____

Legal Testimony (list any legal testimony that might be related to possible interventions addressed by the guidelines):

Client 1 _____

Client 2 _____

Client 3 _____

Other Potential Income Sources (list any interests that may be associated with guidelines recommendations outcomes i.e., stock in a pharmaceutical company that might be subject to recommendation):

Stocks/Options _____

Legal Consulting (topic areas in which you provided medical legal consulting)

Royalties _____

Other _____

Intellectual

(In addition to your CV, list any current or past committee memberships, grants or manuscripts published or in preparation that relationships that might be related to possible interventions addressed by the guidelines):

Other ACOEM Guideline Panels:

Panel 1 _____

Panel 2 _____

Panel 3 _____

Other non-ACOEM Guideline Panels:

Panel 1 _____

Panel 2 _____

Panel 3 _____

Panel 4 _____

Other Relevant ACOEM and non-ACOEM Committees:

Committee 1 _____

Committee 2 _____

Committee 3 _____

Committee 4 _____

Committee 5 _____

Current or Pending Research Grants (e.g., federal, private, foundation):

Agency 1 _____

Agency 2 _____

Agency 3 _____

Agency 4 _____

Other Research Interests (if not previously covered):

Research Area #1 _____

Research Area #2 _____

Research Area #3 _____

Research Area #4 _____

Research Area #5 _____

Research Area #6 _____

If you have other disclosures or potential spousal or familial disclosures, please list here:

8.6. Attachment 6: Training Curriculum

Introduction to Evidence-Based Medicine

- Historical background
 - Practice variance
 - Cost escalation without outcome improvement
 - Role of clinical expertise and judgment
- Dimensions of EBM in Occupational Medicine
 - Diagnosis and testing
 - Work-relatedness
 - Treatment
 - Pain management
- Disability management and return to work
 - Often independent from medical care
- Impairment evaluation
- Improving consistency / reducing variance, improving value and quality
 - Evidence
 - Thought process
 - First principles

ACOEM Clinical Practice Guidelines Process

- Definition of clinical practice guidelines
- Stakeholders
- Purpose
- Committee Structure and roles
- Steps in the process

Asking Answerable Clinically Relevant Questions

- Posing answerable clinical questions
- PICO(T)

Key Principles and Levels of Evidence

- Could the effect be due to chance?
- Harms and benefits
- Randomized Controlled Trials (RCTs)
- Cohort studies
- Case-control studies
- Case series
- Retrospective population studies – claims data analyses
- Cross-system studies
- Causation analysis
- Crossover studies and trials of one
- Evidence rating schemes

Evidence Searches

- Databases
- Search terms and MESH headings
- Focusing the search
- Full text searches
- Related articles and authors
- Documentation (search criteria and search results)

Studying a Study

- Study design
 - Entry/enrollment criteria
 - Definition and standardization of testing or treatment
 - Blinding
 - Allocation
 - Outcomes
 - Dropout rates, non-responders
- Basic statistics
 - Sensitivity and specificity (positive and negative predictive values, likelihood ratios, ROC curves)
 - Confidence intervals and meta-analysis
 - Tests of significance
 - Power calculations, sample size, etc.
 - Number needed to treat

Issues in Musculoskeletal Research – the State of the Art

- Entry criteria
 - Definition
 - Severity levels
- Blinding – dimensions
- Sample and sample size
- Standardizing the intervention
- Multiple simultaneous interventions
- Outcomes under study
 - Pain
- Confounders
 - Litigation
 - Compensability

Systematic Reviews and Meta-Analysis

- Process
- Homogeneity
- Strengths and Weaknesses

Recommendations

- First principles
- Formulation – what a good recommendation looks like
- Process
- Documentation
- Levels and classification schemes (AHRQ, CEBM, other schemes)
- Clarity and explicitness
- Usability

8.7. Attachment 7: Evidence Ranking by Type of Clinical Question

Clinical Assessment Methods (Diagnosis and Testing) (15,14,16,17,18)

- 1a. Clinical practice guidelines validated on a test set
- 1b. Independent blind comparison of patients from an appropriate spectrum of patients, all undergoing the diagnostic test and a good reference standard
- 1c. Absolute SpPins and SnNouts
2. Independent blind or objective comparison
 - Study of non-consecutive patients, or narrow spectrum, all undergoing the diagnostic test and a good reference standard
 - Diagnostic CPG not validated in a test set
3. Independent or blind comparison of an appropriate spectrum but the reference standard was not applied to all patients or was of poor quality

Clinical Treatment Methods

1. Individual high-quality randomized controlled trial with narrow confidence interval
1. All-or-none studies
2. High-quality individual cohort studies or low quality RCTs (e.g. < 80% follow up)
- 3a. High-quality individual case-control studies
- 3b. High-quality retrospective cohort studies

Harms

1. Individual high-quality RCTs with narrow confidence intervals
- 2a. High-quality prospective cohort studies
- 2b. Low-quality RCTs
- 3a. High-quality retrospective cohort studies
- 3b. High-quality individual case control studies

Symptom and Prevalence Studies

- 1a. Prospective cohort studies with sufficient follow-up
- 1b. All-or-none case series
2. High-quality ecological studies
- 3a. Non-consecutive cohort studies or very limited populations
- 3b. Retrospective cohort studies or poor follow-up

Disability Management

- 1a. Individual randomized controlled trial with narrow confidence interval

- 1b. All-or-none studies
- 2. High-quality individual cohort studies or low-quality RCTs (e.g. < 80% follow-up)
- 3a. High-quality individual case-control studies
- 3b. High-quality retrospective cohort studies

Homogeneity means a systematic review that has minimization of worrisome variations (heterogeneity) in the directions and degrees of results between individual studies. Not all systematic reviews with statistically significant heterogeneity need be worrisome, and not all worrisome heterogeneity need be statistically significant. As noted above, studies displaying worrisome heterogeneity should be tagged with a "-" at the end of their designated level.

Clinical decision rules are algorithms or scoring systems which lead to a prognostic estimation or a diagnostic category.

A **high-quality randomized controlled trial** (RCT) should have the following criteria: adequate randomization; concealed treatment allocation; baseline similarity of groups; patient, provider, and assessor blinding; avoided co-interventions; compliance that is acceptable in all groups; an acceptable description for dropout rates; timing outcome assessment; intention to treat analysis; and low risk of bias.

A **high-quality cohort study** is one that clearly defined comparison groups and measured exposures and outcomes in the same (preferably blinded), objective way in both exposed and non-exposed individuals and identified or appropriately controlled known confounders, and carried out a sufficiently long and complete follow-up of patients.

A **poor-quality cohort study** is one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both exposed and non-exposed individuals and/or failed to identify or appropriately control known confounders and/or failed to carry out a sufficiently long and complete follow-up of patients.

A **high-quality case-control study** is one that clearly defined comparison groups and measured exposures and outcomes in the same (preferably blinded), objective way in both cases and controls and identified or appropriately controlled known confounders.

A **poor-quality case-control study** is one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both cases and controls and/or failed to identify or appropriately control known confounders.

Split-sample validation is achieved by collecting all the information in a single tranche, then artificially dividing this into "derivation" and "validation" samples.

An "**Absolute SpPin**" is a diagnostic finding whose Specificity is so high that a Positive result rules-in the diagnosis.

An "**Absolute SnNout**" is a diagnostic finding whose Sensitivity is so high that a Negative result rules-out the diagnosis.

Good, better, bad and worse refer to the comparisons between treatments in terms of their clinical risks and benefits.

Good reference standards are independent of the test and applied blindly or objectively to applied to all patients.

Poor reference standards are haphazardly applied, but still independent of the test. Use of a nonindependent reference standard (where the 'test' is included in the 'reference' or where the

'testing'
affects the 'reference') implies a level 4 study.

Better-value treatments are clearly as good but less costly, or better at the same or reduced cost.

Worse-value treatments are as good and more expensive, or worse and the equally or more expensive.

Validating studies test the quality of a specific diagnostic test, based on prior evidence.

An **exploratory study** collects information and trawls the data (e.g. using a regression analysis) to find which factors are "significant."

A **poor-quality prognostic cohort study** is one in which sampling was biased in favor of patients who already had the target outcome, or the measurement of outcomes was accomplished in <80% of study patients, or outcomes were determined in an unblinded, non-objective way, or there was no correction for confounding factors.

Good follow-up in a differential diagnosis study is >80%, with adequate time for alternative diagnoses to emerge (e.g., 1-6 months acute, 1-5 years chronic)

8.8. Attachment 8: Diagnostic Summaries

General Diagnostic Summary Format

| Author Year (Score): | Category: | Study type: | Conflict of Interest: | Sample size: | Age/Sex: | Diagnoses: | Comparison: | Results: | Conclusion: | Comments: |
|----------------------|-----------|-------------|-----------------------|--------------|----------|------------|-------------|----------|-------------|-----------|
|----------------------|-----------|-------------|-----------------------|--------------|----------|------------|-------------|----------|-------------|-----------|

This format is used in current guidelines. This is the standard format for diagnostic and screening topics. In guidelines published prior to 2014, different formats were used for specific topics. Those formats are listed below:

Imaging/Radiology Studies

Imaging and radiology diagnostic studies will use a table format different from the RCT table. The column headers will vary with each type of imaging/radiology diagnostic tool. Below is a list of imaging/radiology studies with the appropriate table headers.

Roentgenograms (X-Rays)

| Comments | Conclusion | Results | Long term follow-up (mean when noted) | Clinical outcomes assessed | Surgery Performed | Myelography | Blinding of rater | More than on rater | MRI Used | CT used | Type of X-rays | Diagnoses | Area of Spine | Number | Score | Author/Year Study Type |
|----------|------------|---------|---------------------------------------|----------------------------|-------------------|-------------|-------------------|--------------------|----------|---------|----------------|-----------|---------------|--------|-------|------------------------|
| | | | | | | | | | | | | | | | | |

Computerized Tomography (CT)

| Comments | Conclusion | Results | Long term follow-up (mean when noted) | Clinical outcomes assessed | Surgery Performed | Myelography | Blinding of rater | More than on rater | MRI Used | X-ray used | Type of CT | Diagnoses | Area of Spine | Number | Score | Author/Year Study Type |
|----------|------------|---------|---------------------------------------|----------------------------|-------------------|-------------|-------------------|--------------------|----------|------------|------------|-----------|---------------|--------|-------|------------------------|
| | | | | | | | | | | | | | | | | |

Myelography (including CT Myelography and MRI Myelography)

| | |
|---------------------------------------|--|
| Comments | |
| Conclusion | |
| Results | |
| Long term follow-up (mean when noted) | |
| Clinical outcomes assessed | |
| Surgery Performed | |
| X-ray | |
| Blinding of rater | |
| More than on rater | |
| MRI Used | |
| CT used | |
| Type of Myelography | |
| Diagnoses | |
| Area of Spine | |
| Number | |
| Score | |
| Author/Year Study Type | |

Bone Scans

| | |
|---------------------------------------|--|
| Comments | |
| Conclusion | |
| Results | |
| Long term follow-up (mean when noted) | |
| Clinical outcomes assessed | |
| Surgery Performed | |
| Myelography | |
| Blinding of rater | |
| More than on rater | |
| MRI Used | |
| CT used | |
| Type of Bone Scans | |
| Diagnoses | |
| Area of Spine | |
| Number | |
| Score | |
| Author/Year Study Type | |

Single Proton Emission Computed Tomography (SPECT)

| | |
|---------------------------------------|--|
| Comments | |
| Conclusion | |
| Results | |
| Long term follow-up (mean when noted) | |
| Clinical outcomes assessed | |
| Surgery Performed | |
| Myelography | |
| Blinding of rater | |
| More than on rater | |
| MRI Used | |
| CT used | |
| Type of SPECT | |
| Diagnoses | |
| Area of Spine | |
| Number | |
| Score | |
| Author/Year Study Type | |

Ultrasound (diagnostic)

| | |
|---------------------------------------|--|
| Comments | |
| Conclusion | |
| Results | |
| Long term follow-up (mean when noted) | |
| Clinical outcomes assessed | |
| Surgery Performed | |
| Myelography | |
| Blinding of rater | |
| More than on rater | |
| MRI Used | |
| CT used | |
| Type of Ultrasound | |
| Diagnoses | |
| Area of Spine | |
| Number | |
| Score | |
| Author/Year Study Type | |

Thermography

| | |
|---------------------------------------|--|
| Comments | |
| Conclusion | |
| Results | |
| Long term follow-up (mean when noted) | |
| Clinical outcomes assessed | |
| Surgery Performed | |
| Myelography | |
| Blinding of rater | |
| More than on rater | |
| MRI Used | |
| CT used | |
| Type of Thermography | |
| Diagnoses | |
| Area of Spine | |
| Number | |
| Score | |
| Author/Year Study Type | |

Fluoroscopy/Videofluoroscopy

| | |
|---------------------------------------|--|
| Comments | |
| Conclusion | |
| Results | |
| Long term follow-up (mean when noted) | |
| Clinical outcomes assessed | |
| Surgery Performed | |
| Myelography | |
| Blinding of rater | |
| More than on rater | |
| MRI Used | |
| CT used | |
| Type of Fluoroscopy | |
| Diagnoses | |
| Area of Spine | |
| Number | |
| Score | |
| Author/Year Study Type | |

Discography/MRI Discography/Myeloscapy

| | |
|---------------------------------------|--|
| Comments | |
| Conclusion | |
| Results | |
| Long term follow-up (mean when noted) | |
| Surgery Performed | |
| More than one level | |
| More than one rater | |
| X-ray | |
| CT Myelography | |
| CT | |
| MRI | |
| Pressure Readings | |
| Fluoroscopy/imaging | |
| Sedation Used | |
| Intradiscal Local Anesthetic | |
| Injected Medications | |
| Diagnoses | |
| Area of Spine | |
| Number | |
| Score | |
| Author/Year/ Study Type | |

Magnetic Resonance Imaging (MRI)

| | |
|---------------------------------------|--|
| Comments | |
| Conclusion | |
| Results | |
| Long term follow-up (mean when noted) | |
| Clinical outcomes assessed | |
| Surgery Performed | |
| More than one rater | |
| Myelography | |
| X-ray | |
| T2 weighted images | |
| T1 weighted images | |
| Type of CT used | |
| Type of MRI used | |
| Diagnoses | |
| Area of Spine | |
| Number | |
| Score | |
| Author/Year/ Study Type | |

Surface Electromyography (sEMG)/EMG

| | |
|---------------------------------------|--|
| Comments | |
| Conclusion | |
| Results | |
| Long term follow-up (mean when noted) | |
| Surgery Performed | |
| More than one muscle group tested | |
| More than one rater | |
| X-ray | |
| CT | |
| MRI | |
| Needle EMG used for | |
| Surface EMG (Type) | |
| Area of Body | |
| N | |
| Score | |
| Author/Year/ Study Type | |

8.9. Attachment 9: Example of Search Criteria Table

Treatment Searches

PubMed

| Treatment Topic | Diagnosis | Search Terms Used | What you typed in (copy and paste) for RCT | Pubmed Search Details (copy and paste) | Number of Retrieved Article | What you typed in (copy and paste) for SYSTEMATIC REVIEWS | Pubmed Search Details (copy and paste) | Number of Retrieved Article | What you typed in (copy and paste) for POPULATION STUDIES | Pubmed Search Details (copy and paste) | Number of Retrieved Article | Number of Saved Articles | Search Time |
|-----------------|-----------|-------------------|--|--|-----------------------------|---|--|-----------------------------|---|--|-----------------------------|--------------------------|-------------|
| | | | | | | | | | | | | | |

Scopus

| TREATMENT | Diagnosis | Search Terms Used | Copy and Paste for Diagnosis | What you typed in (copy and paste) for Treatment | What you typed in (copy and paste) for RCT | Scopus Search Details (copy and paste) | Total Number of Retrieved Articles | What you typed in (copy and paste) for REVIEW | Scopus Search Details (copy and paste) | Total Number of Retrieved Articles | What you typed in (copy and paste) for Population Studies | Scopus Search Details (copy and paste) | Total Number of Retrieved Articles | Number of Saved Articles | Search Time |
|-----------|-----------|-------------------|------------------------------|--|--|--|------------------------------------|---|--|------------------------------------|---|--|------------------------------------|--------------------------|-------------|
| | | | | | | | | | | | | | | | |

Cochrane Library

| Treatment Topic | Diagnosis | Search Terms Used | What you typed in (copy and paste) for REVIEW | Total number of retrieved articles | Number of saved articles | Search Time |
|-----------------|-----------|-------------------|---|------------------------------------|--------------------------|-------------|
| | | | | | | |

EBSCO (CINAHL)

| Treatment Topic | Diagnosis | Search Terms Used | What you typed in (copy and paste) for RCT | Total Number of Retrieved Articles | What you typed in (copy and paste) for REVIEW | Total Number of Retrieved Articles | What you typed in (copy and paste) for Population Studies | Total Number of Retrieved Articles | Number of Saved Articles | Search Time |
|-----------------|-----------|-------------------|--|------------------------------------|---|------------------------------------|---|------------------------------------|--------------------------|-------------|
| | | | | | | | | | | |

Diagnostic Searches

PubMed

| PubMed Search Details (copy and paste) | Total number of retrieved articles | Search Terms Used | What you typed in (copy and paste) for DIAGNOSTIC | PubMed Search Details (copy and paste) | Number of retrieved article | What you typed in (copy and paste) for SENSITIVITY OR SPECIFICITY. | PubMed Search Details (copy and paste) | Number of retrieved article | What you typed in (copy and paste) for PREDICTIVE VALUE. | PubMed Search Details (copy and paste) | Number of retrieved article | What you typed in (copy and paste) for EFFICIENCY OR EFFICACY | PubMed Search Details (copy and paste) | Number of retrieved article | Number of saved articles | Search Time |
|--|------------------------------------|-------------------|---|--|-----------------------------|--|--|-----------------------------|--|--|-----------------------------|---|--|-----------------------------|--------------------------|-------------|
| | | | | | | | | | | | | | | | | |

Scopus

Cochrane Library

CINAHL

| Treatment Topic | Diagnosis | Search Terms Used | What you typed in (copy and paste) | Total number of retrieved articles | Search Terms Used | What you typed in (copy and paste) for DIAGNOSTIC | Number of retrieved article | What you typed in (copy and paste) for SENSITIVITY OR SPECIFICITY. | Number of retrieved article | What you typed in (copy and paste) for PREDICTIVE VALUE. | Number of retrieved article | What you typed in (copy and paste) for EFFICIENCY OR EFFICACY | Number of retrieved article | Number of saved articles | Search Time |
|-----------------|-----------|-------------------|------------------------------------|------------------------------------|-------------------|---|-----------------------------|--|-----------------------------|--|-----------------------------|---|-----------------------------|--------------------------|-------------|
| | | | | | | | | | | | | | | | |

8.10. Attachment 10: Databases to be Searched

ACOEM searches the following databases for primary sources of original research. It may also search other databases likely to contain references to high-quality medical literature. Additional literature may be reviewed brought to the committee’s attention from interested parties.

1. The National Library of Medicine’s National Institute of Health (PubMed)
2. CINAHL (nursing, biomedicine, health sciences librarianship, alternative/complementary medicine, consumer health and 17 allied health disciplines)
3. The Cochrane Central Register of Controlled Trials
4. Google Scholar
5. Other databases can be added depending on the guideline topic or panel input (i.e., psychinfo was used for the Workplace Mental Health guidelines).

8.11. Attachment 11: Sample Evidence Table

| Author Year (Score): | Category: | Study type: | Conflict of Interest: | Sample size: | Age/Sex: | Comparison: | Follow-up: | Results: | Conclusion: | Comments: |
|----------------------|--------------------------|-------------|-----------------------|---|--|--|------------------------------------|---|---|-----------|
| Bateman 2001 | Cognitive Rehabilitation | RCT | No mention of COI. | 175 patients that sustained a single-incident brain injury either traumatic or vascular | Control Group Mean age: 44.7±13.3 years. Training group Mean age: 41.7±14.3 years. 97 males, 60 females. | Ergometer Aerobic Training (Training Group) Vs Relaxation Training Control Group (Control Group) | 12 weeks following end of training | Significant improvements in exercise capacity ($p < .05$) in the exercise training group ($n = 70$) relative to the control group ($n = 72$) were not matched by greater improvements in functional independence, mobility, or psychologic function, at either 12 weeks or follow-up. | "The benefits of improved cardiovascular fitness did not appear to extend to measurable change in function or psychologic state." | |
| Blake 2008 | Cognitive Rehabilitation | RCT | No COI. | 20 individuals with brain injury | Control group mean age: 46.20±11.27 years. Exercise group: 10.52 years. 15 males, 5 females. | Exercise group: received supervised Quigong instruction once per week for one hour Vs Control group: attended non-exercise social and leisure activities one hour per week for 8 weeks | Follow up at 8 weeks. | Groups were comparable at baseline. After the intervention, mood was improved in the exercise group when compared with controls ($U = 22.0$, $P = 0.02$). Improvements in self-esteem ($Z = 2.397$, $P = 0.01$) and mood ($Z = -2.032$, $P = 0.04$) across the study period were also evident in the | "This study provides preliminary evidence that a brief Qigong exercise intervention programme may improve mood and self-esteem for individuals with traumatic brain injury. This needs to be tested in a large-scale randomized trial." | |

8.12. Attachment 12: Sample Voting Process

When possible, consensus among panel members is sought when developing guideline recommendations statements, including those based on relevant evidence and those based on panel consensus. When unanimity among a panel is not achieved, then a process for formal voting will be used. An example of such a process is described below. Consensus will be assumed if the vote among the panel is 80% or greater in favor of a recommendation. If the vote among the panel is less than 80%, the percentages in favor of and against the recommendation will be recorded and published with the guideline. The GMC may modify or refine this procedure, based on the feedback about its usefulness and other factors.

Example of possible voting process when consensus is not found

Voting on guideline recommendations will be conducted using a modification of the nominal group technique (NGT), a method previously used in guideline development (24). Briefly each member of the guideline Work Group ranks his or her agreement with a guideline recommendation or performance measure on a scale ranging from 1 to 9 (where 1 is "extremely inappropriate" and 9 is "extremely appropriate"). Consensus is obtained if the number of individuals who do not rate a measure as 7, 8, or 9 is statistically non-significant (as determined using the binomial distribution). Because the number of Work Group members who are allowed to dissent with the recommendation depends on statistical significance, the number of permissible dissenters varies with the size of the work group. The number of permissible dissenters for several work group sizes is given in the table below:

| Work Group Size | Number of Permissible Dissenters |
|-----------------|--|
| ≤3 | Not allowed. Statistical significance cannot be obtained |
| 4-5 | 0 |
| 6-8 | 1 |
| ≥9 | 2 |

The NGT is conducted by first having members vote on a given recommendation/performance measure without discussion. If the number of dissenters is “permissible,” the recommendation/measure is adopted without further discussion. If the number of dissenters is not permissible, there is further discussion to see whether the disagreement(s) can be resolved. Three rounds of voting are held to attempt to resolve disagreements. If disagreements are not resolved after three voting rounds, no recommendation/measure is adopted.

8.13. Attachment 13: ACOEM Guideline Development / Revision Process Summary

| Step | Purpose | Individual(s) Responsible | Educational Credentials |
|---|---|---|--|
| Pose Answerable Clinical Questions | - Direct search, following format in Attachment 9 . | Editor, EBPPs | MD, DO |
| Literature Search | -Comprehensive search of the literature focusing on highest level of evidence in Attachment 7 . -Pull articles using inclusion criteria shown in Table A . | Research Assistant(s) Study Coordinator(s) | Undergrad / MS / MPH / PhD / MD (resident) |
| Article Abstraction / Preliminary Development of Evidence Tables | -Read articles -Initial construction of evidence tables for topic, for example Attachment 11 . | Research Assistant(s) | Undergrad / MS / MPH / PhD |
| Article Abstraction / Semi-Final Development of Evidence Tables | -Read articles -Semi-final construction of evidence tables for topic, including critiquing of study design and data. | Research Assistant(s) Study Coordinator(s) | Undergrad / MS / MPH / PhD |
| Evidence Table Review and Finalization | -Over-read evidence tables to ensure that all important aspects of articles are included. -QA/QC | Study Coordinator(s) Physician(s) | MD/DO with MPH (or equivalent) |
| Rate Articles | -Rate the articles based on defined criteria, for example Table B for RCTs | Physician(s) | MD/DO with MPH (or equivalent) |
| Rate Strength of Evidence | -Determine strength of evidence rating for topic based on the quality of the articles as shown in Table C . | Physician(s) | MD/DO with MPH (or equivalent) |
| Draft Summaries | -Draft text summaries of the evidence on each topic citing | Research Assistant(s) | Undergrad / MS / MPH / PhD |

| | | | |
|------------------------------|--|--|---|
| | design, results and quality. | | |
| Draft Recommendations | -Draft recommendations | Physician(s) | MD/DO with MPH (or equivalent) |
| Panel Process | -Review evidence tables and strength of evidence ratings. -Revise recommendations based on discussion, application of clinical judgment and first principles or new evidence. | Multi-disciplinary health professionals | MD/DO/MPH, MS, PT, etc. |
| Guideline Review | -Review/oversight of final guidelines to ensure consistency with methodology and other related guidelines. -QA/QC | Physician | MD/DO |
| External Review | -Review guideline for consistency with evidence and conservative expert clinical practice as well as methodology and usability. | Physicians, physical therapists, occupational therapists, pharmacists, psychologists, other health professionals | MD, DO, PhD, DC, RPT/PhD, DrPh, etc. |
| Stakeholder input | -Review guideline for usability and applicability. | Physicians, attorneys, claims professionals, UR nurses, case managers | MD, DO, JD, RN, DC, RPT, PhD, certified claims managers |
| Pilot testing | -Use guideline, assess usability and applicability. | Physicians, UR nurses, case managers, physical therapists | MD, DO, RN, RPT |
| Revision | -Revisions based on internal and external review comments and evidence. | Physician | MD, DO |
| Approval | -Approve guideline based on content, methodology and quality assurance. | ACOEM Board of Directors | MD/DO/MPH, MS, PT, etc. |

8.14. Attachment 14: External Peer Review Process

Names of potential peer reviewers can be submitted by many sources (e.g., the Panels or committees, the ACOEM Board or leadership, and other professional organizations and stakeholder groups). ACOEM asks other professional organizations to provide nominations for individual peer reviewers for guideline products (see [Attachment 16](#) for list of organizations that are planned to be invited). ACOEM sends a letter to the President or Executive Director of the professional organizations inviting them to nominate at least one individual peer reviewer for each of the updates when they are developed. Individuals invited to be external peer reviewers are required to sign a confidentiality agreement indicating that they will not disclose or discuss contents of the Guidelines until after it is formally released. The Guidelines list the names of all peer reviewers, along with their affiliations for those not desiring anonymity.

Each peer reviewer receives a final draft of the Guidelines and asked to comment on the completeness of the scientific literature evaluation in their topic area, the clarity and technical accuracy of the Guidelines evaluation and summary of the evidence, and the appropriateness of the Guidelines' findings and recommendation statements. Any other comments or suggestions relating to the Guidelines are also welcomed. For updates to guidelines after the Third Edition is published, external reviewers may only be asked to review the new edits/track changes made to the guideline (however, they could request to review the complete guideline again). Peer reviewers are asked to provide comments on the following questions.

1. Appropriateness of the guideline findings and recommendations

| | | | | |
|------|---|---|---|-----------|
| 1 | 2 | 3 | 4 | 5 |
| Poor | | | | Excellent |

Suggestions for improvement/comments:

2. Clarity and technical accuracy of the guidelines

| | | | | |
|------|---|---|---|-----------|
| 1 | 2 | 3 | 4 | 5 |
| Poor | | | | Excellent |

Suggestions for improvement/comments:

3. Completeness of the scientific literature evaluation

| | | | | |
|------|---|---|---|-----------|
| 1 | 2 | 3 | 4 | 5 |
| Poor | | | | Excellent |

Suggestions for improvement/comments:

All comments received are sent back to the appropriate Panels for review. Each reviewer then receives a response letter from the Editor-in-Chief indicating the changes made to the guideline based on their feedback.

8.15. Attachment 15: Professional and Patient Organizations to be Invited to Review the Updates to the Guidelines

**Other organizations could be added to this list throughout the Guideline development process.*

- Academy of Organizational & Occupational Psychiatry
- American Academy of Medical Acupuncture
- American Academy of Dermatology
- American Academy of Disability Evaluating Physicians
- American Academy of Family Physicians
- American Academy of Medical Acupuncture
- American Academy of Neurology
- American Academy of Ophthalmology
- American Academy of Orthopaedic Surgeons
- American Academy of Pain Management
- American Academy of Pain Medicine
- American Academy of Physician Assistants
- American Academy of Physical Medicine and Rehabilitation
- American Association for Hand Surgery
- American Association of Hip and Knee Surgeons
- American Association of Occupational Health Nurses
- American Association of Neurological Surgeons / Congress of Neurological Surgeons
- American Association of Neuromuscular and Electrodiagnostic Medicine
- American Association of Vascular Surgery / Society for Vascular Surgery
- American Board of Independent Medical Examiners
- American Board of Preventive Medicine
- American Chiropractic Association
- The American Chronic Pain Association
- American College of Allergy, Asthma & Immunology
- American College of Chest Physicians
- American College of Emergency Physicians
- American College of Foot and Ankle Surgeons
- American College of Medical Toxicology
- American College of Radiology
- American College of Rheumatology
- American College of Physicians-American Society of Internal Medicine
- American College of Preventive Medicine
- American College of Sports Medicine
- American College of Surgeons
- American Headache Society
- American Industrial Hygiene Association
- American Massage Therapy Association
- American Medical Association
- American Neurological Association

- American Occupational Therapy Association
- American Optometric Association
- American Orthopaedic Foot and Ankle Society
- American Osteopathic Association
- American Pain Association
- American Pain Foundation
- American Pain Society
- American Pharmacists Association
- American Physical Therapy Association
- American Podiatric Medical Association, Inc.
- American Public Health Association — Chiropractic Health Care Section
- American Psychiatric Association
- American Psychological Association
- American Society of Addiction Medicine
- American Society of Anesthesiologists
- American Society of Interventional Pain Physicians
- American Society of Plastic Surgeons
- American Thoracic Society
- Association for Applied Psychophysiology and Biofeedback
- Association of Rheumatology Health Professionals
- California Orthopaedic Association
- California Society for Industrial Medicine and Surgery
- Canadian Neurological Society
- Chronic Pain Association of Canada
- Commission on Accreditation of Rehabilitation Facilities
- Institute for Work and Health
- International Association for the Study of Pain
- International Spine Intervention Society
- The American Orthotic and Prosthetic Association
- The National Pain Foundation
- North American Neuromodulation Society
- North American Spine Society
- Society of Acupuncture Research
- Society for Behavioral Medicine
- Society for Vascular Surgery
- Society of Interventional Radiology
- Society for Industrial and Organizational Psychology, Inc.

8.16. Attachment 16: Stakeholder / Patient Input

This form provides workers, patients, businesses, insurers, union representatives, occupational health professionals, specialty societies and other stakeholders in evaluation and treatment of work-related health issues a means to provide input into the American College of Occupational and Environmental Medicine's (ACOEM) *Practice Guidelines*.

ACOEM has been developing its *Practice Guidelines* since 1997. The *Practice Guidelines* are continuously undergoing review and are developed using a rigorous, peer-reviewed, and published methodology to incorporate the best evidence to guide users to the best treatment.^{1,2} The *Practice Guidelines* are the only comprehensive occupational health guidelines that adhere to the highest standards of evidence-based medicine, including those specified by the Institute of Medicine's *Clinical Practice Guidelines We Can Trust*.³ The purpose of the ACOEM *Practice Guidelines* are to improve efficiency and accuracy of diagnoses, improve effectiveness of treatment, maximize relief of symptoms and improve function, and facilitate return to work in workers with occupationally related illnesses or injuries.

Stakeholders may provide feedback and advice for guidelines whether or not they are undergoing major revision. All comments will be considered during the editing and peer-review processes. For sections not undergoing revision, comments leading to changes that may benefit outcomes will be immediately addressed.

We thank you in advance for your time, feedback and interest! If you have any questions regarding the ACOEM Practice Guidelines, please contact Julie Ording at jording@acoem.org or 847/818-1800, ext. 1362.

Date:

Name:*

E-mail:*

1. Which guideline would you like to comment on?

2. Comment(s), feedback, advice (please indicate page number when providing your comment):

3. Please rate the readability/understandability of the guideline recommendations on a scale of 0-10 (0=impossible to read/understand, 10=easily readable/understandable). If you rate it 5 or less, please indicate why.

0 1 2 3 4 5 6 7 8 9 10

Impossible to read

Easily readable

Comments:

4. Please rate your overall impression of how well the guidance follows the strongest study design and evidence in the literature on a scale of 0-10 (0=low quality, 10=high quality). If you rate it 5 or less, please indicate why.

0 1 2 3 4 5 6 7 8 9 10 I don't know/unsure

Low quality

1. American College of Occupational and Environmental Medicine. Methodology for ACOEM's Occupational Medicine Practice Guidelines-2017 Revision. 2017:1-74. Available at: <https://acoem.org/acoem/media/PracticeResources/Methodology-2017-Update.pdf>.
2. Harris JS, Weiss MS, Haas NS, Hegmann KT, Holland JP, Kistner F, et al. Methodology for ACOEM's Occupational Medicine Practice Guidelines-2017 Revision. J Occup Environ Med. 2017;59(9):913-9. Available at: <https://acoem.org/acoem/media/PracticeResources/Methodology-2017-JOEM.pdf>.
3. Institute of Medicine. Standards for Developing Trustworthy Clinical Practice Guidelines. Available at: <https://www.nap.edu/resource/13058/Clinical-Practice-Guidelines-2011-Report-Brief.pdf>. [KH1]

9. Tables

9.1. Tables A-1 and A-2: Criteria for Accepting Studies as Containing Adequate Evidence (Study Inclusion Criteria)

Table A-1: Criteria for Adequate Evidence for Studies of Clinical Assessment Methods

General criteria for all clinical studies

1. Be published in English in a peer-reviewed scientific publication.
2. Evaluate a clinical method currently available to providers in North America and Europe (and the clinical method that is not obsolete or experimental).
3. Provide original data about efficacy (accuracy) of the clinical method for the condition of interest.
4. Provide an adequate description of the clinical method (or provide a reference where this information can be found).
5. Evaluate subjects similar to the target population of interest (in this case, the general population of working age adults), generally with the number of subjects in each arm of the study to achieve acceptable statistical power. However, sometimes statistical power may not be achieved due to ethical constraints or the newness of the treatment.
6. Be rated as high or moderate quality, using the quality rating process.
7. Evaluate the efficacy (i.e., clinical accuracy) of the assessment method (i.e., the “test”) in a group that contains subjects both with and without the condition the test is intended to assess.
8. Compare the findings of the assessment method (test) to an adequate reference standard for all subjects (not just subjects who tested positive).*
9. Assure that results of the test (assessment method) are interpreted blinded to (that is, without knowledge of) the results of the reference standard, and that the results of the reference standard are interpreted blinded to the test results.
10. Provide enough data to allow calculation of, at minimum, sensitivity, specificity and positive predictive value(s), of the assessment method compared to the reference standard. The calculation of positive predictive value can be accurately determined only if the study includes the prevalence of the particular condition the test is designed to assess in the target population.

*Definition of an “acceptable reference standard” will vary depending on the clinical topic.

Table A-2: Criteria for Adequate Evidence for Studies of Clinical Treatment Methods

General criteria for all clinical studies

1. Be published in English in a peer-reviewed scientific publication.
2. Evaluate a clinical method currently available to providers in North America and Europe (and the clinical method that is not obsolete or experimental).
3. Provide original data about the accuracy of the clinical method for the condition of interest.
4. Provide an adequate description of the clinical method (or provide a reference where this information can be found).
5. Evaluate subjects similar to the target population of interest (in this case, the general population of working age adults) generally the number of subjects in each arm of the study to achieve acceptable statistical power.
6. Be rated as high or moderate quality, using the quality rating process shown in Table B.
7. Evaluate a group of subjects with a representative spectrum of the clinical condition of interest.

8. Be a randomized controlled trial (RCT)** or randomized crossover trial evaluating clinical outcomes in a group receiving the intervention compared to a comparison group receiving either no intervention and/or a different intervention.
9. Evaluate functional outcomes that are important to a patient’s overall health or well-being, or are important to society.
10. Use the same methods for measuring baseline subject characteristics and for assessing clinical outcomes for all groups studied.
11. Provide appropriate statistical comparison of study results.

**Or be a prospective clinical trial where subjects are assigned to treatment groups using a method that does not introduce systematic bias into the study and assures that groups are similar in relevant baseline characteristics.

9.2. Table B: Quality Scoring of RCT Treatment Studies

Studies are rated using the following 11 criteria. Each criterion is rated 0, 0.5, or 1.0, thus the overall ratings range from 0-11. A study is considered low quality if the composite rating was 3.5 or less, moderate quality if rated 4-7.5, and high quality if rated 8-11.

| Criteria | Rating Explanation |
|--|--|
| <p>Randomization:</p> <p>Assessment of the degree that randomization was both reported to have been performed and successfully* achieved through analyses of comparisons of variables between the two groups.</p> | <p>Rating is “0” if the study is not randomized or reports that it was and subsequent analyses of the data/tables suggest it either was not randomized or was unsuccessful. Also, if only the word “randomization” or “randomized” is mentioned only once anywhere in the document without discussion of randomization means, AND a key baseline non-comparability variable is identified, the score is “0” and comments may include “potential randomization failure.”</p> <p>Rating is “0.5” if there is mention of randomization (e.g., computer-based) and it appears as if it was performed, however, there was no randomization method specified, there are no data on the success of randomization, it appears incomplete, or other questions about randomization cannot be adequately addressed.</p> <p>Rating is “1.0” if randomization is specifically stated, a randomization process was specified, and data reported on subgroups suggests that the study did achieve successful randomization.</p> <p>Quasi-randomization, e.g., every-other allocations are rated “0” for this criterion.</p> |
| | <p>Rating is “0” if there is no description of how members of the research team or subjects</p> |

| | |
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| <p>Treatment Allocation Concealed:</p> <p>Concealment of the allocation scheme from all involved, not just the patient.</p> | <p>would have not been able to know how they were going to receive a particular treatment, or the process used would not be concealed.</p> <p>Rating is “0.5” if the article mentions how allocation was concealed, but the concealment was either partial involving only some of those involved or other questions about it are unable to be completely addressed.</p> <p>Rating is “1.0” if there is a concealment process described that would conceal the treatment allocation to all those involved.</p> |
| <p>Baseline Comparability: Measures how well the baseline groups are comparable (e.g., age, gender, prior treatment).</p> | <p>Ratings include a combined assessment for both demographic and outcomes variables. Statistical significance does not need to be present for baseline comparability dissimilarity; a score of “0” may apply if a characteristic(s) or outcome variable(s) difference is likely to affect the study conclusions. Rating is “0” if analyses show that the groups were dissimilar at baseline or it cannot be assessed. Also, a score of “0” may occur if the baseline comparability is too sparse or key elements are not included in the study groups pre-intervention.</p> <p>Rating is “0.5” if there is general comparability, though one variable may not be comparable. A rating of 0.5 should not be given if that variable is a key outcome variable (see above).</p> <p>Rating is “1.0” if there is good comparability for all demographic and outcome variables between the groups at baseline.</p> |
| <p>Patient Blinded</p> | <p>Rating is “0” if there is no mention of blinding of the patient. Mention of patient blinding but without specification of blinding methods in the context of dissimilar interventions that result in improbability of patient blinding are to be rated “0.”</p> <p>Rating is “0.5” if it mentions blinding, but blinding is realistically plausible but the methods are unclear.</p> <p>Rating is “1.0” if the study reports blinding, describes how that was carried out, and would plausibly blind the patient. If the trial reports discrepant results that suggest unblinding occurred, then either 0 or 0.5 ratings should be</p> |

| | |
|---|---|
| | given. |
| Provider Blinded | <p>Rating is “0” if there is no mention of blinding of the provider. Note mention of provider blinding means that the provider was blinded to the intervention s/he administered. This does NOT include having a provider being blinded to which group the patient was randomized and if this is found without other description of provider blinding, this criterion is scored “0.”</p> <p>Rating is “0.5” if it mentions blinding, but the methods are both plausible, while not specifically defined.</p> <p>Rating is “1.0” if the study reports blinding, describes how that was carried out, and would plausibly blind the provider. If the trial reports discrepant results that suggest unblinding occurred, then either 0 or 0.5 ratings should be given.</p> |
| Assessor Blinded | <p>The assessor must be a distinct provider or person performing an independent assessment of the subject. This does not include administration of only a follow-up questionnaire, for which the rating of “0” also applies. Rating is “0” if there is no mention of blinding of the assessor or if there is mention of assessor blinding but no further details of methods to adequately achieve assessor blinding, or the method described will not plausibly blind the assessor.</p> <p>Rating is “0.5” if it mentions blinding, but the methods are both plausible to provide blinding while not specifically defined.</p> <p>Rating is “1.0” if the study reports blinding, describes how that was carried out and would plausibly blind the assessor. If the trial reports discrepant results that suggest unblinding occurred, then either 0 or 0.5 ratings should be given.</p> |
| <p>Controlled for Co-interventions:</p> <p>The degree to which the study design controlled for multiple interventions (e.g., a combination of stretching exercises and antiinflammatory medication or mention of not using other</p> | <p>Rating is “0” if there are multiple interventions or no description of how this was avoided but likely present. Rating is “0” if this is unaddressed. Qualitative descriptions without detailed logs or some other means of showing how these con-interventions were addressed is scored “0.”</p> |

| | |
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| <p>treatments during the study).</p> | <p>Rating is “0.5” if there is some mention and some details of this potential problem that include at least partial control that may include prohibited medications and procedures.</p> <p>Rating is “1.0” if there is a clear description of how co-interventions were avoided. Details of log records for medication use, list of an appropriate set of prohibited medications, additional exercises, etc. needs to be documented with types and frequencies.</p> |
| <p>Compliance Acceptable: Measures the degree of non-compliance.</p> | <p>Rating is “0” if there is no mention of non-compliance or compliance or the results inclusive of tables, graphics and figures does not allow for clarity.</p> <p>Rating is “0.5” if non-compliance is briefly addressed and the description suggests that there was compliance, but a complete assessment is not possible.</p> <p>Rating is 0.5 if there are 2/3, 3/4, 3/5, 4/5, etc. groups with compliance addressed at a rate of less than 20%.</p> <p>Rating is “1.0” if there are specific data and the non-compliance rate is less than 20%.</p> |
| <p>Dropout Rate: Measures the drop-out rate.</p> | <p>Rating is “0” if there is no mention of drop-outs or it cannot be inferred from the data presented.</p> <p>Rating is “0.5” if the drop-out issue is briefly addressed and the description suggests that there were few drop-outs, but a complete assessment is not possible.</p> <p>Rating is 0.5 if there are 2/3, 3/4, 3/5, 4/5 etc. groups with dropout rates at a rate of less than 20% but other groups are greater than 20%.</p> <p>Rating is “1.0” if there are specific data and the drop-out rate is under 20%. If there is a follow up study to the original study and the dropout rate is over 20% due to unforeseen circumstances such as a high mortality rate from, for example, traumatic brain injury, the scoring should be a 0.5.</p> |
| <p>Timing of Assessments:</p> | <p>Rating is “0” if the timing of the evaluations is different between the groups, and/or a more</p> |

| | |
|--|--|
| Timing rates the timeframe for the assessments between the study groups. | <p>than 10% difference (see below).</p> <p>Rating is “0.5” if the timing is nearly identical (e.g., one day apart or less than 10% of the total time, e.g. a 30 day study and 10% would be 3 days difference between groups</p> <p>Rating is “1.0” if the timing of the assessments between the groups is identical.</p> |
| <p>Analyzed by Intention to Treat:</p> <p>This rating is for whether the study was analyzed with an intent-to-treat analysis.</p> | <p>Rating is “0” if it was not analyzed by intent to treat.</p> <p>Rating is “0.5” if there is no mention of intent to treat analysis, but the results would not have been different (e.g., there was 100% compliance and no drop-outs).</p> <p>Rating is “1.0” if the study specifies analyses by intention to treat.</p> |
| <p>Lack of Bias:</p> <p>This rating does not enter into the overall rating of a study. This is an overall indication of the degree to which biases are felt to be present in the study.</p> | <p>Rating is “0” if there are felt to be significant biases that are uncontrolled in the study and may have influenced the study’s results.</p> <p>Rating is “0.5” if there are felt to be some biases present, but the results are less likely to have been influenced by those biases.</p> <p>Rating is “1.0” if there are few biases, or those are well controlled and unlikely to have influenced the study’s results.</p> |

*Simply allocating individuals to groups does not constitute sufficient grounds to assess the success of randomization. The groups must be comparable; otherwise, the randomization was unsuccessful.

9.3. Table C-1: Quality Scoring for Diagnostic Studies

Article (author, title):

| Score | Criteria | Rating |
|-------|----------------------------------|---|
| | Disorder clearly defined | <p>1.0 = Disorder definition supported by history, physical findings or other diagnostic testing that is reproducible.</p> <p>0.5 = Disorder labeled with narrow scope of evidence.</p> <p>0.0 = Case definition labeled without supporting evidence or not reproducible.</p> |
| | Test compared with gold standard | <p>1.0 = Comparison made with gold standard (panel consensus).</p> <p>0.5 = Comparison to established</p> |

| | | |
|--|---|---|
| | | <p>alternative test.</p> <p>0.0 = Comparison to inferior diagnostic test.</p> |
| | Investigative test conducted on all patients | <p>1.0 = 95% or more of patients received investigative test.</p> <p>0.5 = 80% or more of patients received investigative test.</p> <p>0.0 = Less than 80% of patients received investigative test.</p> |
| | Gold standard (control) test conducted on all patients | <p>1.0 = 95% or more of patients received investigative test.</p> <p>0.5 = 80% or more of patients received investigative test.</p> <p>0.0 = Less than 80% of patients received investigative test.</p> |
| | Assessor of investigative test result blinded to disorder | <p>1.0 = Blinding of assessor defined and plausible.</p> <p>0.5 = Blinding not clearly stated but probable</p> <p>0.0 = No blinding or blinding improbable based on methods</p> |
| | Assessor of gold standard test result blinded to disorder | <p>1.0 = Blinding of assessor defined and plausible.</p> <p>0.5 = Blinding not clearly stated but probable</p> <p>0.0 = No blinding or blinding improbable based on methods</p> |
| | Statistical analysis – Sensitivity and Specificity | <p>1.0 = Sensitivity and specificity stated or can be readily determined</p> <p>0.5 = One but not both provided</p> <p>0.0 = Not provided, unable to calculate</p> |
| | Statistical analysis – PPV and NPV | <p>1.0 = PPV and NPV stated or can be readily determined</p> <p>0.5 = One but not both provided</p> <p>0.0 = Not provided, unable to calculate</p> |
| | Normal range of investigative test | <p>1.0 = Normal range of test defined and appropriate for study</p> |

| | | |
|--|---|---|
| | | <p>population</p> <p>0.5 = Normal range defined but unclear if applicable to population</p> <p>0.0 = Normal range not defined or unclear</p> |
| | Timing of testing conducted at same phase of disorder | <p>1.0 = Stated and appropriately measures at same phase of disorder</p> <p>0.5 = Stated but unclear if measured at same phase in disorder</p> <p>0.0 = Unstated or inappropriate interval between testing`</p> |
| | Application of tests followed appropriate quality control procedures. | <p>1.0 = Protocol and application well described and appropriate</p> <p>0.5 = Protocol and application narrowly described for one or both</p> <p>0.0 = No quality control or not described</p> |
| | Summary risk of bias | <p>1.0 = No obvious bias exists</p> <p>0.5 = Probable risk of bias</p> <p>0.0 = Bias effecting results present</p> |

9.4. Table C-2. Quality Scoring for Treatment using Epidemiological Studies

NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE

Note: A study can be awarded a maximum of one star for each numbered item within the Selection, Exposure, and Outcome categories. A maximum of two stars can be given for Comparability. Therefore, an epidemiological study may be score with a maximum of 9 points.

CASE CONTROL STUDIES (Score Sections A-C)

A. Selection

1) Is the case definition adequate?

- a) yes, with independent validation -
- b) yes, e.g. record linkage or based on self reports
- c) no description

2) Representativeness of the cases

- a) consecutive or obviously representative series of cases -
- b) potential for selection biases or not stated

3) Selection of Controls

- a) community controls -
- b) hospital controls
- c) no description

4) Definition of Controls

- a) no history of disease (endpoint) -
- b) no description of source

B. Comparability

1) Comparability of cases and controls on the basis of the design or analysis

- a) study controls for [note the most important factor in Comments] -
- b) study controls for any additional factor [can indicate specific control for a second important factor in Comments] -

C. Exposure

1) Ascertainment of exposure

- a) secure record (e.g. surgical records) -
- b) structured interview where blind to case/control status -
- c) interview not blinded to case/control status
- d) written self report or medical record only
- e) no description

2) Same method of ascertainment for cases and controls

- a) yes -
- b) no

3) Non-Response rate

- a) same rate for both groups -
- b) non respondents described
- c) rate different and no designation

COHORT STUDIES (Score Sections D-F)

D. Selection

1) Representativeness of the exposed cohort

- a) truly representative of the average [describe factor in Comments] in the community -
- b) somewhat representative of the average [describe factor in Comments] in the community -
- c) selected group of users e.g. nurses, volunteers
- d) no description of the derivation of the cohort

2) Selection of the non exposed cohort

- a) drawn from the same community as the exposed cohort -
- b) drawn from a different source
- c) no description of the derivation of the non exposed cohort

3) Ascertainment of exposure

- a) secure record (e.g. surgical records) -

- b) structured interview ⁻
- c) written self report
- d) no description
- 4) Demonstration that outcome of interest was not present at start of study

- a) yes ⁻
- b) no

E. Comparability

1) Comparability of cohorts on the basis of the design or analysis

- a) study controls for [indicate the most important factor in Comments] ⁻
- b) study controls for any additional factor [can indicate specific control for a second important factor in Comments] ⁻

F. Outcome

1) Assessment of outcome

- a) independent blind assessment ⁻
- b) record linkage ⁻
- c) self report
- d) no description

2) Was follow-up long enough for outcomes to occur?

- a) yes (select an adequate follow up period for outcome of interest) ⁻
- b) no

3) Adequacy of follow-up of cohorts

- a) complete follow-up, all subjects accounted for ⁻
- b) subjects lost to follow-up unlikely to introduce bias, small number lost [select an adequate % in Comments], or description provided of those lost ⁻
- c) follow up rate [select an adequate in Comments] and no description of those lost
- d) no statement

9.5. Table D: Strength of Evidence Ratings

Strength of Evidence Ratings are used to designate the quality and amount of evidence that supports a specific guideline recommendation, when taking into account the entire body of relevant evidence found in the literature search. The body of evidence on a topic consists of all studies found that were relevant to the specific clinical question and of acceptable quality. In general, the highest quality of evidence found should be used by the Panel as the basis for the guideline recommendation, unless other factors, such as the potential for harm, are an overriding consideration. When multiple studies of similar quality and relevance are found on a topic, these studies should be evaluated as a group. If results are generally consistent, this would be considered either Strong Evidence (for high quality studies) or Moderate Evidence (for moderate quality studies). In all cases, the rationale for each recommendation and scientific studies used as evidence, should be documented by the Panel.

| | |
|----------|---|
| A | Strong evidence-base: Two or more high-quality studies. |
| B | Moderate evidence-base: At least one high-quality study or multiple moderate-quality studies relevant to the topic and the working population. |
| C | Limited evidence-base: At least one study of moderate quality. |
| I | Insufficient Evidence: Evidence is insufficient or irreconcilable. |

*For treatment, the criteria used by evidence reviewers to categorize the quality of individual randomized controlled trials as high, moderate, or low quality are: adequate randomization, concealed treatment allocation, baseline cohort comparability, patient blinded, provider blinded, assessor blinded, controlled for co-interventions, compliance acceptable, dropout rate acceptable, timing of assessments equivalent, data analyzed by intention to treat, and lack of bias.(17) Each criterion receives a score of 0, 0.5, or 1. See [Table B](#) for a definition of each criterion and scoring level. Studies are considered of low quality if they are rated 3.5 or less, moderate quality if they are rated 4-7.5, and high quality if they are rated 8-11.

9.6. Table E: Evidence-Based Recommendations

| Recommendation Category | Evidence Rating | Description of Category |
|-------------------------------|-----------------|---|
| Strongly Recommended | A | The intervention is strongly recommended for appropriate patients. The intervention improves important health and functional outcomes based on high quality evidence, and the Evidence-Based Practice Panel (EBPP) concludes that benefits substantially outweigh harms and costs. |
| Moderately Recommended | B | The intervention is recommended for appropriate patients. The intervention improves important health and functional outcomes based on moderate quality evidence that benefits substantially outweigh harms and costs. |
| Recommended | C | The intervention is recommended for appropriate patients. There is limited evidence that the intervention may improve important health and functional benefits. |
| Consensus* Recommended | I | The intervention is recommended for appropriate patients and has nominal costs and essentially no potential for harm.* The EBPP feels that the intervention constitutes best medical |

| | | | |
|--------------------------------------|------------------|--|--|
| | | <p>practice to acquire or provide information in order to best diagnose and treat a health condition and restore function in an expeditious manner.</p> <p>The EBPP believes based on the body of evidence, first principles, and/or collective experience that patients are best served by these practices, although the evidence is insufficient for an evidence-based recommendation.</p> | |
| Consensus* Recommended | Sometimes | I | <p>The intervention may be for appropriate to trial for a select group of patients, typically after other interventions have failed.</p> <p>For most patients, the evidence for the intervention lacks efficacy, is of poor quality, or is conflicting and the balance of benefits, harms, and costs cannot be determined.</p> |
| Consensus* Recommendation | No | I | <p>The evidence is insufficient to recommend for or against routinely providing the intervention. The EBPP makes no recommendation.</p> <p>Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms, and costs cannot be determined.</p> |
| Consensus* NOT Recommended | | I | <p>The evidence is insufficient for an evidence-based recommendation.</p> <p>Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms, and costs cannot be determined.</p> |
| NOT Recommended | | C | <p>Recommendation against routinely providing the intervention.</p> <p>The EBPP found at least moderate evidence that harms and costs exceed benefits based on limited evidence.</p> |
| Moderately NOT Recommended | | B | <p>Recommendation against routinely providing the intervention to eligible patients.</p> <p>The EBPP found at least moderate evidence that harms and costs outweigh benefits.</p> |

**In the absence of evidence, these recommendations are based on expert opinion.*

9.7. Table F: Characteristics of ACOEM Evidence-based Recommendations

The ACOEM evidence-based methodology will result in clinical practice and management recommendations with the following attributes (18, 19):

- **Validity:** The recommendation should produce similar clinical outcomes in similar cases.
- **Reliability/reproducibility:** A different panel of experts experienced with evidence-based methodology would come to the same recommendation given the same evidence base and decision making matrix.
- **Clinical applicability:** The recommendation is applicable to a broad population. The recommendation states to which population it applies.
- **Clinical flexibility:** The recommendation identifies known or generally expected exceptions to its use (e.g., comorbidities affecting biological response, genetic differences, psychosocial factors affecting functional recovery, etc.).
- **Clarity:** The recommendation is clearly framed and understandable to clinicians and care managers using it.
- **Multidisciplinary process:** The recommendation is developed with input from relevant disciplines using common methods of evidence analysis and structured consensus development about the strength of the evidence and the likely benefits, harms, and costs of the recommendation.
- **Scheduled review:** The recommendation contains a recommended schedule for future review to assure currency.
- **Documentation:** All steps, evidence analysis, critical discussions and decisions in the evidence-based practice process will be documented and archived.
- **Transparency:** Records of deliberation that affect the evidence-based practice process and any revisions to analysis, recommendations, and conclusions will be available.
- **Board Review:** ACOEM’s Board of Directors will have the opportunity to review the recommendations and provide comments for the Panel to consider.

9.8. Table G: Minimum Thresholds for Evidence-based Recommendations (A, B, C-Level Evidence)

| Class of Intervention | Minimum Study Design | Comments |
|-----------------------|--|--|
| Medications | Randomized, controlled trial (RCT) with placebo treatment arm. Randomized comparative trial is an alternative when there is both an effective treatment that is widely accepted and has a known level of efficacy. | Highest quality study(ies) as rated. Evidence of fatalities or severe adverse effects may reduce the rating. |
| Exercise, Behavioral | Sham-controlled RCT when possible, or Randomized controlled comparative trial (RCCT) when sham-control not possible. Discrete exercise (or other) regimen specified.* | Highest quality study(ies) as rated. Substantial adherence to the CONTENT scale (12)and/or the CONSORT extension for pragmatic trials (13) supports inclusion. |

| | | |
|--|--|--|
| Heat Therapies, Electrical Therapies, Manipulation, Acupuncture | RCT with sham-control when possible, or RCCT when not possible.* | Highest quality study(ies) as rated. Evidence of fatalities or severe adverse effects may reduce the rating. |
| Injections | RCT with sham control. | Highest quality study(ies) as rated. Evidence of fatalities or severe adverse effects may reduce the rating. |
| Surgery | RCT with sham-control. Or, evidence of overwhelming benefit with >95% resolution of problem within 1-2 years and return to normal function in nearly all cases (e.g., Total Hip Replacement, Hernia Repair). | Highest quality study(ies) as rated. Evidence of fatalities or severe adverse effects may reduce the rating. |

*Pragmatic RCTs which include clinical decision making with a limited intervention set and a clear decision making process that is reproducible are eligible for inclusion.

10. Additional Resources

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