

# Methodology for ACOEM's Occupational Medicine Practice Guidelines – 2017 Revision

This document was approved by the ACOEM Board of Directors.

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#### I. 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.<sup>(1)</sup> In 2004, ACOEM released the second edition of the *Guidelines*, based on an updated search and evaluation of the literature.<sup>(2)</sup> The methodology used for those editions was described in the introduction to each volume, and in other publications.<sup>(3, 4)</sup>

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.<sup>(5)</sup>

In 2007, the first guideline using the updated methodology was published. Many additional 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*. (6) 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*(8)) was published. The present ACOEM Guidelines Methodology document has been updated to include these 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.

#### II. Purpose and Scope<sup>(9)</sup>

#### A. Purpose

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

- Improve the efficiency and accuracy with which the diagnostic process is conducted;
- Identify the effectiveness and risks of individual treatments and treatment plans 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 medical care and disability management; and
- Enhance patient autonomy. (10)

#### B. 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 work loss;
- Preventing work-related health problems; and
- Promoting health.

Examples of the broad clinical questions<sup>(9)</sup> that the *Guidelines* may address in these areas are listed in Attachment 1.

The First through Third Editions of the *Guidelines* consisted of two parts – "Foundations of Occupational Medicine Practice" and "Disorders." "Foundations" reviewed prevention; initial assessment and documentation; initial approaches to treatment; work-relatedness; disability prevention/management; pain, suffering, and restoration of function; and independent medical exams/consultations. "Disorders" included complaints related to the neck and upper back; shoulder; elbow; forearm, wrist, and hand; low back; knee; ankle and foot; eye; and stress-related conditions. Section I ("Foundations") is updated by identifying questions that should be addressed regarding best practices for general management of clinical conditions, disability, and medico-legal matters. Section II ("Disorders") is both expanded (based on advancements in diagnosis and/or treatment) and updated by identifying new clinical questions to address for each clinical entity or diagnostic group. Questions are framed in PICO format<sup>(11)</sup> (population of interest, intervention, comparison group, and outcome). The questions for etiology, diagnosis, and prognosis are framed in a modified PICO 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 accepted reference standards for clinical assessment. (See Attachment 2 for criteria considered when developing the questions to address for the updates to the *Guidelines*.)

#### C. Patient Population<sup>(9)</sup>

The *Guidelines* apply to working age adults with medical conditions related to work or that affect the ability to work. In general, the age range under consideration had been 18 to 65. However, many workers are now older than 65, so some 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.

#### D. Target Audience<sup>(9)</sup>

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.

#### III. Organizational Structure<sup>(9)</sup>

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, 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).

<sup>&</sup>lt;sup>i</sup>Additional topics many be included in the update of the Guidelines.

#### A. Evidence-based Practice Committee (EBPC)

The EBPC is comprised of the chairs of each of the 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*.

#### B. Research Team(s)

Trained research teams:

- 1. Draft preliminary clinical questions in PICO 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. Summarize studies in evidence tables.
- 5. Critically appraise, grade and critique each study.
- 6. Draft background text, rationale statements, and recommendations for each guideline topic.

#### C. Evidence-based Practice Panels (EBPPs or "Panels")

Multidisciplinary panels are appointed and trained to develop or update evidence-based practice recommendations. Separate panels are appointed for each body part, system, or skill area covered by the *Guidelines*.<sup>ii</sup> 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 or update 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 (e.g., low back pain or chronic pain).

#### D. 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 Panels 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.

ii Currently, these areas are asthma, interstitial lung disease, low back, neck, hand/wrist/forearm, elbow, shoulder, hip/groin, knee, foot/ankle, eye, chronic pain, opioids, traumatic brain injury, and disability prevention/management.

### IV. 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. 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.

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

The 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.

#### B. Prioritization of Topics for Review and Recommendation

To identify and guide the work of the Panel for each topic or disorder or body system, the Editor-in-Chief and the Research Team, in collaboration with the EBPC, and the chair of each of the Panels, works with the panels to identify clinical questions about important, useful, common, expensive, controversial or questionable work-related diagnoses, tests and procedures. Topics may also be forwarded from Panel members, peer reviewers, Board members, external stakeholders and others. The following procedures are followed:

- 1. The Research Team 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.<sup>iii</sup>
- 2. Diagnoses are grouped into homogeneous diagnostic groups. Tests and treatments are identified as groups, if similar or synonymous, or individually if the criteria for use and evidence of effectiveness are likely to be relatively unique.
- 3. Panels solicit suggestions on areas to include/examine, including identification of commonly used, and/or emerging diagnoses, work linkages, and commonly used (but not necessarily safe or effective) tests, medications or procedures from Panel members and other stakeholders.
- 4. The PICO questions are finalized for a given guideline by the Expert Panel.

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

The Panels, with assistance from the Research Team, formulate recommendations for guidelines in the following manner:

#### 1. Literature Evaluation: Literature Search and Study Selection<sup>(9)</sup>

The Research Team conduct 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.

iii 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.

#### 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. Prospective and retrospective cohort studies are searched if there are no RCTs and systematic reviews identified. 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 and quality grading (see Attachment 7). For evidence of harms, case reports, case series, retrospective cohort studies, and arms of RCTs are sought. For risk factor assessments, prospective and retrospective cohort studies are preferentially sought, with case control or cross sectional studies selected where 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 scheme which is different from the scheme used for RCTs (see Table C). Emphasis is placed on what the test being studied is compared to. Another criterion is data to calculate test specificity and sensitivity can be calculated. 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. In order 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 as a footnote for each evidence table. 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, 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 (9)

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.<sup>iv</sup>

As mentioned, 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)	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 (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).

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 eleven. The categorization of high, moderate, and low quality studies is the same as in treatment-related studies.

After research assistants complete the evidence tables, researchers with graduate-level education (i.e., Master's, PhDs, MDs) 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 the body of quality evidence is assembled, scored and critiqued on a given subject, the body of 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 (9)

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 if needed. 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-

iv"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)."

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	3, 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 <sup>(12)</sup> and/or the CONSORT extension for pragmatic trials <sup>(13)</sup> 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 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.

<sup>\*</sup>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, inperson meetings) utilized to reach a unanimous opinion (or consensus) on both the recommendation and the wording of the recommendation for any individual topic. When consensus is not possible, a vote is taken (see Attachment 12 for a voting process example). Minority statements may be included in such cases.

The health benefits, adverse effects, risks and relative costs of each recommended test or treatment are explicitly considered and discussed in formulating the recommendations. <sup>(9)</sup> Benefits should significantly exceed risks. Each recommendation is to specify to which condition to which 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:
  - o 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) 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., urine drug screening for opioids compliance don't 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. iii 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) 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. (14-16)

Studies that include the general population of adults are necessarily used to develop most recommendations in the guidelines. 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 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 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 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, the more caution 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, the most cost-effective method is preferred.

#### **Rationale Statements**

There should be an explicit link between each recommendation and the supporting evidence. Each recommendation includes an evidence table and list of references. (9) 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 paragraphs 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. (9) 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.

#### **D.** External Peer Review<sup>(9)</sup>

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 posted at the *MDGuidelines* site for a period of two weeks for public comment.

#### E. Stakeholder Input<sup>(9)</sup>

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 input from 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 web site:

https://acoem.formstack.com/forms/stakeholderpatientinput (see Attachment 16 for further details).

ACOEM also seeks input from stakeholders into the scoping of the guidelines by inviting them to submit comments to us through our website (<a href="https://acoem.formstack.com/forms/scopingclinicalquestions">https://acoem.formstack.com/forms/scopingclinicalquestions</a>) on the list of clinical questions we research for each guideline.

#### F. Pilot Testing<sup>(9)</sup>

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.

#### G. 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 any acceptable changes are made to the guideline reviewed. The Panels and the Research Team have complete editorial independence from ACOEM and Reed Group, neither of which influences the Guidelines.

#### V. Updating Process<sup>(9)</sup>

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.

#### VI. Applicability/Tools for Putting it Into Practice<sup>(9)</sup>

#### A. MDGuidelines®

The ACOEM *Guidelines* are available as part of the Reed Group's *MDGuidelines*® which are available at <a href="https://www.MDGuidelines.com">www.MDGuidelines.com</a>. 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.

#### B. Monitoring/Auditing Criteria

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

### Table A-1: 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 Accepting Studies as Containing Adequate Evidence (Study Inclusion Criteria)

#### 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.

<sup>\*\*</sup>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.

#### **Table B: Quality Scoring of 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
Randomization: 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.	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."  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.  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.  Quasi-randomization, e.g., every-other allocations are rated "0" for this criterion.
Treatment Allocation Concealed: Concealment of the allocation scheme from all involved, not just the patient.	Rating is "0" if there is no description of how members of the research team or subjects would have been unable to know how they were going to receive a particular treatment, or the process used would not be concealed.  Rating is "0.5" if the study 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.  Rating is "1.0" if there is a concealment process described that would conceal the treatment allocation to all those involved.
Baseline Comparability: Measures how well the baseline groups are comparable (e.g., age, gender, prior treatment).	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.  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).  Rating is "1.0" if there is good comparability for all demographic and outcome variables between the groups at baseline.

Patient Blinded	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."
	Rating is "0.5" if it mentions blinding, but blinding is realistically plausible but the methods are unclear.
	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 given.
Provider Blinded	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."
	Rating is "0.5" if it mentions blinding, but the methods are both plausible while not specifically defined.
	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.
Assessor Blinded	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.
	Rating is "0.5" if it mentions blinding, but the methods are both plausible to provide blinding while not specifically defined.
	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.
Controlled for Co- interventions: The degree to which the study design controlled for multiple interventions (e.g., a	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."
combination of stretching exercises and anti-inflammatory medication or	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.
mention of not using other treatments during the study).	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.

	<del>-</del>
Compliance Acceptable: Measures the degree of non-	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.
compliance.	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.
	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%.
	Rating is "1.0" if there are specific data and the non-compliance rate is less than 20%.
Dropout Rate: Measures the drop-out rate.	Rating is "0" if there is no mention of drop-outs or it cannot be inferred from the data presented.
The same of the state of the same of the s	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.
	Rating is 0.5 it here 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%.
	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.
Timing of Assessments: Timing rates the timeframe	Rating is "0" if the timing of the evaluations is different between the groups, and/or a more than 10% difference (see below).
for the assessments between the study groups.	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
	Rating is "1.0" if the timing of the assessments between the groups is identical.
Analyzed by Intention	Rating is "0" if it was not analyzed by intent to treat.
Analyzed by Intention to Treat: This rating is for whether the study was analyzed with an	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).
intent-to-treat analysis.	Rating is "1.0" if the study specifies analyses by intention to treat.
Lack of Bias: This rating does not enter into	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.
the overall rating of a study. This is an overall indication of the degree to which biases	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.
are felt to be present in the study.	Rating is "1.0" if there are few biases, or those are well controlled and unlikely to have influenced the study's results.

<sup>\*</sup>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.

# Table C. Quality Scoring for Diagnostic Studies Article (author, title)

Score	Criteria	Rating
	Disorder clearly defined	<ul> <li>1.0 = Disorder definition supported by history, physical findings or other diagnostic testing that is reproducible.</li> <li>0.5 = Disorder labeled with narrow scope of evidence.</li> <li>0.0 = Case definition labeled without supporting evidence or not reproducible.</li> </ul>
	Test compared with gold standard	1.0 = Comparison made with gold standard (panel consensus). 0.5 = Comparison to established alternative test. 0.0 = Comparison to inferior diagnostic test.
	Investigative test conducted on all patients	1.0 = 95% or more of patients received investigative test. 0.5 = 80% or more of patients received investigative test. 0.0 = Less than 80% of patients received investigative test.
	Gold standard (control) test conducted on all patients	1.0 = 95% or more of patients received investigative test. 0.5 = 80% or more of patients received investigative test. 0.0 = Less than 80% of patients received investigative test.
	Assessor of investigative test result blinded to disorder	1.0 = Blinding of assessor defined and plausible. 0.5 = Blinding not clearly stated but probable 0.0 = No blinding or blinding improbable based on methods
	Assessor of gold standard test result blinded to disorder	1.0 = Blinding of assessor defined and plausible. 0.5 = Blinding not clearly stated but probable 0.0 = No blinding or blinding improbable based on methods
	Statistical analysis – Sensitivity and Specificity	1.0 = Sensitivity and specificity stated or can be readily determined 0.5 = One but not both provided 0.0 = Not provided, unable to calculate
	Statistical analysis – PPV and NPV	1.0 = PPV and NPV stated or can be readily determined 0.5 = One but not both provided 0.0 = Not provided, unable to calculate
	Normal range of investigative test	1.0 = Normal range of test defined and appropriate for study population $0.5 = Normal$ range defined but unclear if applicable to population $0.0 = Normal$ range not defined or unclear
	Timing of testing conducted at same phase of disorder	1.0 = Stated and appropriately measures at same phase of disorder 0.5 = Stated but unclear if measured at same phase in disorder 0.0 = Unstated or inappropriate interval between testing
	Application of tests followed appropriate quality control procedures.	1.0 = Protocol and application well described and appropriate 0.5 = Protocol and application narrowly described for one or both 0.0 = No quality control or not described
	Summary risk of bias	1.0 = No obvious bias exists 0.5 = Probable risk of bias 0.0 = Bias effecting results present

#### Comments:

#### **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.
В	<b>Moderate evidence-base</b> : 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.

<sup>\*</sup>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.

**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	В	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	С	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 practice to acquire or provide information in order to best diagnose and treat a health condition and restore function in an expeditious manner. 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.
Consensus* No Recommendation	I	The evidence is insufficient to recommend for or against routinely providing the intervention. The EBPP makes no recommendation.  Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms, and costs cannot be determined.
Consensus* NOT Recommended	I	The evidence is insufficient for an evidence-based recommendation.  The intervention is not recommended for appropriate patients because of high costs/high potential for harm to the patient.
NOT Recommended	С	Recommendation against routinely providing the intervention. The EBPP found at least moderate evidence that harms and costs exceed benefits based on limited evidence.
Moderately NOT Recommended	В	Recommendation against routinely providing the intervention to eligible patients.  The EBPP found at least moderate evidence that harms and costs outweigh benefits.
Strongly NOT Recommended	A	Strong recommendation against providing the intervention to eligible patients.  The EBPP found high quality evidence that the intervention is ineffective, or that harms or costs outweigh benefits.

<sup>\*</sup>In the absence of evidence, these recommendations are based on expert opinion.

#### 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.

### **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 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?

# **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

#### **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. 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.

# 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 evidencebased 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 ☐ PhD ☐ MPH/MSPH  $\Box$  DO  $\square$  MS □ DrPH  $\Box$  DC ☐ Other 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?

# 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) <i>Occupational Medicine Practice Guidelines</i> , 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.
$\Box$ 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 agree with 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/em	ployers):
Organization/Employer 1	
Organization/Employer 2	
Organization/Employer 3	
List those who contract for your ser	vices:
Contractor 1	_
Contractor 2	_
Contractor 3	_
Clinical Practice Focus (list clinical e.g., surgical or pain-control proced	activities that contribute more than 10% of annual income – lures, diagnostic studies, etc.):
Clinical Activity 1	
Clinical Activity 2	
Clinical Activity 3	
Clinical Activity 4	
<b>Business Ownership (list health-reliposition):</b>	ated businesses where you have more than a 10% equity
Business 1	Description
Business 2	Description
Institutions (list institutions that co	ntract for your services):
Institution 1	
Institution 2	
Consultancy (list consulting project than 10% of annual income):	s or activities within the last year that have contributed more
Client 1	
Client 2	
C1:	

Client 1	Topic
Client 2	Topic
Client 3	Topic
Legal Testimony (list any legal tes by the guidelines):	timony that might be related to possible interventions addressed
Client 1	
Client 2	
Client 3	
	list any interests that may be associated with guidelines tock in a pharmaceutical company that might be subject to
Stocks/Options	
Legal Consulting (topic areas in whi	ich you provided medical legal consulting)
Royalties	
Other	
manuscripts published or in prepa interventions addressed by the gui	
Other ACOEM Guideline Panels:	
Panel 1	
Panel 2	
Panel 3	
Other non-ACOEM Guideline Pa	
Panel 1	
Panel 2	

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

Panel 4	
Other Relevant ACOEM and non-AC	COEM 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 previ	iously covered):
Research Area #1	
Research Area #2	
Research Area #4	
Research Area #5	
Dagaarah Araa #6	

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

# Attachment 6 Training Curriculum

#### Introduction to Evidence-Based Medicine

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

#### 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** (30 minutes)

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

## **Attachment 7 Evidence Ranking by Type of Clinical Question**(11, 20-23)

#### Clinical Assessment Methods (Diagnosis and Testing)

- 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**

- 1a. Individual high-quality 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

#### 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 rulesout 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 non-independent 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)

## **Attachment 8**

## **Diagnostic Summaries**

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.

oentgen Author/Year Study Type	Score	Number	Area of Spine	Diagnoses	Type of X-rays	CT used	MRI Used	More than on rater	Blinding of rater	Myelography	Surgery Performed	Clinical outcomes assessed	Long term follow-up (mean when noted)	Results	Conclusion	Comments
omputer Author/Year Study Type	ized Score	Tome Number	ograph Area of Spine	y (CT) Diagnoses	Type of CT	X-ray used	MRI Used	More than on rater	Blinding of rater	Myelography	Surgery Performed	Clinical outcomes assessed	Long term follow-up (mean when noted)	Results	Conclusion	Comments
rap Author/Year Study Type	ohy (i	inclue Number	ding C Area of Spine	Γ Myelog Diagnoses	graphy Type of Myelography	d MR	MRI Used	yelo More than on rater	g Blinding of rater	phy X-ray	Surgery Performed	Clinical outcomes assessed	Long term follow-up (mean when noted)	Results	Conclusion	Commens

В	one Scan	S														
	Author/Year Study Type	Score	Number	Area of Spine	Diagnoses	Type of Bone Scans	CT used	MRI Used	More than on rater	Blinding of rater	Myelography	Surgery Performed	Long term follow-up (mean when noted) Clinical outcomes assessed	Results	Conclusion	Comments
Si	ngle Prot	ton E	miss	ion Co	mputed [	Fomograp	ohy (S	PE(	CT)							
	Author/Year Study Type	Score	Number	Area of Spine	Diagnoses	Type of SPECT	CT used	MRI Used	More than on rater	Blinding of rater	Myelography	Surgery Performed	Long term follow-up (mean when noted) Clinical outcomes assessed	Results	Conclusion	Comments
U	ltrasounc	l (dia	ignos													
	Author/Year Study Type	Score	Number	Area of Spine	Diagnoses	Type of Ultrasound	CT used	MRI Used	More than on rater	Blinding of rater	Myelography	Surgery Performed	(mean when noted) Clinical outcomes as	Results	Conclusion	Comments

nes assessed

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

Fluoroscopy/Videofluoroscopy

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

Discography/MRI Discography/Myeloscopy

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

**Magnetic Resonance Imaging (MRI)** 

1	Author/Year Study Type	Score	Number	Area of Spine	Diagnoses	Type of MRI	Type of CT us	T1 weighted in	T2 weighted in	X-ray	Myelography	More than one		Clinical outcor	Long term foll (mean when n	Results	Conclusion	Comments
	r			ne		U used	used	d images	d images		ıy	ne rater	Performed	outcomes	follow-up n noted)			

Surface E	Electromyography	(sEMG	)/EMG
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Author/Year Study Type	Score	Z	Area of Body	Needle EMG used for	MRI	CT	X-ray	More than one muscle	Long term follow-up	Results	Conclusion	Comments
								O				

## Below is an example of a Diagnostic Summary Sheet for the Eye Guideline:

Author Year (Score):	Categ ory:	Study type:	Conflict of Interest:	Sample size:	Age/Sex:	Population Description	Case Definition	Investigative Test	Comparative Test/s	Results:	Conclusion:	Comments:
Bengtsson 2006 (4.0)	SAP	Diagnos	Sponsored by the Swedish Research Council; Carl Zeiss Meditec, Dublin, California; and funds administered by Malmö University Hospital, Malmö, Sweden. No mention of COI.	N= 101	Mean age of 70 years, 33 male and 68 female.	With ocular hypertension and manifest glaucoma	Ocular hypertension of more than 24 mmHg. Manifest glaucoma, with no more than slight cataract, all lens grading ≤ 2. Threshold sensitivity at the p < 5% and the p < 2% levels in the pattern deviation probability maps.	Swedish interactive threshold algorithm (SITA).	Short- wavelength automated perimetry (SWAP). Lengthier full- threshold (SWAP). Standard automated perimetry (SAP).	The median number at the p < 5% limit was 9 for both full-threshold SWAP and SITA SWAP; 7 for SITA Fast SAP (p = 0.27); and 5, 5, and 4, respectively, at the p < 2% level (p = 0.18). The median false-positive frequency was 1% for SITA SWAP, 0% for full-threshold SWAP, and 3% for SITA Fast SAP. Full-threshold SWAP, identified 1 or more cluster in 65% of all eyes, ITA SWAP detected clusters in 66% (95% CI, 57–76), and SITA Fast SAP detected clusters in 64% (95% CI, 55–74).	"The SITA SWAP identified at least as much glaucomatous visual field loss as the older full- threshold SWAP, although test time was considerably reduced."	Data suggest comparable performance between all 3 tests (SITA, SWAT & SAP) for the detection of early glaucoma limit the testing time was shortened with SITA SWAP.

# **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)	of Retrieve d Article	What you typed in (copy and paste) for POPULAT ION STUDIES	Search Details (copy and paste)	Number of Retrieve d Article	Number of Saved Articles	Search Time

Scopus:

	300pu	э.														
	TREAMENT	Diagnosis	Search	Copy and	What you	What you	Scopus Search	Total Number of	What you typed in	Scopus Search	Total	What you typed in	Scopus	Total	Number	Search
ш			Terms	Paste for	typed in (copy	typed in	Details (copy	Retrieved	(copy and paste)	Details (copy	Number of	(copy and paste)	Search	Number of	of Saved	Time
ш			Used	Diagnosis	and paste) for	(copy and	and paste)	Articles	for REVIEW	and paste)	Retrieved	for Population	Details (copy	Retrieved	Articles	
ш					Treatment	paste) for					Articles	Studies	and paste)	Articles		
ш						RCT										
ш																
ш																
ш																
ш																
Н															$\overline{}$	
															1 1	
															1 1	
- 1																1

• Cochrane Library

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

• EBSCO (CINAHL)

Treatment Topic	Diagnosis		Total Number of Retrieved Articles	,	What you typed in (copy and paste) for Population Studies	Total Number of Retrieved Articles	 Search Time

## **Diagnostic Searches**

## • PubMed:

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

## • Scopus

• Cochrane Library

Treatment Topic	Diagnosis	Search Terms Used- use as a reference to recognize relevant articles	Search Terms Used	Total number of retreived articles	Number of saved articles	Search Time
		Diagnostic, Sensitivity OR Specificity Positive additive value OR Negative additive value, efficacy OR efficiency				

## • CINAHL

Treatment Topic		What you typed in (copy and paste)		What you typed in (copy and paste) for DIAGNOSTIC	retreived article	What you typed in (copy and paste) for SENSITIVITY OR SPECIFICITY.	retreived article	retreived article	retreived article	Time

# 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. Scopus
- 5. Google Scholar

## 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.	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±11.2 7 years. Exercise group±10.5 2 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."	

				exercise group only.	
				There were no	
				significant	
				differences in	
				physical functioning	
				between groups. In	
				view of the sample	
				size, these findings	
				are inconclusive.	

<sup>\*</sup>Quality Assessment Questions (scoring scale = 0, 0.5, 1): 1 = Randomization, 2 = Treatment allocation concealed, 3 = Baseline Comparability, 4 = Patient blinded, 5 = Provider blinded, 6 = Assessor blinded, 7 = Controlled for co-interventions, 8 = Compliance acceptable, 9 = Dropout rate, 10 = Timing of Assessments, 11 = Analyzed by intention to treat, 12 = Lack of bias (not included in scoring).

# 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 full consensus among a panel is not possible, then a process for voting will be used. An example of such a process is described below. The GMC may modify or refine this procedure, based on 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. <sup>(24)</sup> 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.

# 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 2.	Editor, EBPPs	MD, DO
Literature Search	-Comprehensive search of the literature focusing on highest level of evidence in Attachment 7Pull articles using inclusion criteria shown in Table A.	Research Assistant(s)	Undergrad/ MS/MPH/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) Study Coordinator(s)	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.	Study Coordinator(s), Research Associate	MS/MPH/PhD
Evidence Table Review and Finalization	-Over-read evidence tables to ensure that all important aspects of articles are included. -QA/QC	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 design, results and quality.	Physician(s)	MD/DO with MPH (or equivalent)
Draft Recommendations	-Draft recommendations	Physician(s)	MD/DO with MPH (or equivalent)
Panel Process	-Review evidence tables and strength of evidence ratingsRevise 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 guidelinesQA/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.	Multi-disciplinary health professionals	MD/DO/MPH, MS, PT, etc.

## 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

		J		
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.

#### **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 Opthalmology
- 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.

## Attachment 16 Stakeholder/Patient Input

Stakeholders may provide feedback and advice for guidelines whether or not they are undergoing major revision through an online form (https://acoem.formstack.com/forms/stakeholderpatientinput). 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.

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, please indicate why.		
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 $\leq$ 5, please indicate why.		
C 0 1 2 3 4 5 6 6 7 8 9 10 1 don't know/unsure		

## Attachment 17. Monitoring/Auditing Criteria

#### **Opioids**

The provider is recommended to assure:

- 1. Patients prescribed a trial of opioids for chronic pain should have documentation of at least 3 prior non-opioid medications that have been previously prescribed and failed. Target 100%
- 2. Patients who are prescribed opioids for chronic pain for over 3 months should have a signed informed consent form and pain contract. Target 100%
- 3. Patients should be screened for aberrant and illicit drug use prior to initiating, or continuing, prior opioids at the first visit. Target 100%
- 4. Patients on opioids should be prescribed at a morphine equivalent dose (MED) less than 100mg. Target >98%
- 5. Patients on opioids at MED over 100mg are not taking benzodiazepine(s). Target 100%
- 6. Patients who are in violation of his/her opioid contract (e.g., illicit drugs, >1 prescriber, diverting drugs) should have the opioid weaned or stopped. Target 100%
- 7. Patients performing safety sensitive jobs are not taking opioids. Target 100%

**Low Back Pain** (only applies to those without unstable fracture or other impending neurological catastrophe) The provider is recommended to assure:

- 1. Patients are not treated with opioids on the initial, non-traumatic non-radicular LBP visit. Target = 0% treated with opioids
- 2. Patients are not prescribed bedrest for LBP. Target 0% prescribed bedrest.
- 3. Patients are prescribed active exercise program and/or physical therapy (not bed rest) from first evaluation for LBP. Target 100%
- 4. Patients do not undergo MRI within the first 4 weeks with radicular pain but without major or progressive neurological deficit. Target 0%
- 5. Patients are not removed from work for LBP. Target <10% removed.
- 6. Patients do not undergo discography. Target 0% undergo discography.
- 7. Patients do not undergo spinal fusion surgery for non-specific low back pain. Target 0% undergo fusion surgery.

**Cervical Spine** (only applies to those without unstable fracture or other impending neurological catastrophe) The provider is recommended to assure:

- 1. Patients (non-radicular) are not treated with opioids on the initial, non-traumatic neck pain visit. Target = 0% treated with opioids
- 2. Patients are not prescribed bedrest for neck pain. Target 0% prescribed bedrest.
- 3. Patients are prescribed active exercise program and/or physical therapy (not bed rest) from first evaluation for neck pain. Target 100%
- 4. Patients do not undergo MRI within the first 4 weeks with radicular pain but without major or progressive neurological deficit. Target 0%
- 5. Patients are not removed from work for neck pain. Target <10% removed.
- 6. Patients do not undergo discography. Target 0% undergo discography
- 7. Patients do not undergo spinal fusion surgery for non-specific neck pain. Target 0% undergo fusion surgery.

#### Hand, Wrist, Forearm

The provider is recommended to assure:

1. Patients with carpal tunnel syndrome are treated at some point with nocturnal, cockup wrist splinting. Target >50%

- 2. Patients undergoing carpal tunnel release have had a prior glucocorticosteroid injection. Target >80%
- 3. Patients with deQuervain's are treated at the first appointment with glucocorticosteroid injection. Target >40%
- 4. Patients with trigger digit are treated at the first appointment with glucocorticosteroid injection. Target >40%
- 5. Trauma patients have tetanus status documented and compliance is assured with CDC recommendations. Target 100%
- 6. Patients with closed-injury mallet finger are treated with hyperextension splinting. Target 100%

#### Elbow

The provider is recommended to assure:

- 1. Imaging of the elbow is not done at initial evaluation for non-traumatic injuries. Target <10%
- 2. Lateral epicondylalgia patients are treated with an NSAID absent a contraindication. Target 100%
- 3. Lateral epicondylalgia patients without sufficient results from NSAID and elbow strap are treated with iontophoresis with either glucocorticosteroid or NSAID. Target >75%
- 4. Ulnar neuropathy at the elbow patients are taught to sleep with the elbows extended. Target 100%
- 5. Patients with cubital tunnel ulnar neuropathy at the elbow who fail non-operative management undergo simple aponeurotic release. Target >80%

#### Shoulder

The provider is recommended to assure:

- 1. Acute, chronic and post-operative shoulder pain patients are treated with NSAIDs absent a contraindication. Target >90%
- 2. Calcific shoulder tendinitis patients who are insufficiently responsive to NSAID are treated with extracorporeal shockwave therapy. Target >90%
- 3. Adhesive capsulitis patients are treated with glucocorticosteroid injection(s). Target >90%
- 4. Mobilization and/or manual therapy are prescribed for patients with adhesive capsulitis. Target >90%
- 5. Rotator cuff tendinopathy patients are treated with glucocorticosteroid injection(s). Target >75%
- 6. Trigger points/myofascial pain are treated with botulinum injections. Target <10%

#### Hip/Groin

The provider is recommended to assure:

- 1. Patients with hip osteoarthritis are treated with walking exercises. Target >90%
- 2. Patients with hip osteoarthritis requiring analgesia are treated with NSAIDs including aspirin. Target >90%
- 3. Hip arthroplasty patients are provided perioperative venous thrombosis prophylaxis. Target 100%
- 4. Hip arthroscopy patients are provided chondroplasty. Target 0%
- 5. Hip surgery patients are ambulated the day of surgery. Target >90%

#### Knee

The provider is recommended to assure:

- 1. Patients with knee osteoarthritis are treated with walking exercises. Target >90%
- 2. Patients with knee osteoarthritis requiring analgesia are treated with NSAIDs including aspirin. Target >90%
- 3. Knee arthroplasty patients are provided perioperative venous thrombosis prophylaxis. Target 100%
- 4. Knee surgery patients are ambulated the day of surgery. Target >90%

#### Ankle/Foot

The provider is recommended to assure:

- 1. Patients with ankle sprains with Ottawa rules positive examination findings do not undergo x-rays. Target <10% undergo x-rays.
- 2. Patients with ankle sprains are provided active exercise or limited walking. Target >90%.
- 3. Patients with ankle sprains are prescribed NSAIDs. Target 90%.
- 4. Patients are prescribed eccentric exercises for Achilles tendinopathy without complete tear. Target >90%
- 5. Patients undergo postoperative weight bearing exercises within 2 weeks of Achilles tendon repair. Target 100%

#### **Chronic Pain**

The provider is recommended to assure:

- 1. Patients with unimproving upper or lower extremity pain, tingling and numbness of over 6 weeks duration is evaluated with EMG/nerve conduction studies. Target 60%
- 2. Patients with chronic persistent pain are treated with aerobic exercises. Target >90%
- 3. Patients with chronic persistent pain requiring analgesia are treated with NSAIDs including aspirin. Target >90%
- 4. Patients with chronic pain without depression are not treated with SSRI antidepressants. Target 0%
- 5. Neuropathic pain patients are treated with Duloxetine. Target >75%

#### **Occupational Asthma**

The provider is recommended to assure:

- 1. Asthma patients undergo evaluation that includes spirometry pre- and post- bronchodilator. Target 100%
- 2. Asthma patients without confirmed occupational basis are evaluated with serial peak flow measurements. Target 100%
- 3. Skin prick testing for high molecular weight allergens is performed in workers with symptoms consistent with occupational asthma and where commercially available, validated skin testing extracts are available. Target >50%
- 4. Occupational asthma patients are recommended for exposure removal who have severe asthma in a low, moderate or high exposure setting. Target 100%

#### **Interstitial Lung Disease**

The provider is recommended to assure:

- 1. Interstitial lung disease patients undergo evaluation that included spirometry. Target 100%
- 2. Interstitial lung disease patients undergo evaluation that included chest x-ray. Target 100%
- 3. Interstitial lung disease patients who have ongoing potential exposures are referred for evaluation to ensure satisfactory/adequate control of exposures. Target 100%

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## METHODS BY WHICH ACOEM ADHERES TO THE AGREE II CRITERIA

AGREE II ITEM	ACOEM PRATICE GUIDELINE PROCESS	
Domain 1. Scope and Purpose		
Overall objectives of the guideline is (are) specifically described.	The purpose 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.  Each guideline includes a list of specific objectives for that guideline.	
Health question(s) covered by the guideline is (are) specifically described.	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 osteoarthrosis, 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 osteoarthrosis, 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?	
	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 format (population of interest, intervention, comparison group, and outcome).  Each guideline includes a list of specific questions covered by that guideline.	
Population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	Working age adults (~18-65 years) with health conditions related to work or that affect the ability to work. However, many workers are 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.	
Domain 2. Stakeholder Involvement		
Guideline development group includes individuals from all relevant professional groups.	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.).  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 ( <a href="https://acoem.formstack.com/forms/scopingclinicalquestions">https://acoem.formstack.com/forms/scopingclinicalquestions</a> ) on the list of clinical questions we research for each guideline.	

Views and preferences of the target population (patients, public, etc.) have been sought.	ACOEM has a webpage ( <a href="https://acoem.formstack.com/forms/stakeholderpatientinput">https://acoem.formstack.com/forms/stakeholderpatientinput</a> ) 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> .
	The Reed Group also has a feedback process to provide feedback on the guidelines.
	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 ( <a href="https://acoem.formstack.com/forms/scopingclinicalquestions">https://acoem.formstack.com/forms/scopingclinicalquestions</a> ) on the list of clinical questions we research for each guideline.
Target users of the guideline are clearly defined.	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.
Domain 3. Rigour of Development	
Systematic methods were used to search for evidence.	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.
	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.
Criteria for selecting the evidence are clearly described.	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.
	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 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 the recommendations are clearly described.	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".
	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
	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 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); Not Recommended (B); and Strongly Not Recommended (A). The insufficient evidence recommendations are used to clearly denote these are expert consensus recommendations.
Health benefits, side effects and risks have been considered in formulating the recommendations.	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).
There is an explicit link between the recommendations and the supporting evidence.	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.
Guideline has been externally reviewed by experts prior to publication.	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 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 MDGuidelines.®
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 <a href="https://www.MDGuidelines.com">www.MDGuidelines.com</a> . 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 recommendations have been considered.	Cost criteria are noted and included in the guidance. This is considered by the Evidence-based Practice Panels when developing 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 ACOEM <i>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 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.

## METHODS BY WHICH ACOEM ADHERES TO THE AMSTAR CRITERIA

AMSTAR	ACOEM PRATICE GUIDELINE PROCESS
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
2. Was there duplicate study selection and data	of specific clinical questions is also compiled and available at <a href="https://acoem.formstack.com/forms/scopingclinicalquestions">https://acoem.formstack.com/forms/scopingclinicalquestions</a> .  Yes. All ACOEM Guidelines have at least two systematic literature searches performed, and nearly all have had many more than
extraction?	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?	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.
	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).
	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.
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?	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, 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

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	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.
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?	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 spelled out in the methodology documents.
	In cases where evidence is either absent or substantially conflicting, a 4 <sup>th</sup> category, Insufficient Evidence, is used to clearly demarcate consensus-based recommendations.
	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.
9. Were the methods used to combine the findings of studies appropriate?	Yes. There are cases where it is sensible to perform combined analyses, and pooled analyses are performed. In those cases, test for homogeneity (I²), 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.
10. Was the likelihood of publication bias assessed?	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.
11. Was the conflict of interest included?	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.

#### METHODS BY WHICH ACOEM ADHERES TO GRADE CRITERIA

GRADE CRITERIA	ACOEM PRACTICE GUIDELINE PROCESS	
1. Quality of Evidence Consistency		
"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.	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.	
	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.	
	The Research Team staff conducts systematic literature reviews for each guideline topic/question (PICO). 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.	
	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 attudies. 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).	
	Search strategies and methods are recorded in detail per each PICO question, 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 (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.	
2. Explicit Consideration of Evidence		
Explicit consideration should be given to each of	Each article that meets inclusion criteria is reviewed and critically appraised.	
the GRADE criteria for assessing the quality of evidence (risk of bias/study limitations,	For randomized controlled clinical trials and randomized crossover trials, each article is scored on 11 criteria (i.e., randomization,	
directness, consistency of results, precision,	concealment, baseline comparability, patient/provider/evaluator blinding, co-interventions, compliance rate, dropout rate, timing and	
publication bias, magnitude of the effect, dose-	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	
response gradient, influence of residual plausible	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	

confounding and bias "antagonistic bias" although different terminology may be used.

different than that for the entire body of quality evidence on that topic/PICO 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 "L"

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.

A <u>risk of bias</u> 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 <u>confounding</u>. 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 trails may not exist. ACOEM examines the <u>directness</u> 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 <u>precision</u>. Emphasis is also placed on where there are stronger, unbiased, central point estimates (i.e., <u>magnitude of the effect</u>). These are further emphasized where there are such findings that are also consistent across studies.

<u>Dose response</u> 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. 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).

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).

The ACOEM *Practice Guidelines* 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.

#### 3. Quality of Evidence Outcome(s)

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.

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.

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.

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 rating, as such data must be considered sparse or imprecise.

#### 4. Judgments of Evidence Summaries

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.

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.

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.

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

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.

References for specific recommendations, dose, frequency, etc. are also cited to improve clarity and understanding of the sources of recommendations.

#### 5. Balance

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.). 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 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.

#### 6. Expression of Strength of Recommendations

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

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.

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).

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.

#### 7. Transparency

Decisions about the strength of the recommendations

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.

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.

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); Not Recommended, Insufficient Evidence (I); Not Recommended (B); and Strongly Not Recommended (A). The Insufficient evidence recommendations are used to clearly denote these are expert consensus recommendations.

## METHODS BY WHICH ACOEM ADHERES TO THE IOM CRITERIA

IOM CRITERIA	ACOEM PRATICE GUIDELINE PROCESS
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)	
<ul> <li>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.</li> <li>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.</li> <li>2.2 Disclosure of COIs within GDG</li> <li>All COI of each GDG member should be reported and discussed by the prospective development group prior to the onset of their work.</li> <li>Each panel member should explain how their COI could influence the CPG development process or specific recommendations.</li> <li>2.3 Divestment</li> <li>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.</li> <li>2.4 Exclusions</li> <li>Whenever possible GDG members should not have COI.</li> <li>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.</li> <li>Members with COIs should represent not more than a minority of the GDG.</li> <li>The chair or co-chairs should not be a person(s) with COI.</li> <li>Funders should have no role in CPG development.</li> </ul>	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).  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.  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.

#### **STANDARD 3: Guideline Development Group Composition**

- 3.1 The GDG should be multidisciplinary and balanced, comprising a variety of methodological experts and clinicians, and populations expected to be affected by the CPG.
- 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.
- 3.3 Strategies to increase effective participation of patient and consumer representatives, including training in appraisal of evidence, should be adopted by GDGs.

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 psychologists than other body parts due to the predisposing mental health factors plus comorbid conditions of depression and anxiety.

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.

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 (<a href="https://acoem.formstack.com/forms/scopingelinicalquestions">https://acoem.formstack.com/forms/scopingelinicalquestions</a>) on the list of clinical questions we research for each guideline.

ACOEM also has a webpage (<a href="https://acoem.formstack.com/forms/stakeholderpatientinput">https://acoem.formstack.com/forms/stakeholderpatientinput</a>) 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 *Practice Guidelines*.

The Reed Group also has a feedback process to provide feedback on the ACOEM guidelines.

#### STANDARD 4: Clinical Practice Guideline-Systematic Review Intersection

- 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.
- 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.

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.

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.

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 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 numbers and quality of studies in favor/against the intervention or test. This too is clearly spelled out in the methodology documents.

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 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.

In cases where evidence is either absent or substantially conflicting, Insufficient Evidence, is used to clearly demarcate consensus-based recommendations.

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.

There are cases where it is sensible to perform combined analyses, and pooled analyses are performed. In those cases, test for homogeneity (I<sup>2</sup>), 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.
	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.
STANDARD 5: Establishing Evidence Foundations for and Rating Street	
<ul> <li>5.1 For each recommendation, the following should be provided:         <ul> <li>An explanation of the reasoning underlying the recommendation, including:</li></ul></li></ul>	Each recommendation has a description of the benefits and the harms.  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) recommendations may be provided to clearly demarcate the limits of quality studies.  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.  A rating of the level of confidence is included for all recommendations in updated/new guidelines.  A rating of the strength of the recommendation is provided in bold type for all recommendations (see above discussion and methodology documents).  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.
STANDARD 6: Articulation of Recommendations	discussion is often) discussed.
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.  6.2 Strong recommendations should be worded so that compliance with the recommendation(s) can be evaluated.	All recommendations are clearly stated and are in bold type.  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.  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.  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.
STANDARD 7: External Review	
7.1 External reviewers should comprise a full spectrum of relevant stakeholders, including scientific and clinical experts, organizations (e.g.,	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

health care, specialty societies), agencies (e.g., federal government), patients, and representatives of the public.

- 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).
- 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.
- 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.

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.

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.

All comments from eternal 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.

A pre-publication version of all guidelines will be posted at the *MDGuidelines* site for a period of two weeks for public comment.

#### **STANDARD 8: Updating**

- 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.
- 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.
- 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.

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.

The publication date, systematic review dates and proposed updating dates are all documented.

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.

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.