Methodology to Update the Practice Recommendations in the American College of Occupational and Environmental Medicine's Occupational Medicine Practice Guidelines, Second Edition

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Objective: *To ensure that revisions to the second edition of the American College of Occupational and Environmental Medicine (ACOEM) guidelines are as valid and useful as possible.* ***Methods:*** *The ACOEM Guideline Methodology Committee searched and synthesized the evidence-based medicine literature on systematic review and guideline development. The resulting process and tools were tested during guideline revision, and changes were made to the tools and process.* ***Results:*** *The methodology specifies problem formulation, literature search methods, screening of studies, quality rating, summarization of the body of literature, recommendation drafting and rating, "first principles" of medical logic and ethics, training, expert panel review, stakeholder input, external review, pilot testing and Board of Directors approval.* ***Conclusions:*** *The process and tools developed are consistent with international guideline assessment criteria, robust, and internally and externally valid.* (J Occup Environ Med. *2008;50:282–295*)

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When evidence-based best practices are not known to physicians or not used in patient care, the result is unwanted variation in care. Variance in medical care for similar conditions produces less than optimal outcomes and is an a priori indicator of poorer quality care.[1] Despite progress in some jurisdictions, there are still significant opportunities for improvement in occupational medical care. Compared with care for similar diagnostic groups in general medical care, analyses of workers' compensation medical care have shown up to 10-fold differences in resource use[2]; inappropriate use of invasive procedures[3]; and use of physical therapy, injections, opioid medication, and chiropractic for prolonged durations.[4] Medical record reviews of series of workers' compensation patients reveal a high prevalence of testing and treatment unsupported by the medical literature or general medical practice patterns.[3] An apparently unintended consequence of extensive testing and treatment is longer time off work. Excessive testing and treatment is also believed to result in poorer health outcomes and a higher probability of permanent disability. Such variance questionable appropriateness of testing and treatment without concomitant improvement in outcomes are indicators of lower medical quality.[1,5,6]

Clinical practice guidelines based on critically appraised evidence and syntheses of best practices are a demonstrated method of improving the quality and consistency of medical care.[7–10] Guidelines for occupational medicine have been developed and disseminated by the American College of Occupational and Environmental Medicine (ACOEM) as the ACOEM *Occupational Medicine Practice Guidelines* (*APGs*) since 1997 to recommend best practices for care of common work-related health complaints and functional recovery.[11] Based on updated searches, expanded coverage, and updated evaluations of the literature, the College released the second edition in 2004.[12] The methodology used for each edition was briefly described in the introduction to each volume and further described in several other publications.[13,14]

The *APGs* are widely disseminated in the United States and Canada, and in at least two states are defined by statute as presumptively correct for purposes of utilization review and subsequent reimbursement. The *APGs* are also used by other states, care networks, and individual practitioners to guide medical practice, quality improvement, and case management. Thousands of physicians, nurses, case managers, utilization reviewers, adjusters, and attorneys have been trained on the *APGs* through interactive, case-based courses.

Practice guidelines are only as good as the methods used to develop them. The more rigorous the methodology, the more reproducible and valid the resulting guideline recommendations. The methods used to develop evidence-based guidelines should be explicit and transparent.[15,16] The evidence-based medical community, through clinical epidemiology and its application as critical appraisal, has continued to research and identify best practices for conducting a critical review process and synthesizing the available evidence.[17–24] In light of these advances, ACOEM has recently revised and updated the methodology used in developing its *APGs* to ensure that the process continues to be as transparent, consistent, reproducible, and unbiased as possible.

Updated Methodology Development

In early 2006, ACOEM changed to rolling updates of the *APGs*, further expanded the topics covered, and appointed a formal Guideline Methodology Committee (GMC) to design a transparent and consistent methodology for all ACOEM evidence-based products and services, to train the staff and evidence-based practice panels (EBPPs) producing the updates, and to assure proper application of the methodology. This article is a description of that revised methodology.

The ACOEM GMC, comprising the authors of this article, developed an updated methodology. This process included a review of the literature on the critical appraisal of health care research and a review of the literature on the development of clinical guidelines. The results of these reviews provided the evidence used by the GMC to define the ACOEM Methodology, which is being used, subject to future advances, for all ACOEM evidence-based products.

The mechanics of evidence search, initial assessment, critical analysis, synthesis, and recommendation development are central to the accuracy and reliability of the evidence-based medicine (EBM) process. Delineating them in detail allows others to assess the process by which guidelines were developed and to assure integrity and lack of bias. Accordingly, the literature on EBM was surveyed to identify the most current and comprehensive methods for systematic reviews[19,25] and meta-analyses of the literature[23,26,27] and for guideline development.[15,20,28–30] The survey included general EBM texts, articles, and Websites,[17,21,31–35] and those specific to occupational medicine.[14,16,36–38] One reviewer summarized specific methods and tools. The ACOEM methodology was developed from this review and additional references contributed by other GMC members in a series of meetings of the GMC. The methods and processes were tested for utility and accuracy during the development of the revised Elbow and Low Back guidelines, and some changes were made to the original methodology. The methods outlined below are subject to continuous improvement.

Results

The methodology for the development of all ACOEM evidence-based products and services adopted by the GMC and approved by the ACOEM Board of Directors includes 11 steps, which are consistent with the criteria established by the Appraisal of Guidelines for Research and Evaluation (AGREE) Collaboration[18,22,24] and the proposed COGS criteria.[39] These 11 steps and the criteria established for adequate performance are described in the paragraphs below. The 11 steps are as follows:

1. Formulation of (posing) an answerable question
2. Evidence search
3. Ranking and preliminary screening of studies
4. Study assessment and quality rating
5. Synthesis and rating of the body of evidence (see page 4).
6. Formulation of practice recommendations
7. Internal quality review
8. External review
9. Stakeholder input
10. Pilot testing
11. Final review and modification

Formulation of (Posing) an Answerable Question

Well-constructed, answerable questions about individual or population health concerns are critical to all of the subsequent steps in the development of an evidence-based guideline. These "answerable ques-

tions" for each clinical entity or diagnostic group considered should designate the population of interest, intervention, comparison group, and outcome of interest for prevention, treatment and functional recovery, and the reproducibility and performance of diagnostic tests against accepted reference standards for clinical assessment.[37,40,41] With this framework, an example of an answerable question might be: Do working adults with a particular health complaint or diagnosis who receive a single, standardized intervention experience better functional improvement or other areas of clinical recovery than an untreated control group?

This method of defining a question is more likely to produce usable results than a question that is vague or likely to have many caveats, for example: Is penicillin an effective treatment?

Evidence Search

Searches for evidence for the development of ACOEM evidence-based products and services primarily emphasize a search for high- or moderate-quality original studies. Primary databases searched are shown in Table 1.

TABLE 1
Databases Searched for Original Studies, Systematic Reviews and Meta-Analyses

1. The National Library of Medicine's MEDLARS database (Medline) (www.nlm.nih.gov)
2. EBM Online (www.bmjjournals.com)
3. The Cochrane Central Register of Controlled Trials (www.cochrane.org/reviews/clibintro.htm)
4. TRIP Database (www.tripdatabase.com)
5. CINAHL (Nursing, allied health, physical therapy, occupational therapy, social services: www.cinahl.com/cdirect/cdirect.htm)
6. EMBASE (www.embase.com/)
7. PEDro (www.pedro.fhs.usyd.edu.au/)

Ranking and Preliminary Screening of Studies

Primary sources selected for inclusion in the evidence base for ACOEM products and services are limited to those with the strongest apparent study design, pending quality rating. The strength and quality of study design are determined by ranking and rating of the studies according to accepted methods. Generally accepted ranking of study design[17,21,36,37,42–44] for diagnostic testing and clinical treatment methods were modified by the GMC. Systematic reviews in general are not ranked as the best design in reality, as most reviews located during pilot testing of the Methodology, with the exception of many (but not all) Cochrane reviews, did not use systematic searches or quality assessments of included studies. The GMC also excluded level 4 evidence from consideration (case series, poor-quality cohort studies, poor-quality case-control studies, expert opinion without explicit critical appraisal, and expert opinion based on physiology, bench research, "first principles"). The focus was on the best-designed original studies, pending quality grading. For example, studies of diagnostic tests are generally limited to those compared to an acceptable gold standard, and those reporting sensitivity and specificity. Studies of clinical treatment methods are generally limited to randomized controlled trials or crossover trials. Additional literature was also reviewed when there was a paucity of higher-grade literature or if it was brought to EBPP's attention from interested parties.

To narrow the data discovered in the search to that which will be acceptable for further analysis and quality rating, researchers use additional preliminary screening criteria for original research. See Tables 2 and 3 for these additional criteria.

Searches are documented, listing the database searched, the search terms, article type and limits, the time frame searched (in this case, all years in the databases), the number of studies found, the number reviewed in detail, and the number included in the systematic analysis. Despite multiple database searches, many additional studies are discovered in exhaustive manual searches of article reference lists.

Study Assessment and Quality Rating

Studies are first abstracted into evidence tables for easier assessment. See Appendix B for a sample of an evidence table for treatment studies. Each study is formally graded for quality using a modification of the most recent assessment scheme proposed by the Cochrane

TABLE 2
Criteria for Inclusion in Study Rating and Critical Analysis of Studies of Diagnosis/Clinical Assessment Methods

1. Evaluate the efficacy (ie, clinical accuracy) of the assessment method (ie, 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 an RCT
3. Compare the findings of the assessment method (test) to an adequate reference standard for all subjects (not just subjects who tested positive)

TABLE 3
Criteria for Inclusion in Study Rating and Critical Analysis of Studies of Treatment Efficacy

1. Evaluate a group of subjects with a representative spectrum of the clinical condition of interest.
2. Be a randomized controlled trial evaluating clinical outcomes in a group receiving the intervention compared to a comparison group receiving either no intervention or a different intervention.
3. Evaluate functional outcomes that are important to a patient's overall health or well being or are important to society.

TABLE 4
Rating Criteria for Randomized Controlled Trials of Treatment Studies

Criterion	Description
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 treatment and control groups
Treatment allocation concealed	Concealment of the allocation of patients to various arms of the study from all involved, including patients, clinicians, and researchers
Baseline comparability	Measures how comparable the baseline groups are (eg, age, gender, prior treatment)
Patient blinded	The patient is not aware which group he or she is in
Provider blinded	The provider is not aware which treatment he or she is delivering
Assessor blinded	The researcher is not aware which group the results apply to
Co-interventions avoided	The degree to which the study design avoided multiple interventions at the same time
Compliance acceptable	Measures the degree of noncompliance with the treatment protocol
Dropout rate	Measures the dropout rate at different periods of time
Timing of assessments	Assessments and reassessments should be performed at the same time from inception for all study groups
Analyzed by intention to treat	Whether the study data was analyzed with an "intention to treat" analysis

Collaboration Back Group, as shown in Table 4.[19] The studies are quality rated using a 0, 0.5, 1 grade for each item, where 0 = does not fulfill the requirement; 0.5 = partially fulfills the requirement and 1 = entirely fulfills the requirement. A study with a score less than 4.0 is rated as a poor-quality study; a study with a score between 4.0 and 7.5 is rated as a moderate-quality study. A study with a score of 8.0 or greater is rated as a high-quality study.

Synthesis and Rating of the Body of Acceptable Evidence

Once the studies included in the analysis are rated for quality the research staff uses the criteria in Table 5 to determine the overall strength of evidence for a certain topic. The strength of evidence rating is based on the rating system originally used in Agency for Health Care Policy and Research (AHCPR) studies[45] and other guidelines as modified by the GMC. The staff then prepares summaries of the body of evidence and drafts recommendations.

Formulation of Practice Recommendations

Each recommendation includes citations of the specific scientific literature which supports the recommendation.

TABLE 5
Strength of Evidence Ratings

A	Strong evidence-base: two or more high-quality studies*
B	Moderate evidence-base: at least one high-quality study, or multiple lower-quality studies† relevant to the topic and the working population
C	Limited evidence-base: at least one study of intermediate quality
I	Insufficient Evidence: evidence is insufficient or irreconcilable

*For therapy and prevention, randomized controlled trials (RCTs) with narrow confidence intervals and minimal heterogeneity. For diagnosis and screening, cross-sectional studies using independent gold standards. For prognosis, etiology or harms, prospective cohort studies with minimal heterogeneity.

†For therapy and prevention, well-conducted cohort studies. For prognosis, etiology or harms, well-conducted retrospective cohort studies or untreated control arms of RCTs.

TABLE 6
Content of Recommendations for Diagnostic Testing or Treatment

1. The diagnoses for which the test or treatment is indicated
2. The specific indications for the test or treatment
3. The point in the time course of the problem for which it is appropriate
4. Prior conservative treatment that should be tried first
5. Relative and absolute contraindications to the test or procedure
6. The number of tests or procedures that are appropriate at a given time in the course of the problem
7. The potential benefits of the test or procedure
8. The potential harms, including effects on disability and return to work

The recommendations explicitly consider the health benefits, side effects, and risks of the proposed recommendation. Recommendations include the data elements described in Table 6.

The EBPPs for each topic area review and discuss draft practice recommendations from the research staff that includes a review of the quality evidence, evidence tables, and summaries. The strength of evidence rating is confirmed by the EBPP responsible for the topic, with review by the GMC. EBPP members may present additional comments related to their clinical opinions and experience for panel consideration. If a unanimous decision is not possible, an EPPP may vote on the rating of the strength of the evidence to determine a consensus. Dissenters to the consensus may draft minority opinions about the strength of evidence. In practice, this has not happened as recommendations have been unanimous.

Formulation of recommendations requires clinical judgment as well as

TABLE 7
First Principles for Medical Decision-Making and Evidence-Based Recommendations

Application	Category	Principle
Ethics		Clinicians should adhere to ACOEM's Code of Ethics.
		Clinicians should disclose any conflicts of interest (including ownership or other financial arrangements) they may have with any of the testing or treatment methods.
Diagnostic testing		Tests should be performed only if the results will 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.
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, choose the option supported by clinical and statistical significance.
		Treatment should be in accordance with evidence-based practice as described in the Methodology, particularly with respect to prioritization of treatment modalities.
	Use of high-quality evidence	Recommendations should be evidence-based with evidence of efficacy balanced with evidence of benefits 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 goal does not change the risk or benefit calculation for a subsequent treatment.
	Invasive treatment	Invasive treatment may be performed if conservative treatment does not improve the health problem 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.
		In cases where the patient cedes that judgment to the clinician, the clinician's judgment 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.

a full evaluation and consideration of the available high-quality evidence. To aid in framing recommendations, the GMC developed a list of "First Principles" based on the Hippocratic Oath ("First Do No Harm"), medical logic, appropriate sequencing and case management, shared decision-making, support of functional recovery, and relative cost-effectiveness. The First Principles are defined in Table 7. When there is insufficient high-quality evidence of effectiveness or efficacy, or the high-quality evidence is conflicting, and to guide recommendations for alternative tests or treatments when there are several options, these principles are used to guide group decision-making.

The EBPPs then assign a Strength of Recommendation, defined in Table 8, to each recommendation. If a consensus cannot be reached on the recommendation or strength of recommendation, the EBPPs may use nominal group voting if agreement is not possible in the discussion. Once a consensus is reached, the EBPPs will finalize the language and strength rating of the recommendation. If needed and material, a minority opinion can be appended to the recommendation. Again, this has not happened to date due to unanimity of the panels. This process is similar to that used by AHCPR to develop recommendations[46] and by the RAND Corporation in developing quality indicators.[47]

Final recommendations include an accompanying paragraph (typically based on the evidence summary) that describes the panel's conclusion

TABLE 8
Strength of Recommendations

Recommendation	Evidence Rating	Description of Category
Strongly recommended	A	The intervention is strongly recommended for appropriate patients. The intervention improves important health and functional outcomes based on high quality evidence, and the Evidence-Based Practice Panel (EBPP) concludes that benefits substantially outweigh harms and costs.
Moderately recommended	B	The intervention is recommended for appropriate patients. The intervention improves important health and functional outcomes based on intermediate quality evidence that benefits substantially outweigh harms and costs.
Recommended	C	The intervention is recommended for appropriate patients. There is limited evidence that the intervention may improve important health and functional benefits.
Insufficient—Recommended (consensus-based)	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, or collective experience that patients are best served by these practices, although the evidence is insufficient for an evidence-based recommendation.
Insufficient—No recommendation (consensus-based)	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.
Insufficient—Not recommended (consensus-based)	I	The evidence is insufficient for an evidence-based recommendation. The intervention is not recommended for appropriate patients because of high costs or high potential for harm to the patient.
Not recommended	C	Recommendation against routinely providing the intervention. The EBPP found at least intermediate evidence that harms and costs exceed benefits based on limited evidence.
Moderately not recommended	B	Recommendation against routinely providing the intervention to eligible patients. The EBPP found at least intermediate evidence that the intervention is ineffective, or that harms or 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.

about the evidence found on that question and the rationale for the specific recommendation. These paragraphs explain how the panel interpreted and weighed the evidence and how they balanced this against other considerations such as potential harms and costs. The reader is referred to the recently updated ACOEM Elbow and Low Back Disorders guidelines for examples of these statements.[48,49]

Internal Quality Review

The GMC assigns a committee member to each EBPP as a methodology consultant to assist with adherence to this methodology. The GMC reviews all recommendations for which there are questions about consistency with the defined methodology. If the GMC determines that the approved methodology has not been followed, leading to illogical or untenable recommendations, the GMC engages in direct discussions with the EBPP to reach agreement on revision. If there is no agreement or revision, then the matter will be considered by the ACOEM Board of Directors when the document is submitted for Board review.

External Review

ACOEM conducts external peer review of the *APGs* and periodic revisions to 1) assure that all relevant high-quality scientific literature has been found, 2) assure that the important evidence from the relevant scientific literature relevant 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 conclusions and presentation of materials from external topic experts. Professional and patient organizations, as well as panel members, ACOEM Board of Directors, etc., are invited to nominate external peer reviewers.

Peer reviewers are asked to comment on the completeness of the scientific literature evaluation in their topic area, the clarity and technical accuracy of the *APGs* evaluation and summary of the evidence, and the appropriateness of the

Guideline findings and recommendation statements.

Stakeholder Input

In a cyclical manner, ACOEM will seek stakeholder input to understand the needs and preferences of those who may utilize or be affected by the use of clinical practice guidelines in workplace settings and in the workers' compensation system. ACOEM solicits input from clinicians, health care systems, workers or patients, employers, utilization reviewers, case managers, insurers and third party administrators, attorneys, regulators, and policy makers through a variety of mechanisms. Stakeholders will be asked for comments about their experience using existing clinical practice guidelines and related products and their suggestions for future improvements. They are also asked for input on the use of clinical practice guidelines in clinical care, case management, claim administration, claim adjudication, and in the development of policies and regulations.

To ensure editorial independence in the development process, the stakeholder groups will be asked for input about the *APGs*, but will not be informed of panel deliberations or shown drafts of practice recommendations before the formal release of the documents. In some cases, a member of a stakeholder group may participate as a member of a *Guideline* EBPP or may participate in peer review or pilot testing. However, all individuals involved in the *APGs* development, peer review, and pilot testing are asked to keep all information about the panel's deliberations and conclusions confidential until the *APGs* are formally released.

Pilot Testing

The guidelines are pilot tested to determine if the recommendations are clear, easy to use, and are generally useful. Pilot testers are not asked if they think the recommendations or process for development was appropriate.

Board Review

Following internal and external peer review, and incorporation of suggestions into a final draft, the draft is submitted to a subcommittee of the Board for review. This subcommittee suggests revisions or recommends the document for acceptance.

Further Quality Assurance, Control, and Improvement

The process described above is summarized in Table 9. Table 9 shows the iterative nature of study search, abstraction, and quality grading to ensure a valid (reproducible) outcome for those steps. This iteration acts as both quality assurance and quality control. Additional training can be done if there are systematic errors in the process. A plan-do-check-act cycle for content and presentation also operates from the pilot testers, clinicians, and other stakeholders to the Editor, the ACOEM editorial staff, the subcommittee, and the GMC.

Discussion

Clinical practice guidelines based on high-quality evidence have assumed increasing importance in guiding improvement of the quality of medical practice and patient decision-making.[38,50–53] Some of the variance and inappropriate testing and treatment seen in occupational medicine should be reduced if clinicians were given the findings of high-quality studies of testing appropriateness, accuracy and cost-effectiveness, and the efficacy and appropriateness of treatment methods[54] and use those recommendations for the care and management of appropriate patients through effective interventions.

Although there has been substantive improvement in intermediate and final outcomes with the use of the ACOEM *APGs* in California, workers there and elsewhere would benefit from improvements in the consistency and appropriateness of care for work-related health problems. Wide variations in care within cohorts of workers with health complaints and between occupational and nonoccupational care for similar conditions persist in many areas. Care at variance with evidence-based best practices becomes self-perpetuating, often to the detriment of functional recovery.* These data make it clear that there is a serious gap between evidence and practice among those providing care for workers with health complaints.

Use of the ACOEM guidelines under California law has resulted in more appropriate resource use and better outcomes for injured workers. Service use, particularly physical therapy and chiropractic, have fallen dramatically,[55,56] while time off work has decreased.[57]

Clearly Defining "Evidence-Based"

The term "evidence-based" has a very specific meaning when properly used to describe practice guidelines. It describes a specific process of evidence search, grading, synthesis and application. The process includes systematic reviews of the applicable scientific literature, and a panel process used to formulate recommendations based on the body of high-quality literature reviewed. Un-

*For example, in California before the adoption of the *APGs* as presumptively correct, the more testing and treatment used within a cohort of similar nonspecific low back pain cases, the longer injured workers were off work. Yet, the objective of occupational medical care is to restore workers' functional abilities. Intermediate outcomes from use of resources in excess of evidence-based guideline included an incremental $912 in additional resources used for each plain x-ray; $9,972 more than predicted for claims with physical therapy visits in excess of guideline targets (but lower costs than predicted for claims with below-target numbers of physical therapy visits); $28,713 for claims in which the average number of chiropractic visits exceeded guideline targets (but lower costs than predicted for claims with below-target numbers of chiropractic visits); and $89,025 in cost, 2 more years of medical care, and almost 8 more months of temporary disability for each spinal surgery compared with claims without spinal surgery.

TABLE 9
ACOEM Guideline Development/Revision Process Summary

Step	Purpose	Individual(s) Responsible	Educational Credentials
Pose answerable clinical questions	Direct search, following format in Table 1	Editor, EBPPs	MD, DO
Literature search	Comprehensive search of the literature focusing on highest level of evidence in Tables 2 and 3. Pull articles using inclusion criteria shown in Tables 4 to 6	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, Appendix B	Research assistant(s), study coordinator(s)	MS/MPH/PhD
Article abstraction/ semifinal development of evidence tables	Read articles Semifinal 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 7 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 8	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 following the format in Table 9	Physician(s)	MD/DO with MPH (or equivalent)
Panel process	Review evidence tables and strength of evidence ratings Revise recommendations based on discussion, application of clinical judgment and first principles (Table 10) or new evidence	Multidisciplinary health professionals	MD/DO/MPH, MS, PT, etc
Guideline review	Review/oversight of final guidelines to ensure consistency with methodology and other related guidelines QA/QC	Physician	MD, DO
External review	Review guideline for consistency with evidence and conservative expert clinical practice as well as methodology and usability	Physicians, physical therapists, occupational therapists, pharmacists, psychologists, other health professionals	MD, DO, PhD, DC, RPT/ PhD, DrPh, etc
Stakeholder input	Review guideline for usability and applicability	Physicians, attorneys, claims professionals, UR nurses, case managers	MD, DO, JD, RN, DC, RPT, PhD, certified claims managers
Pilot testing	Use guideline, assess usability and applicability	Physicians, UR nurses, case managers, physical therapists	MD, DO, RN, RPT
Review	Review guideline based on content, methodology, and quality assurance	ACOEM Board of Directors or subcommittee	MD, DO with MPH or equivalent
Revision	Revisions based on internal and external review comments and evidence	Physician	MD, DO

fortunately, the term has been misapplied, and there are a number of guidelines and products published that do not conform to evidence of efficacy. The ACOEM methodology is being published to help advance the field of occupational health care and improve the health and recovery of workers. This article should provide for clear communication on the major details of a methodology consistent with best practices in EBM.

The Importance of a Rigorous, Clearly Defined Methodology

Carefully defining, following, and documenting each step in the process of systematic review and

TABLE 10
Attributes of Excellent Clinical Practice Guidelines

Attribute	Description
Validity	The recommendation should produce similar clinical outcomes in similar cases.
Reliability and 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 (eg, 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 are documented and archived.
Transparency	Records of deliberation that affect the evidence-based practice process and any revisions to analysis, recommendations, and conclusions are available.
Approval	The sponsoring organization's Board of Directors approves the recommendations as being high quality guidelines relevant to occupational and environmental medicine.

critical analysis of the literature and guideline development increases the validity and reliability of clinical practice guidelines.[15,16] The updated ACOEM guideline methodology incorporates the best methods of EBM and ideal attributes of clinical practice guidelines (Table 10), addressing the domains suggested by the AGREE Collaboration[24] (Table 11), the proposed COGS checklist,[39] and the process framework of the Scottish Intercollegiate Guideline Network.[20] The methods of discussion and revision by the EBPPs are consistent with the RAND[47] and Agency for Healthcare Research and Quality[53] processes.

The process and tools that resulted from this effort are very detailed and specific in the area of "rigor" in the AGREE instrument. The mechanics of evidence search, initial assessment, critical analysis, synthesis, and recommendation development are central to the accuracy and reliability of the EBM process.

The updated methodology recognizes that clinical practice guidelines should have explicit objectives, content areas, and intended target audiences.[18,22,58] Further, the developers and their potential conflicts of interest, as well as the organizational structure supporting guideline development, should be known to evaluators and potential guideline users. The methodology presented here complies with these requirements (Appendix A).

Critical analysis of the literature and careful evidence synthesis are particularly important for several reasons. Grading the literature for quality is a critical step, as higher-quality studies are more likely to be reproducible and their results less subject to bias. Inferring quality from study design alone may overlook other determinants of quality such as sample size, recruitment bias, loss to follow-up, unmasked outcome assessment, atypical patient populations, irreproducible interventions or cointerventions, impractical clinical settings, and other threats to internal and external validity.[21] Qualitative systems have been a threat to the reproducible rating of such studies.[59]

The ACOEM research team noted several problems in the literature that are likely to be overlooked without structured critical analysis. For example, abstracts alone often did not contain the detail or statistics needed for critical analysis of the robustness of design or the strength of measured effects. Some abstracts misstate the study design, a problem that is often not discovered until the studies are subject to critical analysis. Second, there is often vague and ambiguous reporting in selected studies.[59] This problem is often compounded by studies with multiple cointerventions, and often with no true control group. These studies are essentially uninterpretable. Third, in critically analyzing studies labeled as systematic reviews, the team discovered that, with the exception of most Cochrane reviews, such studies were generally not systematic and did not critically appraise or synthesize studies as is recommended in the EBM literature.[17] The consequences of less than rigorous reviews are also reflected in resulting practice guidelines. For example, the US National Guidelines Clearinghouse requires guidelines to be based on systematic reviews that use generally accepted steps such as structured critical appraisal of identified studies. However, some posted guidelines have underlying reviews that do not evidence critical appraisal of the studies described. Their recommendations therefore sometimes diverge from other guidelines with published, rigorous methodologies.

TABLE 11
The AGREE Criteria and ACOEM Process Application

	Domain	Area	ACOEM Process Application
I	Scope and purpose	1. The overall objectives of the guidelines are specifically documented.	See Appendix B.
		2. The clinical questions covered by the guidelines are specifically described	PICO format – differs for etiology, diagnosis, prognosis, testing, treatment, functional recovery.
		3. The patients to whom the guideline is meant to apply are specifically described.	Working age adults; comorbidities may vary in subgroups.
II	Stakeholder involvement	1. The guideline development group includes individuals from all relevant professional groups.	EBPPs and reviewers include professionals from all involved specialties.
		2. The patients' views and preferences have been sought.	Literature reviews seek such information as does the stakeholder input process.
		3. The target users of the guidelines are clearly defined.	OM clinicians, administrators, claims adjusters, UM reviewers, regulators and the WC legal system. See Appendix B.
		4. The guidelines have been piloted among target users.	Step 9 of the ACOEM methodology.
III	Rigor of development	1. Systematic methods were used to search for evidence.	ACOEM process step 2; see Table 12. Search terms, sources, dates and output are archived.
		2. The criteria for selecting the evidence are clearly described.	See Tables 2–6 and 12.
		3. The methods used for formulating the recommendations are clearly described.	The APG methodology describes a sequence of actions that assures proper evidence quality assessment (eg, Table 7), rating of the strength of the body of evidence (Table 8), and completeness and utility of recommendations (Table 9).
		4. The health benefits, side effects and risks have been considered in formulating the recommendations.	The methodology explicitly examines this balance. See Tables 10 and 11.
		5. There is an explicit link between the recommendations and the supporting evidence.	Each recommendation is linked to a list of references, as is each chapter evidence table. In some cases confidence interval diagrams may be presented.
		6. The guideline has been externally reviewed by experts prior to its publication.	ACOEM methodology process step 8.
		7. A procedure for updating the guidelines is provided	A three year rolling update process is in place using the APG methodology.
IV	Clarity and presentation	1. The recommendations are specific and unambiguous.	These standards are used by the EBPPs, the Editor in Chief, the ACOEM editorial staff and contracted medical editors.
		2. Different options for management of the condition are clearly presented.	
		3. Key recommendations are easily identifiable. The guideline is supported by tools for application.	
V	Applicability	1. The potential organizational barriers in applying the recommendations have been discussed.	Barriers, costs and review criteria will be discussed in accompanying articles and electronic tools, and a new guideline implementation chapter.
		2. The potential cost implications of applying the recommendation have been considered.	Costs are criterion considered by the EBPPs.
		3. The guideline presents key review criteria for monitoring and audit purposes.	
VI	Editorial independence	1. The guideline is editorially independent from the funding body.	
		2. Conflicts of interest of guideline development members have been recorded.	

Several other issues related to the use of studies to construct occupational medicine clinical practice guidelines deserve emphasis as well. First, the population in studies used to formulate recommendations should be comparable to the target population of the guidelines, ie, working-age adults. Second, there should be clear, reproducible diagnostic criteria for the disorder. Third, there should be scientific evidence that that the health problem is caused, generally with biological plausibility and a dose-response relationship, by chemical, biological, physical, or psychosocial factors intrinsic to a job or task. We should note that this may not be the legal definition of "work-related," but it is the scientific one. Finally, there is now general consensus that functional ability is the principal outcome to be sought, rather than symptom decrease, especially when the symptoms or symptom reporting can have several causes and confounders. Re-

lated outcomes include return to work and economic loss.

To systematize decision-making, optimize patient outcomes, and efficiently and effectively use health care resources for recommendations developed in the absence of high-quality evidence, the "first principles" for clinical decision-making developed here use conservative clinical logic to sequence steps of diagnosis and treatment and explicitly consider risks and benefits, including risks of false positives, risks of unproven treatment, and risks of over treatment. These are elements of medical quality, particularly efficiency and effectiveness. Use of these "first principles" in recommendation development should improve patient safety, consistency, efficiency, and effectiveness.

Specifying the strength of recommendations is important to convey the support or lack thereof for diagnosis, testing, treatment, prevention, causation, and other parameters of occupational medicine. The GMC developed a rating scheme for recommendations that explicitly linked each recommendation to the strength of evidence supporting it and including an Insufficient Evidence category to clearly identify recommendations not based on at least level C evidence. This more explicit recommendation rating system will make clinical decision-making easier for busy clinicians and reviewers.

Identification and overcoming of barriers to implementation of guidelines is an active area of research. The Cochrane Collaboration[60] publishes systematic reviews on the subject. To foster acceptance of guidelines and their implementation in practice, guidelines should have certain characteristics, as noted in Tables 10 and 11. Research indicates that guidelines are better accepted by medical providers when they come from credible professional organizations and are developed by unbiased medical professionals, a finding reflected in the RAND Corporation evaluation of occupational medical practice guidelines for the State of California.[61]

Updating Process

ACOEM researchers and panel members review the literature periodically to identify any major changes in the evidence-base by content area. We should emphasize that high-quality studies that dictate major changes in the practice of musculoskeletal medicine and other areas seen among workers are rare. Further, new evidence must be considered in the context of the current body of evidence to determine whether the total weight of evidence would lead to a different recommendation. For these reasons, monthly, quarterly, or semi-annual updates, particularly those that simply post new abstracts, are inappropriate and possibly misleading. Subsequent updates of the *APGs* will include a full review of previous recommendations and review of the updated, graded evidence base. In the absence of major new evidence that would dictate an immediate change in practice, the EBPPs will review the body of evidence and revise recommendations every 3 years using the process described here.

Summary

The ACOEM GMC has developed a rigorous, standardized process to ensure the reproducibility and transparency of the guideline development process. This process and the criteria for identifying and assessing relevant scientific evidence from the published literature are based on generally accepted principles and methodologies of EBM and evidence-based practice guideline development which have been widely discussed and agreed upon internationally.[62–65] Using this methodology results in valid, consistent, logical, and robust recommendations for occupational medicine clinical practice that have the greatest potential to improve the health and function of workers in an efficient and cost-effective manner.

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Appendix A

Objectives, Target Audience, Organizational Structure and Disclosure Policy for the ACOEM *Occupational Medicine Practice Guidelines Objectives*

The objectives of the APGs are to:

- Describe evidence-based best practices for key areas of occupational medical care and disability management;
- Improve or restore the health of workers with occupationally related illnesses or injuries;
- Improve the quality of occupational medical care and disability management.

Target Users

There are three key target audiences for the APGs. The primary audience is providers in clinical and preventive practice, including occupational physicians and other clinicians who care for ill or injured workers and who include injury and illness prevention in their practices. The second audience is those in management or review positions in the healthcare system who can influence the quality of care through care management, utilization review, and financial decisions. This group includes clinical case managers, utilization reviewers, insurers and insurance claims managers, and third party administrators. The third audience for the *APGs* includes agencies and individuals who influence the quality of care through regulatory and judicial decisions, including regulators, policy makers, attorneys, and judges.

Organizational Structure

The organization of the APG development team is multi-level and contains checks and balances. Research staff (Table 1) perform literature searches, screen abstracts, and draft evidence summaries and recommendations. The *APG* Editor in Chief, who is also chair of the Evidence-Based Practice Committee (EBPC), poses answerable clinical questions, and oversees the technical aspects of systematic reviews and recommendation development.

Multi-disciplinary Evidence Based Practice Panels (EBPPs) are appointed following a detailed application and screening process to address one part of the body (eg, the Spine EBPP) and review the original literature, evidence tables, and draft summaries for body parts, systems, or skill areas covered by the APGs.[1] They then refine and finalize the draft evidence-based recommendations for prevention, clinical practice, care management, and disability management, or form consensus recommendations based on First Principles when higher quality evidence is lacking or contradictory.

The EBPC provides guidance and oversight for the development and updating of the APGs. The EBPC reviews and approves the work of the EBPPs. It ensures that the *Guidelines* are consistent and logical internally and with other ACOEM evidence-based products, training, and services.

The Guideline Methodology Committee (GMC) develops the methodology for development, updating and revision of the APGs

and other evidence-based products and services, and, on an ongoing basis, refines, clarifies, and improves it. It trains EBPC, EBPP, Utilization Management Knowledgebase (UMK) Development Team, and *APG Insights* members in this methodology and process. The training includes hands-on small group evaluation of studies and systematic reviews and formulation of draft recommendations.

Disclosure

Guideline development team members disclose potential conflicts of interest in a format similar to the disclosure tables now used for major medical journals. Relationships required to be disclosed include employment, research grants and other research support, fees from Speakers' Bureaus, honoraria, ownership interests, consultancies, Advisory Boards, and other relationships that might be in conflict with unbiased consideration of the evidence.

APPENDIX B

Example of Summary Table of Studies: Interventions

Study Design													
Study citation													
Research question	Does [treatment] result in improved outcomes for [condition]?												
Population	Inclusion criteria												
	Exclusion criteria												
	Study population characteristics												
	Generalizability to working patients												
Methods													
Statistical methods													
Quality assessment	Score*	1	2	3	4	5	6	7	8	9	10	11	12
Relevant outcomes													
Assessed results													
Author comments													
Reviewer comments													

*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 = cointerventions avoided, 8 = compliance acceptable, 9 = dropout rate, 10 = timing of assessments, 11 = analyzed by intention to treat, 12 = lack of bias (not included in scoring).