In the modern day environment, workers' compensation costs continue to be a challenge, with a need to balance costs, benefits, and quality of medical care. The cost of workers' compensation care affects all stakeholders including workers, employers, providers, regulators, legislators, and insurers. Consequently, a continued commitment to quality, accessibility to care, and cost containment will help ensure that workers are afforded accessible, high quality, and cost-effective care.

In 2004, workers' compensation programs in all 50 states, the District of Columbia, and federal programs in the United States combined received an income of $87.4 billion while paying out only $56 billion in medical and cash benefits with $31.4 billion or 37% in administrative expenses and profit. Occupational diseases represented only 8% of the workers' compensation claims and 29% of the cost. The American College of Occupational and Environmental Medicine (ACOEM) has published several guidelines; though widely adopted by WCPs, these guidelines evaluate the practice of medicine of multiple specialties without adequate expertise and expert input from the concerned specialties, including interventional pain management.

An assessment of the ACOEM guidelines utilizing Appraisal of Guidelines for Research and Evaluation (AGREE) criteria, the criteria developed by the American Medical Association (AMA), the Institute of Medicine (IOM), and other significantly accepted criteria, consistently showed very low scores (< 30%) in most aspects of these guidelines.

The ACOEM recommendations do not appear to have been based on a careful review of the literature, overall quality of evidence, standard of care, or expert consensus. Based on the evaluation utilizing appropriate and current evidence-based medicine (EBM) principles, the evidence ratings for diagnostic techniques of lumbar discography; cervical, thoracic, and lumbar facet joint nerve blocks and sacroiliac joint nerve blocks; therapeutic cervical and lumbar medial branch blocks and radiofrequency neurolysis; cervical interlaminar epidural steroid injections, caudal epidural steroid injections, and lumbar transforaminal epidural injections; caudal percutaneous adhesiolysis; and spinal cord stimulation were found to be moderate with strong recommendation applying for most patients in most circumstances. The evidence ratings for intradiscal electrothermal therapy (IDET), an automated percutaneous disc decompression and also deserve further scrutiny and analysis.

In conclusion, these ACOEM guidelines for interventional pain management have no applicability in modern patient care due to lack of expertise by the developing organization (ACOEM), lack of utilization of appropriate and current EBM principles, and lack of significant involvement of experts in these techniques resulting in a lack of clinical relevance. Thus, they may result in reduced medical quality of care; may severely hinder access to appropriate, medically needed and essential medical care; and finally, they may increase costs for injured workers, third party payors, and the government by transferring the injured worker into a non-productive disability system.

Key words: Guidelines, ACOEM, ASIPP, interventional pain management, interventional techniques, evidence-based medicine, systematic reviews, guideline development, AHCPR, AHRQ, IOM, AMA, AGREE, workers' compensation, chronic pain guidelines, low back pain guidelines
T

he American College of Occupational and Environmental Medicine (ACOEM) recently completed practice guidelines regarding the treatment of chronic pain and low back pain. Serious concerns regarding the expertise of the convened panel and the validity of its findings has triggered this evaluation.

Milton Friedman pointed out many years ago: “The only social responsibility of business is to increase its profits.” This statement is well accepted and summarizes the value system that is at the heart of a capitalistic society such as ours. However, these values cannot be allowed to influence scientific evaluations and the recommendations that flow from them. It is even more important when access to health care for an injured worker could be compromised (1-8). The introduction of workmen’s compensation laws was a tremendous social advance, but, unfortunately, it is becoming more apparent in the last few years that the present laws may be manipulated through the misuse and misinterpretation of scientific evidence.

The ACOEM first published its guidelines regarding common health complaints of workers in 1997 (9). In 2004, the college released the second edition of its guidelines (3). Updates to the second edition were published in 2007 to the chapter on low back disorders (10). The chronic pain chapter is still undergoing external peer review (11). These guidelines may prevent injured workers from receiving the majority of the medically necessary and appropriate interventional pain management procedures (12,13). It is difficult to understand why ACOEM even presumes that they are the authority on these issues. The link between many of these conditions and the patients’ occupation is hardly solid, and many conditions, such as degenerative disc disease for example, are likely multifactorial and perhaps not even a disease.

An understanding of background information on guideline preparation, quality, and evidence rating is essential, since most guidelines do not meet the criteria for preparation of guidelines (14-60).

This manuscript will provide a critical and comprehensive review of ACOEM guideline synthesis, medical necessity, conflicts of interest, evidence-based medicine principles, and potential implications on the practice of interventional pain management and potential effects on injured workers and various federal programs.

Is Evidence-Based Medicine Based on Evidence?

Haynes (61) authored a debate on the kind of evidence that evidence-based medicine (EBM) advocates want health care providers and consumers to pay attention to. Similarly, Sehon and Stanley (62) provided a philosophical analysis of the evidence-based medicine debate. In 1992, evidence-based medicine advocates proclaimed a “new paradigm” in which evidence from health care research was deemed the best basis for decisions for individual patients and health systems. In doing so, evidence-based medicine advocates pitted evidence-based medicine against the traditional knowledge foundation of medicine, where the key elements are an understanding of the basic mechanisms of disease coupled with clinical experience (63-68). A fundamental assumption of evidence-based medicine is that practitioners, whose practice is based on an understanding of evidence from applied health care research, will provide superior patient care compared with practitioners who rely on an understanding of basic mechanisms and their own clinical experience (61). However, there is no evidence-based medicine, or for that matter, any convincing direct evidence that shows that this assumption is correct. Nevertheless, the New York Times magazine Year in Review included evidence-based medicine as one of the most influential ideas of 2001 (69).

Evidence-based medicine has long since evolved beyond its initial (mis)conception that evidence-based medicine might replace traditional medicine (61). Consequently, the role of evidence-based medicine is now seen to augment rather than replace individual clinical experience and understanding of basic disease mechanisms. While evidence-based medicine must continue to evolve, it is essential to address a number of issues including scientific underpinnings, moral stance, consequences, and practical matters of dissemination and application (61). In summary, advocates of evidence-based medicine want clinicians and consumers to pay attention to the best findings from health care research that are both valid and ready for clinical application.

Critics of evidence-based medicine claim that, “there is no evidence (and unlikely ever to be) that evidence-based medicine provides better medical care,” and evidence-based medicine is simply “following its own political agenda” (66). Other critics use even harsher rhetoric, claiming that “evidence-
based medicine's assumptions are absurd” (67-73). Some commentators claim a middle ground by saying that evidence-based medicine and other approaches should be harmonized (68). Thus, there are multiple and variable opinions on the issue (70-73).

Sehon and Stanley (62) pointed out that the questions raised by this debate are fundamental to the practice of medicine. Consequently, it is essential to understand the basic nature of evidence-based medicine, the alternatives to evidence-based medicine, as well as the relationship between evidence-based medicine and alternative approaches to medicine. Further, it is also fundamental to understand whether or not evidence-based medicine represents a paradigm shift, and if so, the issues in the debate about how medical care can be provided in accordance with the principles of evidence-based medicine, how it should be accomplished, and the way health care dollars should be spent must be addressed.

A current definition of evidence-based medicine is: “the explicit, judicious, and conscientious use of current best evidence from health care research in decisions about the care of individuals and populations” (74). However, a more pragmatic definition is a set of tools and resources for finding and applying current best evidence from research for the care of individual patients (61). This practical definition incorporates the fact that there are now many information resources in which evidence from health care has been pregraded for validity by people with expertise in research methods, and, better still, it has also been assessed by experienced practitioners for clinical relevance (61). To summarize, this simplifies the clinician's task changing from the largely hopeless one of reading all the original medical literature to find out about current best care, to one of finding the right pre-assessed research evidence, judging whether it applies to the health problem at hand, and then working the evidence into the decision that must be made.

Other key components, which include patient circumstances, can only be assessed by the expertise of the clinician and the preferences of the patient (75). It has been vaguely described in the literature how research evidence, clinical circumstance, and patients' preferences are combined and an optimal decision is reached (76). This has only been described as, "clinical judgment and expertise" but it is considered as essential to the success of evidence-based medicine in providing appropriate patient care.

The fundamental questions in evidence-based medicine are:
- Is the research valid?
- Are the best findings from this research available?
- Is this health care research ready for general application?
- To whom and how does one apply valid and ready evidence from health care research?

Consequently, even though modern evidence-based medicine provides an increasingly sophisticated means for addressing a multitude of questions, at present, the results of any synthesis of evidence-based medicine are only as good as the advocates or developers of evidence-based medicine or guidelines.

At the present time, there is neither evidence that the hierarchy of evidence derived from randomized trials is superior, nor evidence that patients whose clinicians practice evidence-based medicine are better off than those whose clinicians do not practice evidence-based medicine. Thus far, no one has performed a randomized controlled trial (RCT) of EBM with patient outcomes as the measurement of success. Such a trial would be impossible to do since a control group could not be effectively isolated from the research that evidence-based medicine is attempting to transfer, and it would be regarded as unethical to do so (61).

While the arguments about hierarchy of evidence will continue to flourish through the next millennium, it has been shown that the findings of observational studies agree more often than not with the findings of RCTs (77-79). At present, there is no convincing evidence that RCTs are superior to observational studies. Further, we do not understand when a research finding is ready for clinical application. Multiple issues related to this include our primitive understanding of the differences in patient characteristics which preclude utilizing the same research, the same algorithm, the same cookbook medicine applied in the same way, in each or every instance, or not applied at all.

The major disadvantage of RCTs is that the results have limited generalizability to patients, clinicians, and treatment settings different from those in the RCTs (80). In contrast, RCTs emphasize internal validity. Practical or pragmatic clinical trials can address some of the generalizability issues, but can be costly and generally do not address explicitly the underlying organization of care (81,82). Therefore, if practical or pragmatic clinical trials are performed cost effectively, these trials will be the ideal rather than RCTs.
What is Evidence-Based Management?

Two components are necessary to improve the quality of medical care: advances in evidence-based medicine (EBM), which identify clinical practices leading to better care, i.e., the content of providing care (83), and knowledge of how to put this content into routine practice (84). These advances in evidence-based management (EBMgt) identify organizational strategies, structures, and management practices that enable physicians and other health care professionals to provide evidence-based care, i.e., the context of providing care (85). Until both components are in place – identifying the best content (EBM) and applying it within effective organizational contexts (EBMgt) – consistent, sustainable improvement in the quality of care received by U.S. residents is unlikely to occur.

The evidence-base comes largely from the social and behavioral sciences, human factors engineering, and the field of health services research. In addition to RCTs, EBMgt uses observational data and approaches such as the PDSA (plan-do-study-act) quality-improvement method for making small-scale changes to improve care (86).

There are many advantages for using EBM and EBMgt together to treat patients with occupational injuries; however, evidence-based guidelines must actually be based on evidence. Consequently, practice and policy recommendations and interventions are needed to bring both components – EBM and EBMgt, the content and the context – together to provide better patient care.

What Are the Essentials of Guideline Development?

Clinical practice guidelines are commonly defined as “systematically developed statements to assist the practitioner and patient to make decisions about appropriate health care for specific clinical circumstances” (22). Over the past decade, there has been a surge of interest in the use of clinical practice guidelines, fueled by the discovery of large, unexplained variations in physician practice (81,87-96), documentation of significant rates of inappropriate care (97-106), and an interest in managing health care costs and improving quality (16,17,94-96,107-114). Thus, it has been believed that practice guidelines can improve the quality, appropriateness, and cost-effectiveness of health care (87), and can also serve as valuable educational tools. Consequently, several major medical organizations, including the American Medical Association (AMA), the Institute of Medicine (IOM), the Canadian Medical Association (CMA), and the Agency for Healthcare Research and Quality (AHRQ) have carefully formulated the methodology for developing scientifically sound guidelines and rating of the strength of evidence (15,17,19-24,87,115,116). Thus, appropriately developed guidelines not only incorporate validity, reliability/reproducibility, clinical applicability, clinical flexibility, and clarity, but also are developed through a multidisciplinary process, with a scheduled review and proper documentation (22). Guidelines attempt to synthesize the evidence in order to provide a wide range of recommendations for making decisions.

The availability of recommendations for clinical practice is not new; they are as old as the teaching of medicine or even the Hippocratic Oath (116). Ever since the modern era of medicine started emphasizing evidence, guidelines have often been called evidence-based guidelines or recommendations. The original purposes for clinical guidelines were outlined by the IOM (24) as illustrated in Table 1.

Thus, evidence-based guidelines were initially aimed at decision-making by clinicians. In the modern era, evidence-based guidelines have been developed for the full range of clinical activities, from prevention through palliation.

Table 1. The Institute of Medicine (IOM) description of purpose of clinical guidelines.

| ♦ Assisting clinical decision-making by patients and practitioners | ♦ Educating individuals or groups |
| ♦ Assessing and assuring the quality of care | ♦ Guiding allocation of resources for health care |
| ♦ Reducing the risk of liability for negligent care |

Who Is Developing Practice Guidelines?

The guideline movement has spawned an increasing number of “players” who are rapidly developing guidelines, often to serve specific or even proprietary agendas (1,3,10,25-30,117,118).

Government agencies developing guidelines include the AHRQ, the United States Preventive Services Task Force (USPSTF) (52), the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC). These agencies seek qualified and broadly representative individuals for a committee or task force to independently develop evidence-based guidelines.

Professional societies such as the American College of Surgeons (ACS), the American College of Physicians (ACP), the American Society of Interventional Pain Physicians (ASIPP), and many other clinically oriented organizations have developed pertinent guidelines for their specialties (25-30). However, some organizations have developed guidelines for interventions in which they do not have expertise, solely based on the origin of the problem, such as a work-related injuries or spine-related problems. However, for-profit organizations do not disseminate them, but rather sell them to the insurance industry (117,118).

Is There a Uniform Approach to Guideline Development?

Overall, each of the developers has their own approaches, priorities, and at times, their own biases and self-interests (116). Thus, it is important for the consumer to appreciate the authorship of the guidelines to understand that potential conflicts of interest may subtly or not so subtly influence the way the guidelines were developed or structured. Even assuming the best of intentions most of the time, different groups will interpret the evidence differently. Thus, guideline developers with experience and interest in interventional techniques are often inclined to recommend their use, provided the procedures are safe and evidence exists (25-30). Conversely, guideline developers who represent certain agencies will often emphasize a lack of evidence (10,11).

While there is no universally accepted approach to developing and presenting guidelines, the most rigorous approach in widespread use was developed by the AHRQ USPSTF (Table 2) (52).

In contrast, the authors of ACOEM guidelines have utilized an outdated Agency for Healthcare Research and Quality (AHCPR) hierarchy of evidence (extinguished by Congress in 1995), which carries the disclaimer “not for patient care” (119) (Table 3). Grading of recommendations is illustrated in Table 4 as described by Guyatt et al (31). Finally, Atkins et al (51) described the sequential process for the development of guidelines (Table 5).

Table 2. Quality of evidence developed by AHRQ.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Evidence obtained from at least one properly randomized controlled trial.</td>
</tr>
<tr>
<td>II-1</td>
<td>Evidence obtained from well-designed controlled trials without randomization.</td>
</tr>
<tr>
<td>II-2</td>
<td>Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.</td>
</tr>
<tr>
<td>II-3</td>
<td>Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.</td>
</tr>
<tr>
<td>III</td>
<td>Opinions of respected authorities, based on clinical experience descriptive studies and case reports or reports of expert committees.</td>
</tr>
</tbody>
</table>

Adapted from the Agency for Healthcare Research and Quality U.S. Preventive Services Task Force (USPSTF) (Ref. 52)
Table 3. Outdated quality of evidence criteria utilized by ACOEM (10).

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
<th>Benefit vs Risk and Burdens</th>
<th>Methodological Quality of Supporting Evidence</th>
<th>Implications</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Strong evidence-base</td>
<td>Two or more high-quality studies.</td>
<td>RCTs without important limitations or overwhelming evidence from observational studies</td>
<td>Strong recommendation, can apply to most patients in most circumstances without reservation</td>
</tr>
<tr>
<td>B</td>
<td>Moderate evidence-base</td>
<td>At least one high-quality study or multiple moderate-quality studies relevant to the topic and the working population.</td>
<td>RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies</td>
<td>Strong recommendation, can apply to most patients in most circumstances without reservation</td>
</tr>
<tr>
<td>C</td>
<td>Limited evidence-base</td>
<td>At least one study of moderate quality.</td>
<td>Observational studies or case series</td>
<td>Strong recommendation but may change when higher quality evidence becomes available</td>
</tr>
<tr>
<td>I</td>
<td>Insufficient Evidence</td>
<td>Evidence is insufficient or irreconcilable.</td>
<td></td>
<td>Very weak recommendations; other alternatives may be equally reasonable</td>
</tr>
</tbody>
</table>

i. 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.

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

Note: These criteria were derived from the second edition (10). AHCPR was extinguished by Congress in 1995, changing AHCPR to AHRQ. Acute Low Back Pain Guidelines (119) provide a disclaimer “not for patient care.”

Table 4. Grading recommendations.

<table>
<thead>
<tr>
<th>Grade of Recommendation/Description</th>
<th>Benefit vs Risk and Burdens</th>
<th>Methodological Quality of Supporting Evidence</th>
<th>Implications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A/strong recommendation, high-quality evidence</td>
<td>Benefits clearly outweigh risk and burdens, or vice versa</td>
<td>RCTs without important limitations or overwhelming evidence from observational studies</td>
<td>Strong recommendation, can apply to most patients in most circumstances without reservation</td>
</tr>
<tr>
<td>1B/strong recommendation, moderate quality evidence</td>
<td>Benefits clearly outweigh risk and burdens, or vice versa</td>
<td>RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies</td>
<td>Strong recommendation, can apply to most patients in most circumstances without reservation</td>
</tr>
<tr>
<td>1C/strong recommendation, low-quality or very low-quality evidence</td>
<td>Benefits clearly outweigh risk and burdens, or vice versa</td>
<td>Observational studies or case series</td>
<td>Strong recommendation but may change when higher quality evidence becomes available</td>
</tr>
<tr>
<td>2A/weak recommendation, high-quality evidence</td>
<td>Benefits closely balanced with risks and burden</td>
<td>RCTs without important limitations or overwhelming evidence from observational studies</td>
<td>Weak recommendation, best action may differ depending on circumstances or patients’ or societal values</td>
</tr>
<tr>
<td>2B/weak recommendation, moderate-quality evidence</td>
<td>Benefits closely balanced with risks and burden</td>
<td>RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies</td>
<td>Weak recommendation, best action may differ depending on circumstances or patients’ or societal values</td>
</tr>
<tr>
<td>2C/weak recommendation, low-quality or very low-quality evidence</td>
<td>Uncertainty in the estimates of benefits, risks, and burden; benefits, risk, and burden may be closely balanced</td>
<td>Observational studies or case series</td>
<td>Very weak recommendations; other alternatives may be equally reasonable</td>
</tr>
</tbody>
</table>

Is the Critical or Essential Methodology Followed?

Oxman et al (32,53,54) provided guidance for critical appraisal of the evidence. West et al (55) reviewed different instruments for critically appraising systematic reviews and found 20 systems concerned with the appraisal of systematic reviews or meta-analysis. The AMA, IOM, CMA, and AHRQ have all formulated methodology for developing scientifically sound guidelines, standardized approaches have also been developed to evaluate the development and validity of guidelines (15,33-40,120-122). Surprising results have been observed following the evaluation of many guidelines. Shaneyfelt et al (15) evaluated 279 guidelines, published from 1985 through June 1997, produced by 69 different developers. There was no difference in the mean number of standards satisfied by guidelines produced by subspecialty medical
societies, general medical societies, or governmental agencies. Mean overall adherence to standards by each guideline was 43.1%, mean adherence to methodological standards on guidance development and format was 51.1%, mean adherence to identification and summary of evidence was 33.6%, and mean adherence was 46% for formulation of recommendations. Overall, mean adherence to standards by each guideline improved from 36.9% in 1985 to 50.4% in 1997.

The *Occupational Medicine Practice Guidelines* by ACOEM, were evaluated utilizing the AGREE evaluation (41) and other validated and widely applied methods (14). Cates et al (41) evaluated the ACOEM guidelines and concluded that the ACOEM guidelines scored low in stakeholder involvement with a score of 46.06%, rigor of development with a score of 26.66%, and editorial independence with a score of 29.17%, with scope and purpose scoring 79.63%, and clarity and presentation scoring 86.81%. Manchikanti et al (14) provided critical appraisal of 2007 guidelines and revisions (10,11) utilizing AGREE evaluation criteria, AMA, IOM, and Shaneyfelt et al’s criteria (15) for guidelines. Based on the AGREE instrument, Manchikanti et al (14) concluded that the ACOEM guidelines scored less than 10% in stakeholder involvement – domain 2, application – domain 5, and editorial independence – domain 6 with 6.25%, 8.33%, and 4.7%. They also had a score of less than 20% in rigor of development – domain 3, with a score of 18.45%, and less than 40% for clarity and presentation – domain 4, with a score of 34.37%. The only domain with a score higher than 50 was scope and purpose – domain 1, with a score of 73.61%.

Helm (42) concluded that ACOEM complied with only 12 out of the 25 criteria described by Shaneyfelt et al (15). Manchikanti et al (14) also evaluated ACOEM’s revised chapters (10,11) utilizing Shaneyfelt et al’s criteria (15), which met 7 of 25 (28%) total criteria. Further, the met criteria were: 40% for standards of guidelines, development, and format; 20% for standards of evidence, identification, and summary; and 20% on the standards on the formulation of recommendations.

The Institute for Civil Justice and RAND Health (40) evaluated the technical quality of ACOEM guidelines with the AGREE instrument. This study found the validity of ACOEM guidelines for the physical modalities and the remaining content uncertain except for surgical content.

Manchikanti et al (14) also appraised the 2007 guidelines, low back and chronic pain chapters (10,11), utilizing the key attributes described by AMA (19) and IOM (22). Based on AMA’s key attributes of guidelines (19), ACOEM guidelines met only 1 of the 6 criteria, whereas based on 8 key attributes by IOM (22), they met the criteria in only 3 of the 8 key attributes. Criteria were not met for Validity, Reliability/Reproducibility, Multidisciplinary Process, and Documentation, whereas, criteria were met for Clinical Applicability, Clinical Flexibility, and Schedule Review.

**What Are Basic Principles and Critical Elements?**

The National Health and Medical Research Council (NHMRC) (43) described 9 basic principles in the development of guidelines. Shaneyfelt et al (15) outlined 25 criteria, whereas AGREE described 5 domains with 23 criteria (35-37). The Guidelines for Guidelines developed in a World Health Organization (WHO) series identified 19 components (44). Other literature available in assisting guideline preparation is extensive (34,44,45,123-125). The IOM in *Clinical Practice Guidelines: Directions for a New Program* (22) described 8 attributes of good practice guidelines. NHRMC (43) described the following 9 basic principles

- Outcomes (survival rates to quality-of-life attributes)
- Best available evidence (according to its quality, relevance, and strength)
- Appropriate systems to synthesize the available evidence (judgment, experience, and good sense)
- Multidisciplinary process of development
- Flexibility and adaptability
- Cost-effectiveness of treatments
- Appropriate dissemination
- Evaluation of implementation and impact of guidelines
- Appropriate revision of the guidelines on a regular basis

Table 6 illustrates the essential components required for guidelines derived from various commonly used evaluation instruments (AGREE, AMA, IOM, and Shaneyfelt et al’s criteria) (15,19,22,122).
Table 6. Illustration of the essential components required for guidelines derived from multiple evaluation instruments.

<table>
<thead>
<tr>
<th>AGREE (122)</th>
<th>AMA (19)</th>
<th>IOM (22)</th>
<th>SHANEYFELT ET AL (15)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I. Scope And Purpose</strong></td>
<td><strong>I. Organization</strong></td>
<td><strong>I. Validity</strong></td>
<td><strong>I. Standards of Guidelines Development and Format</strong></td>
</tr>
<tr>
<td>1. The overall objective(s) of the guideline is(are) specifically described.</td>
<td>Practice guidelines should be developed by or in conjunction with physician organizations</td>
<td>Practice guidelines are valid if, when followed, they lead to the health and cost outcomes projected for them, other things being equal.</td>
<td>1. Purpose of the guideline is specified.</td>
</tr>
<tr>
<td>2. The clinical question(s) covered by the guideline is (are) specifically described.</td>
<td></td>
<td></td>
<td>2. Rationale and importance of the guideline are explained.</td>
</tr>
<tr>
<td>3. The patients to whom the guideline is meant to apply are specifically described.</td>
<td></td>
<td></td>
<td>3. The participants in the guideline development process and their areas of expertise are specified.</td>
</tr>
<tr>
<td><strong>II. Stakeholder Involvement</strong></td>
<td><strong>II. Methodology</strong></td>
<td><strong>II. Reliability/Reproducibility</strong></td>
<td><strong>II. Standards Of Evidence Identification And Summary</strong></td>
</tr>
<tr>
<td>4. The guideline development group includes individuals from all the relevant professional groups.</td>
<td>Reliable methods that integrate relevant research findings should be used to develop practice guidelines.</td>
<td>Practice guidelines are reliable and reproducible (1) if —given the same evidence and methods for guidelines development—another set of experts would produce essentially the same statements and (2) if—given the same clinical circumstances—the guidelines are interpreted and applied consistently by practitioners or other appropriate parties.</td>
<td>11. Method of identifying scientific evidence is specified.</td>
</tr>
<tr>
<td>5. The patients’ view and preferences have been sought.</td>
<td></td>
<td></td>
<td>12. Time period from which evidence is reviewed is specified.</td>
</tr>
<tr>
<td>6. The target users of the guideline are clearly defined.</td>
<td></td>
<td></td>
<td>13. The evidence used is identified by citation and referenced.</td>
</tr>
<tr>
<td>7. The guideline has been piloted among target users.</td>
<td></td>
<td></td>
<td>14. Method of data extraction is specified.</td>
</tr>
<tr>
<td><strong>III. Rigor of Development</strong></td>
<td><strong>III. Clinical Expertise</strong></td>
<td><strong>III. Clinical Applicability</strong></td>
<td><strong>III. Standards on the Formulation of Recommendations</strong></td>
</tr>
<tr>
<td>8. Systematic methods were used to search for evidence.</td>
<td>Appropriate clinical expertise should be used to develop practice guidelines.</td>
<td>Practice guidelines should be as inclusive of appropriately defined patient populations as scientific and clinical evidence and expert judgment permit, and they should explicitly state the populations to which statements apply.</td>
<td>21. The role of value judgments used by the guideline developers in making recommendations is discussed.</td>
</tr>
<tr>
<td>9. The criteria for selecting the evidence are clearly described.</td>
<td></td>
<td></td>
<td>22. The role of patient preferences is discussed.</td>
</tr>
<tr>
<td>10. The methods used for formulating the recommendations are clearly described.</td>
<td></td>
<td></td>
<td>23. Recommendations are specific and apply to the stated goals of the guideline.</td>
</tr>
<tr>
<td>11. The health benefits, side effects, and risks have been considered in formulating the recommendations.</td>
<td></td>
<td></td>
<td>24. Recommendations are graded according to the strength of the evidence.</td>
</tr>
<tr>
<td>12. There is an explicit link between the recommendations and the supporting evidence.</td>
<td></td>
<td></td>
<td>25. Flexibility in the recommendations is specified.</td>
</tr>
<tr>
<td>13. The guideline has been externally reviewed by experts prior to its publication.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 6 (cont.). Illustration of the essential components required for guidelines derived from multiple evaluation instruments.

<table>
<thead>
<tr>
<th>AGREE (122)</th>
<th>AMA (19)</th>
<th>IOM (22)</th>
<th>SHANEYFELT ET AL (15)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IV. Clarity And Presentation</strong></td>
<td><strong>IV. Comprehensiveness</strong></td>
<td><strong>IV. Clinical Flexibility</strong></td>
<td></td>
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<td>15. The recommendations are specific and unambiguous.</td>
<td>Practice guidelines should be as comprehensive and specific as possible.</td>
<td>Practice guidelines should identify the specifically known or generally expected exceptions to their recommendations.</td>
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<td>16. The different options for management of the condition are clearly presented.</td>
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<td>17. Key recommendations are easily identifiable.</td>
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<td>18. The guideline is supported with tools for application.</td>
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<td><strong>V. Applicability</strong></td>
<td><strong>V. Current Information</strong></td>
<td><strong>V. Clarity</strong></td>
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<td>19. The potential organizational barriers in applying the recommendations have been discussed.</td>
<td>Practice guidelines should be based on current information.</td>
<td>Practice guidelines should use unambiguous language, define terms precisely, and use logical, easy-to-follow modes of presentation.</td>
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<td>20. The potential cost implications of applying the recommendations have been considered.</td>
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<td>21. The guideline presents key review criteria for monitoring and/or purposes.</td>
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<td>22. The guideline is editorially independent from the funding body.</td>
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<td><strong>VI. Editorial Independence</strong></td>
<td><strong>VI. Dissemination</strong></td>
<td><strong>VI. Multidisciplinary Process</strong></td>
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<td>23. Conflicts of interest of guideline development members have been reported.</td>
<td>Practice guidelines should be widely disseminated.</td>
<td>Practice guidelines should be developed by a process that includes participation by representatives of key affected groups. Participation may include serving on panels that develop guidelines, providing evidence and viewpoints to the panels, and reviewing draft guidelines.</td>
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<td><strong>VII. Scheduled Review</strong></td>
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<td>Practice guidelines should include statements about when they should be reviewed to determine whether revisions are warranted, given new clinical evidence or changing professional consensus.</td>
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<td><strong>VIII. Documentation</strong></td>
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<td>The procedures followed in developing guidelines, the participants involved, the evidence used, the assumptions and rationales accepted, and the analytic methods employed should be meticulously documented and described.</td>
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Adapted and modified from AGREE (122), AMA (19), IOM (22), and Shaneyfelt et al (15).
**Occupational Medicine Practice Guidelines by ACOEM**

In response to a barrage of criticism, not only from multiple societies, but also Congress (5), the President of ACOEM acknowledged the concerns of Congress and explained that ACOEM guidelines were rigorous and evidence-based (12).

**Evolution of ACOEM’s Relationship with Industry**

Ladou et al (6) in 2007 exposed the ACOEM and its relationship to industry as a professional association in service to industry. The ACOEM evolved from its organization in 1915 as a professional association of physicians concerned with health hazards in the workplace, then named the American Association of Industrial Physicians and Surgeons (126), to the present American College of Occupational and Environmental Medicine. However, now, as then, most of the officers and directors of ACOEM are either in academic settings or an elite group of full-time medical directors of insurance companies and industrial corporations (6,127,128). The ACOEM also evolved as a political and legislative force in 1967 with the appointment of an advisory committee to influence Congress on the Occupational Safety and Health Act (OSHA), asserting itself as an advocate of limited regulation and enforcement of occupational health and safety standards and laws and environmental protection (6).

**Costs and Consequences of the Workers’ Compensation System**

ACOEM has been described as the principle organization of occupational physicians in the United States, aka, workers’ compensation medicine (6,129). Workers’ compensation programs in the 50 states and the District of Columbia and federal programs in the United States combined paid $56 billion in medical and cash benefits in 2004, an increase of 2.3% over 2003 payments. Of that total, it has been reported that $26.1 billion was for medical care and $29.9 billion was for cash benefits. Employers’ assessed costs for workers’ compensation in 2004 were $87.4 billion, an increase of 7% over 2003 spending. Proponents of cost cutting report that, as a source of support for disabled workers, workers’ compensation is currently surpassed in size only by Social Security Disability Insurance, which covers impairments of any cause that are significant, long-term, and impediments to work (130). However, what is ignored is that most workers who do not return to work become eligible for Social Security Disability Insurance, and thus also depend on state and federal programs for medical care. There is also a wide discrepancy in the cost to the employers for workers’ compensation programs versus the cost of the programs ($87.4 billion vs $56 billion a year – a 37% or $31.4 billion administrative expense and profit margin). In addition, occupational diseases represented only 8% of the claims and 29% of the cost (131). Overall, injuries were more costly than occupational diseases.

**Balancing Costs vs. Quality and Access**

In spite of well-meaning efforts by employers, workers, and providers, workers’ compensation costs paid into the system are soaring (132). Workers’ compensation rates are increasing astronomically, while at the same time access to medical care and benefits are rapidly decreasing. Base rates, which are used by insurers to determine premiums, are rising in a number of states, with some seeing double-digit increases of as high as 20% per year. This is a paradoxical response illustrating major deficiencies in the workers’ compensation system and its management (133).

Workers’ compensation costs continue to be a challenge. Thus, there is a need to balance cost control with ensuring benefit adequacy and quality of medical care (133). The cost of workers’ compensation care affects all stakeholders including workers, employers, providers, state workers’ compensation regulators, legislatures, and insurers, as well as the public, since these costs must be transferred eventually to the consumer. Consequently, a continued commitment to quality, accessibility to care, and cost containment, as well as being alert to emerging issues that can affect these elements, will help ensure that workers are afforded accessible, high quality, and cost-effective care (134).

**Business of Guidelines**

The ACOEM developed guidelines to formulate the practice of medicine that is acceptable to the insurance industry, *Occupational Medicine Practice Guidelines* as the “gold standard” in effective occupational medical practice (135,136). The RAND Corporation performed a rigorous review of the ACOEM practice guidelines and concluded that, “the evidence base for treatment recommendations for non-surgical conditions were of uncertain validity and comprehensiveness” (40). Nonetheless, in March 2004, the ACOEM practice guidelines were implemented in California on an interim basis. Since that time, RAND reports that payors appear to be interpreting and applying the ACOEM guidelines inconsistently, suggesting that this allows cost savings, not quality of care, to be the primary results of its adoption (40).
Conflicts of Interest
Many complaints regarding the ACOEM guidelines surround conflicts of interest. A review by Cates et al (41) reported that there was unanimous agreement that the guidelines did not address possible conflicts of interest. Manchikanti et al (14) felt that the ACOEM guidelines strongly reflected the biases of the guideline authors. In general, guidelines have been questioned on various fronts based on pharmaceutical and medical device company sponsorship, when members of the guideline committee have substantial financial associations with the industry and the relationship of the developing organization to the industry when there is no relevant relationship or expertise in developing the guidelines except for the sole purpose of financial gain (1-15,60). Hasenfeld and Shekelle (38) in evaluating the methodological quality of guidelines looked at 685 disclosure statements by the authors of guidelines and found that only 35% declared a potential financial conflict of interest. Consequently, conflict management is an essential part of guideline preparation. A conflict of interest exists when an individual’s secondary interest, either personal or financial, interferes with or influences judgments regarding the individual’s primary interests, such as patient welfare, education, research integrity, etc. (137). Further, there is substantial evidence that industry funding for research is associated with favorable outcomes for the sponsor (47,138-141) and the financial ties of the investigators with their sponsors, such as stock ownership, consulting income, etc., are also associated with favorable research outcomes for the sponsor (141).

Many conflicts arise from the fact that employees and insurance companies fund occupational health services, and these entities have overlapping, yet distinct, interests (142-144). It has been stated that examples of intellectual and moral independence in occupational and environmental medicine are rare in today’s environment and it is difficult to find an occupational physician with the temerity to speak out on behalf of workers (6).

Financial conflict with incentives is illustrated by the fact that ACOEM sells these guidelines as a product to states, insurers, and large employers and actively promotes as restrictive treatment guidelines – with the force of law – to state regulations/work compensation agencies. At the same time, these guidelines are not easily available to physicians and the general public.

The Updated Changes
A joint position statement on the ACOEM low back and chronic pain chapters (10,11) issued by American Academy of Pain Medicine (AAPM), ASIPP, International Spine Intervention Society (ISIS), Neuromodulation Therapy Access Coalition (NTAC), and the North American Neuromodulation Society (NAMS) (145) pointed out a number of flaws that these societies felt had to be addressed before the ACOEM guidelines would serve as a credible tool to guide clinical decisions.
1. Extremely limited expert review of pain-related tests, therapies, and interventions
2. Elimination of approximately 50 percent of tests, therapies, and interventions
3. Incomplete and outdated evidence
4. Inconsistencies in the application of ACOEM’s evidence-ranking criteria
5. Sale and competitive positioning of ACOEM guidelines

Physician specialty societies develop guidelines to improve care, reduce cost through increased transparency, and accountability in the delivery of medical care. Increasingly, ACOEM has been at odds by developing guidelines for multiple subjects in which they are not experts.

Potential Implications
Clinical practice guidelines have potential implications in assisting practitioner and patient decisions about appropriate healthcare for specific clinical circumstances (22). Consequently, properly developed guidelines are expected to improve the quality, appropriateness, and cost-effectiveness of healthcare (87). Further, appropriately developed clinical practice guidelines also serve as valuable educational tools and reduce unexplained variations in physician practices. However, the process utilized by ACOEM guidelines in development was without validity, reliability, and reproducibility, clinical applicability, clinical flexibility, clarity, multidisciplinary process, and documentation.

The revised chapters of ACOEM guidelines for interventional pain management (10,11), including low back pain and chronic pain, developed by the ACOEM, have not utilized the principles of evidence-based medicine, systematic reviews, and guideline development. Consequently, strength of evidence for both chapters of the guidelines evaluated by multiple means utilizing AMA criteria (19), IOM criteria (22),
the criteria developed by Shaneyfelt et al (15), and based on AGREE evaluation (122) were inadequate in almost all aspects (14).

ACOEM guidelines on low back pain and chronic pain chapters met only 3 of the 8 attributes of good practice guidelines as developed by the IOM based on the congressional mandate (14). ACOEM guidelines have also scored consistently low on AGREE evaluation in the past (14,41). Of the 6 domains described in AGREE evaluation the average scores for chronic pain and low back pain chapters fell below 50% in 5 of the 6 domains and below 10% in 3 of the 6 domains. RAND study (40) concluded that the evidence base for treatment recommendations for non-surgical conditions were of uncertain validity and comprehensiveness. Finally, in the evaluation (14) utilizing AMA’s key attributes (19) and Shaneyfelt et al’s criteria (15), the scores were low meeting only 1 of 6 described attributes of AMA and 7 of 25 criteria by Shaneyfelt et al.

Consequently, the ACOEM guidelines reflect the very conservative view of one professional society, not considered expert in most of the areas reviewed. Further, authors of the guidelines also used criteria in evidence search, synthesis, and linkage with clinical application, not generally accepted. Narrowly defined consensus opinions and conclusions do not recommend the vast majority of widely accepted, evidence-supported treatments, procedures, or tests that are currently covered under Medicare, Medicaid, most commercial policies, many other sets of guidelines, and have been practiced for long periods of time over the years.

The ACOEM guidelines as they have been written and are being applied at the present time may be detrimental to the workers’ compensation system due to the lack of balance between cost control, adequacy of benefits, and quality medical care. This may impede patient access, increase pain and suffering, and increase costs of medical care for non-workers’ compensation insurers and governmental agencies.

A reassessment and reevaluation (48) of the low back pain and chronic pain chapters of ACOEM guidelines (10,11), utilizing the same criteria as ACOEM, presents results that are different from the published and proposed guidelines. The vastly different results in this evaluation (48) illustrated the differences in strength of rating for the diagnosis of discogenic pain by provocation discography, facet joint pain by diagnostic facet joint nerve blocks, and sacroiliac joint pain by diagnostic sacroiliac joint nerve blocks. Similarly for therapeutic techniques, therapeutic cervical and lumbar medial branch blocks and radiofrequency neurolysis, cervical interlaminar epidural steroid injections, caudal epidural steroid injections, lumbar transforaminal epidural injections, percutaneous adhesiolysis, and spinal cord stimulation presented with moderate evidence and strong recommendation applying for most patients in most circumstances (31,48). Further, the evidence rating for intradiscal electrothermal therapy, automated percutaneous disc decompression, and intrathecal therapy also deserves additional analysis (48).

**Conclusion**

A fundamental goal of guideline formulation is to improve quality. It is to inform and enlighten any and all of the involved parties and this includes the public. The use of guidelines to promote policy implementation or that leads to much less restrictive standards of care violates the central tenet behind the development of such guidelines. To then restrict access to the guidelines by making them only available for sale further diminishes their validity.

ACOEM guidelines (10,11) have not utilized essentials of evidence-based practice contingent upon 4 basic and important aspects:

- Recognition of the patient’s problem and the construction of the structured clinical question
- Thorough search of medical literature to retrieve the best available evidence to answer the question
- Critical appraisal of all available evidence; and
- Integration of the evidence with all aspects and context of the clinical circumstances to facilitate the decision process that determines the best clinical care of each patient.

The ACOEM guidelines (10,11) have not followed the sequential process for developing guidelines as described by Atkins et al (51) and illustrated in Table 5. Specifically, the preparatory steps with systematic review(s) and preparation of evidence profile for important outcomes has not been utilized. In addition, grading quality of evidence and strength of recommendations utilizing 6 steps has not been described. Finally, implementation and evaluation has not been documented. Thus, the guidelines are not expert driven and specialty-area focused, are not meant to guide and inform the practice within the specialty; are without broad-based meta-analysis; are focused on a range of interventions not within the realm of occupational medicine; included a small panel of clinicians selected
by ACOEM; there was no inclusion of national medical societies in external review, much less on the author panel; and about 50% of ACOEM recommendations are based on consensus of that panel without direct connection to purported levels of evidence and ACOEM’s 11-point evidence ranking criteria. The guidelines are promoted as a commercial product by sale as a product to states, insurers, and large employers; promoted as the basis for policy implementation; and actively promoted by ACOEM as restrictive treatment guidelines – with the force of law – to state regulators/workers’ compensation agencies.

In summary, ACOEM’s process of guideline synthesis is not consistent with accepted practices by national medical societies for evidence-based guidelines and these guidelines are highly controversial among physician societies and workers. Thus, implementation of these guidelines for interventional pain management may not be applicable for patient care due to numerous deficiencies as explained above. Finally, these guidelines may restrict the independent professional practice of medicine; may result in reduced quality of medical care; will severely hinder access to appropriate, medically needed, and essential medical care; and may increase costs for injured workers, third party payors, and the government by transferring the injured worker into a non-productive disability system.

Acknowledgments

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