

Feedback and Response Regarding ACOEM's *Practice Guidelines*

Editor's note: In the interest of dialogue on a controversial subject, we present here comments by the Reflex Sympathetic Dystrophy Syndrome Association (RSDSA) regarding the upcoming publication of the American College of Occupational and Environmental Medicine's (ACOEM) Practice Guidelines followed by a response on behalf of the ACOEM Guidelines Oversight Committee.

RSDSA Comments on ACOEM's *Practice Guidelines*

In 2010, the American College of Occupational and Environmental Medicine (ACOEM) will be publishing the third edition of *Occupational Medicine Practice Guidelines: Evaluation and Management of Common Health Problems and Functional Recovery in Workers*. The guidelines, according to ACOEM, are intended to help improve or restore the health of those workers who incur occupationally related illness or injuries and are the only "evidence-based guidelines that focus on returning employees to work within 90 days of an injury or illness."

Nevertheless, there is a lot of concern among members of the RSDSA Board of Directors on how these guidelines affect people with complex regional pain syndrome (CRPS). Peter Moskovitz, MD, submitted the following comments to the ACOEM on behalf of the board:

The Reflex Sympathetic Dystrophy Syndrome Association (RSDSA), as a not-for-profit organization dedicated to the awareness, education, advocacy, and research for CRPS, also known as reflex sympathetic dystrophy (RSD), would like to make the following comments on the American College of Environmental and Occupational Medicine Guidelines.

In 2007, the ACOEM published the second edition of the Occupational Medicine Practice Guidelines¹ (the Guidelines). They are an evidence-based review similar to a Cochrane Collaboration. The Guidelines are written as a set of graded recommendations for or against the use of various diagnostic and treatment modalities for low back pain, chronic pain disorders, and elbow complaints. Guidelines for the diagnosis and treatment of CRPS are specifically included.

Other academic and professional organizations (American Academy of Orthopaedic Surgeons, North American Spine Society, Trauma Related Neuronal Dysfunction [TREND] Research Consortium) have convened committees based on the Cochrane model to develop evidence-based guidelines for musculoskeletal, neuro-mechanical, immune, and neuropathic conditions. The ACOEM's Guidelines appear to have been written

without referencing any of them. The ACOEM's "independent" approach may be due to the intended use of their Guidelines for injured and ill workers, but RSDSA sees no reason to differentiate between the treatment of people whose CRPS developed after work-related injury, and those whose did not. The principles of appropriate and necessary medical practice are the same.

The ACOEM Overuses the Term "Guidelines"

One classification of recommendations that grade the value of diagnostic or therapeutic interventions divides them into five categories: (1) standards for an intervention, (2) guidelines for..., (3) choices, (4) guidelines against..., and (5) standards against.... Here a "standard" is used in the medical sense and not the more commonly used legal sense. (In most jurisdictions, a legal "standard of care" is what a majority of comparably educated, trained and experienced practitioners would do under the same circumstances.) A medical "standard" for an intervention is one for which the evidence is so strong that there must be a contraindication against its use. When the evidence for a medical intervention is weak, then the support for a recommendation for or against the use of the medical intervention no longer qualifies as a "guide" to clinical practice. Using an intervention for which there is inadequate evidence is a "choice." Here, good clinical judgment and informed consent are the best guides to medical practice. The Guidelines for chronic pain conditions contain many more choices than guidelines and, although the confusion might be a common error, there is no excuse for it.

The Guidelines are Insensitive to the Many Ways in Which a Painful Condition Presents

The Guidelines, in their ambitious attempt to develop guidelines for a wide variety of injuries and impairments; do not consider varieties of medical conditions. To subdivide types and sorts of CRPS, or any other painful condition, would dilute the scant evidence that exists on the etiology, diagnosis, and treat-

ment of CRPS. Since there are several taxonomies of CRPS, proper clinical guidelines would choose one and defend the choice. Existing clinical guidelines for the diagnosis and treatment of CRPS²⁻⁴ are sensitive to the variety of manifestations of the disease, whereas the Guidelines incorrectly propose treating CRPS as a singular disorder.

CRPS patients are variable in their initial clinical presentation to a medical practitioner. Moreover, the time course and progression of CRPS symptoms are often distinct to the patient. The term “complex” is reflected in the complexity of a practitioner’s efforts to understand the onset and course of this highly debilitating pain disorder. Physicians and physical therapists often develop specialized treatment plans for individual patients based upon symptom history, regions of the body affected by CRPS, and past responses to various types of medical intervention. In specialized CRPS treatment centers, multimodal treatment plans are based upon a given physician’s past experience with managing CRPS symptoms, as well as consulting and collaborating with other healthcare professionals (e.g., neurologists, anesthesiologists, pain psychologists, physical therapists). The treatment plan is dependent on the physical and psychological condition of the patient, and designed to match the patient’s individual therapeutic needs.

The Guidelines Reinforce Normative Judgment

By presenting CRPS as a singular pain disorder, the Guidelines invite clinicians to treat all persons suffering from CRPS alike. Appropriate and necessary interventions, on the other hand, are based on the spectrum of the diagnosis. For CRPS, The Guidelines declare ranges for the “recommended target for disability duration,”¹ but they are without reference to medical literature or advice, other than being the consensus of the 18-member Evidence-based Practice Chronic Pain Panel.

Normative Judgments Are Inappropriate as Criteria for Coverage Decisions

In clinical practice, evidence-based guidelines and normative expectations help practitioners in the initial assessment and care planning. The narrative recommendations of the panel of experienced and respected clinicians who wrote and edited the Guidelines have “the ring” of good sense and they provide the “help” that give a rational context in which the practitioner views each patient’s particular predicament. After the practitioner has the appropriate and necessary evidence about the specific patient, normative judgments do not apply. The Guidelines are helpful, but not prescriptive.

ACOEM’s Marketing Practices, Which Link its Guidelines to Utilization and Coverage Decision-Making, Imply Bias that Questions the Impartiality of its Editorial Review

ACOEM’s Utilization Management Knowledgebase (UMK) website declares the Guidelines, combined with its UMK tools as a professional package: “a user-friendly tool that assists in evaluating, tracking and reporting the medical necessity and/or appropriateness of healthcare services.”⁵ This statement removes the Guidelines from the exclusively clinical realm of “practice.” Furthermore, the Guidelines were published in collaboration with the State of California (a payer of workers’ compensation claims) and the California Medical Association’s survey of practitioners reported wide and varied complaints about how the guidelines were used by utilization managers.⁶

The Guidelines admit a dual role: first, as clinical practice guidelines, and second, as a utilization management tool for employers and payers. ACOEM’s dual role as an academic resource for clinical guidelines and a socio-economic resource for utilization guidelines is inevitable and not without merit. Nonetheless, the theory that evidence-based clinical practice gives the best outcomes and the best utilization of resources is only realized when a) the medical condition is reasonably homogeneous, well defined, and reliably measured, and b) the outcome evidence for or against the intervention is strong. The difficulty in achieving the theoretical ideal belies the usefulness of all guidelines in general, and the usefulness of the Guidelines specifically.

Our use of the term “biased” is not meant to be demeaning nor condescending, but reflects our view that the medical needs of individual patients have been submerged by ACOEM’s goal of defining a “normative” practice for the treatment of chronic pain conditions. Such a goal exists on a spectrum of attitudes about the burden of painful conditions. Some members of our society discuss the burden of low back pain in terms of the millions of sufferers, of their loss of family income, and of their lost quality of life. Other members of society talk about the larger economic cost to our society, about the loss of business productivity, about the burden of insurance premiums and cost-per-day of a worker’s absence. The proposed Guidelines do not adequately represent the first perspective—the individualized medical needs of individual patients.

If the Guidelines properly used the category of “choices” in classifying interventions for clinical decision-making, then the use of the Guidelines as part of a UMK might be justifiable. However, at present the Guidelines should not be used to deny authorization for coverage of prescribed interventions when the “not recommended” classification is by consensus (“I” rating). When the evidence is weak (“C” rating) utilization managers must use a collaborative decision-making process rather than arbitrarily turn a “not recommended” classification into a denial of coverage. Finally, the Centers for Medicare and Medicaid Services (CMS) promote comparative effectiveness research (CER) that is the cornerstone of evidence-based guidelines. CER regulations have been appropriately and responsibly amended to eliminate the use of CER results in making utilization management decisions for coverage of services to Medicare and Medicaid enrollees.

In theory, treating patients properly will decrease their disability and return them to work in the most efficient way. When there is a conflict between a practitioner’s recommendation and the utilization manager’s “standard” criteria, treatment delays are sure to follow, increasing the length of disability and deepening the dispute. By directing and marketing its Guidelines to utilization managers, the ACOEM is taking sides in any subsequent disagreement. The Guidelines, therefore, continue to generate disputes by promoting normative judgments for UM decisions. In such disputes, it is up to the patient (or claimant) to “prove” that the recommended intervention is appropriate and necessary. Resolving the dispute is difficult where evidence is lacking and where the intervention is a choice for which there is no “guideline.” RSDSA, therefore, urges the ACOEM to revise its Guidelines to adequately represent the individualized needs of individual patients. The concept of a patient requiring a specialized treatment plan, designed by that patient’s own health professional team, needs to be incorporated into the Guidelines in a coherent and consistent manner.

The Guidelines represent the completion of an undoubtedly laborious and difficult collaboration among experienced and conscientious panelists and editors. Its limitations show where future research is needed and define the parameters of that research so that the results will be meaningful in refining and revising clinical practice guidelines. The ACOEM must draw a bright line between clinical practice guidelines and utilization management policies. Conflicts are inevitable when caring for people with conditions characterized by pain. The ACOEM may not be able to resolve such conflicts, but it must not deepen them.

Conclusion

The RSDSA strongly urges the ACOEM to recognize and affirm five fundamental principles:

1. The predominant ethical obligation of the practitioner is to the individual patient.
2. Each patient may choose a physician or treatment team.
3. CRPS patients need to obtain an individually designed treatment plan for their debilitating physical and psychological conditions.
4. Normative recommendations are educational and help to rank potential diagnostic and therapeutic interventions, but they are not prescriptive.

5. When evidence is lacking, choices for clinical practice and the authorization for coverage of prescribed services should be a collaboration between practitioners and utilization managers with the best interest of the individual worker/patient foremost.

References

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Response from ACOEM Oversight Committee: The Role of ACOEM's Practice Guidelines in Treatment Decisions

In the preceding commentary, the Reflex Sympathetic Dystrophy Syndrome Association (RSDSA) explored the possible effect of ACOEM's practice guidelines on medical decision-making and on the utilization review process as they might affect patients with complex regional pain syndrome (CRPS).

RSDSA raised questions about ACOEM's guidelines process and urged it to recognize and affirm certain fundamental principles, including: The predominant ethical obligation of the practitioner is to the individual patient; Each patient may choose a physician or treatment team; CRPS patients need to obtain an individually-designed treatment plan for their debilitating physical and psychological conditions; and that normative recommendations are educational and help to rank potential diagnostic and therapeutic interventions, but they are not prescriptive.

Background

Medical practice guidelines provide a framework for consistent and reliable decision-making regarding the diagnosis, management and treatment of injury and illness. Many organizations publish guidelines, ranging from medical specialty societies to private health companies. The potential for improved health care as a result makes this effort important and worthwhile.

Though expert professional guidance has long been a part of medical practice, evidence based guidelines have changed the nature of medical decision support in recent years. Historically, medical guidance was based largely on tradition, uncontrolled clinical observation and authority. As treatment options have increased in recent years, variation in care has resulted, with availability sometimes driving demand rather than intended outcomes. Evidence-based guidelines, developed with rigor-

ously-researched-and-synthesized scientific studies and a process that allows for incomplete science, becomes a mechanism for minimizing variations in care when properly applied to a given clinical situation. EBM uses the weight of scientific evidence to judge the risks and benefits of various diagnostic and medical treatment options, incorporating the highest quality of scientific evidence to guide health care providers toward the most effective health care, considering the risks, harms and benefits.

The difficulties of achieving consensus among clinical experts are well recognized. There are few "easy" answers in determining best practices for medical care. But relying on the principles of EBM helps ensure that the most solid scientific rationale for medical practice recommendations is used.

As an organization striving to improve the practice of occupational and environmental medicine, and to improve health outcomes broadly for workers, ACOEM encourages adherence to best practices as defined by its Occupational Medicine Clinical Practice Guidelines. At the same time, it does not believe that Guidelines should be considered rigid prescriptions for care. They are just that – guidelines – and cannot replace the judgment of the individual practitioner, supported by the best available evidence, which must be exercised with each individual case.

When the available scientific evidence-base for a test or treatment is weak or non-existent, clinical judgment and expert consensus become paramount. The vital role of clinical judgment is formally recognized in a section of ACOEM's Guidelines called Core Values:

"ACOEM Practice Guidelines should be utilized as a basis for high quality care, while recognizing that patient variability exists and there is an active role for the treating physician in designing optimal care for a given injured worker."

To further ensure that logical and reasoned clinical judgment is part of the guidelines development process, ACOEM supports its testing-and-treatment recommendations with a widely accepted set of “First Principles,” which every practitioner should apply. These principles are founded on the fundamental Hippocratic dictum, “First, do no harm”:

1. Imaging or testing should generally be done to confirm a clinical impression.
2. Tests should affect the course of treatment.
3. Treatments should improve on the natural history of the disorder, which in many cases is recovery without treatment.
4. Invasive treatment should be preceded by adequate conservative treatment and may be performed if conservative treatment does not improve the health problem.
5. The more invasive and permanent, the more caution should be exerted in considering invasive tests or treatments and the stronger should be the evidence of efficacy.
6. The more costly the test or intervention, the more caution should be generally exerted prior to ordering the test or treatment and the stronger should be the evidence of efficacy.
7. Testing and treatment decisions should be a collaboration between the clinician and patient, with full disclosure of benefits and risks.
8. Treatment should create neither dependence nor functional disability.

Beyond recommendations supported by evidence and “first principles” of responsible medical management, Occupational Medicine includes a third critical component to help the individual practitioner determine the best individualized course of treatment: the obligation to injured workers to suggest treatments that rapidly return them to work. Rapid return to work has been shown in many instances to minimize ongoing disability and to support recovery. However, no treatment should be continued without limits, unless a functional gain is demonstrated.

Effective treatment options are validated over time as well-designed studies provide better evidence and experience evolves. As the body of evidence related to treatments evolves, the system of evaluating it must be structured so evidence can periodically be weighted for relevance and quality. This requires exhaustive scrutiny of the scientific literature. Unlike other guideline developers, ACOEM bases its recommendations on primary, original-source search and review of all available scientific evidence related to specific treatments. ACOEM then applies nine categories of recommendation, driven by the quality of the evidence supporting the treatment, ranging from “strongly recommended FOR” to “strongly recommended AGAINST.” In each case, the recommendation is based on exhaustive investigation of the strength and quality of the evidence available – which the individual practitioner should assess if the evidence counters a clinical presentation.

ACOEM guidelines provide an exhaustive review of the primary scientific evidence, a methodologically sound process for determining the quality of that evidence, and a framework in which a physician’s clinical judgment and the recognition of patient variability are fundamentally acknowledged and made a part of the equation. ACOEM believes that these components create a balance that advances best practices while protecting and preserving individualized patient care.

In short, when using ACOEM’s guidelines to help identify

effective testing and treatment options, “not recommended” means exactly what it says – either there is evidence that a given test or treatment is ineffective, or that the expert panel composing the guidelines has recommended against a test or treatment on the basis of collective clinical experience and judgment. “Not Recommended” should not be taken to mean “never.” And, by the same token, “recommended” should not be taken to mean “always.” Physician judgment and individual circumstances must always be taken into account.

ACOEM’s guidelines are developed by independent panels of experts who use a transparent, publicly available methodology grounded in science. They are published by ACOEM alone—without “collaboration” with state government, as inaccurately stated in the RSDSA editorial.

At the very heart of ACOEM’s guidelines is the goal of returning function to injured or ill workers. This is fundamental to the work of occupational and environmental physicians, particularly as productive work is among the greatest sources of a person’s self worth—and a societal goal.

Any set of occupational health guidelines—regardless of the developer—may be used by the utilization review community. ACOEM’s first responsibility is to create a scientifically and methodologically sound guidelines system for the use of health-care practitioners; then to ensure that the parameters for its use are clearly explained and publicly communicated.

ACOEM fully agrees with RSDSA that the guidelines should not be used to arbitrarily deny authorization for coverage and recognizes the potential for UR organizations to misapply guidelines in their coverage decisions. Guidelines should never replace the judgment of physicians. ACOEM recognizes that URAC certified UR programs insist that only physicians can deny care.

ACOEM will continue to advocate publicly for a general standard of UR that recognizes patient variability, the need for physician judgment and the avoidance of rigid, unilaterally applied coverage decisions. Furthermore, the obligation of Occupational Medicine is to optimally return the injured worker to pre-injury functionality, regardless of the needed interventions. Optimal utilization should be a by-product.

As stated by the RSDSA, the predominant ethical obligation of the practitioner is to the individual patient. ACOEM agrees that patients should have informed choice and shared decision-making as they consider their healthcare decisions—including selection of treatment providers. While the focus of its editorial is on CRPS patients, ACOEM believes that the notion that patients need to obtain “an individually designed treatment plan for their debilitating physical and psychological conditions” is a general principle that applies to all patients. Every patient should be considered an individual—but a corollary principle is that the patient’s healthcare team should use the best available evidence, rooted in strong methodology, to inform the development of the highest quality treatment plan that will be consistently and reliably effective in improving both symptoms and function. Finally, we agree in principle that medical-care recommendations should not be considered universally prescriptive; they are intended to help practitioners form judgments based on the circumstances of individual cases.

—Jeff Harris, MD; Kurt Hegmann, MD;
Robert McLellan, MD; and Kathryn Mueller, MD
on behalf of the ACOEM Guidelines Oversight Committee

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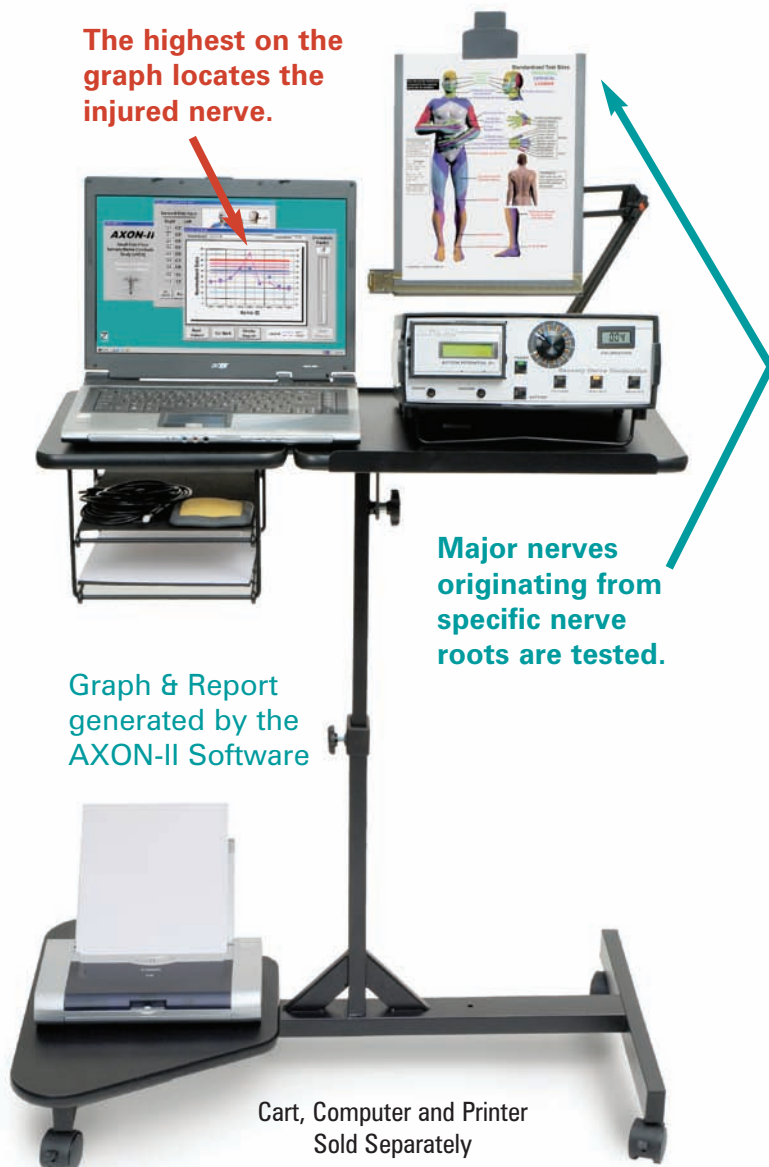
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