

COMMENTARY



Evidence-based Clinical Guidelines for the Management of Acute Low Back Pain: Response to the Guidelines Prepared for the Australian Medical Health and Research Council

INTRODUCTION

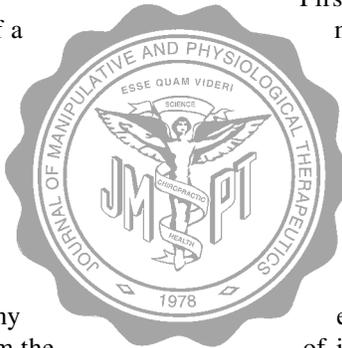
From the point of view of the director of a research foundation that is intimately involved in evaluating and providing documentation of the efficacy and effectiveness of spinal manipulation in managing a variety of clinical conditions, the most well-known of which is low back pain, I found the recent report prepared for the Australian Medical Health and Research Council by Nikolai Bogduk to be disappointing in many respects. These I will attempt to review from the perspectives of public interest, internal consistency, and interventions pertaining to and related to spinal manipulation; other interventions described are beyond the scope of this communication. From these considerations alone it should become apparent that the Bogduk document performs a major disservice to the public by misrepresenting or failing to comprehend much of the evidence at hand, by violating its own presumed rules of conduct, and—worst of all—by arrogantly assuming that the medical profession rather than the public should be the starting point from which guidelines are constructed.

DISCUSSION

A. Double Standard and Pillory of Opinion Are Presented as a Clinical Document

In Bogduk's opinion, the major reason for justifying these guidelines in preference to previous multidisciplinary efforts in both the United States¹ and the United Kingdom² is that consensus or expert opinion is no longer to be accepted as a form of evidence. Bogduk claims that all of his conclusions are preferably based on hard evidence from the published clinical trials, yet nowhere in his treatise is there any indication that his own review of the evidence is either systematic or impartial. As I will make clear in what follows, his analysis of the literature pertaining to spinal manipulation in particular is both flawed and incomplete, seriously undermining the credibility of the entire report.

In his preoccupation with clinical trials as the sole evidence base, Bogduk clearly overlooks a much larger picture regarding the development of sound clinical judgment. Taking a broader perspective, one has to question the validity of randomized clinical trials (RCTs) as the singular source of information regarding meaningful patient outcomes.



First, it is important to recall that only 15% of medical procedures have been found to be supported by any literature references at all³—and only 1% of these are deemed to be scientifically rigorous.⁴ Second, it is easy to forget that sound clinical observations in the doctor's office remain the cornerstone on which all experimental approaches, including RCTs, are based. In the world of clinical treatment, erroneous judgments are as much the product of improper generalizations of the findings of RCTs (which by their definition take place within highly restricted settings) as they are of the quality of the RCTs themselves. Indeed, the entire structure of evidence-based medicine is put into perspective by no less an authority than David Sackett,⁵ who argues that “external clinical evidence can inform, but never replace, individual clinical expertise, and it is this expertise that decides whether the external evidence applies to the individual patient at all, and, if so, how it should be integrated into a clinical decision.”

If Bogduk claims superiority for his report because of its dismissal of expert clinical opinion, then what on earth has led him to admit the advisability of early behavioral intervention for low back pain, “despite the lack of compelling, positive evidence” but on the basis of recommendations (opinions) from authorities? This statement feeds directly into one of the author's recommendations, which appears to suspend strict adherence to the evidence of published clinical trials and instead recommends that “*on face value* [italics mine], however, it seems prudent that practitioners should identify and deal with any psychosocial flags that may be evident.” As welcome as this common sense might be, and as consistent as it is with the aforementioned proposal by Sackett⁵ for developing true clinical evidence, Bogduk appears in this presentation to have taken liberty with his own ground rules and demolished his rationale for developing the new guidelines in the first place.

B. Guidelines Themselves Are Suspect and Not Invincible

Well-documented and significant methodologic problems do exist in the medical guidelines that have been published to date, most often relating to failures to maintain internal standards, rate scientific evidence thoroughly and impartially, or include mechanisms for validation and periodic review and updating.^{6,7} These same problems, in fact, are glaringly evident in Bogduk's own submission.

It is especially important to appreciate the updating process. Bogduk admits that because of a lack of resources, “there is no guarantee that the Guidelines will be updated regularly.” Without the processes of revision and renewal, the guidelines are stripped of their presumed superiority to their predecessors and clearly succumb to the pitfalls recently pointed out in both the *Journal of the American Medical Association*⁶ and *The Lancet*.⁷

One simply needs to look at guidelines published in the *Merk Index* 100 years ago to grasp the folly of either establishing or accepting guidelines as gospel. At that time, the following treatments, which now of course appear outrageous, were recommended for specific clinical conditions: (1) formaldehyde for the common cold, (2) arsenic or ammonia for baldness, (3) opium and morphine for typhoid fever, (4) bloodletting and chloroform for streptococcal infections, and (5) strychnine, ice, and lemon juice for diphtheria.⁸ Does Bogduk simply assume that his guidelines are immune from this kind of clinical misjudgment?

C. Guidelines Clearly Have Been Written to Benefit the Medical Profession Rather Than the Public

The mind-numbingly arrogant tone of this report is painfully evident in Bogduk’s statement that the guidelines are “transparently and unashamedly” developed “with the medical practitioner in mind.” It does not even begin to question the preeminence or infallibility of the medical physician in treating low back pain. Numerous patient evaluations have clearly established that chiropractors are more skillful and responsive than medical physicians in the management of back pain.^{9,10}

Of far more serious import is the question of whether medical physicians are in fact capable of performing complete neuromusculoskeletal examinations as first-contact health care providers. Judging from the results of a recent study of first-year orthopedic residents at the University of Pennsylvania, the answer would appear to be a resounding *no*. In this particular investigation, 82% of the 85 first-year residents failed to demonstrate basic competency on an examination in musculoskeletal medicine that had been validated by 157 chairpersons of orthopedic residency programs in the United States.¹¹ Given that orthopedic residents failed this examination, one would expect all other medical doctors to do no better—and probably to do worse. Extrapolating this finding, one could conclude that having a patient examined only by a medical doctor necessarily deprives him or her of a major, essential portion of the physical examination. By denying that health practitioners other than medical physicians should even be considered in the development of guidelines, Bogduk has obviously delivered a stacked deck that is decidedly not in patients’ best interests.

Bogduk himself provides an excellent example of the self-serving aspect of this line of reasoning in his discussion of psychosocial factors:

In broad terms, if a survey focuses on Psychosocial Factors it will likely find one or more to be significant but, by definition, will find no Biological Factors to be significant.

Conversely, if a survey addresses only Biological Factors it will never find Psychosocial Factors to be significant.

Perhaps there are no other words that could more eloquently describe the undoubtable consequences of wearing the set of professional blinders that Bogduk has donned in creating his entire treatise.

D. No Consideration Is Given to Safety

In terms of the interest of the patient rather than the interest of the profession, issues of safety cannot be ignored. Given the fact that the number of deaths occurring annually within the United States from medication errors alone has been reported to be anywhere from 79,000 to 400,000, this issue clearly needs to be addressed.^{12,13} In terms of spinal manipulation, the most significant problems that have been reported are the following:

- Cauda equina syndrome. Seen after manipulation of patients with lumbar disk herniation, this condition consists of neurogenic bowel and bladder disturbances, saddle anesthesia, bilateral leg weakness, and sensory changes. The frequency of cauda equina syndrome developing after lumbar manipulation has been estimated to be 1 per 100 million manipulations.¹⁴
- Cerebrovascular accidents. Seen after manipulation of patients in the upper cervical spine, these accidents involve the vertebral artery system. The frequency of cerebrovascular accidents has been calculated to be 0.6 per 1 million manipulations, one half of these accidents being fatal.¹⁴

These rates are *400 times lower* than the death rates observed from gastrointestinal bleeding due to the use of nonsteroidal anti-inflammatory drugs¹⁵ and *700 times lower* than the overall mortality rate for spinal surgery.¹⁶ In discussing the alternatives for managing back pain, it is difficult to imagine how this vital issue could have been ignored during the preparation of a set of responsible guidelines.

E. Reference to Providers Other than Medical Physicians as “Craft Groups” Borders on Malpractice

This is arrogance at its worst. The well-documented rise of alternative medical procedures within the past decade, much of it directed toward the treatment of low back pain,¹⁷⁻¹⁹ as well as the establishment within the past year of a completely new national center within the National Institutes of Health, could not have resulted from the presence of mere “craft groups.” Included among the “craft groups” to which the author refers are chiropractors—practitioners who are fully licensed to diagnose and perform complete physical examinations in every one of the 50 states. If they were merely members of “craft groups,” as the author would have us believe, they would not have been awarded primary care gatekeeper status by at least 3 of the nation’s managed care companies—HMO Illinois,²⁰ Family Health Plan Cooperative,²¹ and Texas Back Institute.²¹ Reference has been made elsewhere to the existence as early as 1994 of a “few HMOs that have experimented with delivering limited chiropractic benefits via direct access through chiropractic [independent

practice associations].”²² Finally, the Medical Director of the San Francisco Spine Institute, Arthur H. White, MD,²³ has referred to “new” and presumably enlightened managed care organizations that are using triage organizations to funnel patients into the most appropriate levels of care as rapidly as possible; chiropractors are considered “very appropriate” for this triage and will be invited in increasing numbers to become primary care providers by the “new, more enlightened managed care organizations.”

There is no doubt that Bogduk has “transparently and unashamedly” placed medical practitioners at the center of his treatise, but it is also clear that this has been at the expense of providers who are at least as capable of administering health care to patients with low back pain, if not more so. Once again, the author has violated his own rule barring opinion from his court of law with his egregiously cavalier and unfounded dismissal of chiropractors and other groups of qualified health care practitioners as “craft groups.”

The seriousness of Bogduk’s one-sided attitude toward other providers is not just an affront to public intelligence and entitlement. It approaches the level of malpractice when one takes into account the recent opinion handed down in the Supreme Court of New Jersey regarding a patient who was denied full clinical alternatives on consultation.²⁴ The court wrote as follows:

1. “In turn, the doctor has the duty to evaluate the relevant information and disclose all courses of treatment that are medically reasonable under the circumstances. It is for the patient to make the ultimate decision regarding treatment based on the doctor’s recommendations. Informed consent applies to invasive and noninvasive procedures.”
2. “To ensure informed consent, the physician must inform patients of medically reasonable alternatives and their attendant probable risks and outcomes. Physicians do not adequately discharge that duty by disclosing only the treatment alternatives that they recommend.”
3. “A physician should discuss the medically reasonable course of treatment, including non-treatment.”
4. “Like the deviation from the standard of care, the doctor’s failure to obtain informed consent is a form of medical negligence. Recognition of a separate duty emphasizes the doctor’s obligation to inform, as well as treat, the patient.”

Clearly, this opinion places a great deal of pressure on anyone who is rendering medical care. It should make the issue of continuing medical education paramount in any physician’s agenda. By positioning informed consent as an indicator for “standard of care,” it demands a far more acute level of awareness and appreciation of other health care options than was called for previously. It also refutes any assumption on the part of physicians that they “know better” than to inform patients of all reasonable alternatives—invasive, noninvasive, and even no treatment at all—that are available. Finally, it is a call to arms to people in the research community to ensure that results are adequately and clearly disseminated.

Thanks to this decision, the painstaking process that has led to the Mercy Guidelines²⁵ and then to the Agency for Health Care Policy and Research (AHCPR) Guidelines¹ and the Clinical Standards Advisory Group (CSAG) Guidelines in the United Kingdom² with respect to back care emerges with laurels. It represents a mainstreaming process by which the information that has been carefully gleaned over the past 25 years to validate chiropractic in the management of back conditions becomes a matter of public record. Ignoring such information in clinical practice becomes virtually indefensible, if not tantamount to outright malpractice. Bogduk’s distorted portrayal of low back care, similar to what has emerged from the American Medical Association²⁶ and the Harvard Pilgrim Health Plan,²⁷ thus becomes suspect on legal as well as ethical grounds.

G. IASP Taxonomy and Back Pain Are Presented in Obfuscating Terms

Bogduk goes to great pains to invoke the International Association for the Study of Pain’s taxonomy to rid back pain diagnoses of allegedly spurious and misleading terms. He subsequently admits that “the same sophistication in diagnosis as applies in other fields of Medicine cannot apply to back pain.” Finally, he suggests that the practitioner invoke the term *somatic lumbar spinal pain*, which “conveys the impression that the practitioner knows approximately what is wrong but can’t be certain at present.” All the while, these multiple considerations appear to tapdance adroitly around the immutable fact that medical practitioners do not seem capable of diagnosing musculoskeletal conditions, as discussed above (section C).¹¹ At the very least, there is certainly a rather flaky, shabby aspect to this line of reasoning from an author who has asked us to bar clinical opinions from this discussion and accept only hard evidence from clinical trials.

H. Detection of Trigger Points Is More Reliable than Indicated

The author’s discussion of poor reliability of trigger points is now outdated by a recent report of excellent inter-observer reliability for the assessment of trigger points in the right trapezius muscle.²⁸

I. Categorical Dismissal of MRI Is Not Warranted

According to Bogduk, the use of MRI “cannot be justified for the investigation of acute low back pain, even to screen for ‘red flag’ conditions.” This statement is at cross purposes with published literature that supports the diagnostic efficacy of MRI (1) for clinically suspected low lumbar disk herniation,^{29,30} (2) for major acute injury or symptoms suggestive of infection, tumor, or progressive neural dysfunction,³¹ and (3) possibly for nerve root canal stenosis, through evaluation of the intervertebral foramina.³² Reasons for not admitting this evidence need to be discussed if the rejection is to be accepted as credible.

J. Acceptance of Strength of Evidence Based on Categorical Levels of Evidence Is Misleading

The schedule of levels by which the efficacy of treatments is evaluated makes no allowance for the fact that

seriously flawed RCTs are of less clinical value than well-designed pseudorandomized, cohort, or even case studies. The background and consequences of one such seriously flawed randomized trial are discussed in detail below [section M].

K. Allocation of Space to Recommendations from Certain Clinical Trials Appears to Be Arbitrary

Bogduk's generous assignment of nearly a page of recommendations and 3 pages of discussion to a single trial based on reassurance of the patient³³ strikes this reviewer as unusual. In the absence of well-known ratings by other review panels and guidelines,^{1,2} such a decision appears to be without foundation. By way of contrast, more than 30 clinical trials addressing spinal manipulation are compressed by the author into one half as much space with virtually no recommendations, simply because they appear to be conflicting. There is an unmistakably arbitrary and capricious aspect to these presentations that further compromises the document's integrity.

L. Concept of Back Mobilization Is Erroneously Challenged

The Bogduk guidelines discredit without foundation the numerous challenges that have been made to the belief that the back must remain immobile during an episode of back pain. Bogduk concludes that as long as the precise causative lesion causing back pain remains obscure, the principle is "no more than a generic example of musculoskeletal medicine that has been applied to the back without any concrete link to spinal pathophysiology"—which suggests that doing nothing might achieve an outcome similar to that obtainable with an active therapeutic intervention. However, this ignores such events as scar formation, cross-linking of collagen fibers, and adhesions, which might be expected to result in trauma to soft tissue areas that were not rehabilitated soon after injury. Specifically:

1. Healing without proper motion will cause a disorganized matrix to appear, with adhesions and unnecessary scar formation.^{34,35}
2. Early exercise and joint motion in rehabilitation produce a better collagen concentration, which is superior to scar tissue.³⁶
3. Improved tensile strength is observed in the collagen deposit when proper rehabilitation takes place after injury.^{37,38}
4. If the venous blood supply to paraspinal muscles is depressed for 2 hours (which might be anticipated in some soft tissue injuries), irreversible muscle damage occurs.³⁹

With decreased vascularization, rapid degeneration of the muscle spindles occurs—and subsequent revascularization produces changes in their shape and neural innervation.⁴⁰

M. Heavily Referenced Study by Cherkin et al Is Greatly Overrated and Inaccurately Described

The study by Cherkin et al⁴¹ that appeared in the *New England Journal of Medicine* 30 months ago is an inaccurate

and unfortunate depiction of the patients who normally seek chiropractic care for low back pain. It underscores the dangers of generalizing the results of RCTs, which themselves represent a specialized application of therapies under restrictions that are not necessarily indicative of either the actual therapists or the patients whom they see. Worse, its design flaws are so numerous and serious, as indicated in the summary that follows, that its validity is compromised to the point of collapse. The reader, in any event, is misled as to what is actually shown in the trial.

1. Validity of the intervention. To begin, one must be aware that several chiropractic techniques are applicable to the management of low back pain; among them are low force (the Logan Basic Technique), flexion-distraction, use of a drop table, and traction. In this trial, only one high-velocity technique (side-posture) was applied, and it might not be equally effective for all patients (older people especially). Furthermore, important ancillary procedures that are intrinsic to the chiropractic visit appear to have been denied to patients. In particular, (a) extension exercises were forbidden, and (b) patients were most likely not given any literature—even though these two options are considered parts of a customary chiropractic regimen for office visits. The implication is that these elements were permitted only in the other two arms [educational booklet and McKenzie method] of the trial reported. In short, the chiropractic treatment given in this particular trial appears to have been only a pale shadow of the actual therapy administered to patients in the real world. The fact that back pain recurrences, as reported by the authors, were 50% by the end of the first year and 70% by the end of the second year confirms this point of view, not only for chiropractic but for the McKenzie physical therapy modality as well.

2. Characteristics of the medical booklet. What was the purpose and what were the details of the arm of the trial involving the educational booklet? One is left wondering what form of therapy in real life this was supposed to represent and whether any attention (and of what kind) was given to the patient in addition to the booklet. Finally, no details of any kind are provided as to the presentation and actual contents of the booklet. It is puzzling to find a reference in the Bogduk discussion to "usual care [which] consisted of treatment by a general practitioner and referral to a physiotherapist"—never mentioned in the article by Cherkin et al⁴¹ as published. In this respect, the Bogduk guidelines appear to be simply and unmistakably false.

3. Lack of sufficient attention to patient expectations. To begin, no details are provided as to how patients were polled regarding their expectations of treatment, how the questioning was raised, and whether the instrument was validated. The consequences of patient expectations have been given inadequate attention. Once patients were eligible to participate, how many refused to participate, and for what reasons?

The percentage of patients who had prior chiropractic care for low back pain appears to be substantially lower for the chiropractic cohort [24%] than for the McKenzie and medical booklet cohorts (35% and 40%, respectively),

which raises the possibility of a type II error because of small group size. Yet Cherkin et al⁴¹ themselves, citing another prominent investigation, note that “the British study found the benefits of chiropractic to be most evident among patients who had previously been treated by chiropractors, a group presumably favorably inclined to favor chiropractic care.” Consequently, one can easily argue that the patients in the chiropractic cohort were doomed to encounter diminished outcomes.

4. Baseline characteristics. Baseline values regarding severity among the 3 groups tested appear to create a bias in the outcomes. First, the chiropractic cohort shows the highest tendency in the percentages of patients who, because of low back pain and prior to their therapy, encountered (a) more than 1 day of bed rest (35% vs 24% and 22% for the McKenzie and medical booklet cohorts, respectively), (b) more than 1 day of work lost (39% vs 41% and 30% for the McKenzie and medical booklet cohorts, respectively), and (c) more than 1 day of restricted activity (72% vs 65% and 52% for the McKenzie and medical booklet cohorts, respectively).

Second, the initial bothersome and Roland-Morris disability scores of 4 and 7-8, respectively, are substantially below the values of 6-7 and 10, respectively, that are more frequently observed in trials involving significant low back pain. This means that any observed changes are compressed within an artificially narrow range and that statistical variations become more disruptive. The effect of both of these aberrations is to compromise the monitoring of back pain resolution.

5. Patient compliance issues. Sufficient details regarding patient compliance are lacking; in addition, there would appear to be a wide variance between the percentage of patients whom therapists consider to be in compliance (55%) and the percentage of patients, at least in the McKenzie group, who are self-reporting compliance (78%). How, when, and how often was the question of compliance posed to study subjects? Inasmuch as compliance is closely linked to satisfaction and has a major bearing on outcomes, this issue cannot be ignored.

6. Lack of convincing or meaningful cost data. There is no way to draw a meaningful conclusion from the cost data as they are presented. To begin, requisite statistics regarding costs are totally ignored, so one cannot assess whether costs follow a normal distribution or are skewed (each to a different extent) among the 3 modalities compared. Furthermore, it is incomprehensible that health maintenance organization costs for laboratory services, medications, and radiology should constitute 50% of the chiropractic bill, given that the norm within the United States is that approximately 80% of chiropractic costs are borne within the physician's office and 20% are allocated to external services—and precisely the opposite distribution of cost percentages is observed in the offices of allopathic physicians.⁴²

7. Patient exclusion. Information on the grounds for exclusion and the symptoms of sciatica was not provided. In addition, patients' attitudes toward provider groups should have been assessed for inclusion in the trial, inasmuch as these would have significant impacts on both compliance and outcomes. Localized attitudes would thus have a significant

bearing on outcomes from what might be incorrectly inferred to be a national standard of practice. The fact that this study was conducted in the state of Washington, which has established what are arguably the most restricted scopes of practice for chiropractors in the entire nation, is particularly distressing.

In summary, the study is a poor representation of therapies that have been successfully applied to live patients in physicians' offices worldwide. If left unanswered, these inquiries are of sufficient import to render the data presented in the *New England Journal of Medicine* article seriously compromised and the study as a whole unreliable. In point of fact, the Royal College of General Practitioners, in a very recent systematic review of the literature designed to update the United Kingdom's CSAG guidelines, has concluded that the study by Cherkin et al⁴¹ neither adds to nor detracts from the evidence base regarding appropriate interventions for low back-pain.⁴³ It is therefore clear that Bogduk has committed a major error in accepting this particular study as gospel.

N. Author Displays Inconsistent Attitude Toward AHCPR

The author's dubious dismissal from his study of expert clinical opinion (and of the AHCPR Guidelines in particular¹), as cited earlier (section A), is significantly undercut by his readmission of the AHCPR Guidelines into his discussion as supporting evidence for the use of acetaminophen as a viable treatment option for low back pain. One could easily suspect that this arbitrary obliteration and then resurrection of the AHCPR Guidelines is more opportunistic than grounded in truth, more designed to serve the author's needs than to support a principle.

O. Chapter on Manipulation Blatantly Disregards Its Literature Base

The abhorrent nature of the chapter on manipulation begins with its distortion of the definition of manipulation. Disregarding actual clinical observations regarding the physiological and anatomical barriers of the joint,⁴⁴ Bogduk dismisses these phenomena as “intentions or perceptions of the manipulative therapist” without devoting any further discussion to this cornerstone of chiropractic manipulation. What the therapist actually does in manipulation, in contrast to what Bogduk represents him as doing, is conduct “a manual procedure that involves a directed thrust to move a joint past the physiologic range of motion without exceeding the anatomic limit.”⁴⁵

Bogduk's chapter subsequently discredits the conclusions of pragmatic reviews because they “appear to be functions of the discipline of the author of the review.”⁴⁶ Everything that has been discussed in this critique should make it apparent that the author of the guidelines is guilty of precisely the same crime.

The same chapter presents a distorted account of the systematic review by van Tulder et al⁴⁷ of the literature regarding back pain. Bogduk neglects to indicate that the review plainly states that with regard to acute low back pain, “there is limited evidence that manipulation is more effective than a placebo treatment.” Although contradictory results did not

allow van Tulder et al to compare manipulation with other physiotherapeutic applications, there is no such uncertainty regarding chronic low back pain. Here van Tulder et al unequivocally state that “there is strong evidence that manipulation is more effective than a placebo treatment . . . There is moderate evidence that manipulation is more effective for chronic LBP than usual care by the general practitioner, bed-rest, analgesics, and massage.” From this disparity between what is said in the review and what is actually presented in Bogduk’s guidelines, one can conclude that with regard to manipulation, the latter are misleading at best and deceitful at worst.

The centerpiece of the very short bibliography (10 references) provided in this chapter on manipulation is the study of Cherkin et al,⁴¹ the veracity of which has been taken to task at considerable length above [section M], as well as in an elegant presentation elsewhere.⁴⁸

CONCLUSION

It is hoped that the foregoing discussion of some of the glaring inconsistencies, misstatements of fact, and egregious biases within the Bogduk clinical guidelines has revealed it to be a poorly executed and ill-conceived document that appears to disregard both the conventions of careful scholarship and ethical considerations pertaining to the needs of patients who have experienced low back pain. I believe that the arguments that I have made allow the document to be seen in proper perspective, and I urge that these points of critique be taken into careful consideration in the development of any policies regarding the proper utilization of available health care resources in the management of low back pain.

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