

Debating “Interventions” for Chronic Axial Low Back Pain

CASE SCENARIO

A physiatry journal club is being held on the nonsurgical treatment of chronic axial low back pain (LBP) with the use of interventional spinal procedures. The conference leader has asked the discussion to be based on a case presentation using medical evidence, socioeconomic, and medical ethics principles.

The case is a 53-year-old man, Mr. Payne, who has chronic recurrent LBP. He lives in a large city on the east coast of the United States. He complains of daily LBP, particularly during the last 10 months. Ninety-five percent of his pain is across the lower back above the sacrum, with only 5% radiating toward either the left or right buttock. He denies the presence of numbness, tingling, or weakness in his lower limbs. His neurological exam is normal with no dural tension signs, but lumbar spine flexion and extension range of motion is limited. He is a nonsmoker and is otherwise healthy.

Lumbar spine films and magnetic resonance imaging reveal varying degrees of multilevel (L3–4, L4–5, L5–S1) degenerative disk and zygapophysial (facet) joint abnormalities. There is no significant nerve root impingement noted on magnetic resonance imaging. Electrodiagnostic testing of lower limbs is normal. In the past, the patient has participated in core exercise training, and he has used over-the-counter nonsteroidal anti-inflammatory drugs (NSAIDs) occasionally. He is not interested in opioids.

Mr. Payne is feeling desperate. He is requesting a spinal injection because his brother had good results with injections for “sciatica.” His internist agreed to send the patient to you for “interventional” options, but the insurance company notified his internist that a preapproval request for interventional treatment was denied.

Considering the patient’s persistent pain, lack of sustained functional improvement, his desire to proceed with more “aggressive” care, and current evidence regarding interventional spine procedures, what do you advise? Please suggest treatment options and guidance for the internist in responding to the insurance company.

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Lack of consensus [1] exists regarding the diagnosis and treatment of nonspecific chronic LBP (CLBP). CLBP is a leading cause of physician visits, and the return-to-work rate after 2-year absence is nearly zero [1]. Level I evidence demonstrates that exercise and medical management help alleviate low-disability CLBP in the short term [1,2]. Level II evidence states that NSAIDs [2] and epidural steroid injections (ESIs) [1] are effective in the short term for LBP; in particular, ESIs are more effective for radicular pain.

Surgical decompression, fusion, and artificial disk replacement for degenerative lumbar spondylosis remain con-

troversial, with these procedures having failed to demonstrate a clear advantage over nonsurgical management [3,4(p261)]. However, fusion or disk replacement may be effective in selected patient populations. U.S. investigation device trials have shown 53% success with disk replacement versus 41% for fusion, but this result was based on eligibility criteria that excluded risk factors associated with poor outcomes and only short-term follow-up. The authors of most trials found minimal differences in pain, function, medication use, or disability, with approximately 50% of patients considered clinically nonresponsive. Surgical fusion may im-

prove pain, disability, and return-to-work rate at 2 years in severe disease [1]. Overall, surgical decompression and fusion have no scientific evidence in any randomized controlled trial (RCT) for their efficacy in treating degenerative lumbar spondylosis, spinal stenosis, or back pain [3]. Meta-analysis shows 3 of 4 RCTs failed to demonstrate significant difference in Oswestry Disability Index compared with non-operative management for diskogenic back pain [5]. Complication rates for surgery were 9%-18% compared with 0% for the nonoperative group (including spinal injections) [6].

In this patient with CLBP, facet joint (also known as zygapophysial joint) and disk problems are a common source of pain. Radiculopathy or radicular pain is not suggested by the clinical picture. Interventional procedures may allow more precise diagnosis, facilitation of targeted exercises, and effective pain management for this patient. The World Health Organization states that medical decisions regarding pain control are best made by medical professionals who consider the needs of each patient rather than by regulatory agencies [7]. Mr. Payne's dilemma may be elucidated by considering diagnostic and therapeutic interventions such as lumbar medial branch blocks (MBBs) and radiofrequency neurotomy (RFN). The role of interventional procedures should be considered through the prism of evidence, artful medical decision-making, and cost analysis.

Evidence for Interventional Procedures

Interventional and minimally invasive techniques provide viable options for the diagnosis and treatment of refractory CLBP. Procedural interventions that use spinal injections provide a natural next step in Mr. Payne's care. They are less expensive and have less associated morbidity than fusion. Some providers may suggest ESIs to improve this patient's quality of life by reducing pain and anxiety, and increasing functional mobility and satisfaction [8-11]. At minimum, spinal steroid injections provide a convenient medication-delivery method because they are dosed less frequently than oral medications. This technique may improve adherence and thereby improve pain management [12,13]. In addition, they avoid the irregularities of enteric absorption and first-pass metabolism. However, the paucity of well-designed studies precludes strong recommendations about the efficacy of ESIs for diskogenic pain [14]. Some authors [15] have concluded that ESIs have short-term benefit (2-6 weeks), particularly for radicular pain, with substantial cost, no impact on function or the need for surgery, and generally do not provide pain relief beyond 3 months. However, the level of evidence for ESI efficacy depends on the chosen technique, pathology, and grading of studies. The greatest evidence of benefit for ESI exists for radicular pain [16] rather than axial CLBP. Thus, ESIs are not clearly indicated for Mr. Payne.

Facet joint interventions may provide valuable information about this patient. Because of the limited positive predictive value of imaging and physical examination in the diagnosis of back pain [17], interventional diagnostic techniques such as MBBs are an important and validated exten-

sion of the examination. Accurate anatomical diagnosis via neural blockade can facilitate targeted therapeutic interventions for a particular pain condition. MBBs remain a valid and reliable method in diagnosing lumbar facet pain, which may cause up to 15% of CLBP [18]. Diagnostic limitations of uncontrolled facet blocks include 25%-41% false-positive rates and lack of specificity, partly because of 16% rate of spread of local anesthetic (LA) to the intervertebral foramen and epidural space (0.5 mL of injectate can spread to 6 cm² of surrounding tissue, including lateral and intermediate branches, which innervate other potential pain generators such as the paraspinal muscles, fascia, ligaments, sacroiliac joints, and skin). Additionally, a placebo response of 18%-32%, sedation, superficial LA, and systemic absorption can increase the rate of false-positive results [18]. False-positive rates can be reduced by the use of controlled blocks, but these may not be cost-effective [18]. False-negative blocks can arise from the failure of properly performed MBBs to anesthetize the facet joint (11% rate), inadvertent venous uptake (8%-33% rate), and rare aberrant innervations to the facet joint [18,19]. Despite these limitations, MBBs along with the use of precise technique and a double-block paradigm provide meaningful and valid information.

If facet-mediated pain is diagnosed in this individual, treatment may include intra-articular steroids, although this technique is controversial. Some authors [4(pp 56-64)] claim intra-articular steroids have no demonstrated efficacy for facet joint pain. Yet, prospective observational trials [20-29] have shown some benefit from facet corticosteroid injections. Intermediate-term benefit was demonstrated with intra-articular hyaluronic acid [30], normal saline [31,32], and LA [33]. However, the largest controlled trial found no difference between intra-articular steroid, LA, or saline [32].

Lumbar medial branch ablation with the use of RFN remains the best and most enduring treatment for facet-mediated CLBP [4(pp56-64)]. RFN demonstrates strong evidence of efficacy in the short term and moderate evidence for long-term relief of lumbar facet joint pain. The authors of 3 randomized trials of RFN (after confirmatory diagnostic blocks) found pain reduction up to 12 months, suggesting a number needed to treat of 1.1-1.5 [34]. The authors of a prospective study of patients with response to serial LA blocks and electromyographically confirmed needle placement found 87% of patients had 60% pain relief and 60% of patients had at least 90% relief at 12 months after RFN, with an average duration of pain relief of 10.5 months [35]. Furthermore, repeat RFN was effective in the long term without diminution of benefit. For instance, the second through fourth RFN had a mean duration of 9 to 11.6 months or longer [35]. Absent evidence of beneficial surgical intervention for degenerative facet joint-mediated pain, intra-articular steroid injection and RFN remain treatment options in select patients who do not respond to treatment with exercise and oral medications.

Other interventional techniques, such as trigger point injections, dry needling, intramuscular injection of Botox or corticosteroids, acupuncture, and prolotherapy, cannot be

recommended because of limited evidence, but they may be useful for short-term benefit in refractory myofascial pain [4]. For intrinsic disk pain, the literature does not support one treatment convincingly over another. There have been various percutaneous intradiskal interventions that have been studied. For example, intradiskal electrothermal therapy has undergone RCTs, with some authors suggesting modest improvement in axial lumbar pain more than functional improvement in highly selected individuals [4(pp80-95)]. Because the evidence is conflicting or sparse for various treatments of CLBP, we must combine evidence with clinical experience to individualize the treatment plan for Mr. Payne.

The Art of Medical Decision-Making

Medical decision-making is a multidimensional process that includes physicians, health-plan administrators [36], and patients. Each party bears unique characteristics and responsibilities to ensure continuity of our medical system. Administrators may have the advantage of objective detachment while making prospective care decisions and are less likely influenced than physicians by clinical contact and empathy for observed patient suffering. They may be best positioned to adopt the objective skepticism of an epidemiologist and thus serve the patient indirectly by practicing cost containment in an attempt to keep care accessible for everyone. Although bonus pay for care restriction may provide a conflict of interest for the administrator, he or she must consider decisions carefully and is accountable for malpractice, including tortious breach of contract, fraud, misrepresentation, negligence, vicarious liability, breach of warranty claims, and liability for failure to allow care that is medically necessary and that may result in injury and breach of fiduciary duty (failure of a person with discretionary authority over disposition of assets to perform their legal duty to act in the best interests of the beneficiary) [36]. For instance, the Supreme Court of the United States ruled that the 1974 Employee Retirement Income Security Act (ERISA, a federal regulation pre-empting state law on employee benefits including health plans) does not always exempt insurance administrators from malpractice.

The physicians' advantage in direct clinical assessment is often more meaningful than the written clinical report, which is usually the sole source of information for insurance administrators. Conversely, physicians may be susceptible to subjective bias and, thus, a myopic view of cost savings in favor of treatment that has the potential of pain relief and improved function. Physicians must also be especially cautious in rendering care decisions because they are exposed to the threat of malpractice.

Contemporarily, patients play an increasing role in health-care decisions. For instance, information has become more accessible on the Internet, and the patient-physician interaction has transitioned from paternalistic to informative, interpretive, and deliberative models [37] of consultation and negotiation related to medical care. Patients are influenced by anecdotal evidence from personal acquaintances, as reflected

in this case by Mr. Payne's brother. It is the responsibility of the physician and payor to provide objective consultation. This puts the patient's experience in context, permits the parties to negotiate effective treatment strategies, and considers the broader context of cost-containment. Payors, physicians, and patients thus bear a common responsibility to contain costs while allowing broad access to effective care.

It is certainly the prerogative of the insurance company to exercise cost-containment strategies. However, profit-driven care has been described by some to lead to the degradation of the medical profession [36]. Courts have determined that third-party payor networks can exert enough control over physician decisions that their status as independent providers is negated. Moreover, some health maintenance organizations have threatened to terminate physicians for providing nonprofitable care. Courts have determined that this threat is sufficiently powerful to nullify the exercise of independent medical judgment [36]. We must avoid the extremes of health-care rationing motivated by year-end bonuses by third-party payors and likewise the temptation for physicians to perform unnecessary procedures for the sake of reimbursement. The World Health Organization states that medical decisions regarding pain control are best made by medical professionals who consider the needs of each patient, rather than regulatory agencies [7]. However, an effective system would evenly distribute power between payors, physicians, and patients to orchestrate checks and balances on health expenditures.

Cost Analysis

Interventions offer Mr. Payne a cost-effective approach between (ineffective) medical management and (nonindicated) fusion. Insurance companies can refuse treatments such as functional restoration therapy based on the "price tag," despite evidence of long-term cost-efficacy through lower health-care use and earlier return to work [4(pp 65-69)]. Similarly, interventional therapy may be cost-effective for Mr. Payne. One could calculate the health-care expenditures for the past 10 months as follows (using local charges in Baltimore/Surrounding Counties, Maryland): \$380 in primary care physician visits (\$38/monthly visit for pain management), \$300 on naproxen (\$0.15/250-mg tablet taken 500 mg twice per day), \$198 on NSAID side-effects (\$0.66 per \$1 spent on NSAIDs), \$3439.54 on physical therapy core exercise training (\$72.06 for evaluation plus \$116.12/hour 3 times weekly) [19], and general damages. Although there is no third party from which to collect damages, the courts, payors, and patients have established the fair market value of pain and suffering (including physiological injuries, loss of consortium, earning capacity and quality of life) as approximately 2-4 times the cost of medical bills (\$8635.08-\$17270.16). However, because Mr. Payne has presumably not missed work, we can estimate minimal general losses at \$4317.54 [39].

In contrast, a 3-level diagnostic facet MBB followed by a 3-level RFA would have a hospital reimbursement of

\$2034.32 (including physician and facility, but not pharmacy and radiology fees) [38].¹ Given the average duration of effectiveness of RFA >10 months, this procedure would pay for itself if it resulted in 47% less use of the primary care physician, NSAIDs, and physical therapy (not to mention the intangible costs of pain and suffering). Alternatively, lumbar fusion would average a total hospital reimbursement of \$15.2-\$18.2K [40].

Conclusion

There are >200 treatments for CLBP, none of which has demonstrated clear superiority. Clear understanding of the evidence, including its strengths and limitations, permits the art of blending patient preferences, resource availability, and clinical experience to negotiate a reasonable treatment plan. Escalating patient demand for interventional procedures may reflect changing societal or cultural beliefs. The reduction in reimbursement by payors directly affects access to care. We must carefully consider the balance of decision-making power to orchestrate an effective system of checks and balances. In this way, we can defend patient care, physicians' independent judgment making, and resource management. Physiologists must continue to refine the evidence and develop clearer algorithms for matching each patient with the best evidence-informed treatment combinations.

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¹ Physician reimbursement calculated using state: MD, city: Baltimore based on 80% Medicare payment. CPT codes from *Spine J*. 2008 Jan-Feb;8(1) (see source above). Physician fees calculated according to local formula: [($\$20 \times \text{average minutes per procedure}$) + 120] \times 0.94 = facility fee. Based on averages of 10 minutes per facet injection, 15 minutes per ESI or neurotomy.

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Dr. Standaert Responds

This case presents us with a common challenge in the outpatient management of patients with spinal disorders, namely identifying the root cause or causes of the patient's pain, suffering, and disability, in order to provide recommendations regarding appropriate treatment. There are some distinct features of this case that make this task difficult, including the chronic nature of the pain, the relatively nonspecific findings on diagnostic evaluation to date, and the failure to respond to what seem to have been appropriate conservative measures. To advance the patient's care, we will have to take a broader approach to comprehensive rehabilitation than has been offered thus far. For our discussion with the medical residents, there are 2 primary issues we have to address. First, we have the issue of how best to manage our patient. Second, we have to identify the appropriate means of responding to the insurance company regarding further care needs. Both of these have to be approached with some awareness as to the current state of our literature regarding chronic spinal pain as well as the very dynamic socioeconomic forces currently at play in the field of medicine, particularly as they relate to interventional spine care.

Regarding the patient's medical presentation, the persistence of his pain as described in the history suggests that one of several scenarios has occurred: an appropriate medical diagnosis has not yet been established; the appropriate medical diagnosis has been made, but the treatment offered thus far is ineffective or inadequate; or additional factors contributing to the patient's ongoing pain and disability have not been addressed. It is clear that the findings noted on this patient's imaging are fairly common in those of similar age without low back symptoms, complicating the diagnostic assessment [1]. There is the option of further diagnostic testing and interventions to arrive at a more precise anatomic diagnosis. However, we need to be aware of the limitations in attempting to identify reliably the specific cause of LBP and to recognize that whatever the purported "pain generator" may be, psychosocial factors are much stronger predictors of the ultimate outcome of those with LBP than any biomedical factors [2-4]. Just as the extent of our anatomic assessment to date may be inadequate for some physicians, so is our under-

standing of the individual psychosocial history of this patient.

From an interventional perspective, there are some significant difficulties with taking a position for the use of spinal injections in a patient such as Mr. Payne with CLBP and multilevel degenerative changes. Although there is some literature supporting the use of RFN for intermediate relief of LBP in highly selected patients [5], the overall tone of the literature on the use of spinal injections for those with CLBP is decidedly negative. The most recent Cochrane Review on interventional care for subacute to CLBP concludes "there is insufficient evidence to support the use of injection therapy in subacute and chronic low back pain" [6]. Even a slightly more optimistic review of the role of ESIs in the treatment of CLBP noted that no definitive statements regarding their efficacy could be made given the current limitations of the literature [7]. In the same journal, a systematic review of facet interventions notes that there is no documented form of conservative treatment that has proven effective in the treatment of facet mediated pain and that RFN "remains the only available treatment" [8]. However, this review did not draw any conclusions regarding the efficacy of neurotomy given the limitations of the literature. From the study by Dreyfuss et al [5], there does not appear to be a role for the widespread use of facet joint neurotomy in the large pool of those with nonspecific LBP such as Mr. Payne. When considering the literature on ESIs for radicular pain, a condition generally perceived as more responsive to radicular pain than axial LBP, we are faced with literature such as a review by Armon et al [9], which states that the routine use of ESIs to treat function or provide long-term pain relief is not indicated, and a study on cost-effectiveness of ESIs in radicular pain by Price et al [10], which concludes that they "do not provide good value for money." Although some may take issue with the approaches of these articles, their presence in the literature and the consistency of their message is not lost on payors and cannot be readily dismissed in the culture of evidence-based medicine.

Taking a larger socioeconomic perspective, the troubles with the quality of evidence regarding interventional procedures in the treatment of CLBP are compounded by data on

use. Studies on the database of the Centers for Medicare and Medicaid (CMS) show a dramatic increase in the use of interventional spinal procedures during the last decade or more [11,12]. Manchikanti et al [11] noted a 197% increase in pain management procedures per 100,000 Medicare beneficiaries from 1997 to 2006, including an increase in facet procedures alone of 543%. From the available data, it is likely that a significant number of these procedures are being performed inappropriately. The Office of the Inspector General for CMS recently completed an audit of facet injection procedures and found a large number of areas of concern, including a lack of uniformity in coverage standards. Impressively, 63% of the procedures audited from 2006 did not meet Medicare program requirements [13]. It is also not clear that the increasing use and costs associated with spine care are improving the status of individuals with spinal problems. In a recent study, Martin et al [14] found that although expenditures for spine care increased 65% from 1997 to 2005, the percentage of individuals in the population with self-reported spinal problems increased over that time and their overall mental, physical, and social functioning were worse.

Beyond the sheer numbers of injections, we are also faced with problems of significant variability in the use of spinal procedures in the United States. Friedly et al [15] noted an 18.4-fold difference in the use of ESIs between the highest and lowest health referral regions in the country. Somewhat disturbingly, the authors of this study found that areas with greater injection rates also had greater surgical rates and that areas with greater injection rates had larger percentages of patients receiving both injections and surgery. Although an indirect measure, these data do not seem to support the assumption that providing more injection services will reduce the need for spine surgery. The extensive geographic variation also seems to indicate a lack of consensus on treatment paradigms and has frequently been cited in other areas of medicine as indicative of a problem with our health care delivery system.

CMS and a number of other large payors have identified some of these issues as problematic. In its model of value-based purchasing, CMS directly refers to the problem of geographic variation in medical care, the need for transparent reporting of quality measures, and the avoidance of unnecessary services [16]. Given all of this, presenting an argument that “physicians know best” and should be allowed to treat as they individually see fit might appear inconsistent with the literature and likely will hold little weight in evidence-based discussions of treatment coverage.

Getting back to Mr. Payne, perhaps a more thorough understanding of this individual is in order before considering interventional approaches. Specifically, an exploration of his psychosocial history and the treatment offered to date may be more helpful than placing a needle in his spine. Unlike some of the disagreements noted in the literature on spinal injections, the literature on the importance of psychosocial variables in the presentation of those patients with CLBP is very consistent. A number of factors such as fear-

avoidance behavior, catastrophizing, depression, anxiety, specific work-related factors, and a number of others pertaining to the social history and belief systems of an individual with LBP are of profound importance. These factors have been consistently shown to affect the transition to chronic pain and to be important in the disability associated with that pain [2-4].

Although this patient has participated in physical therapy, it may be helpful to explore the details. Some might consider Mr. Payne’s failure to respond to “core stabilization exercise programs” an adequate trial of rehabilitation given the prominence of this exercise approach in our current clinical environment. However, core-stabilization exercises have been shown to be no more effective than other less-specific activating treatment approaches may not be the “be all and end all” of a rehabilitation program [17,18]. It has been suggested that the actual benefit to a number of exercise approaches for those with CLBP may largely be attributed to their effect on fear-avoidance behavior [19]. Perhaps a better understanding of our patient’s beliefs as they relate to his injury, pain, and treatment and a re-exploration of an alternative activating treatment paradigm may be helpful for him, hopefully resulting in minimizing fear-avoidance beliefs, improving function, and a establishing a locus of control within the patient. Furthermore, treating his chronic pain may also involve addressing concurrent problems of depression and sleep disturbance

In the case presented, I would advocate pursuing a more extensive and appropriate history before proceeding with additional treatment or even providing further recommendations. It is highly likely that we will be able to identify pertinent psychosocial factors, a sleep disturbance, an unsatisfactory view of his previous physical therapy, a lack of compliance, depression, or any of a number of other issues that may lead us to the development of a more appropriate treatment protocol. The likelihood that one or more of these factors underlies the patient’s pain presentation would appear to be many times greater than the chance that he will be in the extremely small percentage of patients with LBP who respond favorably to RFN, for example. There are many other options in terms of medication, cognitive-behavioral care, exercise, and education (all of which have documented efficacy and are noninvasive) to address the true issues underlying the patient’s pain, suffering, and disability.

As for the insurance company’s stance on any further interventional care, I would let it stand for now and would explore other choices. Given the literature described above, a counter-argument to the insurer based on the perceived “medical necessity” for interventional care in this patient at this point in time would appear to be relatively weak. There may also be some importance to saving argument or confrontation for a time when there is a clear clinical imperative and a strong foundation of evidence. There is certainly a need for further care and investigation in this patient, but the primary option does not appear to be interventional. If a number of the other factors above can be addressed and a more focal interventional approach appears to offer a reasonable chance

of improving the long-term outcome, an appeal could be made, at that point, with a more clear indication as to the role of proposed treatment.

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Drs. Brand, Ky, and Christo Rebut

The overall impression from the literature on spinal injections for CLBP is simply inconclusive rather than nonsupportive. No single approach has demonstrated definitive superiority, and much of the current evidence base is criticized for serious methodologic and technical deficiencies, lack of RCTs, and insufficient or conflicting research, thus making evidence-based selections of one treatment over another nearly impossible. Although the most recent Cochrane Review on interventional care for subacute and CLBP indeed concludes that “there is insufficient evidence to support the use of injection therapy in subacute and chronic low-back pain,” it also states that “it cannot be ruled out that specific subgroups of patients may respond to a specific type of injection therapy” [1]. Psychological intervention is certainly appropriate with this case. However, that does not preclude the need for precise diagnosis. If Mr. Payne happens to be in the subgroup of individuals with CLBP with proven facet-mediated pain, he may be eligible for evidence-proven interventions such as RFA.

Furthermore, the Cochrane authors recommend “well designed RCTs with homogenous patient populations, a clear target condition, a clear-cut treatment rationale, and a sufficiently long follow-up period” [2]. Although this systematic review of facet interventions did not explicitly include a conclusion statement regarding the efficacy of neurotomy,

the authors noted that inaccurate operative technique used in systematic reviews and RCTs of RFA precluded a legitimate test of RFA. Furthermore, with proper patient selection, controlled diagnostic blocks, and anatomically accurate RFA technique, efficacy data indicate that 80% of patients can obtain $\geq 60\%$ relief of pain, whereas 60% of patients can obtain $\geq 80\%$ relief lasting ≥ 12 months.

Although increased expenditures for spine care are concerning, data on use [3,4] must be cautiously interpreted. Although 63% of facet injections audited from 2006 did not meet Medicare program requirements, this number is misleading because only 8% of them were determined to be errors of medical necessity. The majority were errors in documentation (38%) and coding (31%), for which the Office of the Inspector General for CMS recommended that CMS assist carriers to strengthen safeguards such as automated edits and to clarify complicated billing instructions [5].

To manage increasing numbers of patients without increasing health expenditures, it will be necessary to become more efficient. The principle of *primum non nocere* dictates that algorithms must use the least-invasive (often the least-expensive) treatments available first, advancing to more interventional approaches as necessary. Spinal injections must be maintained as a treatment option for the appropriate patients.

Interventional options may not be termed a “medical necessity” by the insurance industry, but they certainly provide valid diagnostic and treatment options. In the spirit of cost containment, it is standard of care to exhaust less-expensive and less-invasive options before advancing to more focal, interventional approaches.

In the case of Mr. Payne, it would be reasonable to assume that the insurance company has not preapproved his interventional treatment because it has a relatively expensive up-front cost. Future noncoverage decisions on interventions that have relatively strong evidence, such as RFA [6], threaten to stymie further research on interventional procedures.

Proactive medicine, as opposed to reactive medicine, must be promoted to provide effective health care. Preventive health measures such as promoting exercise in schools and programs such as “Exercise is Medicine™” (through the American College of Sports Medicine [7]) encourage a new paradigm of exercise prescription that can occur with every patient encounter. Indeed, physiatrists are uniquely positioned to extol the virtues of exercise prescription. This may ultimately serve to minimize situations such as that of Mr. Payne. For instance, if he had engaged in more conditioning before fixing his fence, it may not have resulted in a back injury. Unfortunately, however, there also remains little evidence that exercise prevents the development of LBP. There-

fore, in addition to proactive health promotion and preventive health, physiatry must promote continued research including subgroup analysis and the development of standardized protocols relating to both procedural techniques and clearer treatment algorithms.

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Dr. Standaert Rebutts

I appreciate the extensive comments of Drs. Brand, Ky, and Christo regarding the application of interventional care options in the case of Mr. Payne. However, in the context of a patient with chronic pain, it is my opinion that their discussion glosses over the importance of the individual's psychosocial factors and places a greater value on the literature regarding spinal interventions than may be warranted. Given this, I disagree with the framework of their clinical approach to Mr. Payne. There is not a high likelihood that “procedures” will provide Mr. Payne substantial and sustained pain relief and improved function. Specifically, further discussion regarding the utility of medial MBBs and RFN for lumbar facet joints is warranted.

Although specific lumbar facet joint interventions have some substantiating literature regarding their use in the treatment of LBP in highly selected patients, I do not believe the findings are as robust as has been suggested. The evidence that intra-articular injections can provide lasting relief of pain in patients with non-specific LBP is sorely lacking. Although there are better data on lumbar RFN, this is also relatively thin. In 2003, there were 2 systematic reviews published on this topic. One was a Cochrane review that noted conflicting evidence for the effectiveness of RFN in the lumbar spine [1]. The other review, by Slipman et al [2], concluded that “current studies fail to give more than sparse evidence to support the use of interventional techniques in the treatment of lumbar zygapophyseal joint-mediated LBP.” A more recent evidence-based review [3] of spinal interventions published

in 2009 found the evidence insufficient to reach any conclusion on the efficacy of RFN in LBP. There is only one published randomized, controlled trial of RFN in LBP that uses a controlled double block protocol and multiple RF lesions along the nerve [4]. This study by Nath et al [4] randomized 40 patients and compared within-group differences for multiple outcomes. Although the authors identified some areas of relatively increased improvement in the treatment group (not for LBP, however), the study has methodological issues that significantly limit its applicability, including a diverse patient population, inadequate randomization given the apparent differences between the treatment and control groups, and an inability to compare the final scores between groups (which were actually almost identical for overall pain and LBP).

Also, this study began with almost 400 patients undergoing MBB, ultimately identifying 40 for randomization. Similarly, the observational study by Dreyfuss et al [5] screened 460 respondents to identify the 15 who ultimately underwent RFN. Given these statistics, I find the number needed to treat of 1.1-1.5 quoted by Drs. Brand, Ky, and Christo for this procedure to be misleading. Clearly the number needed to treat would be much less favorable in the study of Nath et al [4] if all patients undergoing MBBs were included. Given the results from their study, Dreyfuss et al [5] actually concluded: “the results of the current study, however, sound a warning against the wholesale implementation of lumbar medial branch neurotomy” (p1276).

Overall, the literature supporting the use of RFN in the management of CLBP is at best limited. Even the small amount of positive data that is available applies to such a highly selected subset of patients with LBP that its applicability to the general population of patients with chronic nonspecific LBP is questionable. If one accepts the commonly described prevalence of lumbar facet joint-mediated pain to be 15% of all those with CLBP, then one could reasonably extrapolate that the number of patients expected to have substantial relief of their LBP from RFN would ultimately represent a low single digit percentage of *all* patients with CLBP.

The literature on interventional care, including RFN, must be compared with the far more extensive body of literature supporting the role of depression, psychological distress, fear avoidance, and a number of other psychosocial variables in the occurrence and reporting of LBP, as well as the transition from acute to chronic spinal pain [6-8]. If we don't embrace this salient point, and don't consistently take an appropriate history regarding these issues and act upon the relevant factors identified, we will overuse interventional care, drive up costs, expose patients to the risks associated with interventions, and continue to "medicalize" a much more complex biopsychosocial problem. This will both keep patients from accessing care appropriate for their problems, and alter the insurance and reimbursement landscape as payers are clearly having difficulty discerning the true value of interventional care. In fact, this may be what is already happening regarding coverage of facet procedures as payers assess the rapid rise in use in the absence of data showing widespread benefit. RFN should only be considered in the very small minority of patients with LBP who have been appropriately treated and extensively screened for other issues that may be contributing to their pain, suffering, and failure to respond to care.

Going back to Mr. Payne, I believe that it is inappropriate to advocate an approach based entirely upon an optimistic

interpretation of a narrow aspect of the literature that may be completely detached from the individual presenting for care. The next logical step for treatment for someone with refractory, ill-defined, CLBP should not be to consider what else we can do *to* the patient. Rather, we should consider the person and try to understand why nothing to date has worked, and why he or she continues to suffer. There is certainly a role for interventional spine care, but to use it effectively we have to move away from the concept of chronic pain as a "thing" that we can remove, inject away, or ablate, and instead, pay closer attention to the entire individual presenting with pain.

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