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## CME / CE Information

**CME/CE Released: 09/02/2010; Valid for credit through 09/02/2011**

### Target Audience

This activity is designed for physicians, psychologists, nurses, pharmacists, and other healthcare professionals and research scientists interested in the evaluation and management of chronic low back pain, including those specializing in pain management, anesthesiology, rheumatology, psychiatry, neurology, and internal medicine.

### Goal

This activity will bring together clinical and research experts to review and discuss the evaluation, treatment, and prognosis of patients presenting with low back pain. The activity will consist of 3 lectures and a question and answer session to provide an in-depth and comprehensive discussion of the epidemiology, disparate etiologies, and clinical assessment of both acute and chronic low back pain. Evidence-based treatment strategies, including pharmacologic and nonpharmacologic therapies, and the evolving research into early interventions for patients at high risk for transitioning from acute low back pain to chronic low back pain will also be presented.

### Learning Objectives

Upon completion of this activity, participants will be able to:

1. Discuss the differential diagnosis for low back pain and the importance of clinical red and yellow flags in evaluation of low back pain.
2. Integrate evidence-based pharmacologic and nonpharmacologic therapies into a comprehensive treatment plan for chronic low back pain.
3. Evaluate early interventions for acute back pain in patients considered at high risk for transition to chronic low back pain.

### Credits Available

**Physicians** - maximum of 1.50 *AMA PRA Category 1 Credit(s)™*

**Nurses** - 1.50 *ANCC Contact Hour(s)* (1.5 contact hours are in the area of pharmacology)

**Pharmacists** - 1.50 *ACPE Contact Hour(s)* (0.150 CEUs)

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All other healthcare professionals completing continuing education credit for this activity will be issued a certificate of participation.

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### Accreditation Statements

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**This activity is supported by an educational grant from Lilly USA, LLC.**

## Authors and Disclosures

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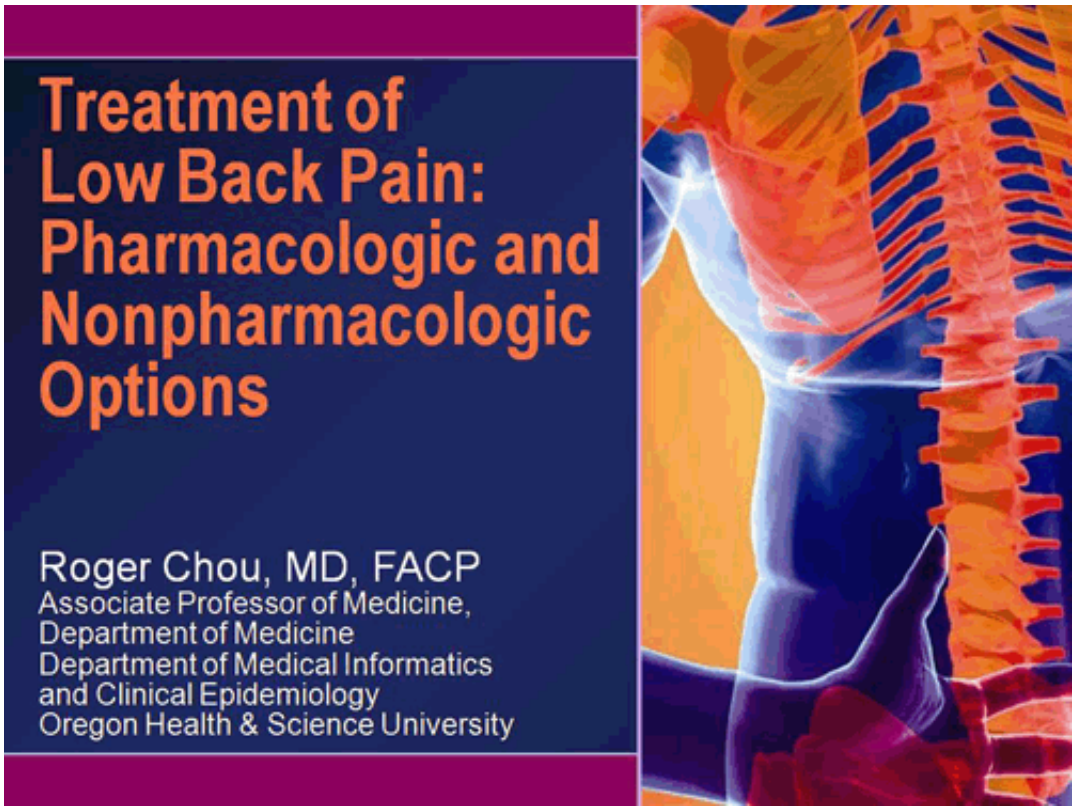
Dr. Chou has disclosed that he has no actual or potential conflict of interest in regard to this activity. His presentation will include off-label discussion of anticonvulsants, benzodiazepines, and tricyclic antidepressants for the treatment of low back pain.

# Treatment of Low Back Pain: Pharmacologic and Nonpharmacologic Options CME/CE

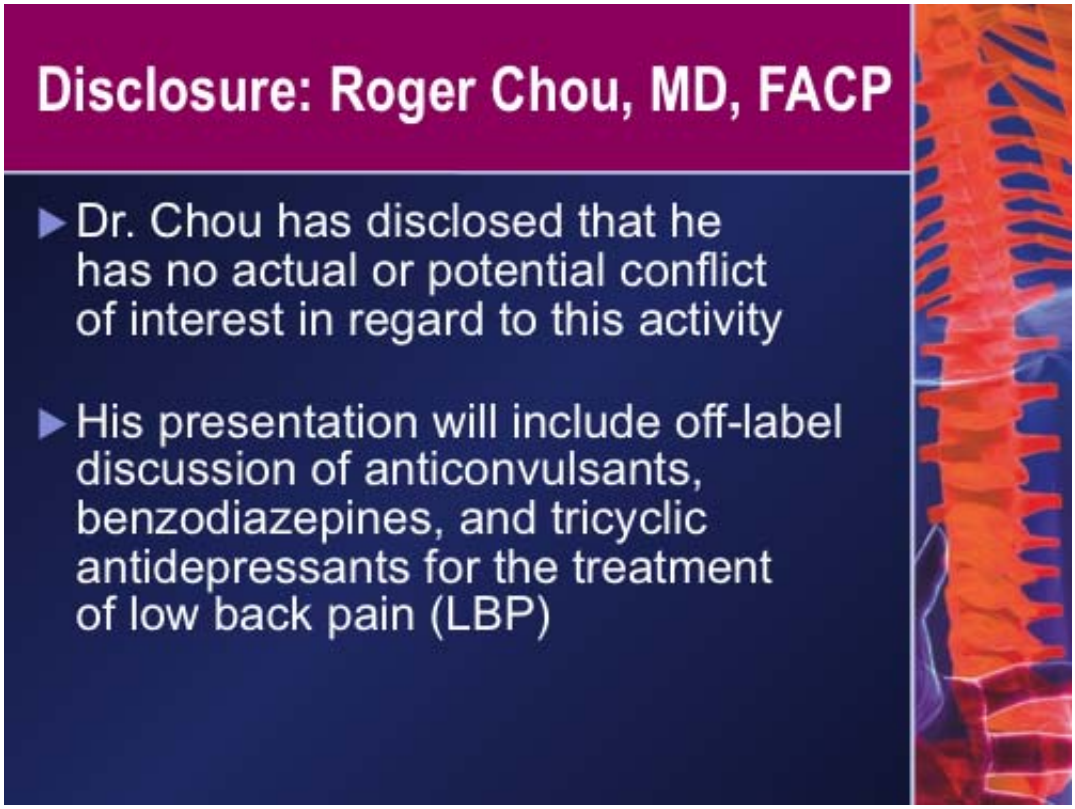
Roger Chou, MD, FACP

Posted: 08/09/2010



**Slide 1.**

Thanks, Barry. I'll be talking about different treatments for LBP, of which there are many, as most of you in this room know.



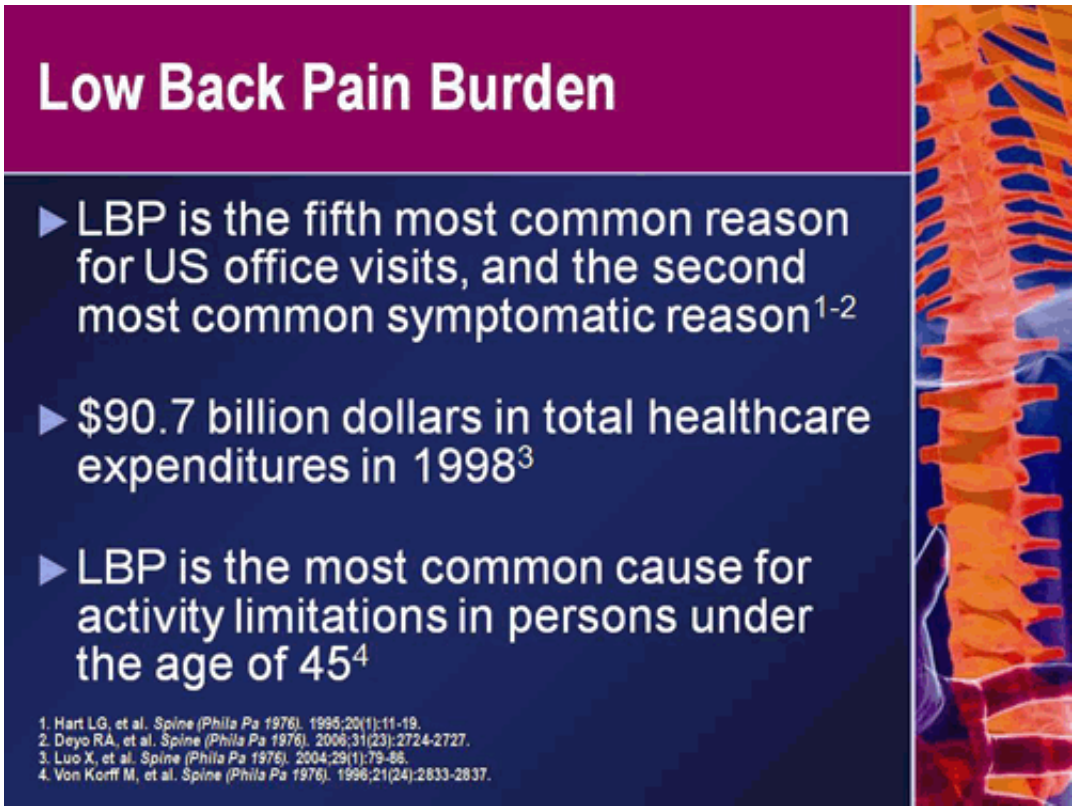

**Slide 2.**

This is the conflict of interest disclosure. I don't have any conflicts to disclose. I will be discussing tricyclic antidepressants, benzodiazepines, and anticonvulsants, none of which have been approved for treatment of LBP.


**Slide 3.**

We'll be trying to integrate the evidence-based pharmacologic and nonpharmacologic therapies and to how you

treat a person with LBP. This builds from the idea of how you evaluate someone and then subsequently treat them.

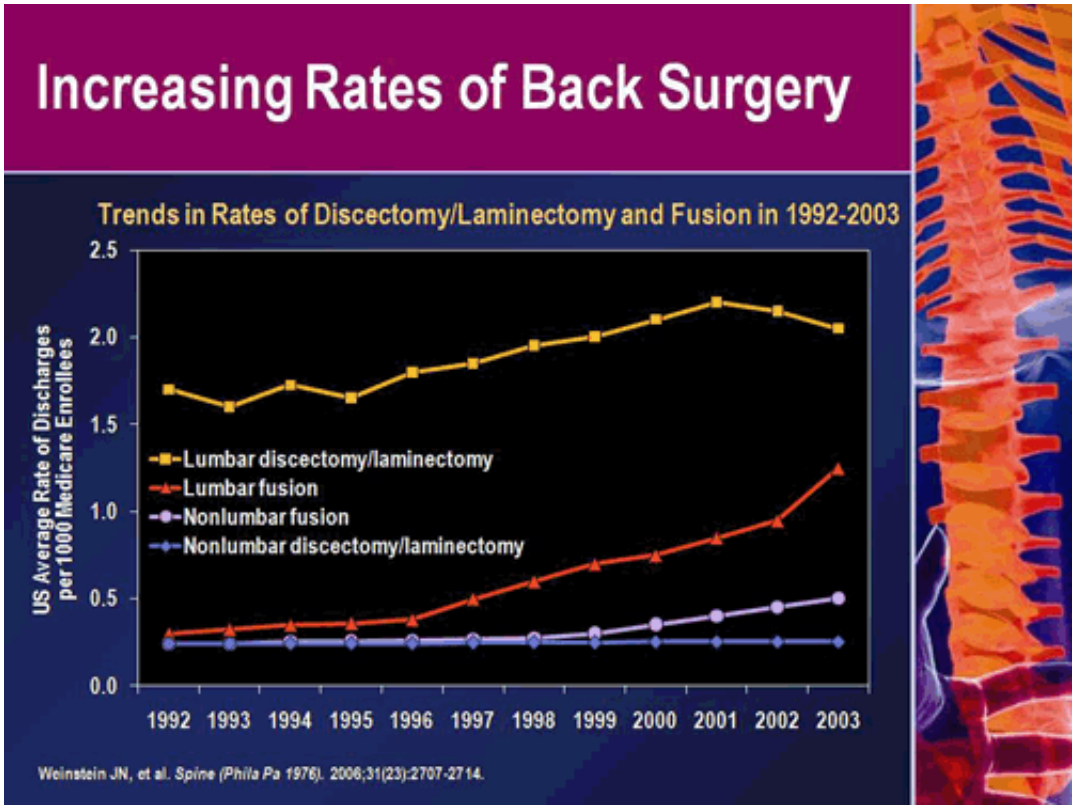



**Slide 4.**

Barry already started talking about the burden of LBP, which we all know is extremely high. Back in the 1990s, it was shown that LBP is the second most common reason for going to the doctor—the second most common symptomatic reason, I should say—number 1 being simple upper respiratory infections (URIs). A recent study by Rick Deyo and his group shows that that's still the same; it's still the second most common symptomatic reason for office visits. The data that we've seen are that the costs are well over $100 billion now. These costs are from 1998, and I'll show you a slide in a second that shows how costs have changed.

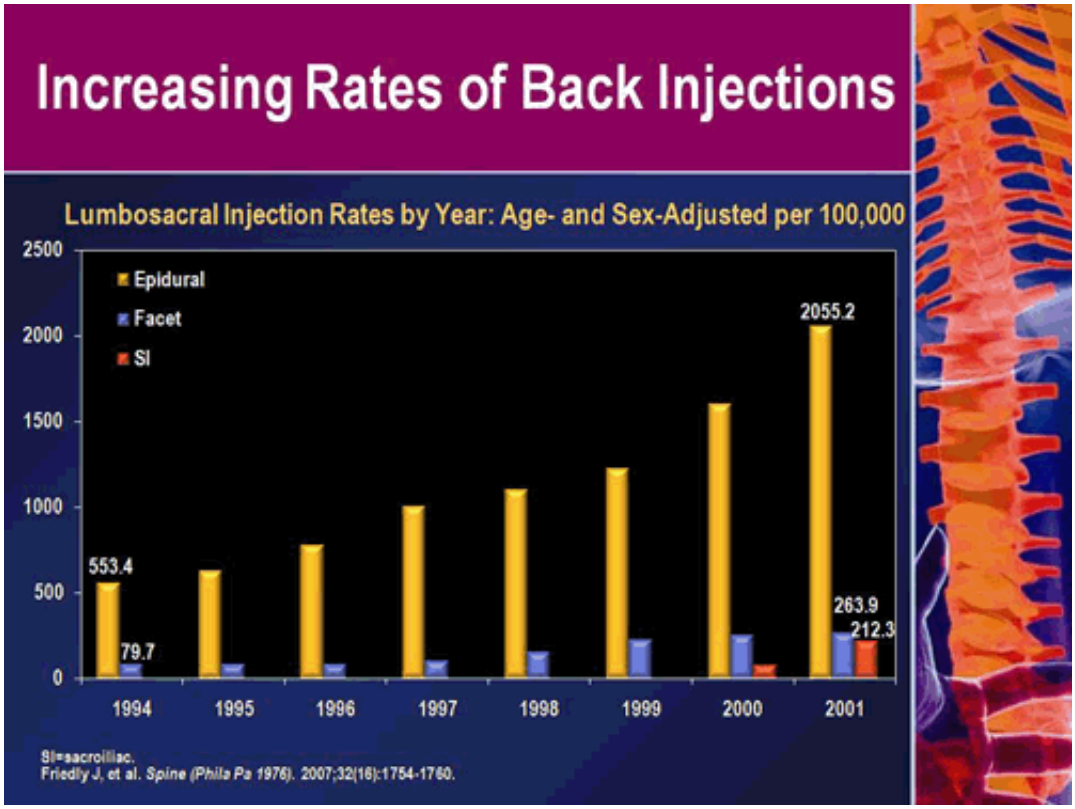
LBP is the most common reason for activity limitations in younger adults for disability, and the costs of not being able to work or being less productive at work because of LBP probably outweigh the direct costs.

## Increasing Rates




**Slide 5.**

This slide shows some of the patterns that are going on. So this shows rates of back surgery. The important line to look at is fusion rates. This shows that over about a 10-year period, rates of spinal fusion have gone up about 3-fold. The United States already started at doing about 5 times more back surgeries than the United Kingdom, and about twice as many as other developed countries. We remain in the front, and we continue to do more and more of these procedures. Fusion surgery, of course, is the most commonly done surgery for nonspecific LBP or radicular LBP, and it's often done with very expensive add-ons, like bone morphogenic proteins and instrumentation. Some of the billing data indicate that it is $50,000+ per surgery.



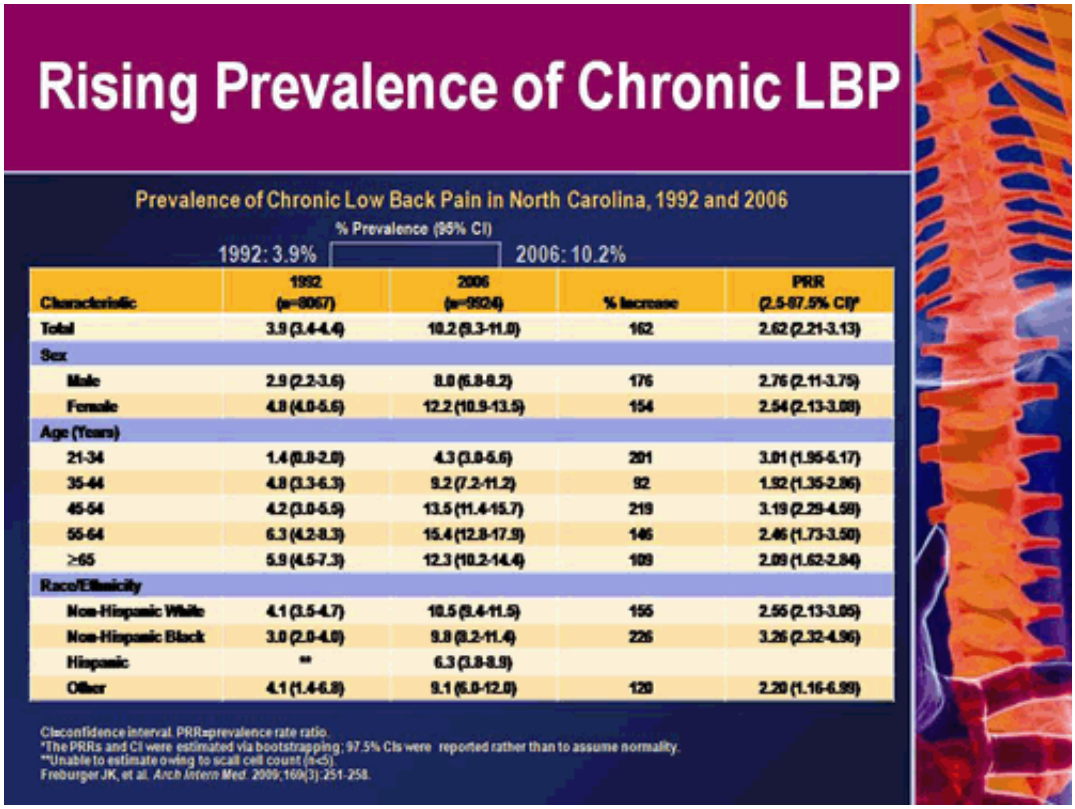

**Slide 6.**

This shows some of the patterns with different types of back injections. So, if you look at the the yellow bars, this is epidural steroid injections, which have gone up about 4-fold over a 10-year period. Facet joint injections have gone up about 3-fold; these bars don't look as impressive because they're smaller, but it's actually also about a 3-fold increase, so we're also doing many more back injections.

It's not necessarily a bad thing, of course, for people to be doing more surgeries or injections. The problem is we haven't been able to show that places where we do a lot more of these procedures, people actually do much better.


**Slide 7.**

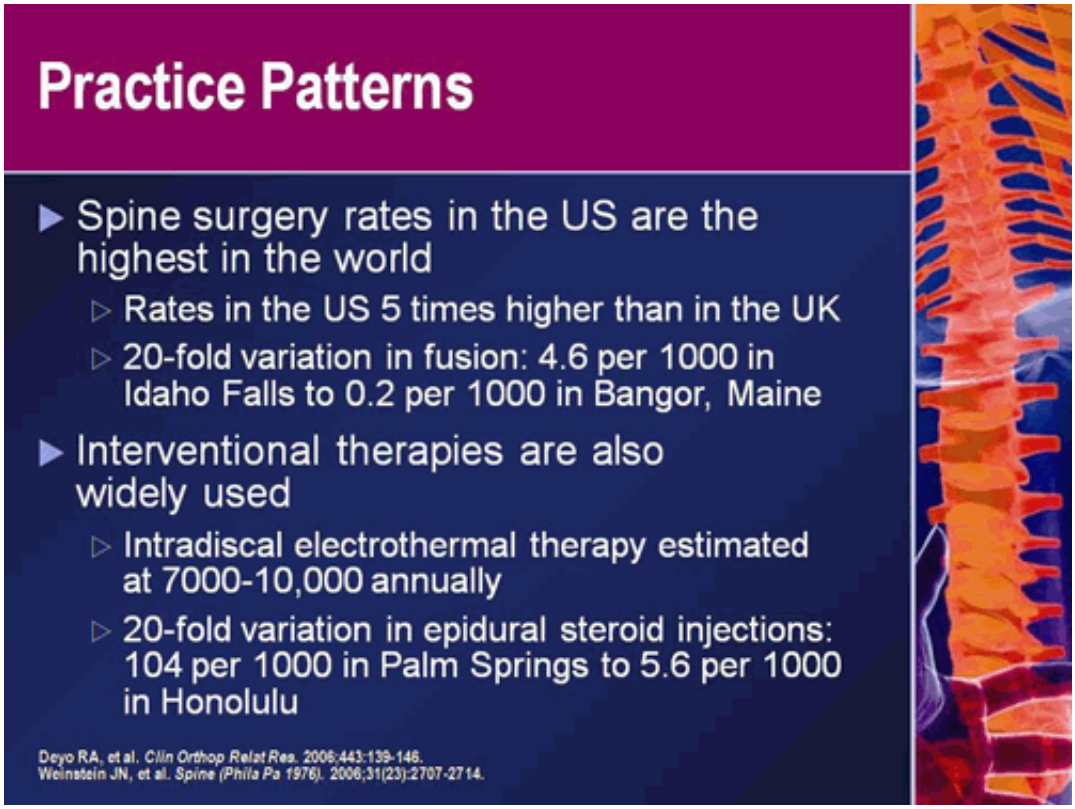
We're also spending more on LBP, so this shows the cost associated with LBP. There's been about a 50% increase in cost per person over a 10-year period.




**Slide 8.**

This slide shows the results of a survey. The important numbers are this top one here and this one over here. This was a survey performed in North Carolina adults in the community. They asked adults whether they had back pain that was interfering with their activities. In 1992, about 4% of the survey persons said they did. In 2006, that's more than doubled; it's now about 10.2%. So, it looks like we're not making progress, and if anything, the situation looks like it might be worse now than it was 10 or 14 years ago.

**Practice Patterns**



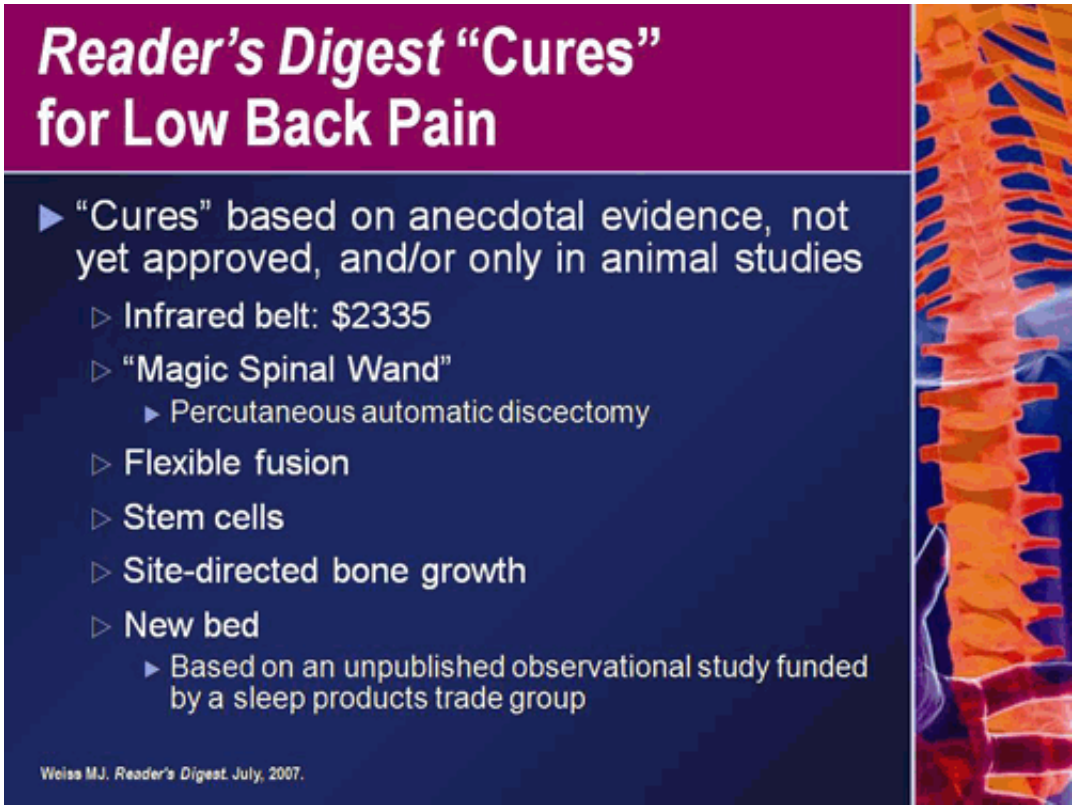

**Slide 9.**

We've seen huge variations in practice patterns. Spine surgery rates, as I said, are the highest in the world. They are 5 times higher than in the United Kingdom and at least twice as high as other countries, and we see huge variations even within the United States, where you see a 20-fold variation in fusion rates just depending on where you live. These aren't explainable by patient characteristics, so if you live in Idaho Falls, you're much more likely to undergo a fusion surgery than if you live in Bangor, Maine. The problem is that if you live in Idaho Falls, it doesn't look like you actually do all that much better as a result of all these surgeries.

Interventional therapies are also widely used, and we're also seeing these huge practice variations. The issue with practice variations and why they are a concern is because they indicate areas where practice appears to be haphazard or it may be arbitrary. It's not necessarily that these are often signals that people are providing practice that isn't based on science necessarily.


**Slide 10.**

Guidelines are important, so there's a lot of misleading information out there that readers that have access to. This is an article that came out in *Reader's Digest* about 3 months before our guideline came out. The front cover screams "New Cures for Low Back Pain: End Your Back Pain Agony."




**Slide 11.**

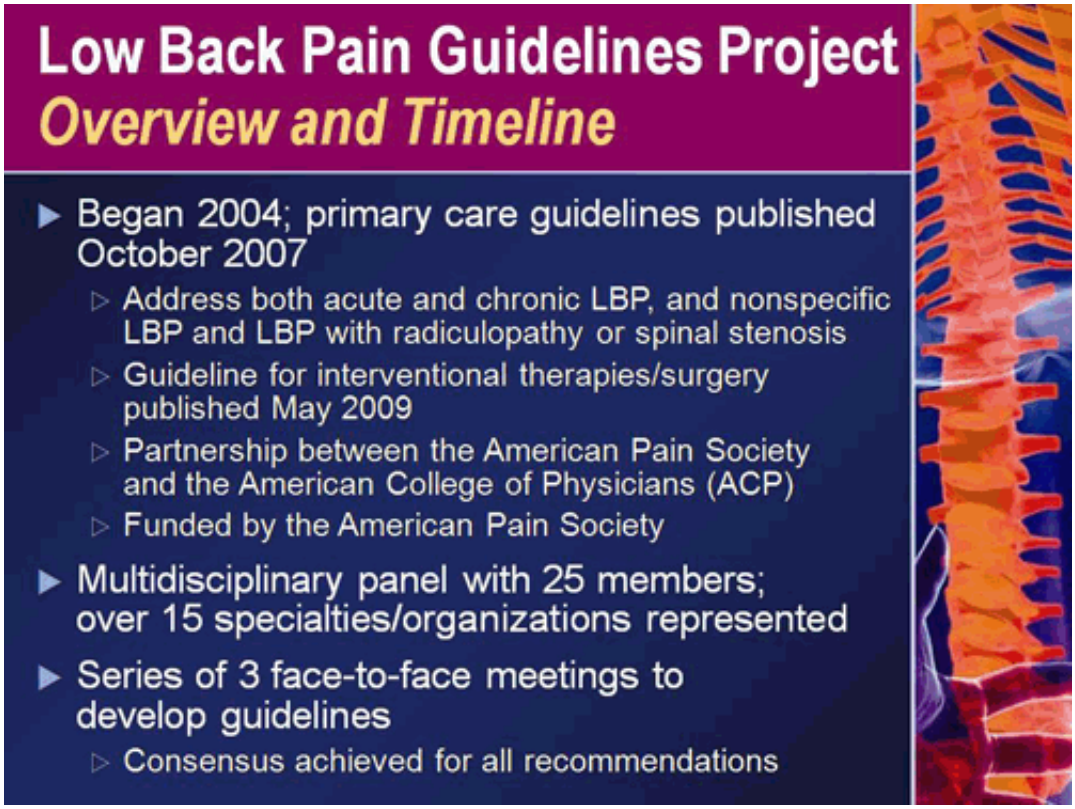
So, let's look at some of these cures. The first one is an infrared belt—not approved by the FDA and, oh by the way, we think it's going to be about 2300 bucks. The next one is what they call the Magic Spinal Wand. So this comes from the "Hogwarts School of Medical Devices." It's really percutaneous automatic discectomy, which doesn't sound as good as a Magic Spinal Wand, but that's a procedure that you know was touted as an alternative to microdiscectomy and standard open discectomy. It's largely been abandoned because it hasn't been shown to really offer any advantages and might actually be a little bit worse.

Flexible fusion, stem cells, site-directed bone growth: these were the next 3 "new" cures that were listed in this article. None of these are approved in people. So, if you're a mouse or a rat with LBP then maybe you're in luck if you can get into one of these studies. But, if you're a person, it's not really very helpful.

And, the last one was just get a new bed, right? And, this is based on an unpublished, uncontrolled observational study, and what they quoted was a sleep-products tradesperson. So, not what I would call reliable evidence.

So, you know, however many millions of people read *Reader's Digest,* this is the kind of information that is out there, and it's out there in other forms as well.

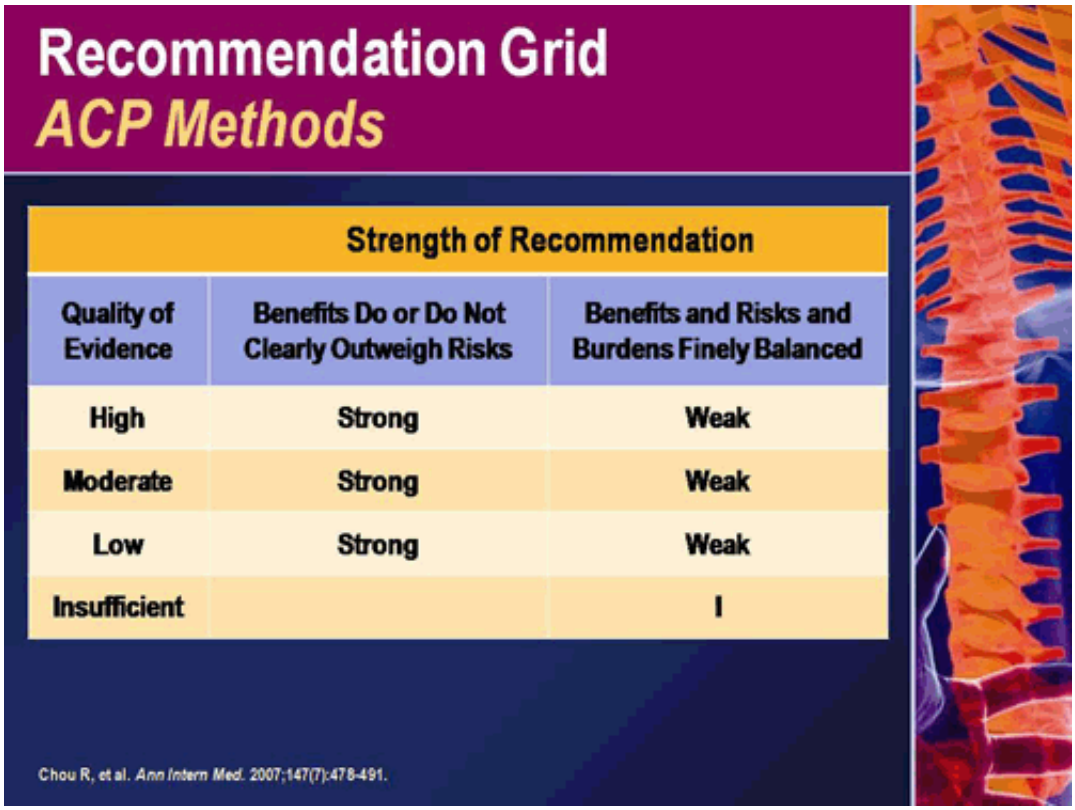
**Low Back Pain Guidelines Project**




**Slide 12.**

The Low Back Pain Guidelines Project began in 2004. We published our primary care guideline in October 2007 in *Annals of Internal Medicine.* It's actually the second most downloaded article ever in *Annals of Internal Medicine.* We had a second piece of this on interventional therapies and surgery that was published in May 2009, in the journal *Spine.* This is a partnership between the APS and the ACP; it was funded by APS.

We assembled a large, multidisciplinary panel with 25 members that ranged anywhere from primary care to surgery to interventional therapy, psychology, chiropractic, etc. We had a series of 3 face-to-face meetings to develop the guidelines, and we actually achieved consensus on all the recommendations, which is pretty remarkable when you think about getting 25 pretty well known experts in their fields all coming from different perspectives in the room. It's like herding cats, but we were able to do it.



**Slide 13.**

This just shows how we grade the recommendations. So you'll see that Barry already showed you some recommendations, and I'll show you some more. But we basically grade the recommendations as strong or weak, and then we also grade the strength of the evidence supporting the recommendation. If you see a strong recommendation, we think that that means that in the judgment of the panel, the benefits clearly do or they clearly don't outweigh the risks. If it's a weak recommendation, this means that they think that the balance of benefits-to-harms is not as strong.

The reasons why a recommendation can be weak is if the evidence isn't as strong, if the benefits aren't large, or if there are significant harms, or costs, or burdens associated with the procedure. The quality of the evidence gives you an indication about how certain to be in the evidence. When we say that we think something is based on high-quality evidence, this means that we don't think that if somebody publishes a new trial that that's likely to change the conclusions. We think that the estimate of the effectiveness is established. If you see a moderate or a low, this means that we don't think that that's quite as clear and that it's possible that new evidence could change that conclusion.

If we're saying something is based on insufficient evidence, that means that we really don't have enough evidence to judge whether something works or not, or to understand what the benefits relative to harms are.

**Principles of Selecting Therapy**


**Slide 14.**

Here are some basic principles for selecting therapy for LBP. As Barry alluded to, for most patients we're going to end up saying that it is nonspecific LBP. Labeling somebody with nonradicular LBP who doesn't have evidence of a specific cause, trying to say that they have degenerative disc disease or facet joint arthritis, or one of these other things, in most cases, really doesn't help inform therapy choices. We treat these patients the same, at least in the initial stages.

Most patients with acute LBP will improve regardless of which therapy is chosen. So, it doesn't help to say that their pain is coming from the disc or from the joint or from the muscles or something else, because they're going to get better regardless of what you say. For chronic LBP, therapies are only moderately effective, and I think it's

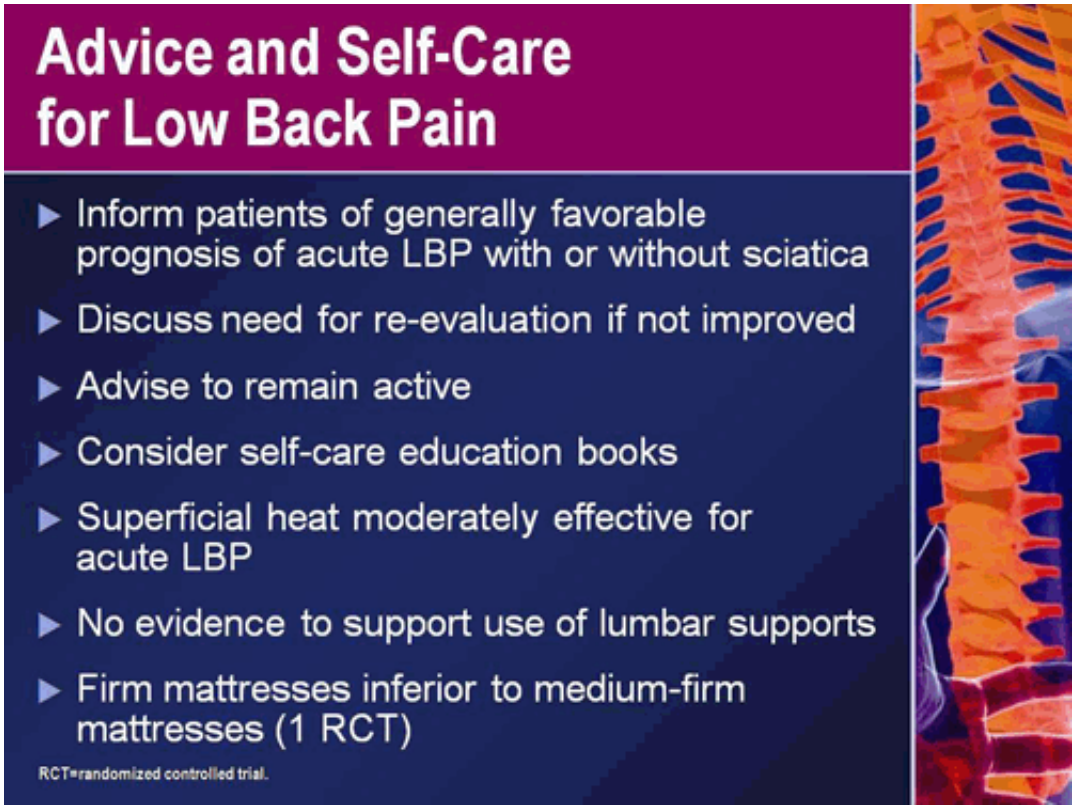
important to be upfront with patients about that to set realistic expectations. Patients tend to want you to take their back pain away completely. On average, what we actually see is people improve by about a point or 2. So, they go from a 7 or 8, and they maybe go to a 5 or a 6, that kind of thing.

Use interventions with proven efficacy. This sounds basic, but really the principle is if you've got a bunch of interventions that might work, you should focus first on things that are supported by better evidence. Noninvasive approaches seem to be the way to go for most LBP; it's hard to show that surgery and other interventional therapies add that much for most patients who have chronic LBP, so start at least with the noninvasive approaches. And again, as Barry alluded to and Bill will talk about some more, consider the psychosocial factors.

**Treatment of LBP: Self-care Options**


**Slide 15.**

The first recommendation on treatment addresses self-care options. I think Barry already mentioned this. But it's basically we think every patient should have this: provide patients with evidence-based information about their expected course, advise patients to remain active, and provide information about effective self-care options.




**Slide 16.**

Patients should be told that they have a generally favorable prognosis. You want to give people hope that they're going to get better just by natural history. This is true whether you have sciatica or whether you have nonradicular LBP. Discuss the need for reevaluation if not improved; you don't want to give patients the impression that they can go home and if their back pain doesn't get better they should just suck it up for another, you know, several months. You need to tell them when they need to come back.

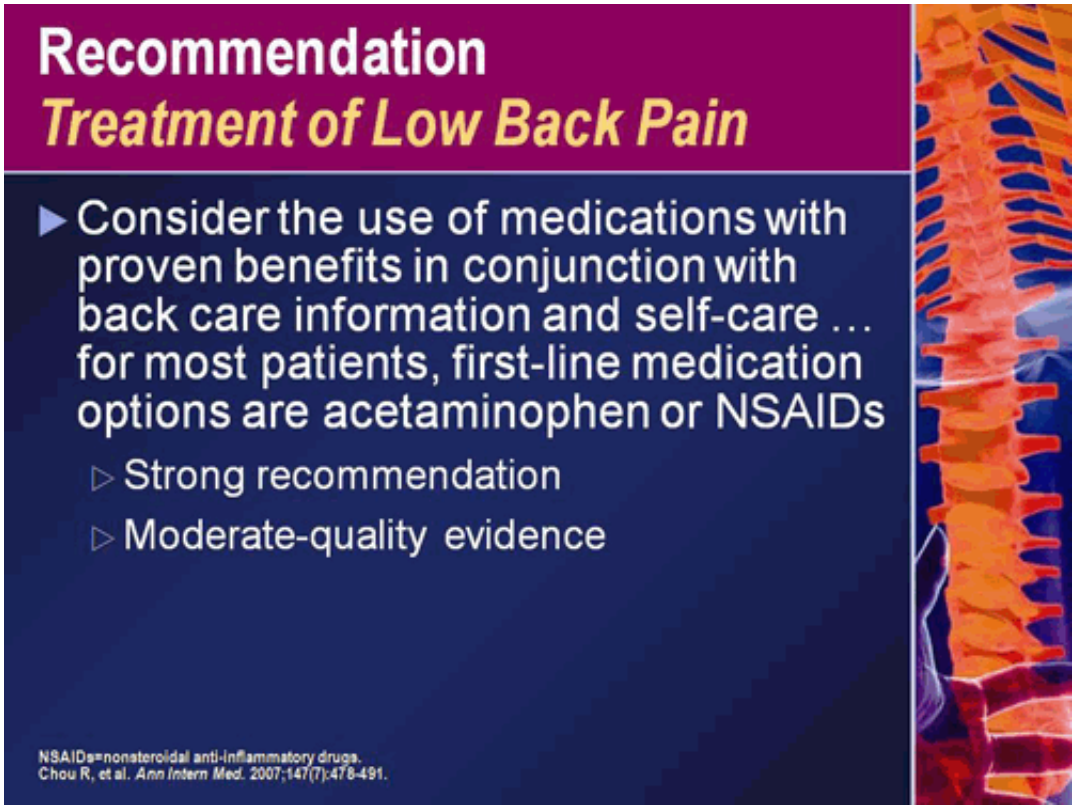
Advise patients to remain active; there have been a number of trials looking at bed rest vs recommending that people remain active, and they've consistently shown that if you remain active, you get back to work faster and the pain goes away faster.

Self-care education books can actually be a very useful supplement to information provided by the doctor. They're inexpensive, and there are some good ones out there, like *The Back Book*. And, there are other groups that are producing these things. So, there is always this concern about time, and this can be an efficient way to provide information without cos ting a lot of additional time.

Superficial heat is moderately effective for LBP. People always ask about cold, but we actually don't have good trials looking at whether cold works for acute LBP. Superficial heat actually seems to work even in the very hyperacute setting. One of the trials actually looked at people who called 911 because they had such bad back pain. Acutely, they put a warming blanket on the back and th ere was actually pretty good improvement.

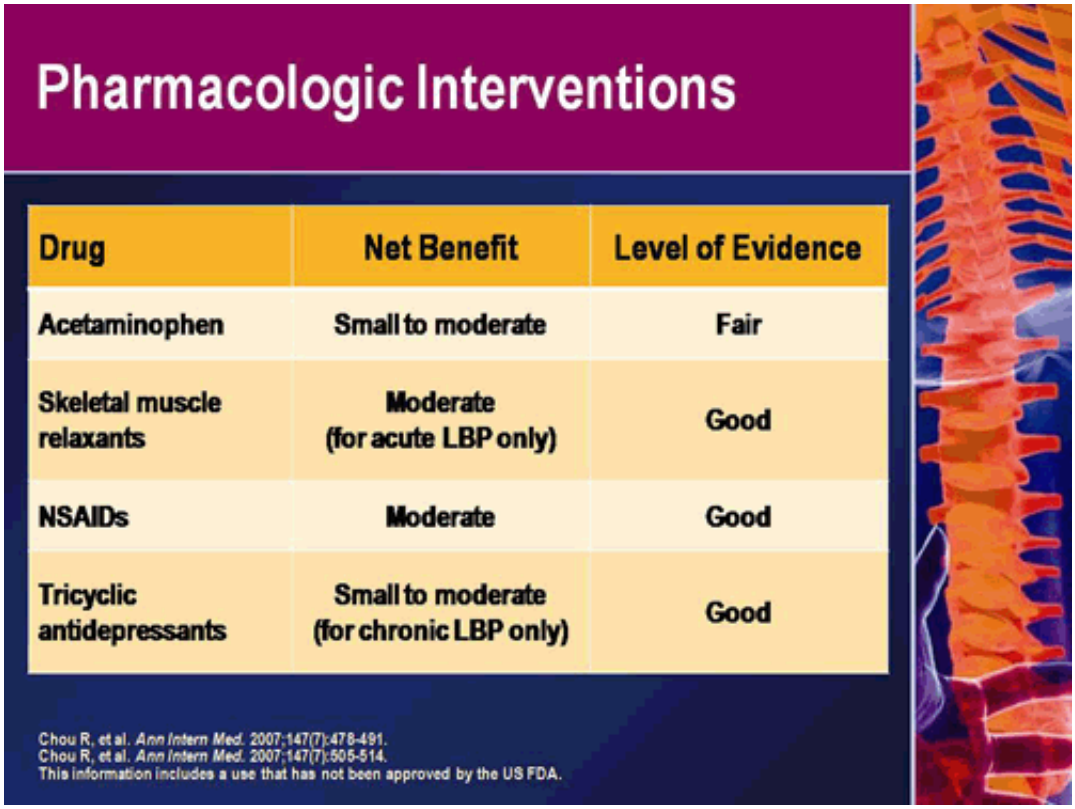
There's no evidence to support use of lumbar supports, which patients will often ask about, and now there are actually a couple of trials that have looked at very firm mattresses vs less firm mattresses, and the very firm mattresses actually don't seem to be as good, which may be different from what a lot of our perceptions are.

## Treatment of LBP: Medication




**Slide 17.**

The second recommendation addresses medications for LBP. It considers the use of medications with proven benefits in conjunction with back care information and self-care. For most patients, the first-line choices are going to be acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs).



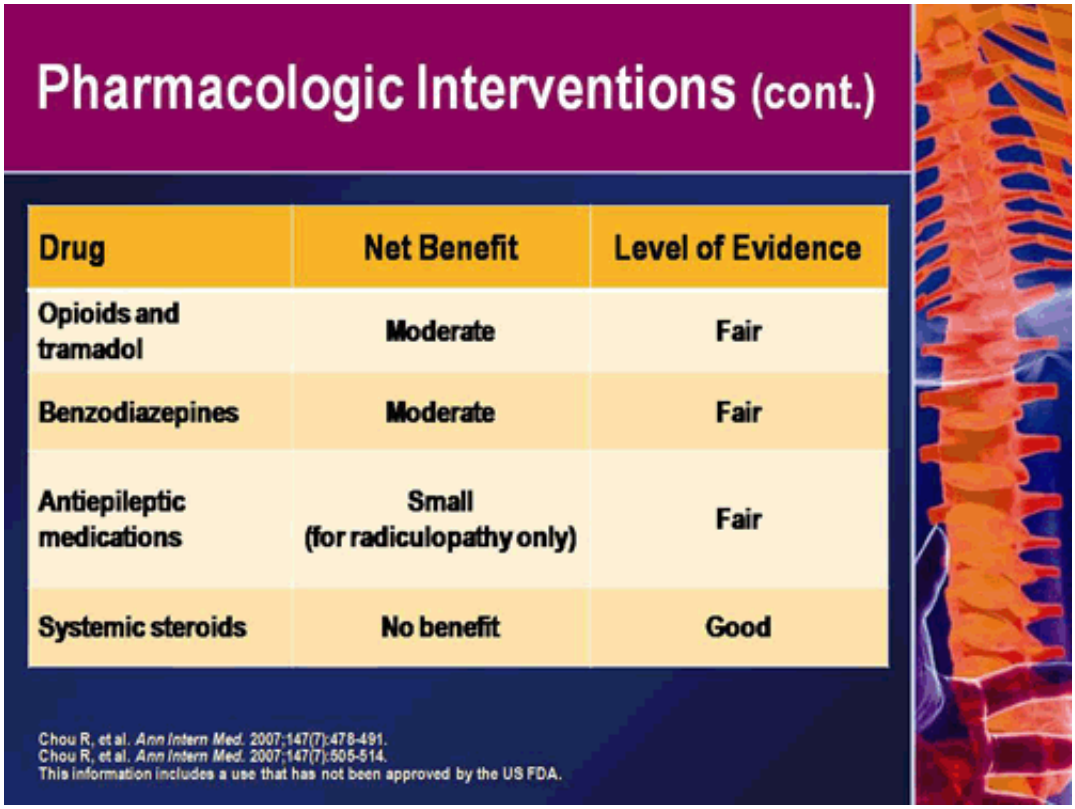

**Slide 18.**

This table shows our very basic summary of the evidence for various medications. As you can see for acetaminophen, the net benefit is not large. We rated it as a small to moderate—we're talking 5 to 10 points on a 100-point pain or function scale—and the evidence is actually only fair quality because there aren't that many studies for LBP. The reason it's rated as a first-line option is really a safety assessment; among the medications

it's still one of the safest medications provided you use it at the correct doses in the appropriate patients despite all the concerns about liver toxicity, etc.

NSAIDs look like they're a little bit more beneficial in terms of pain relief as an analgesic. And also, it's recommended as a first-line option because, despite the cardiovascular and gastrointestinal (GI) risks, it's still relatively safe with short-term use in appropriately selected patients. Skeletal muscle relaxants are associated with moderate benefit for acute LBP. They're not recommended as a first-line agent because they all cause sedation. Certain skeletal muscle relaxants have other issues, like carisoprodol is metabolized to meprobamate, which is associated with addiction and abuse. Carisoprodol is actually being taken off the market in the European Union because it's felt to have no advantages over other skeletal muscle relaxants and increased risks.

Tricyclic antidepressants are associated with a small to moderate benefit for chronic LBP. I think the key thing to remember about antidepressants in general is that many patients with chronic LBP have depression, and they're undertreated for it. One of the studies has shown that < 50% of patients with chronic LBP and depression actually are on any treatment for it at all.




**Slide 19.**

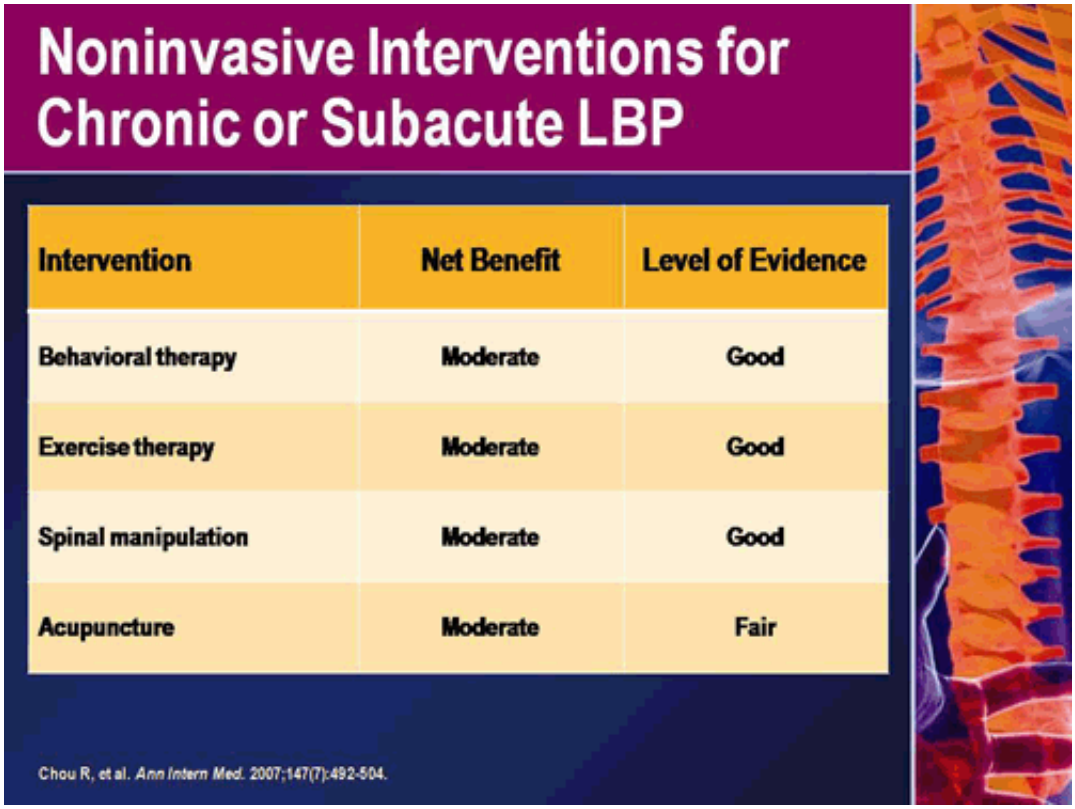
Opioids are not a first-line option. Obviously, they are associated with some benefit, but they obviously also have some issues in terms of abuse and addiction risk. Benzodiazepines are not approved for treatment of LBP but are actually used as skeletal muscle relaxants or an alternative to skeletal muscle relaxants, and they have similar issues to the skeletal muscle relaxants in terms of the sedative effects. And, of course, there is some addiction risk as well, or abuse risk.

Antiepileptic medications have only been evaluated for radiculopathy. The benefits are small and they have only been looked at in short-term trials, so it's hard to make a blanket recommendation about them at this point. Systemic corticosteroids are often still given for LBP, either with or without radiculopathy. There's no benefit from these drugs from a number of studies.

## Treatment of LBP: Nonpharmacologic Therapies


**Slide 20.**

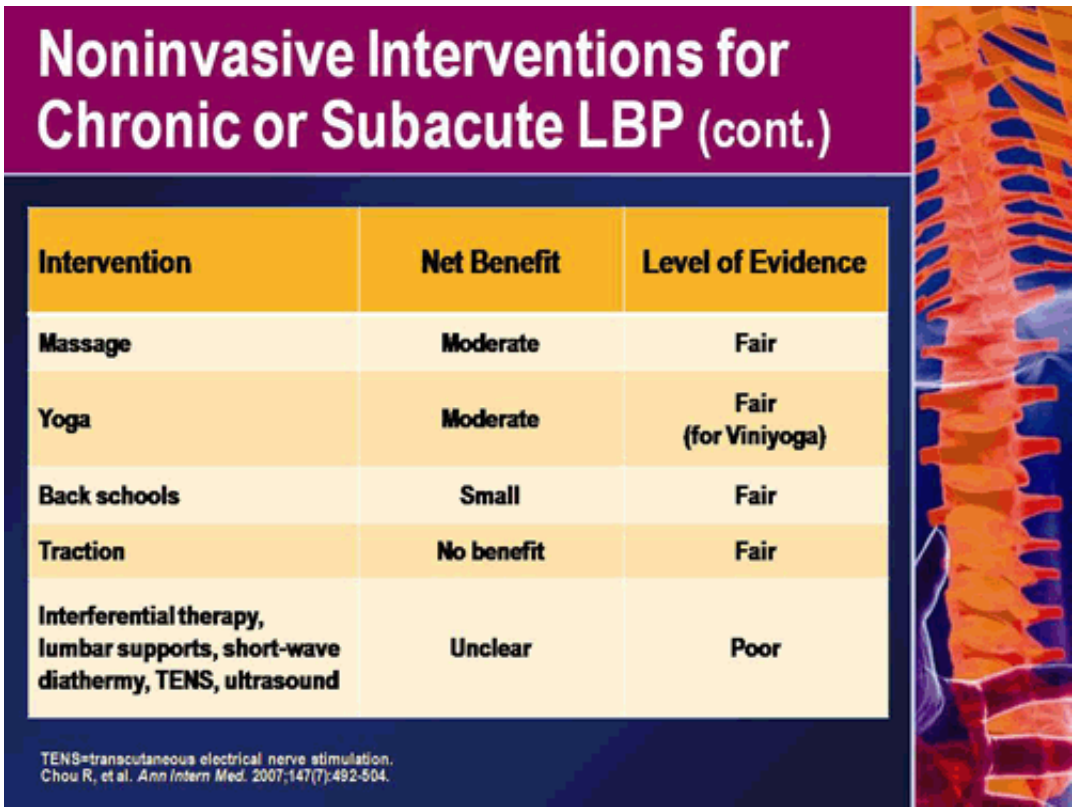
The next recommendation addresses nonpharmacologic therapies. For patients who did not improve with self-care options, consider the addition of nonpharmacologic therapy with proven benefits. For chronic or subacute LBP, options are intensive interdisciplinary rehabilitation, exercise, acupuncture, massage, manipulation, yoga, cognitive behavioral therapy, and progressive relaxation.




**Slide 21.**

So as you can see, there's a menu of things that seem to be similarly effective for LBP, mostly for chronic or subacute LBP. It's hard to show that these nonpharmacologic therapies work very well for acute LBP, probably because the natural history is so good in most people with acute LBP. It's hard to show that something improves

on that. Just a couple of notes on some of these interventions: for acupuncture, the quality of evidence is only rated as fair, and it's because what we see is that acupuncture is clearly better than no acupuncture, at least most of the studies have shown that. The problem is that acupuncture is not clearly better than just kind of randomly sticking needles into somebody, not into acupuncture points, and I think there's a lot of uncertainty or disagreement about how to interpret that.



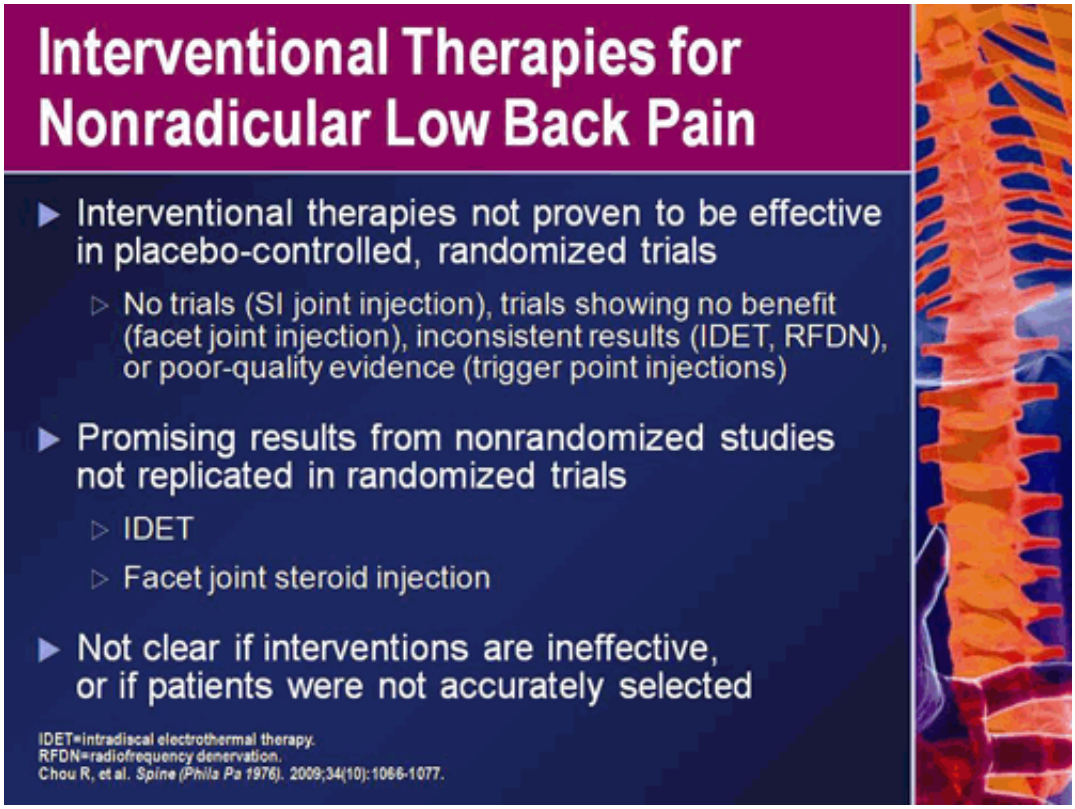

**Slide 22.**

For massage, the Level of Evidence is rated as fair because there aren't a lot of trials. For yoga, there also aren't a lot of trials yet, though it does seem to be similarly effective compared to exercise, etc. This bottom row here addresses what we often refer to as physical modalities—or most of those are physical modalities—and we really don't have enough evidence to estimate what the benefits and harms of those types of treatments are.

## Treatment of LBP: Interventional Therapies


**Slide 23.**

The first recommendation for interventional therapies is for nonradicular LBP. In patients with persistent nonradicular LBP, facet joint corticosteroid injection, prolotherapy, and intradiscal corticosteroid injection are not recommended. There's insufficient evidence to adequately evaluate the benefits of other interventional therapies for LBP.



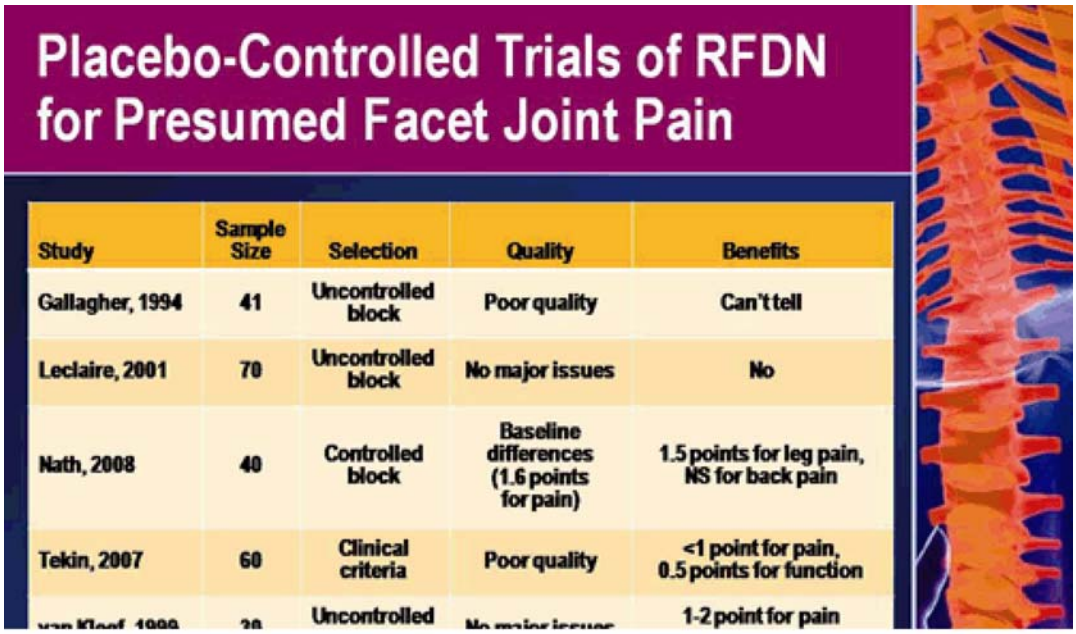

**Slide 24.**

Interventional therapies haven't been shown to be effective in placebo-controlled, randomized trials. We either have a situation where there's no trials, like SI joint injection; trials that have shown no benefit, like a facet joint injection; inconsistent results, like intradiscal electrothermal therapy (IDET) or radiofrequency denervation (RFDN);

or poor quality evidence trigger point injections. I will give an example of the evidence in the next couple of slides.

We've seen promising results from nonrandomized studies that have not been replicated in randomized trials. For IDET, for example, there was a nonrandomized, controlled study that showed that IDET was associated with a 4-point improvement in pain compared to no IDET. But when you actually do the randomized trials, you either get no benefit or 1-point benefit. So, the observational studies clearly are exaggerating the treatment effects.

It's not clear if the interventions are ineffective, or if patients were not actually selected. There's still a lot of uncertainty about how to identify somebody with facet joint pain or discogenic pain, and I think this is going to remain an issue. Are we able to properly select patients for these therapies?




**Slide 25.**

This shows the trials of RFDN. There are basically 6 trials out there and, as you can see, there are some issues.


**Slide 26.**

The trials that are highlighted here: this is poor quality, you can't make much of that; this one is also poor quality, so you can't make much of that either; and this study actually looked like it was designed pretty well except that when they did the actual RFDN, it looks like they went perpendicular to the nerve instead of parallel, and that's thought to be an inadequate ablation technique. So, most people would agree that you can't really make much of those 3 trials and kind of have to dump them.


**Slide 27.**

So, you're left with these 3 studies. The problem here is that this trial used uncontrolled block, and so did this trial, which many people in the interventional pain world think is inadequate for selecting patients now. One of

these studies showed no benefit, and the other showed a 1- to 2-point benefit. If you focus on the only trial that did a controlled block, you can see that there are big baseline differences in pain that were exactly equal to the effect that they saw for leg pain, which is not actually the main target of treatment for facetogenic nonradicular LBP. There was actually no effect for back pain.

So, this is why it's very hard to figure out what's going on with these procedures. You have very small trials with methodologic issues and inconsistent results. RFDN is actually—other than epidural steroid injection—the interventional therapy with the most evidence at this point.

## Treatment for LBP: Surgery

**Slide 28.**

The next recommendation is on surgery for nonradicular LBP. In patients with nonradicular LBP, common degenerative spinal changes and persistent and disabling symptoms discussed risks and benefits of surgery as an option. This is a weak recommendation.

**Slide 29.**

The benefits of surgery, namely, in most patients, fusion, is very dependent on the comparator. If you compare fusion vs standard nonsurgical therapy, the benefits are less than 15 points on a 100-point pain or function scale. So, there is some benefit; it is not what we would call large, but you get some benefit. There's no difference, however, when you compare surgery to intensive interdisciplinary rehab. The problem, of course, is that it is hard to get interdisciplinary rehab, or at least hard to get that covered.

All of the enrollees in these trials failed over a year of nonsurgical management and were not at higher risk for poor surgical outcomes. So, these were carefully selected patients, which is not always the case in real life. Fewer than half of patients who undergo surgery experience optimal outcomes—which we defined as relief of pain, return to work, and decreased analgesic use. So, we recommend basically a shared decision-making approach. The benefits aren't large. There are treatment options out there, but, in some patients they may have some benefit there. We certainly don't recommend it as a first-line option and really think that it's a minority of carefully selected patients who should undergo surgery.

## Options for Radicular LBP and Spinal Stenosis

**Slide 30.**

Interventional therapies for radicular LBP: in patients with persistent radiculopathy due to herniated lumbar disc, discuss the risks and benefits of epidural steroid injection as an option.

**Slide 31.**

The evidence on epidural steroid injections is that in some higher-quality trials, we are seeing short-term benefits, but the data are inconsistent. We think some of this inconsistency may be due to the comparator that's being evaluated in these trials, meaning that the trials that seem to show benefits are those that compare an epidural steroid injection to a soft-tissue injection; the ones that don't seem to show a benefit are the ones that compare an epidural steroid injection to an epidural saline injection. That raises the question of whether it's not the steroid at all that's doing the effect but just putting something into the epidural space or volume or space issue. Nobody's actually done a trial of an epidural saline vs nothing, so we actually don't know whether that's true or not. But, that idea has actually been around for many years.

There's been no trials consistently showing long-term benefits. We don't know what the best route is; transforaminal has become a very popular way of doing epidural steroid injections, but we don't actually know if that's better than traditional intralaminar route. There's limited evidence of no benefit for spinal stenosis; this

seems to be an increasingly used indication for epidural steroid injection. Because the benefits aren't small and they're relative short lived, again, we recommend a shared decision-making approach as a short-term treatment option.

**Slide 32.**

Surgery for radicular LBP and spinal stenosis: in patients with persistent radiculopathy due to herniated lumbar disc or persistently disabling leg pain due to spinal stenosis, discuss the risks and benefits of surgery as an option.

**Slide 33.**

Discectomy is associated with more rapid improvement in symptoms compared to nonsurgical therapy, but we actually know that patients improve either with or without surgery. If you have a herniated disc with radiculopathy, you get better with time. People improve by an average of 30 points. We don't see progressive neurologic deficits if you delay surgery or don't do it immediately, and you start to see the curves come together after about 1 to 2 years in a lot of patients.

Many of the trials evaluate standard open discectomy or microdiscectomy; those are the preferred approaches still, so again, we recommend a shared decision-making approach. Patients who really are not as worried about the surgical complications and risks and who highly value short-term improvements in pain and function are the ones for whom you might want to consider discectomy.

**Slide 34.**

For spinal stenosis, we see kind of the same pattern, except the improvements don't tend to be as great over time with spinal stenosis. If you just leave people alone, the natural history is not as favorable. You still see benefits of surgery, at least initially, and they do seem to start to diminish with long-term follow-up, but it seems to be more sustained than with discectomy for herniated disc.

## Summary

**Slide 35.**

So, in conclusion, the quality of evidence for different LBP therapies really does vary. We do have a number of therapies that appear similarly and moderately effective for LBP; those are the ones that we think should be prioritized when you're making treatment decisions. Guidelines can provide clinicians with the useful framework for choosing therapies. There are a number of factors that may affect your choices that include patient preferences, whether something is available in your setting, and the costs, etc.

We think shared decision-making is very appropriate for especially the more invasive therapies. We're talking bigger risks and relatively moderate or small benefits, and these are really situations where patients need to be accurately informed about the limitations and potential benefits before you do these things.

So, I think I'm going to hand this over to Bill McCarberg for the last presentation.

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2. Evidence-Based Evaluation of Patients With Low Back Pain [http://cme.medscape.com/viewarticle/726140]
3. Treatment of Low Back Pain: Pharmacologic and Nonpharmacologic Options [http://cme.medscape.com/viewarticle/726139]
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