

RALPH E. GAY: My name's Ralph Gay. I'm an associate professor in the Physical Medicine and Rehabilitation department. And my clinical life is spent in the Spine Center, and I'm Vice Chair of the reorganization that's going to be occurring in the Spine Center over the next few years, under the direction of Rick Marsh in Neurosurgery.

And when we started looking at the things that we need to start paying attention to, one is care pathways. But care pathways are largely driven by larger data than just, what do you do with a specific individual patient?

So I wanted to go over clinical practice guidelines. This is not going to be drilling you with what you need to be reciting every time you see a patient, but I want you to think about the big picture of what clinical practice guidelines are, where they come from, and what their role is. I just have one disclosure there.

And I would like you to understand the goals and limitations of clinical practice guidelines as best we can in this time frame. The process of developing them. We won't go into great detail there, but I think you need to understand where they come from. It's not just a bunch of fat guys sitting around a table, deciding what you should do.

And then to some degree, you need to be familiar with the guideline implementation process. But we're not going to go into that a lot. I've got some other things at the end I want you to think about.

So first of all, why clinical practice guidelines for low back pain? Well, why practice guidelines for anything? Well, we want to standardize treatment to some extent. We can't fully standardize it, because every patient's different.

But back pain is a really big problem, bigger than most of us realize. And the lifetime prevalence is about 84%, according to the most recent data. It's number six on the Global Burden of Disease list worldwide. Up to 60% of people with acute low back pain still have pain a year later when they're surveyed. And as many as 5% to 7% of them have severe, disabling pain.

So it's not the story that you learned in school, that everybody gets better no matter what you do in three to six weeks. All you have to do is keep them happy in that period of time. That's not the way it is. It's a very big problem clinically.

It's also a big problem from an economic standpoint. The most recent data, which is probably five to eight years old now, is that back pain costs the US economy about \$102 billion in direct cost. And the indirect costs are thought to be maybe as much as five to six times that. That's 10 times what it was 20 years ago. And so it keeps on going up, and it's a very expensive problem.

Not only that, it's resource-intensive. Not everybody with back pain goes to see a provider, but fully a fourth of them do. And about 9% to 10% see a physician, and that makes up a lot of primary care physician visits, about 5% of all of them in the United States. In other countries, it can be higher.

What complicates this further is that everybody treats back pain. We all do. Therapists, physicians, chiropractors, massage therapists, licensed acupuncturists, you name it. And so there's not one concerted effort at trying to decide what's best to do for these patients.

It's really a disease without specific biomarkers, so it's very hard to measure. I can't measure a test and say, oh, you have back pain like I can say, oh, you have elevated glucose and you probably have diabetes. So it's hard to tell when the problem is really better, other than the patient doing more physically and having less pain.

Unfortunately, the treatments have very modest effect sizes, and there are no treatments that have large effect sizes. So what that means is that from a statistical standpoint, you have to have well-designed, large trials in order to tell that there are real differences between treatment groups. And for a long time, that was a problem in the literature.

The literature's another problem. It's very large and it's very confusing, because you have people using different terminology, coming at it from different directions. And it just shows you how big the problem is.

As an example, I gave just simply the literature on spinal manipulation, which is a small segment of it. There are more than 50 randomized controlled trials now on spinal manipulation. There are just as many systematic reviews of spinal manipulation as there are trials. And now you're seeing systematic reviews of systematic reviews, trying to say, well, what's the best systematic review that we can get our hands on? So the truth is not really very clear to see in all of this.

So having said all this, how should we take care of people with low back pain? We here at Mayo say, OK, the needs of the patient come first. We want to just consider the best interests of the patients. I think that's very laudable. We need to do that. We need to be very cognizant of safety of treatments. We need to avoid ineffective treatments. We want to try to do things that reduce pain, decrease disability, and prevent recurrence, if possible.

But we should also be aware of the cost and the treatment burden of what we do. And sometimes, we do too much for patients that don't need it, and other times, we do too little for patients that need more. And it's hard to tell sometimes who needs what treatment.

So ideally, we'd provide evaluation and treatment, and we'd base that on the best evidence we can get our hands on. And we do that and consider those factors without regard to our biases, without regard to our tunnel vision that we carry with us from our training and from our niche within the professions.

And also without financial incentives, which is a real problem here in the United States. I like to tell my residents that in the United States, we get what we pay for. If you pay more for something, you get more of it. It's like economics. If you tax something, you get less of it. In medicine, if you pay for it, you get more of it.

So ideally, we would be able to carry the flag of evidence-based medicine into the realm of back care and make sense of that. The problem is with this confusing literature, what evidence, and who's medicine? Because there's a lot of different people with their brand of medicine that believe that they can help.

So this is where clinical practice guidelines come into the realm. And the idea is that you systematically locate, evaluate, and summarize the scientific evidence. And then you make assessments on disease management and diagnosis. And you look at that critically, and then you can make recommendations as to how most people should be treated based on that.

And often, these clinical practice guidelines include implementation guides, because we all know that it's one thing to know what to do. It's a completely different thing to get it done. And so we all have stresses in practice, and it's always sometimes hard to do-- not always, but often hard to do the right thing.

So the methodology of developing these clinical practice guidelines is very similar to a systematic review, except you need to make sure that you have stakeholders well represented. You have to have an audience in mind. And the ones we're going to talk about today, the audience is primary care, because that's where most people go in the beginning when they have problems with low back pain.

So if that's your audience, you don't want all the people making the clinical practice guideline decisions to be neurosurgeons and neurologists and PM&R specialists. You want them to represent a wide variety of people so that there's a lot of buy-in when the guidelines are actually developed. And not only that, it increases the internal validity.

You have to develop a search strategy, but that's based on the question. What is your question? Is it, how should you do pain management with opioids? No. The question is, how do you take care of low back patients in a primary care office? So your search strategy is driven by your question.

And then you have to decide what data you're going to collect. Unfortunately, there's very little data with low back pain that is meaningful, so we end up looking at Oswestry scores and Roland-Morris scores, and time out of work and cost of treatment. These kind of things that we can say make sense to us.

Things that 20, 30 years ago that we thought made sense, like is the range of motion any better, doesn't. It doesn't-- you know, inherently, you would think that it makes sense, but it doesn't really translate into meaningful data when it comes to outcome.

So we have to look at outcome and biomarkers, both at the individual level, such as pain, function, recurrence of pain, and the societal level. Cost, disability. And then we have to look at measures of quality, because not all of the studies that we look at are of the same level.

And so you all are familiar with the levels of evidence. There are several different tiers. But you know, level one, two, three, four. Those things have to be considered, just like you do in a systematic review.

And then after that, you have to synthesize it all and come down with recommendations. And sometimes you have to say, this is a strong recommendation or this is a moderate or a weak recommendation based on the amount of evidence that you have. So it's a fairly complicated process.

There are problems with this process, though. One is that the way of doing it is not fully standardized. And so some people will vary in how they do the analysis or how they grade the evidence or those type of processes, and it will affect the validity of the outcomes.

And the guidelines are based on best evidence. Evidence changes. And so these guidelines actually have shelf lives. You cannot really depend on a guideline that's 20 years old, because it's no longer valid. It may say the same thing, but you need to make sure that the most recent evidence is in there.

And bias occurs. Just like in anything else that goes into print in our journals, there's bias. Sometimes we can tell where the bias is, and sometimes we can't. But there are tools that have been developed to try to determine bias within these documents, and it largely has to do with grading. And this is done by multiple graders, and they have to agree.

Grading, what's the purpose? How did they present the data? How was the data analyzed? What is the intended audience? And what they said in the recommendations, was it really supported by what they found? So looking for internal validity within the document.

OK. So we have clinical practice guidelines, but where do we go to find these things? I'm sure that some of us are aware of, like, the ICSI guidelines, which I'll give as an example. Well, that's kind of a home-grown thing from Wisconsin and Minnesota, but people from Mayo were involved in putting those together.

This is the first clinical practice guideline in low back pain that was widely disseminated. And this was 1994, 20 years ago. The AHCPR guideline number 14. I don't know if anybody remembers that. I still have a copy of it on my shelf. That's how I got this picture.

But unfortunately, it's outdated now. It said some good things, and we learned about things like red flags. That's where that term really became popularized, is after this data came out. But they did the guideline for the same reasons that we're talking about, because the prevalence of the problem, the high cost, inappropriate or suboptimal treatment, and increasing research. So it still has to be updated. A good guideline will have a plan for updating it built into the guideline.

OK. So we can go to the National Guideline Clearinghouse. And this is a government website, and it has all kinds of guidelines. They do have criteria for what gets put in here and what isn't. but it's pretty loose. There are industrial guidelines in here. There can be guidelines that are developed by other than academic groups. And so it's a little bit of a mixed bag.

But they do go through, and you can systematically look at the pluses and minuses and compare guidelines. They have tools on the website for doing that. For instance, though, here under diseases in that left-hand column, there are 2,548 diseases that there are guidelines in this bank.

And so we drill down under musculoskeletal. There is no category that says low back pain. You have to search for it. And so you get anything related to low back pain, so you have to pick and choose as you go through there. So this is one place you can go and find guidelines. Most of us can go find guidelines for a condition at our professional organization website, like the AAPMNR or the APA or APTA. Yeah.

So there will be guidelines there. But the problem with those sometimes is that guidelines developed by specialties tend to be a little bit more biased. And so you have to be concerned about that.

This is an example of a reasonable guideline. This is the ICSI guidelines. This is an independent nonprofit group that's supported for Minnesota and Wisconsin health care plans.

And so they get together. They pull stakeholders together, and they develop these guidelines that are then used by the plans. And they're out there to be used by most anyone who wants to use them. And this is just kind of a summary of what you do with acute low back pain. We're not going to go through the individual steps here.

But there are a lot of guidelines, and there are probably in the neighborhood of 60 or 70 very decent guidelines on low back pain out there. So how do you decide what to use? How do you decide what's applicable to your practice?

So again, we go to the literature, because what we have to do is find where someone has gone through and synthesized and graded these guidelines to find out really what the best ones are and to see if they agree. And so basically, you have systematic reviews of guidelines, just like you do of randomized controlled trials.

So if we go in and just put in clinical guidelines and low back pain into PubMed, we get a list of different articles, and some of them are what we're looking for. This is from the *European Spine Journal*, 2010. Bart Koes and his colleagues are well known for doing this type of work.

And I'm going to summarize kind of what they found for low back pain. And they looked at both acute and chronic low back pain to see what the science said about it.

And the guidelines they looked at, most of them were from a country, 13 different countries, and only one guideline from each country. And then two were international guidelines. Otherwise, they were developed by an international panel. And it had a pretty heavy influence in regard to Europe. But that's OK. They sometimes do better work in this area with populations than we do.

So their summary of common recommendations for treatment of low back pain, either acute or subacute back pain. They considered those together. Reassure the patients. It's a favorable prognosis. And most people do get better. Even despite those statistics we threw out, most people get better. Advise them to stay active.

Prescribe medication if necessary. In Europe, paracetamol. Here, Tylenol, nonsteroidals. Those are the first-line medications. Second line-- second line is nonsteroidals. And then consider muscle relaxants, opioids, or antidepressants. So they're not telling you exactly what to give patients. They're saying, consider these things, and maybe do it in this stepwise fashion.

Discourage bed rest. Do not advise a supervised exercise program. That's very different than the way that we think here in the United States. I think anybody that comes in with back pain, our gut reaction is to send them to the therapist. But if it's acute back pain-- and I don't see too many acute back pain patients. Usually when I see them, it's because they failed things. There isn't good evidence that it's going to make any difference in the first few weeks.

Now to us, we've got our bias again. But these are recommendations coming from a group of people looking at the literature and saying, there isn't evidence to support that.

For chronic back pain, discourage use of modalities. So we fall right in there. We say, we don't like passive modalities for chronic pain. Short-term use of medication or manipulation. Manipulation's one of the areas in all these guidelines that kind of depends on the bias of the group doing it. Sometimes they'll say, well, that's something to use. Other times they'll say, well, it's not as strong as-- the evidence isn't as strong as what we'd like, so you can use it if you want.

Supervised exercise therapy usually comes up on all of these for chronic low back pain. Cognitive behavioral therapy and multidisciplinary treatment. So when they're talking about exercise down at the bottom here, that asterisk says, guidelines that consider subacute and chronic low back pain recommendations-- or rather recommend exercise-- but note that there is no evidence that one form of exercise is superior to another.

European guidelines advise against exercise as it requires expensive training and machines. So this, again, is something that in our minds, we do a lot of exercise. We want our patients to do it. We think it's good for them. But the type of exercise that they get, there may be a difference, but there's no difference in the literature, if you look at the trials. The main thing is to get them to exercise, to get them to be active.

Here's another systematic review of clinical practice guidelines that came out about the same time. They took a little bit of a different tack. They only looked at English language guidelines, where the other ones looked at guidelines from all over Europe. And here, they looked at guidelines for acute low back pain, chronic low back pain, and low back pain with neurologic findings.

So this is kind of the summary of what they came down with. So they had 10 guidelines that met their criteria for quality and for the definition that they put in there to meet the question.

Recommendations for assessment of low back pain that were emphasized, rule out the serious spinal pathology and neurologic involvement. We all do that. That's the red flags that we're always asking patients about.

Identify risk factors for chronicity and measure symptoms and functional limitations. We don't do that very well. Those are the yellow flags. Those are these patients, patients with some psychological stress that's going to complicate their recovery. We should be systematically looking for those things.

For acute low back pain, patient education, short-term use of acetaminophen, nonsteroidal anti-inflammatory drugs, and spinal manipulative therapy. Very similar to what the other group found with primarily European guidelines.

And then they say for chronic low back pain, consider adding back exercises, behavioral therapy, and short-term opioid analgesics. Fairly similar list. They're not telling you what to do for any one particular patient. They're saying, these are the things that the literature would support as being reasonable.

You notice there's nothing here about traction. Every once in a while, I send a patient to get traction, because I'm out. I don't have anything else to offer. What else have we got to try to help this person? Doesn't say anything about TENS units, you know.

So you can find literature on those areas, but there's very little evidence that they're really helpful in the long run. And it's a hard pill sometimes for us to swallow. But again, often we get the patients that have already failed the primary care track.

Recommendations for low back pain with neurologic involvement. This is the only one of them that I reviewed where they talked about it. But then they say, OK. Now you might consider getting some three-dimensional imaging, an MRI or a CT so that you can see if this patient is a candidate for other therapies such as epidural steroid injections.

Most of the guidelines that look at the injection therapies for back pain will say there's no evidence that the facet injections are helpful. We order them regularly. And so we're not doing a very good job sometimes of following the guidelines. And that's the hard part, is looking that patient in the eye that's in front of you and deciding what's best for them.

And then we can't please everybody, so this is another systematic review. Came out of a group primarily of academic physical therapists in Italy. And they said, well, you know, these other reviews, they were pretty good, but they missed some important articles. They missed some important studies. Well, they didn't miss them. It's just that the way they posed their question, they didn't fit the criteria.

And so they did their own and said, well, you really ought to emphasize physical therapy. But they didn't really come down with-- they did a good job of looking at the literature, and didn't come down with anything that was really different than had already been said. So if we look at the literature critically, we're probably going to come to similar conclusions about what can help patients with back pain and what can't.

So the main recommendations or the higher quality guidelines that are out there for low back pain are very similar. Assessment, rule out the bad things. Look for red flags. Look for indications of a poorer than usual outcome. The psychosocial issues, the yellow flags.

Treatment, it varies to a minor degree based on the stakeholders that are represented in the group that put the guidelines together. But it basically encourages you to reassure the patients with acute pain that things are going to get better. Stay active. Stay as active as possible. Use Tylenol, acetaminophen. And if you need to, we can do some other things, such as multidisciplinary involvement with chronic low back pain if you're not getting better.

It's hard, I think-- I did an eConsult this morning on a patient who's had pain for six weeks. Isn't getting better. We did X-rays. There's nothing unusual for a 60-year-old man in the X-rays. But the doctor's like, what do we do? What do we do? Well, we keep doing what we're doing. As we all know, sometimes it takes longer than we expect.

Well, what about where the rubber meets the road? If we implement these guidelines, does it really make any difference? Has anybody looked at that? Well, some people have tried to look at it. Not as many as I would have expected.

There are a couple early articles about implementing guidelines, one out of the VA, and they found it to be very cost-effective. Here is a study where they just went-- and this is a qualitative study where they went and asked occupational therapists, physical therapists, and general practitioners, what are the problems with implementing the guidelines? You know, why can't we do this? What makes it hard?

And it was interesting, because the occupational therapists, they were ready to buy into it. We can do this. The physical therapists said, well, I don't think the guidelines tell us enough about which treatments might help my patients. And the primary care doc said, I don't think the guidelines tell me enough about the pathophysiology and how to make decisions based on the individual pathophysiology.

So the problem is that we think we're smarter than what the literature would say we are, and we try to out think them. And I think that's not good, unless we do it in a methodological manner where we can prove that our thought process is useful. And we'll talk about that in a little bit here.

This is a study out of Australia where they looked at the economic impact and the resource impact of instituting guidelines in a large health care system. And basically, they concluded that to implement the guidelines-- not just disseminate them, but implement them-- it's very intensive and takes a lot of work. And they're not sure, based on their analysis, that you're going to get a payback financially from that.

So we should be looking for more evidence in regard to implementation. There are a lot of places you can go to help you put together plans for implementing guidelines. And some of these guidelines actually come along with them, they have plans to help you decide where to start. And so that's helpful when that's the case, but I think every health system is going to be different.

So can we do better, though? Can we develop care models that improve upon the guidelines? And there are groups that are working on this. And this is the thought I want you to really carry out this, is how do we figure out who we can help by doing more aggressive treatment? And when do we just need to back off and not do much, because they're probably going to get better anyway?

So we typically see a patient and we make this assessment, this gut-level assessment. They're bad. No, they're not too bad. And we decide what treatment based on that. If I think they've got a lot of pain, well, I'll offer them some opioids. Well, their pain's not bad, so let's do Tylenol. You know, and then you have to weigh in all the factors about, OK. They have kidney problems. Are they hypertensive? Do I use nonsteroidals for pain control for medication?

Do I send them to therapy or do I say, I want you to go walk every day for a couple of weeks and come back and see me? And since we're not given a lot of time for follow-up, sometimes that's a difficult decision to make too.

So are our assumptions correct, though, when we make those assumptions? Do we really pick the best treatment for the best patient? So there's literature that's emerging now that's saying we don't do a very good job of that.

If a patient's risk of failing the usual treatment can be quantified, can we develop treatment models that relate to their specific risk level of outcome? And this is known as stratified management. It's going on in a lot of different areas of medicine.

But there's one group in particular that has started to do this with back pain, and that's Keele University in the UK. And it's primarily a physical therapy model, and they have done most of their research in the National Health system in the UK. And they've found that, yes, we can predict and stratify the risk of bad outcome or inadequate outcome from the typical treatment that we do for patients.

So they've developed this tool called the STarT Back Tool. And it's a fairly simple tool. It's nine items. My back pain has spread down my legs at some time in the last two weeks. Agree or disagree? It's either you agree or disagree. If you agree, you get a point. If you disagree, there's no point.

I have pain in the shoulder or neck at some time in the last two weeks. I've only walked short distances because of my back pain. In the last two weeks, I have dressed more slowly than usual. It's not really safe for a person with a condition like mine to be physically active.

Worrying thoughts have been going through my mind a lot of the time. I feel that my back pain is terrible, and it's never going to get any better. In general, I've not enjoyed all the things I used to enjoy. And then overall, how bothersome has your back pain been in the last two weeks?

So you score this. And basically, if they score low, zero to three, it's low risk. These people are probably going to do well. They have an intermediate area called medium risk, four through nine.

But if you look at the last five items, those are the ones that are worrying thoughts, and people with my problems shouldn't be moving. And these are the people we worry about, the people who are afraid of pain, the people who feel that they're doomed because of this. And these are the people who don't do well.

So they're in the high-risk group. If you get four or five of the last five items, then you're high risk. And there's a new study that actually is just accepted-- it's not even in print yet-- where they did a further analysis of this and said, well, you know, we can probably put this into two groups, not just in one group. We can probably say either they're going to do well or they're not. And then you can devise treatment geared toward that.

So what they've done is they've done several different clinical trials using this tool to stratify patients. And then they would have the patient get the matched treatment, which was primarily therapy for the low-risk patients or encouragement. And for the medium and high-risk patients, there were additional levels of psychological support during therapy.

So they put the therapists through an appropriate amount of training. It wasn't extensive at all. I think it was something like 16 or 18 hours for the high-risk training. And they did a trial. So they randomized these people after they were risk stratified. And there were 568 in the intervention group that went either to medium or high-risk-- or rather, low, medium, or high risk. And then there were 283 in the control group. And the control group got just the normal, usual care.

And it's interesting, because the physicians didn't decide what to do. The patient came into the physician's office and said, I've got back pain. Then they said, good. We're going to send you to see a physical therapist. So the physical therapist did the screening and did the treatment, and they decided, along with the physician, if other things needed to be done later. But most of this was actually therapy-driven.

So these graphs kind of tell the story here. So the one on the left, A, that's all patients together. The bottom line-- is that blue? I'm colorblind. That's the intervention group, and the others the control-- no, the intervention group is the top line. Control group's the bottom.

And the low risk is B. You see there's not a lot of difference there. And there was basically nonsuperiority. There was no clinical significance there that they thought was important.

And C is the medium-risk group, and there was a bigger difference between there both at four months and then 12 months when they followed them through. Then D is the high-risk group, and there was a big difference at four months that was statistically significant, but there was not statistical significance at 12 months, which was interesting. And there was discussion in the article that's interesting about that, if you wish to pursue it.

But what they could say is that if you looked at the people who were stratified, whether or not there was a difference at 12 months, there was a big difference on work loss and cost savings, and it averaged out to 675 pounds as far as the cost saving per individual in the study.

Since then, they've done a similar study in the family practice setting and they came to similar conclusions. So they stratified care for back pain that was implemented in the family practice, and they found that it led to significant improvements in patient disability outcomes, less time off work. In fact, it was a half. 50% reduction in time off work. And it didn't increase health care costs, and so they recommended wider implementation. And like I said, there's a new study that just came out. And so they may end up simplifying this scoring even further.

So in summary, clinical practice guidelines seek to systematically locate, evaluate, and summarize the scientific evidence and make recommendations for evidence-based evaluation and treatment. They're developed in a fairly rigorous manner today. And some of them, you will find in the literature. Some of them won't be in the literature. Most of them should be in the Clearinghouse here in the United States.

And they should include multiple stakeholders so that you reduce the bias. And they can be a very valuable tool if they're followed. Implementation is always the fly in the ointment with anything. And in this case, that's no different.

Although costly, it can improve clinical outcomes while avoiding unnecessary treatment and reducing costs. And hopefully, there will be other clinical pathway models coming down the road for us to consider so that we can even have further improvement beyond that. So questions? Yes?

AUDIENCE: It almost seems like the guidelines for the acute care low back pain is almost a discouragement to even come in and see the physician, because the same things they can do at home. It's almost like it's trying to get folks to rethink about what they do for low back pain. Because if you go in and see a doctor, they're going to tell you, keep doing what you're doing. Take some Tylenol. You don't need to pay a doctor to tell you to do that. Am I [INAUDIBLE]?

RALPH E. GAY: No. And there are certainly models where they don't see the physician. They see a nurse practitioner or a therapist. And we have to realize that not everybody with back pain sees the doctor. There are those people, though, that are either bothered enough by it or worried enough by it that they do.

I think that's where we-- where I get into trouble is that the patient is sitting in front of me. They've been out of work for a week. They don't think they're getting better fast enough. I feel that it's my job to do something.

And sometimes it's better not to do as much. The initial trial in the stratified management, one of the interesting things they found out is that in the control group, about 47% or 48% of the patients with acute low back pain were referred to a therapist. Under the stratified plan, that was, like, below 20%.

So we sent a lot of people in that study, a lot of people were sent for therapy that I can't say it hurt them. But if you're looking at the overall cost containment across a population of people, it was probably unnecessary therapy if they got just good advice from the primary physician.

Like I said, we take a lot of-- we have a lot of stock in exercise and therapy. But when we look critically at the literature for exercise for low back pain, yes, there's an effect. But walking may be just as good as doing other things. We don't know. Other questions?

AUDIENCE: Are we looking to implement the STarT Back guidelines in primary care?

RALPH E. GAY: That discussion hasn't occurred yet. I'm not sure exactly what the plan is going to be with the rollout of the new Spine Center. But-- or spine practice, I should say. But that doesn't keep us from doing it otherwise. The thing is if we stratify it, we ought to have a plan of what to do with that information. It's a fairly simple tool to use, and you could just use a summary score in your note. But it's something for us to consider, I believe.

AUDIENCE: You mentioned something about MRIs and CTs. Talk about radiographs [INAUDIBLE]?

RALPH E. GAY: No, we didn't-- yeah. And the bottom line is for acute low back pain without significant neurologic findings and without red flags, there's no reason to get them. It doesn't change treatment at all. We get way too many X-rays. And everybody knows that, every study shows that. We get way too many MRIs. Because more often than not, what we see doesn't have anything to do with the pain they have, unless they have, like, a radiculopathy. Yes?

AUDIENCE: Did any of you look at follow-up, either PT phone calls or nurses with compliant therapies or things like that?

RALPH E. GAY: That's a really tough issue to get to, compliance. There are a lot of people working on that. Most of the compliance data on exercise is by diaries. We don't have good ways of doing that with motion monitor systems or activity monitoring systems. We can tell if they moved. We can't tell if they did their exercises right or wrong. So that's a whole different question, but I'm not aware of specific data on that from these studies. Thank you.

[APPLAUSE]