A CMS Medicare Administrative Contractor
http://www.NGSMedicare.com

National Government Services, Inc.

Moderator: Dr. Meredith Loveless

March 10, 2022

1:00 p.m. CT

Coordinator: Welcome and thank you for standing-by. For the duration of today's conference all participants will be a listen-only mode. I'd like to inform all parties that today's conference is being recorded. If you have any objections, you may disconnect at this time. I would now like to turn the conference over to Dr. Meredith Loveless. Thank you. You may begin.

Dr. Loveless: Hello. Welcome. I'm Meredith Loveless, I'm a CMD with CGS Administrators. And I'm joined by contractor medical directors from NGS, WPS, Nordian and Palmetto who welcome you to today's meeting. I thank all of our attendees and our panelists for taking time from your day and practices to be part of this process.

This meeting is an evidence review meeting. It's part of the LCD modernization process as a result of 21st Century Cures Act that calls for local coverage determination to be based on robust evidence review. The purpose of this meeting is for our expert panel to serve in an advisory capacity to review the quality of evidence that we would consider in development of an LCD.

Our (CAC) is advisory in nature and final decisions and issues rests with (MACs). Our experts represent a vast clinical experience. And since the process demands

a focus on the evidence, we will ask all of our panelists to share evidence-based feedback.

I also want to recognize there are many experts who are not on our panel today. And we have jurisdictional CAC members from across the country who are attending today's meeting. We want to make sure that we that you know that we value your input and feedback and that you are also part of this process. So for those who are not serving on the panel, if you can submit your comments in writing to your local (MACs) with a conflict of interest form, we can consider those comments.

In addition, once a draft policy is developed and released, there will be an open comment period and an opportunity to present at jurisdictional open meetings. All feedback from the comments and open meetings will be considered in the final policy development.

On this screen lists all of the contract medical directors who are representing the (MACs) today and have worked hard in helping to get the panelists selected and here today and through this process. I'm now going to ask our panel to introduce themselves, to give a little bit of their background and also declare any conflict of interest. And we'll go in the order that's on the slides so starting with Brian Jacobs.

Mr. Jacobs: I'm Brian Jacobs. I'm a nurse anesthetist in Iowa. I'm here on behalf of the American Association of Nurse Anesthetists. I've completed one of our fellowships in pain management and have been practicing pain management for the past six years. I'm also currently a PhD student in pain and associated symptoms research at the University of Iowa. If anyone needs a post-doc in the next year or two, otherwise, I have no conflicts of interest to disclose.

Dr. Loveless: Thank you. Dr. O'Brien.

Dr. O'Brien: Yes, Dave O'Brien. I'm currently at the Department of Orthopedics and Rehabilitation at Wake Forest University Baptist Health in Winston-Salem, North Carolina. Then finished my residency in PMR in1995 and did a sports and spine fellowship in '96. I'm the Director of the Interventional Spine and Musculoskeletal Fellowship since 2001 and continue that currently.

As far as any disclosures. I actually have been a CAC advisor for American Academy of Physical Medicine Rehab with Palmetto for a number of years. I'm on the NASS Board of Directors for a number of years. I've also been on their coverage committee and currently still am a senior reviewer for the coverage policies. And also the CPT Advisory of the AMA.

I did do some work last year up until June with Turning Point Health Solutions advising them about their policies, and some reviews. Have not done that since June of last year. And I volunteer some time for Spine Intervention Society, their health committee.

Dr. Loveless: Thank you so much. Dr. Varghese.

Dr. Varghese: Hi. Thank you for having me. My name is Dr. Varghese. I'm an Associate Professor of Clinical Physical Medicine and Rehabilitation at the University of Missouri in Columbia, Missouri. I've been Medical Director of their pain management program for the last 15 years.

I did my residency at University of Missouri and then my fellowship at Emory University before starting at the University of Missouri 15 years ago. I don't have anything to disclose.

Dr. Loveless: Thank you. And Dr. Beall.

Dr. Beall: Yes. Doug Beall. .I'm an interventional radiologist practicing in Oklahoma City Private Practice. I trained in radiology, interventional radiology and board

certified in radiology in the Interventional Pain Management Training, Georgetown, Hopkins and Mayo Clinic.

And I'm Director of Interventional Spine Services at Oklahoma Spine Hospital, Director of the fellowship program. Conflicts of interest mainly include research and development with multiple medical device companies. I've got royalties from multiple textbooks and different publications in the past, and I've submitted all these in total previously. Thank you.

Dr. Loveless: Thank you. And I'm hoping Dr. Gulur has been able to join us. We're having a little connection trouble.

Dr. Goldzweig: She's still trying. It's (Peter), I just got a call from her about two minutes ago. There's something going on where she's at with cell phones and regular phone. She can't get through. (Linda) I don't know if you could call Dr. Gulur and maybe help her get into the conference.

Linda: I don't know if I can. I did talk to her and I gave her our number to call but I haven't heard back from her. She said she was going to call me back.

Dr. Goldzweig: She's still getting the same message. She just texted me.

Dr. Loveless: Okay. Linda If you could please continue to work to get her connected, that would be great.

Linda: Okay.

Dr. Loveless: Dr. Ward,

Dr. Ward: Hello. Good afternoon. My name is Michael Ward. I'm a clinical rheumatologist and clinical researcher focusing primarily on patients with axial spondyloarthritis. I had been in the past the principal investigator for the

American College of Rheumatology, clinical practice guidelines for axial spondyloarthritis. And I have no conflicts.

Dr. Loveless: Thank you. And Dr. Vorenkamp.

Dr. Loveless: Dr. Vorenkamp won't be on today. Dr. Upadhyaya have you been able to join us?

Dr. Upadhyaya: Yes, I'm here -

Dr. Loveless: Awesome. I'm glad you made it.

Dr. Upadhyaya: Upadhyaya.

Dr. Loveless: If you could just introduce yourself and any conflicts of interest,

Dr. Upadhyaya: I'm Cheerag Upadhyaya. I am neurosurgeon with fellowship training spine in spine surgery I did my training at Michigan and UCSF. I do serve on various committees as well as J5 CAC for Neurosurgry. I'm also an AMC CPC advisor. I have no other financial conflicts of interest in terms of the industry funding,

Dr. Loveless: Awesome. And Dr. Dubreuil.

Dr. Dubreuil: Yes hi. I'm Maureen Dubreuil. I'm a rheumatologist at Boston University School of Medicine in VA Boston. I am also a clinician and researcher focused in axial spondyloarthritis. I serve on the board for the spondyloarthritis research and treatment network, which is a nonprofit organization.

And my only financial conflict of interest is an upcoming advisory board for UCB Inc. Pharmaceutical Company. Thank you.

Dr. Loveless: Thank you. And Dr. Cohen.

Dr. Cohen: My name is Steven Cohen, the chief of pain medicine at Johns Hopkins. I'm a professor of anesthesiology, neurology, physical medicine and rehabilitation and psychiatry and behavioral sciences. I'm also Director of Pain Research at Walter Reed National Military Medical Center and a professor there as well.

My conflict is on - I guess, the senior investigator on a multi-center study examining radiofrequency ablation for sacroiliac joint pain that is finished, it's in preparation, and it was sponsored by Avanos. That money is paid to my institutions. Over.

Dr. Loveless: Thank you so much. And have we had success in getting Dr. Gulur connected yet? I'm not sure if there's a problem with her connecting since the operator had transferred off. (Alicia) If there's any assistance that you can provide to Linda to get Dr. Gulur connected, that would be great.

Alicia: Yes. I'm seeing if maybe we can add a line on a cell phone and try and get her in.

Dr. Loveless: Okay. And if you are not currently speaking, if you could put your lines on mute just so that we don't get any background noise. And our first question was for Dr. Gulur, so I'm going to go ahead and we're going to move to the next. So for those just joining in I'm Dr. Meredith Loveless. I'll be moderating today. And I'm actually going to move to question number two and then we'll come back to question one once we get Dr. Gulur connected. So we're going to jump ahead. Question number two: should you evaluate for depression and treat prior to sacroiliac joint interventions? And Dr. Ward is going to open this question for us.

Dr. Ward: Yes, so Michael Ward here. Some of the literature that was provided, there were several articles that at least indirectly addressed this topic. But I will say that they didn't find anything that precisely addressed the specific topic. So going sort of in order the treatment recommendations. The current recommendations from the North American Spine Society had several recommendations that were,

as I said, indirectly related to the question of depression and SI joint interventions.

For example, they had a recommendation that non-structural causes of low back pain may be considered in patients with diffuse, low back pain and tenderness. Sort of a nonspecific recommendation for how people should be evaluated.

They had a recommendation that antidepressants are not recommended for the treatment of low back pain with a grade A recommendation based on four randomized controlled clinical trials. They had a recommendation that cognitive behavioral therapy in combination with physical therapy provided benefits greater than physical therapy alone in pain relief - grade A recommendation based on 11 randomized controlled trials.

They reported that there was conflicting evidence on cognitive behavioral therapy alone in improving depression in patients with low back pain. So they did not provide a recommendation either for or against cognitive behavioral therapy in that condition.

And lastly, they had a recommendation saying that there was insufficient evidence for or against the addition of cognitive behavioral therapy or psychosocial interventions for patients undergoing interventional or surgical treatment for lower back pain saying that they didn't know or there was insufficient evidence to say that it would provide incremental benefit.

In summary, there were some recommendations that they had made that were indirectly related to this specific question. But, my assessment of their recommendations was that there was no real added value in evaluating and treating depression before SI joint interventions.

There was a second article of recommendations by the American Society of Interventional Pain Physicians and their guidelines made no mention of depression or psychosocial interventions at all. And thirdly, the appropriateness criteria reported by the Spine Intervention Society, they also made no mention of screening or treatment of depression prior to SI joint injections or interventions.

There was one primary research article by Cohen, I guess here on the call - maybe that's you, that evaluated non-organic (signs). For example, nonanatomic tenderness or, discrepant physical exam and found that these features were not associated with the quality or magnitude of treatment response to SI joint interventions.

And lastly going over the trials that were included in the literature review there were at least three trials which excluded patients with untreated depression as part of their inclusion criteria. All of those three were for radiofrequency ablation evaluations but none of the observational studies that were listed there had any exclusions based on preexisting depression or untreated depression.

So my summary of this literature is that there's no evidence to support of the treatment of depression or evaluation for depression prior to instituting SI joint intervention.

Dr. Loveless: Thank you so much for that thorough evaluation. And do any of the other panelists want to add anything to this question?

Dr. Cohen: Yes. This is Steven Cohen. Not throwing anyone under the bus, but I was actually asked to comment on this question as well. So, and I guess it was based on a study that we had that was just published - very, very large nine centers, 346 patients who received procedures for back pain including sacroiliac joint pain.

And I guess I was asked because the results were actually stratified based on the degree of depression. So people who were not depressed 57% had a positive

categorical outcome. And then it almost linearly declines. So people who are mildly depressed (46%), people who are moderately or severely depressed, (36%.) And if you were very severely depressed, this is based on Quick Inventory of Depression Symptomatology (QIDS), it was actually less than 20%.

And if you look very strongly at the literature between things like depression, anxiety, sleep, it's clear that, you know, having chronic pain can cause people to not sleep well and be depressed. But actually, it's a bidirectional relationship and the reverse is more true. So people who are depressed or don't sleep well and injure themselves are more likely to not get better with interventions including procedures.

So, and almost every really high quality federally funded study that's looking at efficacy excludes people with poorly controlled symptomatology. So I agree, this is an area that's kind of high risk, high reward but I don't think that everyone needs a quick depression inventory (QIDS) before they undergo a procedure.

But if you're a doctor and someone is severely depressed, they're way more likely to not get better. That is the strongest predictor out of over 30 predictors that were looked at in this study that had 350 patients. I think it's a really simple thing to ask people if you're depressed.

Even if you're a family doctor, you should ask people if they're depressed especially when it can have a profound effect on something that you do. Over.

Dr. Upadhyaya: Can I - this is Cheerag. Would I be able to ask a question?

Dr. Loveless: Yes.

Dr. Upadhyaya: Just would there be a recommendation or is there just, Cohen, based on what you were saying in terms of screening patients for depression with a formal screening exam or anything like that?

Dr. Cohen: Yes. I mean, I think that a lot of people are not really trained to screen people who are depressed. What do you do if they're depressed? We always have problems because if they answer yes, I do lots and lots of clinical trials, I have about $20 million is PI in federal grants. And if somebody has test positive on a suicide question or they answer something affirmatively, it's a big, huge problem. We have to do a lot of things and I'm not sure that everyone is trained to do it. But I think a really simple thing: how are you feeling? Are you depressed or are you sleeping well? These are really basic things that one might argue every single doctor should be asking a patient, certainly a pain doctor right? That's why pain medicine is a recognized specialty by ACGME for psychiatry to some specialty training.

So I don't think that they need to fill out a questionnaire but I think people with poorly controlled depression should probably be evaluated. I don't think that somebody who's undergoing elective surgery for back pain with poorly controlled depression. I think most surgeons would not operate or most ethical surgeons would not operate until this is directed.

And like I said, it might be that these people never become not depressed but at least it doesn't have to be uncontrolled, very severe depression. A very, very simple thing.

Dr. Loveless: Thank you so much. And I'm going to check in if we were able to connect with Dr. Gulur.

Woman: I do think we have the operator trying to dial out to Dr. Gulur...

Dr. Loveless: Okay.

Woman: and see if that works. I don't know if it's worked yet.

Dr. O'Brien: This is Dr. O'Brien. I thought Dr. Cohen brought up a lot of great points. I guess the question is for the purpose of this specific subject for depression evaluations prior to the treatment of SI joint interventions, is there be a formal criteria to evaluate for depression?

Or I think that most of us have practiced pain and musculoskeletal medicine screening for this indirectly. We meet with patients and it's just part of our practice that if we see somebody that's severely depressed and there's a lot of issues we get that addressed and figure out a place in our treatment algorithm.

But I'm not sure as far as the coverage policy what should be required or not required. And just asking the rest of the panel and then Steve in particular, if there should be something specific worded that should be mandated as part of the coverage policy for SI injections and procedures that should be required or not?

Dr. Cohen: This is Steve Cohen again, I wish I was an expert. But I have a joint appointment in the Department of Psychiatry at Johns Hopkins. They have an inpatient pain unit. It's a very complicated thing because when people go to that inpatient pain unit, it's covered under psychiatric benefits.

And a lot of the people they're getting their depression and substance use disorder under control. And are very smart people who run the program. And they say while they're getting it under control you can treat common pain problems.

It's hard to come out with a general policy because there are always going to be exceptions. I would hate to say that everyone has to get an inventory and be screened for suicide. But I think that really, in some way, again I am not an expert on this, that severe depression or poorly controlled depression should be addressed before people get procedures because they're very unlikely to get better.

And like I said, that's kind of a common thing that people see in psychiatry and general medicine. People have diffuse pain problems. It's very difficult to explain them. And then when it's explored further, it turns out that their husband, their wife just left them. Their kid dropped out of school and they lost their job. And when this gets it, it just makes things worse.

Dr. O'Brien: Yes, no. I think it's a great point. So I guess my proposal would be perhaps dropping some language to the point that patients that are being considered for these interventional sacroiliac procedures should have any coexisting psychological or depression related illnesses stabilized prior to considering moving forward. Something to that effect. That, in other words, everybody's has depression some days but there's a difference between having controlled stable mental illness that people should undergo appropriate treatments for versus people that are psychologically or emotionally unstable.

So maybe some wording that patients that are being considered for these procedures should be emotionally and psychologically stable. And if not then those things should be addressed perhaps prior to proceeding with any of these interventions. I don't know if that would be appropriate or not?

Dr. Varghese: Can can I make a comment? This is Dr. Varghese. So it's been my experience that if somebody presents with major depressive disorder that's active, they rarely present with just SI joint pain. Very focused, you know, isolated low back pain that would present for what we're talking about today. Oftentimes, these patients present with Dr. Cohen mentioned diffuse widespread pain.

In that situation we're kind of getting off-topic. If somebody presents with depression and they're not suicidal and they have very focused SI joint pain with as literature demonstrates a three or more provocative maneuvers with high confidence, it's very safe to do an SI joint injection to demonstrate if they actually present with SI joint pain.

You may or may not have to do two blocks based on the literature, but if you're talking about a patient who presents with widespread pain or diffuse pain with active depression, that's a totally different thing compared to what we're talking about today in my opinion,

Dr. Loveless: Oh, some really valid and interesting discussion, and I think we could probably talk about this our whole meeting because it's quite interesting. I'm going to ask if we have additional comments on this to submit it in writing so we can move forward. I think someone had - if there's a wrap up comment, that's fine and then we're going to move forward to make sure we cover everything.

Dr. Upadhyaya: Yes. This is Cheerag. I just wanted to carry. Dr. Varghese's point just to one extension which is that some of the later questions start evolving into SI joint fusion. And I think there could be a little bit of a distinction also made between patients for when it comes to this question of depression injection versus what would effectively be a permanent change in the patient's biomechanics and bony anatomy with a fusion.
So if they are thinking about it from that depression standpoint as well, but I won't belabor it any more than that.

Dr. Loveless: I think it's a valid point too. Thank you. And I'm going to go to question number three. Which I'm going to turn over to you.

Dr. Upadhyaya: Yes. Thank you. So the question I have with this one at least, was with the obese patient. What should be done prior to injection or radiofrequency treatment? So having gone through everything, the approach that I had regarding the obese patient is should anything be done in terms of considering weight loss or any of those sorts of factors when it comes specifically to the obesity?

And I couldn't really find any good evidence for or against it. It really just seemed like it wasn't something when I was doing literature search identified a ton of direct, useful, scientifically structured information.

I did send an email to everybody and I can just quickly run through it. There was an article about the technical difficulties and there were several articles that would suggest that there were some technical challenges with ultrasound guidance.

And (Wang), for example, described potentially using the CT if you've got patients who have some degree of obesity. There was another one just in general that's a joint pain concerning weight loss as a way of managing the SI joint pain. And then a series of articles regarding the technical challenge, particularly with some of the ultrasound guided techniques with a certain level of obesity.

And I think the BMI cutoff seemed to be somewhere around 30 to 35 although I'm sure we all know that the distribution of the obesity is going to make a difference as well when it comes to the technical challenge of placing it.

I think that would basically summarize - what I would hope to find was evidence that said something about weight loss either for or against or non-value. But I just didn't find any good information when it comes to injection or radiofrequency treatment.

Dr. Loveless: Thank you.

Dr. Cohen: So I hate to do this, but these were the two points that I was asked to comment on by the committee.

I just want to - so that's a great presentation. I wanted to point out that in that same featured article in Regional Anesthesia Pain Medicine, that obesity was also a really, really strong predictor of treatment failure.

However, I think it's a slippery slope to withhold treatment from people who are overweight. And I do also think that, the effective treatment of back pain can facilitate participation in exercise programs, in social functioning. Over.

Man: Yes, Dr. Cohen. I think I found your article as well, and I did go past it relatively quickly. So, yes, I think the perspective that I was approaching when it comes to this particular question and I agree that it did suggest that there was a failure.

It was more if you treat the obesity or lose some weight focusing on the word prior in the question, would that then change anything versus as you rightfully pointed out, would you withhold the treatment even if there's a chance of failure? So fair point, and I appreciate the comment.

Dr. Loveless: Thank you very much for that discussion. And I know that they are working with Dr. Gulur to utilize a different line. Has that been successful?

Woman: So far we have not had any success. I think the last thing was to see if Dr. Gulur had a landline to use. The operator was not able to get through.

Dr. Loveless: Okay. And I know Marc is working with her as well. So we'll continue to work on getting her on and move over to Question 4. Dr. Dubreuil, if you could address Question 4 for us.

Dr. Dubreuil: Yes, So this question addresses the need for a trial of two classes of medications prior to an SI joint procedure or a trial of physical therapy.

In regards to the question about medication treatment I found no studies evaluating specifically SI joint pain and pharmacotherapies. What I did find was

guidelines related to treatment of nonspecific low back pain, both from NASS and the ACP, American College of Physicians.

In terms of the Spine Society recommendations, there are three recommendations in favor of medication therapies, Grade A being the highest recommendation for topical capsaicin for three months or less. Grade B recommendations in favor of non-selective NSAIDs and for cautiously limited and short duration opioids.

There were recommendations indicating insufficient evidence for or against topical lidocaine, anticonvulsants, antidepressants and oral and intravenous steroids. And the NASS document did not address muscle relaxants.

In terms of the ACP guidelines, which were from 2017, acute low back pain was recommended to be treated with non-pharmacologic therapies first, including heat massage, acupuncture and spinal manipulation.

If patient and clinician preferred pharmacologic therapy, the recommendation was for NSAIDs first or for muscle relaxants. They found moderate quality evidence and this was a strong recommendation.

For chronic low back pain with the definition being four weeks or longer, the recommendation was again to start with non-pharmacologic therapies, including exercise, rehab, acupuncture, mindfulness based stress reduction or cognitive behavioral therapy. And if those were inadequate, then to move on to medications, which included NSAIDs as first line and then second line tramadol specifically or duloxetine.

So my recommendation and interpretation of these two leading society guidelines is that the only recommendation in common is for NSAIDs. I think it would be reasonable to try the recommendations that each society

recommended separately, the topical capsaicin, short duration limited opioids or non-benzodiazepine muscle relaxants.

But I do not think it's reasonable to require a trial of two classes because there are no two classes that are consistently recommended across professional societies.

Do we want to pause and discuss medications briefly and then move on to physical therapy?

Dr. O'Brien: Yes. This is Dave O'Brien. I'm kind of hesitant to require - I think a multi-modal approach to conservative treatment is appropriate and that can include medicines or no medicines and therapy and so forth. I do believe therapy should be tried personally.

But some people cannot tolerate NSAIDs. They have comorbid issues such as hypertension, renal disease, that that might be a bad idea. Also, the NASS guidelines that are being referred to are really just lumping everything into low back pain. So it's not specific to this issue of SI joint pain. So that should be taken into some consideration that these were guidelines based on just low back pain literature, which encompasses a lot of things.

So I just think as far as the coverage policy that if they should fail conservative treatment or conservative treatment should be tried and that should include physical therapy with or without appropriate pharmacologic interventions based on the individual patient.

Mr. Jacobs: This is Brian Jacobs. I agree. You know, for some of our patients, I'm not sure that pharmacologic therapies should even be considered conservative therapy. And a lot of these patients are already on some of these medications before they get to our clinic. So I'm not sure it would be prudent to trial them on a new muscle relaxant or a new NSAID just to get them to the point of interventional care.

Dr. Dubreuil: Any other comments about medications? Okay. I'm going to move on and just briefly summarize the literature regarding physical therapy.

This was addressed by a 2017 systematic literature review by Al-Subahi and colleagues in the Journal of Physical Therapy Science. In total they found nine studies that met their inclusion criteria.

There were three studies of exercise, three of Kinesio tape and four that included manipulations. Only one of these studies, and it was one of Kinesio tape, compared the intervention to a placebo or sham treatment.

So almost all of these were comparing active treatments to each other. And therefore, it's very difficult to quantify the effect that physical therapy has relative to not doing physical therapy. However, the authors' conclusions from this systematic review were that physical therapy is effective in reducing pain and disability and SI joint dysfunction.

Subsequent to this systematic review, there were two other studies that I was able to find published later. A 2019 study by Kamali, et al, which was a trial comparing different physical therapy modalities, so again comparing active treatments. This compared exercise to manipulation.

Participants were required to have a minimum duration of pain. I think of a few months. But in reviewing their Table 1, most people had pain lasting for years, which is an indication of very long natural history of SI joint pain for many people.

With most of these interventions, the main improvement in VAS measured pain was 60%. They also had improvements in the Oswestry Disability Index over 40% and there was no difference between the treatment groups.

A 2021 trial by Javadov, et al, compared three treatment groups, one with manual therapy and home-based SI joint exercise. The second group was manual therapy and lumbar exercise and the third group was lumbar exercise alone.

This study included only women. They were required to have a minimal VAS pain score of 3 and at least 1-1/2 months of pain. All three groups had reductions in pain, but the reductions were greater for those that included manual therapy.

And those in Group 1, which was manual therapy and home-based SI joint exercise had the greatest improvements of pain. They also had resolution of most of their provocative SI joint tests and reductions in disability.

So my interpretation of these data overall is that there's generally low quality data just because of comparing active interventions to each other. But the existing body of evidence does support physical therapy as an effective intervention in reducing SI joint pain and disability.

Dr. Loveless: Thank you so much. And for the discussion, I also am interested if our subject matter experts, if anyone disagrees on a minimum of four weeks of noninvasive conservative therapy for SIJ pain and if so, why?

Dr. O'Brien: This is Dave O'Brien. No. I don't disagree with the four weeks. I would, however - I'm not sure about requiring physical therapy. There's been some studies showing that a physician directed home exercise program is often as effective as some formal physical therapy.

And now with technology and Epic and you're allowed to - it's much easier to print out exercises, review those with the patient, how to do them at home. And they've got YouTube videos and links you can give patients now. So where patients were traveling to a physical therapist office is financially or physically difficult, I think that should be a reasonable alternative to require physical therapy or a physician-directed exercise program is reasonable.

Dr. Loveless: Thank you so much. And we're going to continue, Dr. Dubreuil, with Dr. Ward to discuss Question Number 5. And this is the role of an injection or radiofrequency ablation of the SI joints in management of inflammatory arthritis forms such as axial ankylosing spondylitis, traumatic or other spondyloarthropathies. And so our rheumatology experts will take over here.

Dr. Ward: Yes. So this is Mike Ward and Maureen and I will split this question. So our primary source here was the current American College of Rheumatology Treatment Guidelines for Axial Spondyloarthritis that specifically addressed the role of sacroiliac joint injections with local glucocorticoids.

And the population under consideration by this group was patients with ankylosing spondylitis who had isolated active sacroiliitis despite treatment with NSAIDs. And then the question was is treatment with locally administered glucocorticoids more effective than no treatment with locally administered glucocorticoids?

And the recommendation based on systematic literature review through 2019 was conditionally in favor of local glucocorticoids in this patient population based on, unfortunately very low-quality evidence, with primary evidence being two small randomized controlled trials, one of which was not blinded and therefore high risk of bias, but both of which demonstrated substantial reductions in pain over a follow-up of anywhere from 1-1/2 to 18 months. Maureen?

Dr. Dubreuil: Thank you. So I'll just summarize the observational and open label studies that were included and not ACR Guideline review.

The observational studies comprised 268 patients and 457 SI joint injections, I believe. And among these studies, there was a significant improvement in pain in over 90% of those who received injections. The mean duration of response was eight months.

And of those observational studies, several of them demonstrated improvements of bone marrow edema on MRI, improvements in inflammatory markers and reductions in NSAID use, leading to this ACR recommendation conditionally in favor.

So my interpretation of these data are that SI joint injections are a reasonable (adjunctive) treatment to systemic therapies for axial spondyloarthritis among those who have sacroiliitis that their predominant or only feature while they're awaiting the effects of systemic therapy.

SI joint injections could also be a reasonable option for those with spondyloarthritis who have some contraindication to escalating therapy or starting therapy, a systemic therapy. So that could include people who are pregnant or those who have had a severe infection.

But it is my opinion that SI joint injections are not a reasonable monotherapy for individuals who have spondyloarthritis and have involvement somewhere outside of the SI joint. So those folks would require systemic therapy unless there are some contraindications to everything else.

And Dr. Ward, did you have any other comments or any other interpretation?

Dr. Ward: No. I completely agree. We think this is useful (adjunctive), particularly if, you know, the SI joint is sort of involved and painful out of proportion to the rest of

the axial skeleton or peripheral joints and there's some reason why systemic treatment either can't readily be given at a particular time or there are some temporary contraindications.

Dr. Loveless: Thank you so much. And do any of our other panelists have any comments to add?

Dr. Beall: I do. And this is Doug Beall. I want to add this is a Level 1 open labeled, randomized controlled trial by (Zheng). And this was done in 2014, 155 patients.

And these are primarily acute back pain or selected for SI joint pain by at least a 50% response to a fluoroscopically guided SI joint injection randomized to RFA or celecoxib. So Celebrex is the other arm and followed out to six months resulted in a statistically significantly better improvement in pain at a very high level of statistical significance as compared with the celecoxib arm. And this is a Level 1 open label RCT.

Dr. Loveless: Thank you. Thank you very much. Before we move to the next question, Dr. Gulur is unable to connect so she is sending her response to Dr. Goldzweig, one of our CMDs. And Peter, has she been able to send that to you yet?

Dr. Goldzweig: No. I have not received it yet, but she did mention she will be sending it to me.

Dr. Loveless Okay. So once she receives that just let me know and we'll go back up to that first question.

Dr. Goldzweig: Very good.

Dr. Loveless: So if no other comments on Question 5, we will move to Question 6. And to all of our panelists for the articles that that are mentioned like the (Zheng) 2014 and several of the physical therapy articles you mentioned Dr. Beall, and throughout, if you could kindly send me those references.

If you just send the reference, the name, I can pull the articles. But if we can get those that's important that we have the accurate reference that you're referring to because we appreciate you identifying those sources for us.

So for the next question, I'm going to turn this over to Dr. O'Brien. And this is regarding the ICD-10 codes that you feel are appropriate for SI injections or RF and the the CPT Code 64625, which is the code for radiofrequency ablation of the SI joint, let's go ahead and have that included in here. So this would also include 64625 in the question. And over to you, Dr. O'Brien.

Dr. O'Brien: Yes. So the question is, do you feel there's sufficient evidence to support the following SI ICD-10 codes for SI joint injections and/or RFA? And again, you added that additional CPT code, which is appropriate for an SI joint RF to that list.

For the first one, sacroiliitis, not otherwise classified, I thought was appropriate. The next two would include spondylosis without myelopathy or radiculopathy of the lumbar or lumbosacral. I thought those should be excluded as the next one, spondylosis without myelopathy or radiculopathy sacral, the sacrococcygeal joint region more accurately describes the problem in the sacral region.

And then the second part of that question was, do you agree that there's insufficient evidence to support the following diagnosis codes for SI joint (unintelligible) RFA.

The diagnoses listed were more lumbar related due to lumbar stenosis, radiculopathy. The sacrococcygeal joint specifically, which is not the SI joint, trochanteric bursitis of the hips is not specifically an SI problem and post-laminectomy syndrome is not necessarily an SI joint problem. Neither is the fracture of the lumbar vertebrae or, you know, degenerative - disc degeneration.

So I thought those should be excluded. And I did add in my email six new diagnosis ICD-10 codes I thought would be appropriate. And that included M46.1, which is sacroiliac inflammation. The code also for arthritis of the sacroiliac joint, ankylosis of the sacroiliac joint, degenerative joint disease of the SI joint, disorder of the sacroiliac joint and then chronic sacroiliac pain.

So I thought those were appropriate ICD-10 codes to add to the list of codes that should be appropriate for these procedures.

Dr. Loveless: Thank you very much. And if our panelists have any additional thoughts on these codes or the additional codes that Dr. O'Brien brought up, their appropriateness, please comment.

Mr. Jacobs: This is Brian Jacobs. I agree with, excluding the codes Dr. O'Brien identified, including the six new codes related to sacroiliac joint.

Dr. Loveless: And for sake of time, does anyone disagree? Well that was simpler than I expected. Thank you, Dr. O'Brien.

Dr. Goldzweig: Meredith, this is Peter. I have Gulur's response to the first question.

Dr. Loveless: Great. Well then let's go ahead if there's no additional comments on Question Number 6, we're going to return to Question Number 1. And...

Dr. Goldzweig: The question...

Dr. Loveless: So, Peter, if you can start with that first question and then Dr. Beall and Dr. Dubreuil will follow.

Dr. Goldzweig: Sure. So for the first question, is physical exam findings consistent with SI joint dysfunction, which may lead to intervention? In 15% to 30% of chronic low back

pain patients, especially those that are older, the SI joints are often the cause of pain.

Common symptoms include maximum pain below L5 vertebral body, pain aggravated with sitting and transition to sitting and sitting to standing, referred pain to the buttocks, groin, thigh and occasionally below the knee.

Patients with a history of lumbosacral trauma or history of procedures such as fusion often display lumbosacral pain. Physical exam demonstrates Fortin's point, that is localized tenderness with palpation over the sacral sulcus. Physical exam maneuvers that provoke SI joint related pain include the FABER test, the Gaenslen, thigh thrust, sacral thrust, distraction and compression.

No single test has a high predictive value for diagnosing SI joint pain. It has been reported in the evidence that a history of maximum pain below L5 and a positive finding of at least three of six of the above tests predict a 70% to 80% likelihood of a positive response to a diagnostic interarticular SI joint block.

The standard of diagnosis of SI joint pain remains a positive response to fluoroscopy guided intraarticular injection of local anesthetic. And she does have a list of references to support her argument.

Dr. Loveless: Thank you. And is there any comment on this portion before we move to the next section?

Man: No.

Dr. Loveless: Thank you. All right. Dr. Beall?

Dr. Beall: Okay. So this is the use of the imaging for SI joint pain and dysfunction. So in general, this can be helpful to confirm the degenerative changes, but degenerative changes are not necessarily helpful in confirming pain.

These are normal. This is seen really early on. Cohen, a different Cohen, described this up to 25% of everybody on plain film evaluation at age 50 and then Vogler described it as 77% by the early age 30. So this is not particularly helpful in assessing degenerative changes.

CT scanning has a little bit of limited value in correlating pain versus appearance based on a low sensitivity and specificity. MRI is especially helpful for neoplastic disease and to detect inflammatory arthropathies, spinal arthropathies, infection, tumors. Nuclear medicine bone scanning has been shown by (Curtis Lipton) in Maine to have the low sensitivity, but a high specificity.

And although none of the modalities are very good for correlating with pain, these are especially helpful when excluding such things as trauma, stress fractures, inflammatory changes and cancer involvement.

Also, a second category here given the fact that transitional lumbosacral anatomy is about 15% of the population and sacral dysplasia has been reported in up to 26% of the population. These things are almost as common as the incidence of blue eyes the United States.

And so to be able to have adequate evaluation of the CT and MRI, the cross-sectional evaluation for intervention is very important to be able to determine, especially if you go into SI joint fusion, where you would fuse and what this looks like in the presence of that transitional lumbosacral anatomy.

So in summary, imaging is useful for patients with stress fractures, trauma, inflammatory changes, neoplastic involvement and infection but not especially helpful in separating out patients who have painful degenerative changes versus those who do not have pain from their degenerative changes. And also given the variable anatomy to sacrum and the imaging and the variability of the

SI joint itself, imaging is very helpful for interventional treatments and for SI fusion.

Dr. Loveless: Thank you very much. And do we have any additional comments on this question?

Man: I think Dr. Beall brings out a good point, that although imaging may not diagnose SI joint pain, it's very useful at evaluating for other sources of sacral pain that may mimic SI joint pain for many of the reasons you just mentioned.

Dr. Loveless: Thank you. And I'll turn it over to Dr. Dubreuil.

Dr. Dubreuil: Okay. Thank you. So I'll first address evaluation for infection, which is just the simpler of those two questions. In regards to data supporting a strategy for evaluating for infection, I was able to find no literature supporting either patient factors or a specific strategy for evaluating for infection among people presenting with SI joint pain. So my comments are related to my clinical experience and training.

In terms of people who should be evaluated for SI joint infection, there are individuals who have subacute or acute onset of severe, typically unilateral buttock pain with exam findings that suggest SI joint involvement that we just addressed at the top of this question. Typically, they have other signs of infection, either like physical exam or laboratory studies or imaging. They may be individuals who have risk factors for infection, such as those who are immunocompromised; have known exposures to TB, risks for brucellosis.

They may have risk for hematogenous seeding or very rarely. direct infection of SI joints If people have this concern for infection, they should go on to have an evaluation with soft tissue imaging that can image both the SI joint but also the surrounding soft tissues. And if there's a fluid collection, they would go on to have an image guided joint aspiration or aspiration of that fluid collection.

In terms of evaluation for inflammatory disease, that family of diseases under consideration is termed axial spondyloarthropathies. So this includes the prototypic form of disease, which is ankylosing spondylitis. For these folks, the predominant feature is inflammatory back pain. So an inflammatory pattern to their back and buttock pain or other axial pain due to inflammation at the sites of tendon attachments throughout the spine, with the SI joint being one of the most common sites.

These folks do warrant systemic treatments because of the risk for going on to develop permanent bony damage at other sites, and highly effective therapies that are available.

And so for individuals who develop the other axial or buttock pain before the age of 45, so this includes adults and children, or people who have common extra spinal manifestations of spondyloarthropathie being inflammatory bowel disease, psoriasis, or eye inflammation, uveitis or episcleritis, they should go on to have an evaluation, ideally by a rheumatologist or another clinician, who's experienced in diagnosing spondyloarthropathie.

And typically this evaluation would include systemic inflammatory markers, as well as a pelvic MRI with specific sequences and HLA B27 genetic testing. I'd be happy to hear comments.

Dr. Loveless: Thank you for that thorough answer for all three of our panelists, and Dr. Gulur if she can hear us, for her contribution to that question. Are there any other comments on question 1? Then we are going to speed ahead to - back to question number 7, and this is for Dr. Cohen. This question has multiple parts. I'll turn this over to Dr. Cohen.

Dr. Cohen: Thank you. I'll try to answer all the parts. Does the evidence support single diagnostic injections or multiple, and what's the therapeutic cutoff? And then I'll

go over outcomes. So without a reference standard, you know, the validity and accuracy of diagnostic injections is always speculative. So for prognostic purposes, you know, the false positive rate varies based on many factors; the placebo response rate. And there are seven SI joint studies that report false positive rates by doing two blocks.

And if you throw out the two outliers on both sides, the median is around 30%. So that's very similar to what you see with lumbar facet injections

But you also spread injectant to other pain generating structures. So for almost all diagnostic procedures, almost every single one, lower blocks are more specific.

Using sedation, superficial anesthesia, for conditions with a low prevalence or pre-test probability, like let's say lumbar facet in younger people, the chance of a positive block being false positive is higher than a positive block being a true positive. Right? So for SI joint pain a lot of it depends on how you select patients.

So you could increase the pre-test probability by selecting patients for diagnostic blocks with multiple provocative texts. And although many studies report this, not all do. There are several that don't, including that recent 2022 nine center studies.

The other problem with doing two blocks is that when they classify a block that's both positive, it's usually a block that's positive and then a block with negative. So the only data that we have on this, is by Rick Derby back in 2013, the lumbar facet pain. And he found actually false negative rates of 47%. And he used 75% as a cutoff. But it was 47% for people that had less than 50% relief and people who had between 50% and 74% relief.

If you look at the randomized control trials for SI joint fusion, these are almost all industry sponsored and almost every single one of them used a single block with

50% threshold and they all reported positive outcomes. So clearly if people are using one block with 50% pain relief for surgery which has very significant risks and costs, many people would consider it being inconsistent for doing it with something like radio frequency ablation, which is cheaper and less risky.

It depends on what your goal is. So clearly, if the goal is to maximize patient benefit and access to care, you would never do two blocks. So I have been the chair of the cervical and lumbar facet guidelines. So those have 14 and 17 international organizations including the US Departments of Defense and Veterans Affairs. And it was recommended both times for only one block.

If you look at the therapeutic cutoff of 50% versus 75% there are old guidelines that were initially kind of developed for lumber facet joint pain from the 1990s from SIS and they said you should have almost 100% relief. For SI joint in the book from 2013, which is being revised now by Milan Stojanovic, they said that less than 50% is the negative block; 50% to 74% might or might not be a positive block. It's equivocal. And greater than 75% is a positive response.

But again, these were kind of developed in the 1990s. And the impact guidelines which came out and these are followed by the FDA and the ERP medicine agency in almost all studies. They consider a 30% or a 2 point decrease in pain to be clinically meaningful. So if you look at the randomized trials for SI joint pain I will go over you have Maugars study, they consider it 50% to 70% as fair results, over 70% relief as good results, and they used one month outcome.

If you look at the two Luukkainen studies these are periarticular SI joint injections, they didn't have a categorical outcome measure that they used one month. So that was their endpoint. If you look at our - the largest study, so randomized trial and Mayo Clinic proceedings from 2019, we used a 2 point or greater decease in pain at one month and positive satisfaction.

And if you look at ours, that (Rapham?) study that we were talking about, we also used 50% or greater pain relief lasting at least one month. And coincidentally, we found that if you had between 50% and 79% immediate relief, after the procedure, that you were more likely to have a positive outcome at one month than if you had 80% or greater relief.

There are about 20 studies that have looked at difference in the outcome of a definitive procedure like radio frequency. And, stratified by the results of the prognostic block. So it's been done for cervical facet radio frequency that's us, for celiac, plexus, neurolysis, it's Mike Erdek. For lumbar facet radio frequency multiple times including by (unintelligible) and Milan Stojanovic who is the editor and chief of the SIS's new pain journal, (unintelligible) for spinal cord stimulation.

For SI joint radio frequency by us or pulse rated frequency, like also across the board, and almost all have found there is no difference in long term outcomes between cutoff of 50% and cutoff at 75% or 80%. One of the only studies that did find statistically significant difference in favor of a higher outcome, was by our group. (Ian Chen) is the first author.

A 265 patients for genicular nerve radio frequency ablation. And the issue with genicular nerve blocks is that they have no diagnostic value. They appear always prognostic. And almost everybody has a positive block.

So if you look at like the radio frequency studies ours - the first placebo controlled trial looking at SI joint radio frequency ablation, the criteria where it's 75% or greater relief after a single injection and a positive outcome with 50% or greater relief. But positive pacing global impression of change in three months.

Noles Patel's is also a randomized control trial. They used greater than 75% pain relief after two lateral branch blocks, and a positive outcome was greater than 50% pain relief or 10 point or greater reduction in ODI at three months. So again,

three months. Then (unintelligible)'s rate, you know, placebo controlled trial is the only negative one for radio frequency.

They used a 2-point decrease in pain from a single SI joint injection to select patients and their outcome was a 2 point or greater decease in pain. They didn't say when their primary endpoint, but they allowed people to cross over three months. So again, three months. So that's the Mint study, they selected patient greater than 50% pain relief from lateral branch block. Their primary endpoint was three months and the positive outcome was greater than a 2 point decrease in pain that was also positive for the SI joint.

The meta study again, randomized controlled, they were more selective. They used greater than 80% pain relief after two interarticular injections. Again, which is a little strange because, you know, the lateral branches that are targeted for radio frequency ablation, they don't enervate the joint capsule. They enervate the ligaments. So that has to be very clear. So it was a little inconsistent, but their primary endpoint was 3 points.

And they didn't have an outcome measure but they considered 2-point reduction overall as the minimal clinically important difference between groups. And finally, in our study, so this is in preparation, but it's the largest randomized trial. And it's 210 patients that were 17 or 19 sites. The selecting criteria was greater than 50% pain relief after SI joint injections and lateral branch block. And greater than 2-point decease in pain of three months at a positive pacing global impression of change.

So that was a positive outcome. So it seems to be for radio frequency, three months, and that's consistent with the lumbar and cervical facet guidelines. And my other disclosure is that I had been the chair of those guidelines. And, you know, usually between 30% and 50% pain relief. If you try to extrapolate to other conditions, I'll just give you examples. Like the big epidural steroid injections that were published in New England Journal of Medicine, three and six weeks.

The Friedley study also published in the New England Journal of Medicine NIH, their primary endpoint for a steroid injection was six weeks. There's a study that's finished. They're looking at the data. They worked with the US Food & Drug Administration. They're trying to get - the company is trying to get the first ever steroid approved for epidural use. They're called (Skylex?). And the FDA says four weeks is a reasonable outcome.

So, you know, as I said, so radio frequency and the use of three weeks, was based on a study that we had done where we did surveys of patients and physicians before a very, very large randomized trial. And three months was considered reasonable. Those are also mentioned in the action guidelines. So those are the successors to the impact guidelines. So lots of information. I'm happy to take questions.

Dr. O'Brien: Yes. This is Dave O'Brien. I thought Steve well outlined the heterogeneousity within the literature and different criteria. And I would tend to agree that of those that get greater than 50% relief compared to those that get 75% relief, and go into a more defensive procedure, there may not be much difference in the outcomes from some of the studies I've read.

I guess one concern I had is if we only do one block and it's a false positive, and then that patient gets put into a treatment program, and may have basically repeated procedures for a misdiagnosis for some period of time what's - that's obviously not ideal or cost-effective.

And Steve can correct me if I'm wrong, but I thought he was involved with the study looking at the percent to assess RFA and going from one block to two blocks was almost, you know, 39%. I think it was up to 60% with two blocks assess rate.

And there's a small study compared to no blocks which is only like a third of the patients got better. So NASS has looked at this, SIS and other organizations, and some of their guidelines do recommend dual blocks for those purposes, to minimize proceeding with treatments on patients that actually don't have the problem.

The other kind of thing that is a little bit of a mess with this issue, is a lot of the studies were obviously based on interarticular blocks in response to that. Whereas, for RFA we're not doing an interarticular procedure. And that's where they are recommending two positive blocks for lateral branch blocks and L5 dorsal anus block, as a prognostic evaluation to help diagnose or predict what people will respond to RFA at the SIJ joint.

So I think in coverage policy I think there's one thing to look at an interarticular block if somebody is thinking about a fusion, and getting a positive response. But I think it's - and I personally think based on some literature and the significance of undergoing SI joint fusion, that the two block protocol is appropriate. And I'm not sure why we wouldn't do the same thing as - once they get diagnosed with this and they undergo RFA, especially if they're younger, they may be getting repaid procedures from numerous years.

And I think having a confirmatory block to at least isolate that patient population that'll respond appropriately, is a reasonable thing to consider incorporating.

Dr. Cohen: Thank you. Very, very interesting. So I think I know a lot about this. I've spoken with almost all of the directors of these organizations that speak to (Melan) who is, you know, now the editor of the SIS's new guidelines and the editor and chief of their journal. And I had been the the chair of both the lumbar and the cervical facet guidelines committee.

So the SIS Guidelines about these blocks, they came out in the mid-1990s. So we lived in a different world. Back then people were getting spine fusions very easy. And, you know, they were getting put on very high and aggressive doses of opioids. That was also before impact said that 30%, clinically meaningful. And across the globe, like I said, not just the FDA but the (unintelligible) medicine agency, basically uses the same thing - 50% is a substantial responder, 30%.

The best data that we have on this so clearly that's the rationale for two blocks is that it reduces the false positive rate. But the other thing is the more blocks you do and this is inevitable, right? It increases the false negative rate. And the only data that we have on this is Rick Derby's data who is from the SIS. And so he found that there was a 40%, 47% false negative rate.

So people who had a have a negative block then you get the block repeated 47% of them are positive and then 74% of those then out of the people who underwent radio frequency, so there were eight of them, six of them had a positive outcome. So he concluded 47% false negative rate. So that's the problem.

And clearly, at the current reimbursement rates, you know, our - that 2010 study by us that you just quoted, zero block is the most cost-effective. Because the Journal of Anesthesiology for a while that was the most publicized article and they had a big, huge webinar. So it was run by (Jim Rathnell?) and (unintelligible) and (Martin Van Cleese?), who just passed away three weeks ago, who has a PhD in radio frequency ablation. And they said one block needs to make sense.

The other problem with doing two blocks is there are two other things. So all of the studies for surgery, they do one block. So that's an inconsistency that really has to kind of be addressed. And if you're looking at spine fusion surgery, most studies don't do any blocks, right, they don't do discography.

And the other thing is a really high percentage and you make a comment about SIS, so (DJ Kennedy?) now I think is the President of SIS and he'll be the President of AEP (unintelligible) who said, when he does two blocks, when he's forced to do blocks he goes about 90% of the people have a positive response to a second block.

And it might be that these people aren't blinded so, people don't want to come back for a second block especially if you work and you have to bring an escort. So you basically say I'm sorry, you have to do a second block. I know you want this treatment. Your insurance company covers it. So for whatever reason it is, you don't really have two blocks so you're subjecting people to additional costs, additional risks, and like I said, it doesn't really seem to have a big difference. And you have to weigh the costs of and access to care.

So more blocks will be creating the false positive rate. But absolutely you will start to have false negative rates. You'll have people who kind of drop out and it's not cost-effective. You know, CMS, all of the people who can make it cost-effective by either reducing the amount that we get reimbursed for diagnostic blocks themselves, or just increasing the cost of radio frequency ablations, then it would become more cost-effective.

So like I said, you're going to decrease the number of people overall who have a successful procedure; you're going to increase the cost. That's what ends up happening with multiple blocks. And like I said, that's what our study clearly showed the lumbar facet. And that's what (Nick Boggs?) just even, you know, who was the initial advocate for two blocks. He even wrote like the big editorial he says, the travesty of cost-effectiveness, is that in the United States, you know, it's not cost-effective.

And the problem with, you know, having these false negative blocks is that what do you do with these people? Then they end up getting surgery or they get put

on opioids because there's nothing else that's really a great treatment. So I think like is aid, that we should be really prioritizing access to care.

Dr. O'Brien: Hey, just a quick question. So this - I mean the discography question aside, I mean because that goes down a different road for fusions, right, in terms of why you're doing a surgery here, going down that road. And I'm not sure the utility of discography. But the study where the false negative rates goes up with two blocks, how many patients were included in that study?

Dr. Cohen: So their Rick Derby's study - so it's very hard to interpret his things. I mean I can - it's...

Man: It was a very low

Dr. O'Brien: Yes. That's why I'm asking the question is that I mean we're extrapolating from one study. And if the numbers aren't great, can we truly say based off one study that okay it's going to increase the false negative rate?

Dr. Cohen: But we don't have other studies. So that's kind of the problem if you're looking at false negative. And yes, it's very hard also to extrapolate for lumbar facet blocks, to something else. So retrospective study, 229 patients who underwent medial branch block.

Again, not all negative blocks had a second block that out of those who did, 47% were the people with a negative block, had a positive block. And then out of the people with a second positive block who underwent radio frequency, 75% had a positive outcome.

So I think it's kind of problematic that if there were major operations including SI joint fusion where they use a block - a lot of them use 5 CCs. One single block, they had 50% pain relief and then they end up getting the fusion. And we're

trying to say well, you know, you're going to have radio frequency procedure which there are multiple, multiple studies that show efficacy and effectiveness. And we're acquiring kind of a higher threshold for them to undergo a less invasive procedure. So there is no doubt that there are inconsistencies.

Dr. O'Brien: Right. - I see your point. I would just say you could ask a question if that is the one block that's on SI joint fusion sufficient. And is that an appropriate thing? And then you appropriately brought up the fact that many of those SI joint fusion trials are industry sponsored. Right? And many of the people involved in those trials have consulting agreements. And so there's inherent conflict that is always going to be there with some of those - some of that data as well.

Dr. Beall: This is Doug Beall. I just have a quick comment. So (unintelligible) this literature here, and generally I agree with what Steve said about one block and the threshold. But, you know, it ranges all the way up from Joe Fortin's, you know, early mid-'90s study with 50% relief all the way to Paul Dreyfuss's study shortly after that, with 90% as a threshold. And then there's, you know, 70%, 75% by Broadhead, Maigne and Curtis Slipman had an 80% threshold. But general and (Laslo?)'s paper thrown in there as well.

But all of this kind of agrees with one block and if somewhere in the range of 50% to 75% is adequate. And I don't want to belabor it. And maybe less is appropriate.

Dr. Cohen: And the industry guidelines, the impact guidelines would say 30% is clinically meaningful. I just have to emphasize that this is really followed across the entire - not just the US Food & Drug Administration, but this is followed all over Europe.

Dr. Beall: Yes. I don't disagree with that.

Dr. Loveless: I'm not a pain management or anesthesia, so excuse me if I'm not understanding something that's basic to your practice.

But I'm hearing the interarticular blocks would let you know if the patient was going to respond therapeutically or potentially if they had benefit from fusion. But not necessarily predictive of their response to RFA where the lateral branches might be more predictive. So how do you select which patients would receive therapeutic treatment versus an RFA, and should they be getting different blocks for different assessments?

Dr. Cohen: Right. This is a great, great question. And it's very hard. But if you look at a lot of the studies, you know, what they did? Did they do screening blocks, and when you do an interarticular block a lot of it goes extraarticular because the joint capacity is probably a little bit more than 2 CCs. So there are studies and I can go over every single one of these. I always lecture on this topic. But on - there's probably greater evidence for - I mean the best studies are Mayo Clinic proceeding study, patients were randomized, they didn't know what they got.

But basically intra and extraarticular injection, the positive rate of a block is almost the same. So young people are more likely to have extraarticular sacro iliac joint pain from ligament injury, things like that. Whereas older people with bilateral symptoms, they might have less tenderness because it's not their ligaments, it's deeper.

You know, bilateral symptoms, they're more likely to have intraarticular. So the indications for fusion in their studies, and I haven't read all of their studies, but generally it's instability or like severe degenerative joint disease, whereas the indications for for radiofrequency is it should be extra-articularbecause those lateral branches innervate the ligament.

So what people usually do is they do a block. It might be intra-articular. It could be extra-articular, but intra-articular blocks often go into the ligament. They're usually just not confined to the joint space, so they go out into the ligaments.

And then a lot of the studies - and these were sponsored by Avanos, which makes cooled radiofrequency, so there's - they're three of the studies. Then they require a positive lateral branch block.

You can't do a lateral branch block as a diagnostic tool because those lateral branches don't innervate the joint capsule and they may or may not - they certainly don't innervate all of the bone but - so those are purely prognostic blocks.

So it is possible that that people end up getting a screening injection, and then if that's positive and you want to do radiofrequency ablation, don't make them do another screening injection.

A lateral branch block might make sense so that's prognostic, right. We're blocking these nerves with low volume. This is going to tell us what type of pain relief they're going to get if we do radiofrequency of these nerves.

Dr. Loveless: Thank you.

Dr. Cohen: So in other words they're - yes, they're different purposes.

Dr. O'Brien: So the intra-articular block to add on to what Steve said helps to evaluate for intra-articular pain, and that's why a lot of the guidelines recommend injecting not much more than 2 cc's from a diagnostic standpoint.

And if they get good relief with that whether it's one block or two, then perhaps fusion would be of benefit unless they can get a prolonged therapeutic improvement from a steroid injection like those with the spondyloarthropathies.

But if you don't - they don't respond to an intra-articular block but they still have this SI joint kind of picture on their exam and a lot of buttock pain, then perhaps the lateral branch blocks from a diagnostic standpoint or prognostic standpoint

to evaluate whether they respond to RFA is - would be the appropriate next step to consider.

I feel the facet pain relief, whether it's 50 or 75, is one thing. I don't think we're supposed to be looking at cost or deciding where appropriate coverage policy is.

But if you do it - a - an extra block that's - they positively respond to and 65% success rate with RFA on those people compared to like 40% if they only get one block, you know, that's 25% difference.

Is it - and these people will often come back for repeat procedures, so of those extra 25% that are coming back that really aren't getting good relief, you know, I mean, that's just the way I'm thinking about it.

That's why I kind of lean towards the dual block as far as the 10% pain relief. I think there's more gray there about what the appropriate cutoff is, but I'm not sure I have a hard time understanding the cost-effectiveness of justifying one block or going straight to RFA on something that's not been clearly diagnosed.

Dr. Cohen: Yes. So that's the 2010 paper so obviously the the zero block. So in the two-block group there are - you're paying for radiofrequency. You're paying for two blocks so there's definitely going to be less people who benefit, right, because every block that you do there's a potential for false negatives so less people benefit.

But the overall costs because of the ratio of cost, the rate - the payment ratio between radiofrequency and block. So it's not only the cost per successful treatment, which is going to be much higher, but the overall costs are higher and that's not even including that people have to miss work and an escort has to come in for the - these blocks like you say.

But that's not the case in every single country, right, because if it - if there's countries where the cost of radiofrequency is five times more than the cost of blocks, then it's cost-effective to do, more than one block because you want to prevent radiofrequency.

That's why discography is always cost-effective. And the last point is the studies for SI joint fusion are really flawed. So they did one block. They had 50% pain relief and most of them used - a lot of them used 5 cc's.

So 5 cc blocks - maybe the capsule is rupturing or it's diffusing all out into the ligament, but we don't know why they're getting pain relief so those studies are terribly flawed.

Dr. O'Brien: Yes, I don't disagree with that at all. But getting back to our project - and the CMS staff can correct me if I'm wrong we're not a - supposed to be addressing costs.

Dr. Loveless: Yes, that is accurate.

Dr. O'Brien: And so if we're saying that RFA is a very expensive procedure, then we should do two blocks to really confirm the diagnosis. No matter what the RFA costs in the United States compared to other countries, why - if we want to get an accurate diagnosis, then why would we not do two blocks if we would do it if the treatment was going to be expensive.

Dr. Cohen: false negative rate.

Dr. O'Brien: Well, that's based on one small study.

Dr. Loveless: I think we've got more to discuss on this topic, and I think it's going to overlap with Question Number 8. But to ensure that Dr. Varghese has ample time to

answer his questions, I do want to get those two questions done and then we can return to this as we go through Question Number 8 and then additionally at the end if needed.

. So if I can jump ahead to Question 9...

Dr. Varghese: Hi. Yes, Dr. Ebby Varghese. So my question - is there literature to support a role for cryoanalgesia? In the stack of the literature that we received I don't - there wasn't an article that specifically talked about cryoanalgesia.

I asked for - and I'll - for what I should base my opinion on. I was sent a - an article called Novel Non-Opiate Regional Analgesia, Cryoanalgesia, Percutaneous Peripheral Nerve Stimulation and there's - on the local anesthetic, and that article really discussed what cryoanalgesia is and its role really in addressing peripheral nerves.

There isn't really an application for addressing joint pain, and that's the topic we're talking about. So, you know, to answer the question there isn't any literature that I received that says that cryoanalgesia is appropriate for thick or iliac joint pain, whether that's acute or chronic.

Dr. Loveless: Thank you. We have not identified literature either, but it is - there is some use of it, so that's where we want to know what the evidence is so I appreciate that.

Dr. Varghese: Sure.

Dr. Varghese: My experience with - I was just going to say my experience with the cryoanalgesia is fairly recent and really specific - specifically using it to address - right now we're exploring chronic shoulder pain and for neuralgia and then I know anesthesia uses it often for intercostal - or addressing intercostal nerve pain post - pre- and post-operatively prior to, you know, thoracic cavity-type procedures.

Dr. Loveless: Any other comments on cryoanalgesia? So if we can jump all the way ahead to Question 15...

Dr. Varghese: Yes, I appreciate that. So my question there is there evidence to support the administration of the sacroiliac joint injections at the same time as injections in other locations such as epidural and SI joint injections in the same session?

So that's a - an interesting question. When I looked at the literature, really the only thing that was consistent throughout was addressing the lateral branches, and then L5 dorsal ramus when doing blocks of radiofrequency ablation to address sacroiliac joint pain.

When you look at the physical exam literature that was provided to us and the requirement of - or the - how should I say it - the significant increase in sensitivity and specificity when you have three positive provocative maneuvers for SI joint pain.

And I think it would be really difficult if you're trying to make an appropriate diagnosis to address the different structure at the same time that you're doing an SI joint injection because it would skew your outcomes.

I mean, if you look at - an article in the physical therapy literature that was provided to us that talks about the variety of different things that can cause low back pain.

Not any particular one requires the number of provocative maneuvers the sacroiliac joint pain needs really to give yourself confidence to address that.

Obviously, if you think of - that a patient had a radiculopathy rather than just subjective findings that - reported by the patients, if you obviously see weakness

in a myotome, in a kinesis and nerve distribution allowed to reflex, then you're probably not going to address the SI joints.

You're probably going to move towards getting imaging and looking for some type of evidence that would support your clinical diagnosis. If you take an excellent history and do an appropriate physical exam, I think based on the literature you're going to do only one intervention per one structure to start addressing the patient's pain problems.

Dr. Cohen: A lot of these studies did intra-articular injections and they did kind of small volumes. So a lot of people call it sacroiliac complex pain, right, because it could be from ligaments.

So it's hard to imagine that provocative maneuvers would be positive - equally positive when you have ligament disc pain. There's a lot of studies that shows the presentation is different from Japan for like upper joint, lower joint, the ventral part of the joints, the ligaments, capsular (towers), synovitis, just bone pathology with the osteophytes.

And I would say that our study from 2022 found there was no correlation whatsoever with SI joint outcomes based on a positive Gaenslen and FABER or Patrick's Test.

So I think that there is some other literature by - in the physical therapy – (Mark Glasswood?) is traditionally one of the leaders in this, I think term it like a centralization versus lateral pain.

So it's kind of - I like that Fortin finger test. If people say that this is the most prominent part of their pain, if it's tender over there and it's near the PSIS - that there's a really good chance that they have SI joint pain.

And again the, gold standard is, are these really diagnostic blocks. A lot of those studies - and they're not all positive where provocative tests predict response to blocks.

But they are - for low volume intra-articular injections and again radiofrequency at least, you're not targeting the ligaments.

Dr. O'Brien: I like that. So specifically, regarding Question 15, I don't see any logic in doing multiple injections in multiple areas of the spine on the same day on that patient. Epidural injections, facet injections and SI injections diagnostically and therapeutically are for different indications and reasons.

If you did an epidural injection at the same time you do an SI injection, especially using an anesthetic, it doesn't tell you anything so you lose all your diagnostic information, and what we're talking about is primarily diagnostic injections, these SI joint injections or lateral branch blocks.

So I don't see any logic in allowing multiple spinal injections to be done on the same patient in the same day for this condition. It doesn't seem to make any logical sense, and you'd lose all your diagnostic abilities and you don't really know what you're treating.

Dr. Cohen: That's said perfectly. I would add this one caveat, because SI joint pain frequently co-occurs with greater trochanteric pain syndrome. If someone's coming - if it's very difficult for them to travel, they're disabled, if they're coming from very long periods of time and I really feel it's important for them not to have to take another flight to come back for two separate injections and I feel that it's medically necessary then I do those procedures.

And if - I do one with local anesthetic and I might do the trochanteric bursa injection just with steroid so it does not lose the diagnostic validity.

Dr. Varghese: So if I can also comment there - just an extension to your point Dr. Cohen. Piriformis myalgia, not piriformis syndrome, the piriformis muscle attached to the front of the sacrum to the greater trochanter - a lot of patients present with sitting intolerance, which is classic for SI joint pain.

Patients can present with what seem to be radicular symptoms, though it may be more of a spasm of the piriformis muscle or dysfunction of the SI joint causing piriformis muscle spasm and presenting as a sciatica.

I think that is the only time that I do a second structure - because it's just off the inferior pull of the SI joint. So I would do an SI joint injection and then the piriformis muscle trigger point injection, and then I send them to therapy to address it, assuming they're not presenting with any other physical advanced findings suggesting a true radiculopathy.

Dr. Loveless: Yes.

Dr. O'Brien: So I'd play devil's advocate. And if you think they have piriformis syndrome causing radicular pain, then why not just do a piriformis block? And - because you just want a diagnosis. Since you don't know what's causing their problem. And I'm not sure if there's literature shows about SI problems causing piriformis problems and piriformis syndrome that supports.

Dr. Varghese: Well, that's right.

Dr. Loveless: Can I just clarify who the last person to speak is on the piriformis trigger point? I just didn't catch who was speaking.

Dr. Varghese: That was doctor - that was me, Dr. Varghese.

Dr. Loveless: Thank you.

Dr. O'Brien: And this is Dr. O'Brien with my comments regarding - I - and I still don't understand the logic. I think if you think the piriformis muscle is the problem, then do a piriformis block.

I think if you block multiple areas around the hip or SI joint, then you're not going to get what you're treating. I mean, a trochanteric bursitis is easy to diagnose.

And those rare occasions where somebody just puts steroid like Steve said in the bursa - if the patient has to fly to see him for this, that's understandable but that's, 1% of the patients we're talking about.

I mean, these people are coming in with back pain. There's a lot of lumbar structures. They're referring to the buttock and we're doing the blocks to diagnose where the pain is coming from to then determine whether it'd be appropriate for another type of treatment or hopefully a therapeutic benefit.

But I just don't see the logic in doing facet blocks, epidurals and SI joints -- and I've seen this out in the community -- and/or hip injections. And they all use anesthetic and steroids in each of these areas, so I don't know what's being treated and I'm not sure it makes sense.

, I think there should be a good medical necessity for performing a procedure and then to rule in or rule out something in these situations that they're - we're primarily doing it to help diagnose their condition.

Dr. Loveless: Thank you. I think that was a great discussion. And if there is no further comments on that question, I'd like to move us back to Question Number 8.

Dr. Beall: This is a series of corollary questions to Question Number 8. So the assessment of the clinical literature to conclude the role of RF in the management of SI joint dysfunction - so there's ample clinical literature in this area.

This includes six Level 1 manuscripts and five sham-controlled RCTs, two by Nilesh Patel, Dr. Yongjun Zheng, van Tilburg and Mehta. And this - first started by (Ferrante) in the early 2000s for introducing the bipolar technique along - to create a strip lesion just medial to the SI joint at <1-centimeter intervals, and this was followed shortly after that by monopolar technique to target the lateral branches, the primary dorsal rami.

And this was done in several studies, which reported greater than 60% pain relief in - for six months or more. And in addition to the unipolar, the bipolar, there has been other techniques that have been used.

Techniques for ablation to target the lateral branches of the primary dorsal rami include unipolar and bipolar RFA and heated and cooled RF, which are essentially the same thing with a different technique.

So out of the highest-quality data, the six Level 1 manuscripts refer to sham trials that were published - showed a comparison between groups show - those treated with RFA were four times more likely to achieve a 50% or greater pain reduction.

The most recent sham-controlled trial showed relief of pain in both groups–had a statistically significant relief of pain for the group treated with strip lesioning, so this is a slightly different technique.

Five of the six Level 1 trials showed statistically significantly better outcomes as compared with either nonsurgical management or sham treatment. And then in addition to these Level 1 trials, there are several meta-analyses that have supported RFA of the SI joints for patients treated with RFA, neurotomy that had

statistically significant improvement in pain and function; also quality of life scores as compared with controls.

This whole subgroup analysis achieved the same thing, and there is a book chapter that goes through the interventional pain medicine evidence and recommended that SI joint pain should start with conservative treatment, followed by intra-articular injection followed by RF and that's also supported in some additional studies that I'll talk about in just a second.

So in summary, there are multiple different RFA techniques that may be used in managing symptoms from the SI joint dysfunction. The highest-quality Level 1 evidence has six Level 1 manuscripts in all but one, shows statistically significantly better outcomes as compared with nonsurgical management or sham.

The meta-analysis also supported the treatment of the SI joint with RFA, showing significantly better pain and functional improvements in those who were not treated with RFA.

So I'll move on to the first additional question here. Does the literature support cooled versus heated RF? And I want to clarify here that these are both techniques using heat.

The cooling of the tip is designed to reduce charring and expand the ablation zone in terms - and all the way out to about 600 cubic millimeters, and so this is just a different technique - both using heat.

And whenever we say cooler that's what we mean, but they both use heat for radiofrequency ablation. So Kapural showed in his retrospective review of 27 patients with pain who underwent RFA to the lateral branch or of the sacrum had significant improvements in pain and function that was durable to at least four months.

And in a later study, the randomized controlled trial by our Dr. Cohen compared cool RF to placebo and found significant improvements in pain and function from the patient's baseline status and a greater global perception of effect.

(Karman) studied 15 patients for - with chronic SI joint pain and found immediate pain score reduction of 8 to a 3 at six months, an ODI decreased from 36 to 14 at the same time.

And then - and (Patel) showed in the randomized controlled trial the lateral branch RFA was significantly better in terms of pain, function, quality of life to a sham treatment.

And then there's a negative one. The only negative trial was one by 2016 by van Tilburg. It failed to show significantly improved pain from RFA over sham, but this study was criticized due to the statement in the trial itself for the diagnosis of SI pain - may have included patients without SI pain.

That's just the statement the authors included in their own trial, so it's worthy of mention. And then after this, strip lesioning shows in - with some of the longer RF ablation devices included - concluded that there was significant reduction in pain over a - three months' time period as compared with Celebrex as I mentioned previously.

And then - and it is a large, randomized controlled trial comparing cool RF to standard medical management in 210 patients, so 50% more reduction in back pain with the - following Si joint injection selection.

These patients were selected specifically with an SI joint injection at an average of 10 years, and this is unpublished data so I now just got the early release of three months' data, including a statistically significant reduction in pain and improvement in function, quality of life, disability and global perception change.

So in summary, for this there's ample literature support for cool RFA including case reports, case series, two meta-analyses, three systemic reviews, four blinded sham-controlled trials and a large multicenter trial.

So in addition to this high-quality data, there's also six Level 3 and 4 manuscripts, an additional three technology contributions to the literature. So in summary - there's strong support for both heated and cooled RFA for the - treating the SI joint dysfunction pain.

So a natural extension of that is the next question. Is one superior to the other? So there are multiple RCT's, including sham-controlled trials that we just mentioned, comparing SI joint RF to standard medical management, but there is only one Level 2 trial that compared thermal and cooled RF, and so this trial failed to show any difference between cooled RF and thermal RF.

So in summary to this, there's multiple RTCs including sham-controlled trials, large trials comparing RFA to nonsurgical management or standard medical management, and all showing statistically significant benefit and - between group comparisons of SI joint RFA over nonsurgical management, regardless of whether the traditional RFA or cooled techniques were used.

I'm just going to go ahead and go through these last few. Can all branches be reached? As was indicated previously the answer to that is no. Solonen had a great anatomic description that says the dorsal innervation comes from the lumbosacral trunk, superior gluteal nerve and the dorsal rami of S1 and S2.

And then the ventral - the anterior joint was integrated by the ventral rami of L5 and S2 so that's - difference between the dorsal and ventral rami and the dorsal rami reached the lateral branches and the ventrals or not.

So there are some reports saying that the innervation from the noxious stimuli are largely present in the dorsal portion. And most recent studies showed that although most of the innervations from the post reports to joint - there's still some contribution of the anterior portion of the joint by L4, L5 and S1.

So to summarize this, most but not all nerves that are transmitting the noxious stimuli can be reached by the dorsal treatment methods. Onto the next one, how long should treatment be considered before it is successful?

So the best quality data measurements as we've discussed ranged between six months and one year, and there is a significant improvement measured out to at least six months in a number of these.

When SI joint - Vanaclocha had a great paper comparing SI joint to nonsurgical management and SI joint fusion. It showed a response of six months for the RFA. Moving on to kind of quality-adjusted life years, Blissett had a paper and this is based on nice data that says, "SI joint injections in terms of qualities - or the - for RF or no RF is about the same as RFA only, and then RFA following physical examination or other conservative measures are about the same and slightly lower qualities than SI joint fusion."

So - and also this is based on cost-effectiveness at 7.9 months. So summary of this - based on the current literature and what's clinically sustainable and pragmatic and adequate length of time per RFA of the procedure to be effective in terms of duration is six months. And that's it.

Dr. Loveless: Just a little, right. No, it's a lot of questions and we'll open up for additional discussion.

Dr. Cohen: Yes. I mean, that - that's a good summary. Here's how I think of it. So the lateral branches converge onto the foramen, right, the sacral foramen and it's very variable. That - they vary in terms of number and location.

So there could be one. There could be four so even if you were to do simulations and pre-stimulation and you got amazing stimulation and you were positive, you were there, you could still miss 75% of the nerves, so you need to have some kind of lesioning strategy that captures the nerve.

The advantage of cooled radiofrequency is that the lesion is much, much larger and it's also greater depth. So the total area lesioned is really eight times. So, for something where you have a lot of variability in the number of nerves, the location of nerves you have to have of a very aggressive lesioning strategy.

And, cooled RF is, kind of the fit. So there's lots of studies in that if you strategically place these electrodes, you can kind of capture the nerves. The lateral branches go like if they run at different depths.

So in Paul Dreyfuss's study, he had found when he was doing a lateral branch blocks that you have to do them at different depths. So that's kind of another advantage that you have like I say a deeper lesions.

So I think it makes a lot of conceptual sense, why radiofrequency would be effective. We had done a study. It's old. It's over ten years old and we looked at outcome predictors for lateral branch there weren't a huge number of patients. I think there were a little bit less than 80. And there was a trend for cooled radiofrequency to do a little bit better than conventional radio frequency so if there were more patients.

And of course, if you're really comparing two different techniques so if you need 299 patients to show a difference between, radio frequency and a sham radio frequency, if you're comparing two different radio frequency techniques so it becomes a comparative effectiveness study. You need exponentially more patients than that. You might need 800 or 900.

So I think that. , it's very hard to show superiority, comparing two different techniques in a clinical trial because they're all very, very underpowered.

Dr. Beall: Yes. So Steve, this is Doug Beall again. Just a comment that I agree with that exactly it. I think it's a trend, takes very large number…The only one that showed a comparison between the techniques is that level two Chia-Lung Shih article that I quoted and that had what, 195 patients.

I mean, this is very difficult to show anything more than a trend, and that's what cooled RF does. It shows a trend toward better results, but to show significance would require a mammoth sized trial.

Dr. O'Brien: And to summarize, correct me if I'm wrong, but a variety of these techniques show benefit.

Dr. Beall: Yes, they basically all showed benefit. …

Man: Yes.

Dr. Beall: Whether it be traditional heated cooled, strip lesioning, quadrupole lesioning, they all showed consistent benefits.

Dr. O'Brien: Yes. I think it's important for any coverage policies to make it clear, because I think coders and insurance company nurses and so forth get confused when they see code RF thinking it's cryoablation.

Dr. Beall: Cryo, yes.

Dr. O'Brien: It's not so…

Dr. Beall: Yes, that's why I tried to call that out, because, it's still heat. It's just cool at the tip for wider range ablation. So that's right. It - all this cool RF is still heat treatment, not cryo.

Dr. Loveless: Thank you for making that clear. Are there any other comments for Question 8? So we'll jump ahead to Question 10, since we already did 9. And Dr. Upadhyaya?

Dr. Upadhyaya are you on the line? Dr. Upadhyaya?

Operator: And it looks like he lost connection. Do you want me to try recalling him?

Dr. Loveless: Yes please. While we do that, we'll move ahead to Question 11.

Dr. Upadhyaya: Hey, this is Cheerag. I wasn't sure. I feel off for some reason, I just got back on.

Dr. Loveless: Oh, great. Well perfect. Let's go back to Question 10.

Dr. Upadhyaya: Yes, Should diagnostic injections be required before fusion? If so, one or two. And so, I sent this out to everybody. I found a few articles that either talked about injections or directly addressed the question, I think as best you can.

I'll reference Cohen's point earlier that a lot of the surgical trials involved the caveats around more conflict of interest so I won't belabor that.

I do think that there have been some recommendations for two diagnostic injections, but as I was trying to look through the data there was one study by (Polly) where they looked at a subset of other studies whether SI joint block would predict outcome of fusion.

Now the threshold they needed was 50% threshold before they got to an SI joint fusion. And the degree of pain improvement after that, it didn't make any difference in terms of the outcome after that but they did have that threshold.

Beyond that, I didn't find really any great studies that directly answered this specific question as it pertains to SI joint fusion related to a block that did distinctly show we're going to do these blocks and then look at the outcome and does one or two make a difference.

Dr. O'Brien: Yes, this is Dave...

Dr. Loveless: And what does that evidence, what is your practice?

Dr. Upadhyaya: Yes. So clinically yes two is generally what I tend to focus on and what I've seen most folks require or frankly, what many of other payors would require as well. And, having done this literature review, I'm not sure that can be founded with robust data, but yes two.

Dr. O'Brien: Yes, this is Dave O'Brien. The trouble is that there is pretty much this is all industry studies, I believe. And I think he gets back to when you're doing a definitive procedure like a fusion, which may or may not be that reversible to maximize the accuracy of the diagnosis. That's why I know the North American Spine Society and some others recommended two blocks to help confirm and rule out any false positives before proceeding with fusion.

Dr. Beall: So to throw a different opinion out there, this is Doug Beall, I do a block and that's it. And typically, the patients that I treat, we take them through conservative treatment, we do injections followed by an RFA followed by fusion in that order, almost always. And by the time we get down to the permanent changes of a fusion, we know whether the pain is coming from the SI joint or not because it's been effective that the previous treatment is just ineffective in regard to duration of effect.

Dr. Cohen: Yes, so David you're saying you do a block and you do have them get an RFA before you go on to a fusion, right?

Dr. Beall: That's not Dave. That's Doug Beall.

Dr. Cohen: Oh, sorry, Doug apologies.

Dr. Beall: Yes it's okay. Yes, I'd say it's almost always in that order. Sometimes we don't do an RFA if we're pretty sure it's in that location and go ahead with the fusion. But a vast majority of our typical patient populations, we go from injections, to RFA, to fusion, and we use the typical duration of pain relief by injection and RFA. And if it's not, six months to a year more then we go on to the next step.

And by the time we get to the latter part of the treatment algorithm, we're pretty darn sure, somebody's had, physical exam, test, injections, they've had RFA and that's just they have failed in terms of duration relief, not response.

Dr. Cohen: Yes so that makes sense, you're the question around false positives or you're basically trying to reduce that possibility, right, by putting them through all of this stuff.

Dr. Beall: Yes.

Dr. Cohen: I think correlates with essentially, what I'm seeing generally out there.

Dr. Beall: Yes that's why, I support one block because if you do perform it like this, least invasive to most invasive using the inverse - I mean it's tomatoes. You're pretty sure by that time. And I don't really want to be required to have another block. And some we've already done lots of stuff already.

Dr. Upadhyaya: Yes I - so the question could be modified right, diagnostic injections be required? So that's one question one. And again, I can't say that there's data that says that that - the answer to that is yes or no. I think it'll just be expertise and general practice.

And then this idea of it it's one or two, I think it depends to your point about how do you - how do you go about thinking about it? If you've got a robust algorithm and the patients are kind of getting funneled through then, the intent of having two is already being addressed. For those who don't have such an intense algorithm, , perhaps two a better way to go..

Dr. Cohen: Yes, I mean, I would just say this, that the - kind of the stringency of selection criteria should depend on kind of the evasiveness and the cost and the risks of the procedure. So if you have a kind of a risky, expensive procedure like a fusion, then you need to have selection criteria that has very high positive predictive value and specificity.

So under these circumstances, it could be justifiable to do two blocks, and those blocks would probably not be exactly with the same local anesthetic because you're likely to get the same results. Although the whole paradigm of a block with lidocaine and a block with bupivacaine is flawed. So even the SIS people say that you only have 54% sensitivity when you do it that way. So there's false negatives.

But that becomes justifiable when you have a really stringent selection criteria if you have a very invasive definitive procedure. And that's why I would say that radio frequency if very similar to lateral branch blocks, in terms of like serious complication rates. And even costs are not that much different. Over.

Dr. Beall: Yes, so to go back to routine clinical practice, I think most people have the algorithm of going from less invasive to more invasive and also maybe more definitive. But, to require a routine clinical practice of two blocks to me doesn't really make a whole lot of sense I mean, for the reasons that have been described previously by (Steve) and the answers on the pre- procedure block magnitude release.

So I really think just going through clinical practice, there's just one block and to make something that does not really adhere to routine clinical practice, a requirement of two blocks, maybe if that's historic, including all injections, all RFA I mean that could be feasible. But two blocks just pulling that out of the clear blue sky does - it's not pragmatic, nor is it helpful to me.

Dr. Loveless: Thank you for the interesting discussion - it's always difficult in areas that that lack evidence, so we appreciate your expertise. And Peter did Dr. Gulur send you an answer for Question Number 11?

Dr. Goldzweig: Yes, I have it for 11 and her and also the third question as well.

Dr. Loveless: Great so we have Question 11?

Dr. Goldzweig: Yes. Question 11, "What does the evidence say in terms of the number of SI injections that are reasonable within six months and 12 months and time between injections?" And then the third part is about the number of RFAs at 12 months and the minimum time to treatments.

She states: There's really a lack of very strong evidence in the literature to support the exact frequency or timing of the SI joint inter-articular injections at six to 12 months.

But using the criteria that she was able to find within the literature, as well as other criteria that are used for a similar type of injections such as ESIs, her suggestion is there should be no more than two of these injections per six-month period and no more than four in a 12-month period.

And to ensure adequacy from relief from these injections, she believes you must demonstrate at least a 50% relief that lasts a minimum of eight to 12 weeks before repeating the injections. I don't know if anybody wants to spin anything there before I move on to her answer on the RF.

Dr. O'Brien: Yes this is Dave O'Brien. I think there was two types of injections. Sometimes we're doing it to diagnose and they just use anesthetic. And other times, we're trying to do a therapeutic. So for therapeutic obviously, I think most of us would agree that you need a certain percent of pain improvement for a certain amount of months to justify repair in the future. Because if it doesn't last long after one or two tries, we're kind of spinning our wheels.

But from a diagnostic standpoint, if, say, somebody did a block and they had a equivocal response or maybe a positive response but their pain came back quickly and their had bad arthritis and, thinking about doing fusion, there's no reason not to repeat it, a couple of weeks later to confirm the diagnosis if that's what the criteria the doctors want - payors want.

So for diagnostic block, I think waiting two weeks, I mean, there's really not a great reason to wait two weeks, but just to be consistent with other policies is reasonable.

And now I know they had a - I think it's a KX modifier for diagnostic blocks for a facet set that's added on to the codes to differentiate that from a therapeutic injection. So that may be something for you to consider for SI blocks to differentiate diagnostic block from somebody that's getting a therapeutic injection that should have prolonged improvement in their condition.

So, I just bring that out there as a point that for diagnostic blocks this is fine, not a reason not to repeat a second block rather quickly. But I would agree that for therapeutic injections, we obviously want to see a more durable, longer-term improvement in pain and function than just a week or two.

Dr. Goldzweig: Fair enough. Anybody else have any comments before moving to RFs?

Dr. O'Brien: I also add I didn't see anything here about documentation requirements, but for diagnostic blocks, I think the pre and post pain scores on the day of the procedure would be worth considering for documentation requirement for these procedures.

For therapeutic - for repeat therapeutic injections, obviously, I think the response from a previous injection percent improvement in duration of improvement, whether it's three months or six months or seven months to justify repeat therapeutic procedures is important, as we already have in many coverage policies.

Dr. Goldzweig: No understood. For radiofrequency ablation again same thing with the data. But what data there is, she supports two injections per 12-month period or one every six months.

Dr. O'Brien: I mean, again, the literature is lacking for this, but for facet procedures, they generally require greater than 50% relief for at least six months. And I think that would be reasonable approach for SI joint RF procedures and the need to repeat them to document if those people fit that scenario. Obviously, they only have a month or two of improvement, I'm not sure it's worth - I personally don't think it's worth repeating the procedures if they don't get the long-term efficacy of some sort.

Dr. Goldzweig: Okay thank you. That is all I have for that question.

Dr. Loveless: Thank you very much. And so we'll move to Question 12. And this question is for Dr. Cohen and Brian Jacobs.

Mr. Jacobs: Steve I'll go first if that's okay?

Dr. Cohen: Sure.

Mr. Jacobs: "So does the literature support any indications that SI joint injections need to be performed under sedation or anesthesia? And how about for RF?"

So guiding language regarding sedation for these procedures is available from the American Society of Anesthesiologists Pain Medicine Committee, who suggest sedation is usually unnecessary for procedures like, sacroiliac joint injections.

As it relates to diagnostic use of sacroiliac joint injections, Cohen and colleagues in 2014 included the use of sedation during diagnostic procedures at the sacroiliac joint may increase the rate of false positive blocks, although a similar consensus guideline for sacroiliac joint injections are not yet published. So multi society working group addressing diagnostic lumbar facet injections also does not recommend routine administration of sedation for these procedures in the absence of reasonable indications.

Again, if we're going to extrapolate from practices in lumbar spine, the ASIS guidelines from 2020 for facet joint interventions in low back pain have level two evidence with moderate strength to avoid opioid analgesics during diagnostic facet injection and level two evidence with moderate strength. That moderate sedation may be utilized for patient comfort to control anxiety for therapeutic facet injections.

Moving on to RF, while there's no direct evidence to attest to the utility of patient sedation during SI ablation again, the American Society of Anesthesiologists Pain Medicine Committee suggests factors such as anxiety or comorbid medical conditions may require moderate sedation or utilization of the anesthesia care team during procedures which require the patient to remain still for prolonged periods of time, such as with sacroiliac joint RFA.

Indeed, many of the clinical trials of sacroiliac joint innovation procedures, including those included in the evidentiary review literature package utilized patient sedation during SI RFA. Anything to add to that?

Dr. Cohen: Yes I would say that, that the guidelines across the board, including the, Pain Management Committee as were a pain medicine SIS all recommended against routine sedation for simple procedures such as sacroiliac joint blocks. That's not true for radiofrequency.

The only study to really examine this was our study was a very strong crossover study. And in every single group, the parallel group which has 73 patients crossover an omnibus sedation was associated with a much higher positive block rate.

The ACAP guidelines a very flawed because they're based on Manchicanti's work, and these people were all getting serial facet blocks so they weren't getting radiofrequency. They were almost all on opioids. They had spine fusions, but they were getting facet blocks and they didn't not measure pain relief after the blocks (unintelligible) pain medication and then they kind of asked them.

There are several other studies that have looked at this. There's a group from Delaware. They did two studies. Basically, they (Cutadalla?) was the first one, and then Kim was the second one. And they concluded that, that most people don't need routine sedation.

And there's some evidence that using sedation for a diagnostic procedure is associated with poorer outcomes for definitive procedures. So Mike Erdek in 2010 this was for sacroiliac plexus neurolysis. People who had sedation for the sacroiliac plexus block, they had a 39%success rate, whereas 73% of people who did not have sedation had a success rate.

And we have another study it's actually in press. I'm going over today, the page proofs. It's about sympathetic blocks. And if you have sedation during this sympathetic block, 72% had greater than 50% pain relief, so they were diagnosed with sympathetically maintain versus 51% who did not receive sedation. The P value is .051.

So like I say, the use of sedation not only increased risks, increased costs and undermines the validity of the diagnosis, but because it undermines the validity of the diagnosis, the definitive procedure is likely to be less successful. Over.

Mr. Jacobs: I believe that's well stated and I agree.

Dr. Loveless: Thank you. Thanks for the thorough evidence and guidelines search for that because I know that's not necessarily easy to find either, so I appreciate your work, both of you. Any further discussion on Question 12?

We're moving to Question 13, we're almost there, everyone. Thanks for hanging in and your attention. I know we have a lot to cover so I appreciate the - your attention. Dr. O'Brien and Brian Jacobs for Question Number 13.

Dr. O'Brien: Yes, it said the question is, "What should the minimum level of education training be to perform an SI joint injections and RFA?"

And I did take a jab and spin off an email to everybody. But to be honest with you I kind of rushed this a little bit and we looking at the LCDs for Palmetto and probably I think some of the others are the same they have a list there about provider qualifications.

And I think the way that's worded just changing it from facet joint injections and radiofrequency neurotomy to sacroiliac injections lateral branch blocks and sacroiliac radio frequency ablation procedures I think other than - I mean just

changing that wording I think the current provider qualifications that you have in your LCDs which I think just came out less a year ago last April 2021, is worded very appropriately. And it's very- I mean it's very similar to what I wrote but I think it's actually worded better.

Mr. Jacobs: Yes, and I sent Dr. O'Brien my review and essentially the same thing. The wording there covers that there's an understanding - I mean, in addition to training certification that's - has oversight by some national accrediting organization, the language in there relates to understanding of the relevant anatomy, pharmacology, diagnosis and management of the underlying condition technical performance of the procedure management of complications and safe utilization of associated imaging modalities.

The only permutation I saw room for relative to what's already been published in some of the LCDs is that I imagine not all providers. And maybe this is different now because it's been around long enough but are getting exposure to sacroiliac joints radio frequency lesioning.

And so the way the language states it in the other LCDs, is that if you didn't get that in your formal training, then maybe you were unqualified to do it. So just so that there's enough wiggle room in there because as pain science advances, we're getting new approaches and techniques, , strict lesioning with a single device versus like a (unintelligible) technique. Just as long as there's enough wiggle room in there, that reasonable training would occur in the setting of like a continuing education setting for those providers who don't have that exposure.

Dr. O'Brien: Yes the current LCD regarding that says a basic requirement for payment is training and/or credentialing by a formal residency fellowship program and/or other training program that is accredited by nationally recognized body and who's core curriculum includes the performance and management of these procedures addressed in the policy.

So I mean, I think I can go on, but I believe that's all reasonable. And obviously, providers need to be licensed to perform the procedures. So yes, I would just go back and look at your LCD for facet and I think, just change it from facet to these procedures, it's going to fit very well.

Dr. Loveless: Thank you both. Any other comments on training or education? Excellent. And we're on our last question, and then we'll have time for any questions from the CMDs or additional discussion. And so (Peter) if you could please share Dr. Gulur's response to this question.

Dr. Goldzweig: You got it and it will be short and sweet. "How common is it to need SI joint interventions bilaterally? The incidence of unilateral pain is often the hallmark of SI joint disease. The frequency of bilateral as a joint pain has been reported in literature to be less than 10% of patients with SI joint disease. Of these 10% or less than 10%, the highest reported incidents are with ankylosing spondylitis reactive psoriatic arthritis, and conditions where the bilateral sacroiliitis are more common, short and sweet.

Dr. Cohen: Yes, so I agree that SI joint pain, but I do think that I will say that there is a bimodal distribution, right? So younger people, people in the military, athletes, they often have, , one-sided pain, unilateral pain. They have, there's often trauma.

And then you do have a subset of people who are, who are older and may have osteoarthritis. And similar to people with knee osteoarthritis or hip osteoarthritis when it's mild, one side hurts more and then it becomes as it progresses and become more (unintelligible) more severe and both sides hurt and develop degeneration.

So I do agree with that. But I think that there is definitely a subset of older people who have bilateral pain. Over.

Dr. Loveless: Any other comments on Question 14? So without further comments on that question, I have a question for our experts and the panel.

So somebody that has pain and they get a diagnostic and/or therapeutic injection and they see improvement, how do you determine based on evidence to support when they get therapeutic injections? How often would these be used as the primary treatment? So getting a therapeutic injection every three months for an unspecified amount of time versus moving to RFA?

Dr. O'Brien: Well and that's kind of a little difficult to answer, but I think the problem is some physicians are scheduling people - so put it this way. If the policy says three months or it says four months, they're doing the procedure and then they're scheduling another procedure to come back with anticipated, another injection three months later when that's not the intent of the procedure or the policy.

These typically state that you want to get 50% improvement in their pain and improve function for at least that amount of time. And in my experience, it - I almost never have anybody - I mean, if I did two injections that's probably the most. I'm, not doing them every three months.

Well we don't see the patients back unless their pain recurs if they have a good therapeutic response. So I think that's how most honest doctors would approach this.

But some patients are under the impression they need this for maintenance and so forth. So if they're getting them every three months regularly, then they're obviously not lasting three months. I mean, it's not like the pain just comes back exactly the three months mark each time.

So I don't know how you'd - I'm not probably answering your question. So I mean, that's not by the rule of the coverage policy. That's by the rule of Medicare action

and stuff to review the medical specificity of repeat injections. But, like I said from a diagnostic standpoint, so I think NASS said when we're doing lateral branch block to diagnose the joint you can bring the patient back two weeks later and do the second block. And there's no reason not to do it one week later.

So from a diagnostic, if you're doing purely diagnostic inflammatory block there should not be any time limit necessarily when you repeat that. But I mean, two weeks is reasonable - not unreasonable.

But for therapeutic, then, I think the patient has to be reevaluated to determine the effectiveness of the previous therapeutic intervention. And so a lot of doctors will see somebody back a month or so later and determine the efficacy of the shot. And then if the - and then if their pain comes back six months later or two years later and if you bring them back and there's the same problem, repeat the thing that worked.

So I'm not sure if I answered your question or how you wordsmith it in a policy. But I think the documentation to do a - repeat therapeutic procedure just needs to document the duration of relief and percent pain and whether that happens to be at the three or four month mark, then so be it.

But I think it's atypical for people to repeat them every three months I think a very small, very small like less than 5% of patients should be getting three or four injections a year. I mean, the same thing with epidural injections. They've done studies where the average patient may only need two even though there may be outliers that are doing them more than that because the follow-ups around that.

So I think it's part of the documentation requirement to coverage policy. Like I said, for diagnostic blocks, I think it's good to make them document the percent pain relief at the time the procedure is completed. And then I have then obviously hard copies of the films to document, , unless they're allergic to

contrast in the joint or the nerve - the block viral branch blocks or RS I think you should consider if this is going to be standard practice, , for all payers to add the KX box - diagnostic box to differentiate it from a therapeutic. Well are all probably reasonable things to incorporate to make it more clear to providers how to approach this.

Dr. Beall: So this is Doug Beall. I've got a comment of bilaterality and unilaterality of the pain. So don't necessarily agree with the vast majority of these are unilateral. But also the vast majority of my SI joint infusion patients have five infusions or longer segment fusions that cross five one.

And most of the time they do present with unilateral pain. But then after that's treated, the other side starts to hurt as well. And so the biomechanical data on this shows pretty clear that this is transmitted across both SI joints. There's good meta-analysis done recently that shows this.

And yes, so most of the time it's one side versus the other. But the cumulative effect of this is very, very commonly bilateral, especially after fusion. And these are the exact patients that have SI pain. So I want to make sure we know that and make sure that's a situation where you can expect a bilateral pain or whether it's described as unilateral presentation or accumulative effect is a bilateral patient it needs to be parsed out at least understood that's often the case.

Dr. Cohen: This is Steven Cohen. I would say that most of the randomized trials, including ours and Dr. Patel's and this new 210 study patient, so they require people who get significant pain relief from the blocks and it does not last three months.

But again, it's - if you look at these other studies, right, if you look at the epidural steroid injections studies sponsored that are funded by the NIH, if you look at the FDA study with - it's called the CLEAR trial, where they're looking to get pain

relief they designed this with the FDA. They determined that one month would be the primary outcome measure. And if you look at all those other SI joint studies -- and I went over them -- usually it's four weeks is the primary outcome measure.

So SI joint injections, if you're an elderly person and you have osteoarthritis, you - you're probably not going to do well with radiofrequency ablation because you have osteoarthritis and you don't have ligamentous injury.

There's also you bring up the multi-specialty working group and now they're putting together, they're close to finishing it guidelines on the total steroid dose in a year. And I believe that - I'm not the chair of that, but I'm on that committee, I think it's Nori Benzon is the chair. I think it's about 200 milligrams per year.

So you definitely need to limit the number of injections. I don't see a problem with four per year. And like I said, it's not a - not an easy thing.

Dr. Loveless: So in the facet literature it was a little more clear in terms of, therapeutic versus RFA. And with the SIJ literature, I don't think that there is a lot of literature to help answer who gets RFA versus who gets continued therapeutic injections. So is there any literature that helps to guide that? And if there's not, what? What are our expert's thoughts on on how to make that call?

Dr. Obrien:: Well, if you already allow one therapeutic procedure to be - we repeat that for six months with 50% relief, then at a minimum they allow a repeat therapeutic SI joint injection with 50% relief for (unintelligible) cheaper and easier than RFA. So that would be the the minimal allowed would be two injections a year.

But these are injections and it's not RFA. So whether it's three months of improvement or four months of improvement, I don't think any of us know the exact right number. And unfortunately, all these people are getting treated with

steroids for other problems -- shoulder problems, other joint problems. Sometimes they may develop a disk herniation. So all these are concerns.

But from a therapeutic standpoint, if you're allowing a repeat RFA at six months, then they definitely would allow a repeat injection in six months because they're both therapeutic procedures and the injections a lot cheaper. But I believe it is reasonable to repeat SI joint injection if they had, in my opinion greater than three months of improvement from the previous injection.

And I think having at least three injections a year is reasonable. Whether people would advocate for more than that for 90% of the population, I don't think it's probably needed more than that.

There may be some outliers and small subsets of patients that may need more, may have comorbidities where they wouldn't tolerate other interventions. I mean, if we're looking at the vast majority of patients, I think having up to three injections, therapeutic injections a year is reasonable, in my opinion. It keeps them functional and keeps their pain under control.

Dr. Loveless: And I just want to open the floor to our members if they have additional questions or if any of our experts have additional comments that they want to share before we wrap up.

Well I think we went over a lot of information, and I very much appreciate all of our experts' time in preparing for this meeting and sharing your expertise with us, as well as the research on the evidence and your interpretation. I felt I think you all did a wonderful job, and I very much appreciate each of you and your contributions to this process.

And so one final call if anyone has any further questions and if - since I'm hearing silence, I think we'll be able to wrap up.

And if I can just remind our experts, if you can please share any additional comments that you have on the questions within a week. And also, if you could please send me the references that you've mentioned throughout the - throughout our discussion to make sure that we have all of these references accurate as we continue to analyze this literature and work forward on this process.

Thanks everybody again and thanks for our audience for your attention. And a reminder to our jurisdictional cast members that we welcome your comments. Please contact your local MACS to submit those. We will ask you to share that without a conflict of interest form.

And thank you very much everyone. I hope you have a wonderful afternoon and evening.

Coordinator: That concludes…

Man: All right, good night, thank you.

Coordinator: Today's conference.

Man: Thank you.

Man: Thank you, everybody.

Coordinator: Thank you for participating…

Man: Good night. Thank you.

END