LCD Evidentiary Discussion Regarding **Facet Joint and Medial Nerve Branch Procedures**

Meeting Date and Time:	May 28, 2020
Facilitator:	Dr. Meredith Loveless
Location:	Teleconference
Attendees:	Not to disclose

Introduction

Dr. Loveless: I want to welcome everybody and thank you for taking time out of your busy schedule to join us today. I'm Meredith Loveless, one of the medical Director CGS administrators and I'm joined by the contract medical directors from all the MACs.

So, we'll go to the next slide with everyone's name.

And on behalf of all of us, I welcome you to this meeting. Today's meeting is an evidentiary review meeting.

So, part of the LCD modernization as a result of 21st Century Cures Act is a call for local coverage determinations to be based on robust evidence review. The purpose of today's meeting is for our expert panel to serve in an advisory capacity to review quality of evidence used in the

development of an LCD. The CAC is advisory in nature and the final position on all issue's rests with the MAC. While our experts represent vast clinical experience, since the process demands are focused on the evidence, we will ask our panelists to only share evidence-based feedback. For those who have participated in the CAC process prior to 21st century, an LCD was presented and then comment shared. In the new process we seek input prior to the development of the LCD and that's what today's meeting represents.

I'm confident you'll find today's panelists as leaders in the field and world experts on the top topic of that. I also understand there are many experts that are not on our panel today, and we have CAC members from across the country, that have joined us on this call. We have several hundred jurisdictional CAC members with us today on the call. We very much value your input and feedback and assure you that you are part of this process.

For our jurisdictional CAC members, we're going to ask if you can please submit your votes and comments in writing to your local MAC and we'll ask that you complete a conflict of interest form for that process as well.

The purpose of doing this after the meeting is if you have additional comments to share after the discussions and areas you think we need more information about. Once the draft policy is developed and released our Jurisdictional CAC members and for anyone else involved, we're going to ask that you submit comments and there'll be an opportunity to present at the jurisdictional open meetings as well. We'll be looking at the feedback from these comments as well as from the open meeting and that will play an important part in the consideration for the final policy development.

I now want to welcome and thank our panelists for their time and willingness to share their expertise.

This panel was nominated by their peers and respective societies. They have a broad representation in terms of geography, practice, setting, background, and medical, and medical specialty. And their introductions are just a brief overview of their accomplishments.

In alphabetical order, I want to welcome Dr. Barnhill.

Keith Barnhill, PhD, CRNA, ARNP, DAAPM

Dr. Barnhill is a clinical instructor and the president of Premier Pain Management in Iowa. He is credentialed in pain management through the American Academy of Pain Management and a graduate of the U.S. Army/Texas Wesleyan University program in nurse anesthesiology and has

a doctoral degree in nursing education, He serves as adjunct faculty with the University of South Florida Simulation-Based Academic Fellowship in Advanced Pain Management.

Steve Cohen, M.D.

Dr. Steven Cohen is Professor of Anesthesiology & Critical Care Medicine, as well as Physical Medicine & Rehabilitation, at the Johns Hopkins School of Medicine and Uniformed Services University of the Health Sciences. He is Director of the Bloustein Pain Treatment Center, Medical Education and Quality Assurance for the Pain Management Division at Johns Hopkins, and Director of Pain Research at Walter Reed National Military Medical Center. He has over 250 peer-reviewed articles, reviews and book chapters, multiple awards and has led the way for several novel treatment innovations. He is editor of the peer reviewed journal Pain and on the editorial board of many pain journals and is a member of multiple pain management societies. He is a retired Colonel in the U.S. Army, and member of the U.S. Army Medical Advisory Board.

Michael Creamer, M.D.

Dr. Michael Creamer is board certified by the American Board of Physical Medicine and Rehabilitation with a subspecialty certification in spinal cord injury medicine and pain management. He completed his residency in PR& R at Northwestern University. He has been recognized in *Orlando Magazine* as a "Top Doctor" since 2002. He is a clinical professor for Florida State University in Department of Geriatrics. He has served on the Board of Trustees for the American Osteopathic College of Rehabilitation Medicine and is Medical director of the Muscular Dystrophy Association.

Joshua Hirsch, M.D.

Dr. Hirsch is director of Interventional Neuroradiology, chief of the Interventional Spine Service, vice chair of Interventional Radiology Quality & Safety and associate Departmental Quality Chair. Dr. Hirsch has published over 450 papers, 40 chapters and edited multiple books in the peer-reviewed literature and offers extensive experience in minimally invasive spine surgery. He is a founding editor of the Journal of NeuroInterventional Surgery and is a past president of both the American Society of Spine Radiology (ASSR) and the Society of NeuroInterventional Surgery (SNIS), on the board of the ASIPP, the Society for Injectable Osteoarticular Biomaterials and the American Society of Neuroradiology (ASNR). He is chair of a committee for academicians at the American College of Radiology.

David Kennedy, M.D.

Dr. Kennedy is a professor and chair of physical medicine and rehabilitation at Vanderbilt University Medical Center. His practice focuses on non-operative and interventional spine. After residency in PR&R he completed a spine and sports fellowship. His research has focused on the safety and efficacy of interventional spine procedures and he has pioneered safe injection techniques. He is the recipient of numerous research grants and he has published over 90 peer-reviewed journal articles, over 50 published abstracts, and over 20 book chapters.

Laxmaiah Manchikanti, M.D.

Dr. Manchikanti is an interventional pain physician practicing in Paducah, KY for the last 40 years. He is board certified in pain medicine and anesthesiology by the American Board of Anesthesiology (ABA), American Board of Interventional Pain Physicians (ABIPP), and the American Board of Pain Medicine (ABPM). He has an extensive background in the subject matter related to facet joints with extensive publications including manuscripts on the diagnostic accuracy factors influencing the diagnosis, and therapeutic options of facet treatments. He is the primary author of Comprehensive Evidence-Based Guidelines for Facet Joint Interventions in the Management of Chronic Spinal Pain: American Society of Interventional Pain Physicians (ASIPP) Guidelines, which will be published soon.

Timothy Maus, M.D.

Working with the Mayo Multidisciplinary Spine Center, Dr. Maus founded an interventional pain practice 20 years ago, which has since been his primary practice focus. He has been the founding Co-Chair of the Mayo Interventional Spine Group, responsible for all interventional spine pain procedures at Mayo Rochester and the Mayo Clinic Health System. He has been the co-investigator in an NIH funded Mayo laboratory seeking novel analgesic strategies. He is the immediate Past President of the Spine Intervention Society and sits on its Board or Directors.

Thomas Simopoulos, M.D.

Dr. Simopoulos is Director of the Arnold Warfield Pain Management Center, Co-director of the Spine Center and an anesthesiologist in the Department of Anesthesia, Critical Care and Pain Medicine at Beth Israel Deaconess Medical Center (BIDMC). He is also an Assistant Professor of Anesthesia at Harvard Medical School. His research in the areas of interventional pain management focus has been on the outcomes of patients receiving percutaneous disc decompression and radiofrequency lesioning. In addition, most of his current work is on improving the outcomes of patients undergoing spinal cord stimulation for pain by studying

complications and developing strategies for potential mitigation. As division director, he is focused on building a research infrastructure to encourage junior attendings, residents and fellows to pursue research.
Benjamin Schwachman, M.D., J.D.

Dr. Shwachman specializes in pain medicine and pain medicine anesthesiology in Covina, CA with over 50 years of clinical experience. After his residency in Anesthesiology he attained his JD degree. He holds licensures in Pharmacology, Medicine, and Law. He is a Diplomat of the American Board of Anesthesiology and of the American Board of Pain Medicine.

His multiple memberships the American Societies of Anesthesiologists, American Academy of Pain Medicine, and the International Spinal Intervention Society. He has worked as both attorney and physician and has contributed to the literature in both fields.

Deborah Tracy, M.D., MBA

Dr. Tracy was appointed to serve on the Medicare Carrier Advisory Committee, First Coast Service Options, representing the Florida Society of Interventional Pain Physicians in 2007. Since that she has been involved in the evolution of Medicare's local coverage determinations for physicians in the State of Florida, US Territories and has engaged in the many challenges in the creation of policy to maintain access to care while preserving the beneficiary fund. She currently serves on the ASIPP BOD, the Florida Society of Interventional Pain Physicians, BOD; is Chairman of the Board of Trustees for HCA Oak Hill Hospital and Residency Program.

I want to welcome our esteemed panel and thank you again for your contribution.

I also want to point out that at the final phase of our meeting, during the discussion, there'll be an opportunity for questions. Questions can be entered directly into the GoToWebinar format. So, we'll be able to see those questions or comments coming from our Jurisdictional CAC members and our attendees.

I do ask that everybody attending the call, keep their phone on mute, so we don't have any background noise and to help us all be able to hear our panelists clearly.

Slideshow, the voting process voting will be done on a scale of 1 to 5, with one being low confidence in the literature and five being the highest confidence.

A score of 2.5 is considered intermediate confidence that there was that critical literature to support the question.

Next slide.

Finally, the today's questions are also available in the, in the PowerPoint that's attached to today's meeting.

I am going to now turn today's meeting over to Marc Duerden of National Government Service. Mark's background is in physical medicine and rehabilitation and spinal cord injury and he'll be moderating the questions section.

After each panelist answers the question, we'll have a discussion, and, the panelists will be voting, fill out, or vote on the color after the call. Voting results will be posted to the MAC's website with the transcript and audio after the meeting. This may take several weeks before it's posted. Our jurisdictional cap members will turn their voting incorrectly to their MAC.

All of our panelists have completed a conflict of interest form, and we will ask them to share pertinent conflict of interest the first time they speak.

We ask our panelists to read the question aloud in case anyone is having any technical difficulties, seeing the question, and we will try to adhere to the timeline and the agenda.

Our panelists are also asked to submit written comments after the meeting.

With no further ado, I'm going to turn this over to Marc.

Dr. Deurden: Thank you very much, Meredith. I appreciate that. So, my name is Marc.

We're breaking this down into three sections. The first section of questions is going to be regarding procedure efficacy. Second section will be regarding patient selection, and the last will be more procedurally related type of questions.

Section one. In this section, I would like the panelists to place emphasis in their answers regarding, and it'll say in the questions, the diagnostic versus therapeutic types of injections that are given and to consider the location , cervical, thoracic or lumbar spine injections.

So, it's because lumbar spine in the literature seem to be a little more effective, and then the thoracic and cervical less so. If the panelist could go in that direction, I would appreciate it.

OK, I'll turn the time now over to Dr. Barnhill for question number one.

Dr. Barnhill: Hello everyone, can you hear me?

Dr. Duerden: We can hear you. OK, thank you for having me.

Question number one: What is your level of confidence there's robust clinical literature to support the use of diagnostic facet joint injections?

Do you want me to give my score now or wait till I present the evidence?

Dr. Duerden: You can give your score. I scored a three for intermediate.

Dr. Barnhill: And the reason is, there's limited support for facet intra-articular injection. But here's the research that I found. According to Cohen and others, in the 2019 consensus practice guidelines, the Multi-Specialty International Working Group found that actual lumbar joint injection was less predictive for response to radiofrequency ablation than the medial branch block and identified the evidence as grade B with low level of certainty. These results are based on a review of five studies. Those are Birkenmaier, Cohen, Cohen, van Zundert and Bogduk. This grading is based on the Modified U.S. Preventive Services Task Force Criteria, In Europe, which Cohen presented in the 2020 Guidelines, The Greater Manchester Combined Authority in 2018 failed to commission intra-articular facet injection, instead, recommended medial branch nerve blocks. The Spinal Intervention Society, SIS, recommended that medial branch blocks replace intra-articular injections as a diagnostic indicator.

Now, reasons for less predictive response to lumbar intra articular injections were related to the high technical failure rate, difficulty in standardizing injected volumes for testing and the potential to produce more harm example, joint capsule rupture.

In the mid lower thoracic region, Atluri in 2012 evaluated two prospective studies and concluded, that there was good evidence to support facet intra-articular injections, as an accurate diagnostic application. However, the North American Spine Society in 2016 listed the diagnostic intra articular joint injections as a non-validated procedure for diagnosing facet joint pain. Their rationale was that intraarticular injections blocked the articular surfaces and the interior joint capsule. One exception or case for diagnostic intra-articular injection would be pain potentially derived from the atlanto-occipital and atlanto-axial joints, which do not have medial branch nerves. If the intra-articular route is used, they also recommended dual blocks to decrease the potential high false positive rate.

In 2016, a review by Manchikanti and others looked at the US and Australian data on patients with whiplash or chronic neck pain. After excluding disc herniation and radicular pain, they found that 11 diagnostic accuracy studies to consider facet intra articular injection as a level two evidence determination.

Finally, Cohen's stated nicely “that the accuracy of the prognostic intervention depends on the accuracy of the diagnosis, including identification of the anatomic structure responsible for the

pain and the correlation between the prognostic injection and treatment effect, which in turn is contingent on the efficacy of the procedure."

Dr. Duerden: Thank you very much. Are there any panelists that would like to opine?

Dr. Manchikanti: Thank you, again for inviting me here. I have no conflicts.

Dr. Barnhill did a good job about describing the intra-articular facet joint, but for diagnostic purposes, but that is not what we are talking about. This is a very important question, of course. But entire foundation for facet joint interventions depends on appropriate diagnosis, which may not be made without diagnostic facet injections. Physical examination and a clinical assessment are strongly recommended. However, this can only lead towards potential diagnosis, but not actual diagnosis. The images are not diagnostic. It is a universally accepted fact that intra articular injections are not recommended for diagnostic purposes. Medial branch blocks, or facet nerve blocks, are the choice that is high level of confidence with robust political literature, are the same.

Our recent analysis of the evidence for guideline showed that there are a total of 19 diagnostic disparities 10 in the lumbar spine, 10 in the cervical spine, and three in the thoracic spine. Further, utilizing 80% criteria as standard, with control compare it to local anesthetic blocks with control and pain relief. The evidence is Level 1 to 2 for lumbar spine and 2 for cervical and thoracic spine. The prevalence rates and false positives ranging from 27% to 40% and 27% to 47% in the lumbar spine, 29% to 60%, and 27% to 63% in the cervical spine, and 34% to 48% and 42% to 58% in the thoracic spine. So, all in all, medial branch blocks are very valid and there have been validated in numerous studies, 39 that we picked up, make inclusion criteria.

I think the evidence is very strong here. I would say, the level of evidence is 4 on a scale of 1 to 5. Thank you.

Dr. Tracy: I think this question is kind of confusing, because all the other questions in this questionnaire are related to intra articular injection, separating it from the median branch. In this first question, we just used statement diagnostic injections, so Dr. Barnhill addressed intraarticular versus medians branch injections, and Dr. Manchikanti addressed the value of medium branch blocks. So, I would have to say this question is confusing, I would agree with Dr. Manchikanti and state a score 5 for facet diagnostics sections. Thank you.

Dr. Duerden: Would your opinion changes if the question was read Intra articular injections as opposed to just set joint injections? Meaning that you know that the intra articular is being different as the medium branch block.

Dr. Tracy: Yes. Yes, I would, in that same section, number three, does asked a question in that manner.

Dr. Duerden: So, did it change your answer?

Dr. Tracy: So, you're asking me, is that set intra articular injections? What would I assign? I would assign a three.

Dr. Barnhill: I was interpreting that question is strictly intra-articular injection.

Dr. Maus: A quick comment, I think the evidence is clear that intra-articular injections do not have substantial validated diagnostic accuracy, whereas there is robust body of literature supporting medial branch blocks. One item that has not been mentioned, which denigrates intra-articular injections as a diagnostic procedure is that the facet capsule is known to be fenestrated and there can be leakage of the local anesthetic from the intra articular space into the adjacent tissues, so it may not, does not, even have face validity. Thank you.

Dr. Duerden: Thank you, Dr. Maus, I appreciate that. Dr. Cohen are you trying to speak?

We can't hear you, doctor Cohen, or at least I can't.

Dr. Tracy: But one thing I did want to say, in the body of literature, of the 20 articles, I didn't write them down at this moment, but 2 or 3 of them had said they found, intra-articular injection to be helpful in the younger population with segmental joint infusion or inflammation.

Dr. Duerden: Thank you, Dr. Tracy. So, is there any others, has Dr Cohen has been able to get on?

If not, what I will do is, I will go to question two, section one, and we will turn the time over to Dr. Cohen. So, let's see if we can get Dr. Cohen on the phone.

Dr. Hirsch, could you tell us what the final question you would like us to answer, is, whether it's media branch block or facet joint injection. Just how you tell you want the final answer to read.

Dr. Duerden: Thank you, we want it to be read intra articular set joint injections.

Dr. Cohen: Can anyone hear me yet?

Dr. Duerden: Yes.

Dr. Cohen: So this is actually covered really, really well in those guidelines. So medial branches, it's not possible to actually block the medial branch without blocking the dorsal ramus or the lateral branches. Because even a tiny volume, ½ cc, spreads into an area of about six square centimeters, so it's not possible. And those other branches of the intermediate branch, the lateral branch they innovate the paraspinal muscles so you can't just block the medial branch. As Kaplen showed, there is between 10 and 15% of people who have innovation to the facet joints, that are not medial branch nerves, so nonmedical branch nerves.

So, there's always going to be false-positive and false-negative rate with medial branch blocks. Intra-articular injections have been used to diagnose knee pain or hip pain very, very

infrequently because that the American College of Rheumatology Guidelines don't depend on this there's three different ways. People have said t that's self-evident. Right? If, you numb a joint and your pain goes away, that that's the source of the joint.

The problem with intra articular injections, and you can see this from our FACTS study, and I think for Lynch study is a really, really, really high technical failure rate with intra-articular injections. So, intra-injections have the theoretical potential to be diagnostic, medial branch blocks we're using them, as predictive or prognostic tests. Predicted would be the right word to see if I'm doing a radio frequency ablation on those same nerves will alleviate pain. It's impossible to come up with sensitivity, specificity, or any other accuracy tests, because there's no other reference standard.

Dr. Duerden: And would you like to go ahead and continue with the second question as well?

Dr. Cohen: What is your level of confidence there is there a robust clinical literature to support the use of therapeutic joint injections, to relieve pain and improve functioning?

So, let us start with intra articular... I'm sure that I will make a lot of enemies here. So, we're not talking about radiofrequency ablation. We're talking about injections, correct?

Dr. Duerden: That is correct.

Dr. Cohen: And I appreciate you taking on the IA facet joint question, OK. Yeah, for some reason, I thought that I had the 1 or 2 blocks, or the 50% or higher relief. But I'll go over here again.

So, there are several randomized trials that have looked at intra articular facet injections.

So, you have two that were published in the New England Journal of Medicine, one by Carette and one by Les Barnsley, both very, very clearly negative. And these patients were selected well because they had diagnostic tests. There are several others, Lilly's study that didn't pre-select patients really kind of negative and he's ___?___. There is our FACTS study, which was published in Anesthesiology and DJ Kennedy has a great study. All of them show that intra-articular steroids don't work. And as I said, there's a very, very high failure rate to these.

So, there's not a lot of evidence saying that intra articular steroid injections work. Now I'll go over medical branch block and I apologize in advance because the there's Dr. Hirsch. Hi Josh, and Dr. Manchikanti and they were on the ASCIP guidelines. So medial branches are, this is not really medial branch neuritis, technically, that can possibly happen from a nerve being entrapped beneath the mamo-accessory ligament. But we're not talking about a mononeuritis over here, we are talking about facet joint pain.

And nobody uses genicular nerve blocks, femoral nerve blocks to treat knee arthritis. We don't use obturator nerve blocks to treat hip arthritis. We're not using ankle blocks or sciatic femoral

nerve blocks as a long-term treatment for ankle arthritis. Nobody is using that. So, the procedure as medial branch blocks as a therapeutic procedure it lacks any internal validity. Now, there are studies by Dr. Manchikanti's group that show long term benefit. But let me say something here, about this. If medial branch blocks gave relief to everybody, right, or to 50, 60, or 70% there would be no discussion on radiofrequency ablation. We wouldn't need it because that would be higher than the success rate for radiofrequency ablation. First of all, local anesthetic injections of any nerve never gives long-term pain relief. Otherwise, everybody who got a labor epidural would be paralyzed, they wouldn't be able to walk. Everybody who got a regional anesthesia block would have the same issue. If medial branch blocks, which are used to select patients for radiofrequency ablation studies, if MBB provided long term relief, we wouldn't be able to enroll anyone in studies because they wouldn't have pain. But that's not true. There's one study by NASS [North American Spine Society] that actually showed, more than 15% of people had relief and they didn't enroll in the study, but it didn't say how long that relief is. But all the other studies that show good flowcharts, like, Van Kleef, Van Kilberg, Van Wijk and the Cohen study, all of these studies, you know, the reason that people enrolled in radio frequency versus sham radio frequency or something else is because they did not get long relief from medial branch block and the FACTS study is probably the best at this and this showed really that about 11% of people got pain relief at one month. And that was a double-blind study.

Dr. Duerden: Because of time, we can build on this with Dr. Creamer's comments and answer to question number three. So, Mike, could you take that?

Dr. Creamer: Thanks, Marc. I appreciate it. I think some of these issues probably have already been addressed by our prior discussion. But Question three, does the clinical literature support the use of therapeutic intra-articular facet joint injections as robustly as medial branch blocks or medial facet joint injections?

So, some the questions we've already mentioned, Dr. Manchikanti review, "Systemic Review and Best Evidence Synthesis of Effectiveness of Therapeutic Facet Joint Interventions in Managing Chronic Spinal Pain" concluded the evidence was level 2 for the lumbar, cervical and thoracic branch blocks for long-term effectiveness. The article indicates that intra- articular injections the evidence was level three for lumbar and cervical intra-articular injections. No trials available for thoracic intra-articular injection therapy.

The FACTS study lead by Dr. Cohen concluded that facet blocks are not therapeutic, but they provided a prognostic value before radiofrequency ablation.

Dr. Manchikanti presented in a Postgraduate Medicine Journal on cervical zygapophysial facet joint effectiveness of interventional management strategies. And he indicated in that article level two evidence for facet joint nerve block and level three evidence for cervical intra-articular injections.

Doctor David Kennedy reported in the journal of Pain Medicine in 2019, a comparison of intra-articular steroids versus saline for treatment of lumbar zygapophysial joint pain. This was a prospective randomized, double blind placebo-controlled trial. His conclusion was intra-articular steroids were not effective for reducing the need for or time to RFA for Z joint pain.

A similar report by the same author in the American Journal PMR in October 2018 the same findings were reported.

There was a report Dr. Dong Kwak at the Journal of Experimental Therapeutic Medicine published November 2019. “The outcome of intra- articular lumbar facet joint injections according to the severity of facet joint arthritis,” their conclusion was, in particular, lumbar facet joint intra-articular injection were effective but the study was limited due to its retrospective designed, small sample size and lack of evaluation of long-term effects.

There was another study Stefena Lakemeier in July 2013, in Anesthesia Analgesics which was a randomized, controlled, double blind study, comparing intra-articular and lumbar facet joint injections with RSA and found similar outcomes outcome at six months in pain relief and functional improvement.

And then there was a review article published in World Journalists of Orthopedics Journal of Orthopedic May 2016, by Dr. Manchikanti indicating the level two evidence for facet joint nerve blocks for long-term improvement, (longer than 6 months) level three evidence for lumbar intra-articular for short-term improvement.

Then, Dr. Cohen's study that had been already mentioned in Regional Anesthesia and Pain Med. February 2020, Stephen, Dr. Cohen, recommended against the routine use of therapeutic facet injections, and intra-articular facet joint injections studies reviewed demonstrated a lack of evidence for intra-articular facet joint injections. And obviously, in that article, we've already discussed some of the unique issues for intra-articular injections of steroids use. So again, given that finding, you know, given the question of being robust, I graded a score of two as regarding answering that question.

Dr. Duerden: Thank you, Dr. Creamer. Because I kind of cut you off on question two. I'd like to give you an opportunity to respond to 3 and 2 as well, if you'd like.

Dr. Manchikanti: OK, I just want to clarify a few issues here. What we have been talking about, we all know that there is L5 dorsal ramus and medial branches, not the sole supply, that's why we call them facet joint nerves. That is a more appropriate term. here, Dr. Creamer is talking about an acute pain model, that is what happens in labor. Chronic pain patients are different from acute pain. If you take that in 1901, epidural injections were just getting started. The first injection for pain was just _?___. The patient really ____?_____several weeks several months, Evans, __?__, all these people they were using just the local anesthetic blocks. Treating the patients, steroids were not used until 1952, so, but up to 51 years, it was only the local anesthetic,

then it started with it. The issue here is: a multi-dimensional phenomena acute pain and chronic pain, chronic pain, is complex, bio-psychosocial phenomenon, whereas acute pain is different, we all know that it is a uni-dimensional, chronic is a multidimensional, so response rate is significantly different. Local anesthetics do show really lost input several weeks and months. We have performed multiple studies in an epidural, or facet joints injection and showing an average relief 13 to 16 weeks, even without steroids. When you use the steroids it is slightly better, not that much. The local anesthetics and the duration of relief and chronic pain is different. It is based on alteration of multiple paths or physiological mechanisms including noxious, peripheral stimulation, desensitization of pain pathways, and exit trees of the neurotransmitters.

In fact, the model we are using is based on an acute pain model. That is how, when we go for the concordance pain relief, duration of the action of the local anesthetic Bladuck (?) started this phenomenon. He said positive if short acting local anesthetic is less than seven hours, less than not, more than, and long acting less than 24 hours. But that is not what we see in our chronic pain practices. And he also said it is 100% pain relief, we don't follow that. If you look at the relief, we have studied this on multiple occasions, our patients show that relief is much longer, six days or so after the first block. That is 80%, and almost 3 to 4 weeks with the second block. Success with the first block and 3 to 4 weeks and 4 to 8 weeks with the second block.

So, this is all different theories. I'm running out of my time, so I'll stop there. Thank you.

Dr. Duerden: Thank you, sir. In the interest of time and stay with the schedules, I would like to move to question number four and turn the time over to Dr. Hirsch.

Dr. Hirsch: Hi, Josh Hirsch. No conflict of interest in terms of doing facet joint interventional consulting, I did report that I do consult with Medtronic, but nothing to do with facet joint interventions.

This question is a little updated it, but I think, works very well. Does the clinical literature support the safety of repeat facet joint injections beyond there injections per year? Please answer for both inter-articular injections and medical branch blocks. And while one of my good friends reported that he thought he was going make enemies, I want to say that as a designated subject matter expert, I don't feel my job is making enemies or friends. But just passionately report the evidence here. Keeping that in mind, I think, if we're talking about safety. It's fair to state the presumed. I think most people believe intra Articular injections and medial Branch Books are really pretty safe. Again, that's a presumed bias. Look forward to hearing the other answers.

The original framing of the question had to do with steroids, and I think with COVID- 19 we're actually seeing some change in practice with what social distancing being practiced by some conventionalists. I mean, there's been many papers that have reviewed complications of both intra-articular injections, medial branch blocks. I would say in preparation for this call, I have

extensively reviewed the safety of single and repeat facet injections with steroids beyond three injections per year again. I think the differentiation was made before and is important because of the way.

Interruption — I should continue.

OK, I would, I would say, because the question that came up, I would just point out that no other aspects of my work I, I study steroids quite a bit, and of course, steroids can be harmful. We are talking about relatively low doses here, CGS itself provide and references for this call one I wasn't familiar with. So, thank you. I would draw attention to Kim et al, which was one that CGS provided, because I think it's important as it is used to frame the discussion. They reported in The Journal of European Radiology 12,000 procedures, intra-articular facet joint steroid injections, and they reported adverse events in 99 patients, which is 1.63% for patients. The complications are astounding to me with seven cases of infectious Spondylitis, one progress to aspergillosis in the spine, one has uncontrolled infective endocarditis, and neurological. Well, I mean, for practical experience, I don't think somebody in Boston would get very many referrals with those types of numbers, and they really did not represent what I have seen in the literature, where I think the perspectives that, whereas there's debate, as we've heard about the efficacy of some of these procedures. That's not very much about the safety.

In 2012, Manchikanti, who is a panelist on this discussion, looked at 7500 episodes using real branch block, over 18 months, and a high-volume practice, with three full-time positions. In contrast to Kim, none of the cases require hospitalization or developed major infection. I think that's the perspective that most people have. I would be remiss if I didn't state that infection is a possibility with both facet joint injections, intra-articular, medial branch block or frankly, any intervention that we do. In this context, I think it's worth noting, and what the question I think was alluding to is that in common practice, steroids are not used in medial branch blocks, but they are in intra-articular facet joint injections. So, in my mind, both of these procedures are safe. If we are thinking about facet joint injections, the Kim Articles and with which was provided by CGS and we're thinking about the use of steroids, I would perhaps say, that it's associated with moderate risk, and give it a three. My confidence level, regarding medial branch blocks, which don't involve steroids, typically is high. I think the data is strong. And I would give the four or even a five.

Dr. Deurden: Thank you.

Dr. Hirsch: Thank you, sir.

Dr. Duerden: Dr. Kennedy, could you proceed to question number five?

Dr. Kennedy: Sure. The question the is, what is your competence in the clinical literature to support the efficacy of facet joint interventions in each of the following regions? Cervical facet, lumbar facet, thoracic facet?

Clearly, there's overlap with other sections. what would include intra-articular steroids and radio frequency, really to give each intervention in each final level of beyond the ability of what a three-minute response allowed. Therefore, really tried to provide overriding themes around the two most common procedures, injection of corticosteroid, and radiofrequency ablation.

An injection of corticosteroids into the facet joints or even along the medial branches has really been evaluated by several studies' rigor from pragmatic outcome studies, to the placebo controlled explanatory studies. The majority of the literature is in the lumbar spine, but studies do exist in cervical spine and a very limited extent thoracic spine. The literature is highly variable on reported outcome, with quality studies showing both no effect and profound results.

This is likely due to the fact that corticosteroids are physiologically active medication and thus more likely to treat a physiologic process such as inflammation. In small study to specifically selected patients based on radiographic markers of inflammation (such as T2/STIR MRI or SPECT scans), corticosteroids were found to be more effective than not. This is in contrast to other well-done study that did not use the selection criteria and demonstrated a lack of effectiveness.

Radio frequency neurotomy the medial branches also has a large volume of literature including the placebo controlled explanatory studies in both the cervical and lumbar spine. Less data existence in the thoracic spine, due to the variability of the neural anatomy in this region and requiring large volume blocks and lesions. Collectively for the cervical and lumbar spine the literature is among the most robust in the spine world. The reporting outcomes from RF procedures do vary between the studies. However, this variance appears to be at least partially predicted by the rigor of the diagnostic criteria used for subject enrollment and the technical details of the procedure.

Given the prevalence as, a pain has been reported at 15 to 45%, in the lumbar spine and 36% to 67% of cervical spine, if studies do not adequately exclude those with facet mediated pain, they would enroll more subject without facet mediate pain. When viewed in this manner, studies such as the MINT trial quickly become clear outliers was 72% of subjects having a positive block. This number is divergent from any other published literature on topic.

Increasing diagnostic rigor with more blocks and greater percent really tend towards more profound outcomes, however, this is at the expense of potentially denying an effective treatment to some do the known possibility of a false negative block. We looked across multiple, well-done studies with appropriate technique and selection criteria, reported results at 100% pain relief post RF has been reported 46 to 70% of subjects at six months. There's also been reported within an associated reduction and opioid use, increased function, and even decreased overall healthcare utilization. So, even after subjects had are enrolled in these studies, after having typically failed conservative treatment, this body of literature demonstrate a much greater efficacy than any conservative treatment.

According to 2016, AHRQ report on non-invasive treatments or low back pain, which stated, "when present," observed benefits arrangements 5 to 20 points on 100 point scale, to remind the group, this is otherwise, what we would call clinically not significant, and they also said, "effect on function was generally smaller than effects on pain." And so, while the interventional spine and pain societies really debate, whether it's 50%, 80%, 100%, single, or dual blocks are required to have sufficient relief from the procedure, that has a strong safety profile, other conservative treatments were told to proceed generally, all, fail to even reach an MCIC in controlled trails even when compared to wait list or other treatment that likely produce a nocebo effect.

Dr. Duerden: Excellent. Thank you, Dr. Kennedy. So, before we leave this section, or any of the panelists want to provide any additional opinion regarding the body of discussion we've had regarding the procedure efficacy?

Dr. Manchikanti: Again, I think we still are questioning in giving a rating: inter-articular injection or medial branch block that is confusing me at least in my mind, and many of the panelists. I think. Dr. Kennedy, he did a great job. I don't have any issues with radio frequency neuroanatomy, or intra-articular injections. But I do think there is an issue with facet joint nerve blocks. Actually, there are more studies supporting facet joint nerve blocks and more recently, even in thoracic spine, the evidence is level two across the board for lumbar, cervical, the thoracic all regions, with moderate strength of recommendation. Again, acute pain model is different. If we have, if we stick to this acute pain model, two hours, 45 minutes relief, that's not going to work, and we have to go into chronic pain model. And some of the studies have quoted all that done in worker, workers' comp injuries, motor vehicle injuries, and Australian's. Americans are different, Medicare population is different. So, we need to take into multiple variables into this consideration.

Dr. Duerden: Thank you.

Dr. Tracy: May I add one more item here, please? This is Dr. Tracy. I also had confusion on question four, whereas Dr. Hirsch so eloquently stated the use of steroids. The way I interpreted it was repeat injections beyond three, as we approach epidurals, we're allowed to do three in a year. So, the way I interpreted that question was; "that would you say if you did more facet injections in a year than three?" I don't know if I'm wrong on that, but my score changes in terms of the essence of the question.

Dr. Duerden: Thank you for that clarification. The question emphasis will be on injections beyond three injections per year.

Dr. Tracy: OK, so I would like to hear Dr. Hirsch's response to that, please.

Dr. Duerden: Certainly.

Dr. Hirsch: So I think that there's some confusion in general, as it relates to three a year, if you looked at the MPW generated letter where most of the, or should I say SIS generated letter, where most of the MPW participated and by way of clear disclosure, I'm involved with multiple societies that signed on to that letter. There's discussion about five, and here there was a question about three. I think, that part of the challenge is differentiating between diagnostic and therapeutic, and when I looked at the coverage programs for CGS versus some of the other MACs that are on here. I think that's also reflected in how and how the procedures are supported.

The five interventions, I think, accumulates both the diagnostic and therapeutic as people in general, I do not they are giving five therapeutic injections over the course of the year. I think as it relates to medical branch blocks, which customarily do not include steroids.

You can, really, from a safety point of view, gives three or more without having to worry about safety. Because, again, the literature that I saw, I saw quite a bit and reference to Manchikanti's paper, 7500 episodes, really reports no serious adverse outcomes to that. The Kim paper gives me a little pause. It does talk about to facet joint intra-articular injections. I think that whether it's on the basis of that or on the basis of the FACT that you're using steroids more typically I would not be comfortable with the number five, but it does seem to me that three therapeutic injections would be OK. But for the reasons I outlined before, I would recommend the same numbers that I did differentially for medial branch blocks versus intra-articular facets for the question of three or greater.

Dr. Duerden: Thank you, Dr. Hirsch. And I appreciate the input and from Dr. Tracy as well. So, for clarification, please answer the fourth question based on beyond three injections per year, in regards to the fifth question. First, currently on intra-articular injections, as opposed to the medial branch blocks and breaking those down as the primary procedure for the cervical, lumbar, and thoracic sets that were asked. As we move to Section two, and this actually goes right, Dr. Manchikanti, prior statements. We're going to talk about patient selection as the chronic pain patient and the degree of rigor in which we need to assess to provide these types of procedures. So, I'll turn the time over to Dr. Manchikanti.

Dr. Manchikanti: Thank you, sir. Again, on question five you are saying, that relates to only intra-articular injections?

We were under the impression that, when you said that said facet joint interventions, that's why Dr. Kennedy talked about radio frequency so much. And then, we talked about facet joint nerve blocks. So, is that only inter-articular injection or does that include all three?

Dr. Duerden: No, I would like to focus primarily on the intra-articular injection part of that question. And I apologize for the lack of clarity in that question.

Dr. Manchikanti: Section 2, question 1: Does the literature support the statement, rigorous beneficiary selection and inclusion criteria are necessary to reduce false positive diagnosis and/or

false positive error rates when using facet joint injections and procedures? We all know that the false positives are extremely common, even utilizing 80% criterion standard with a chronic pain model.

We have shown that the false positives in the lumbar spine are 27% to 47% in cervical spine, 47% to 63% and in the thoracic spine, 42% to 58%. However, if you use the single block technique, false positives are going to be much higher, especially if you use 50% or less. So, as I said in the beginning itself, appropriate selection criteria is crucial, for facet joint interventions. To avoid unnecessary diagnostic and therapeutic interventions, and to reduce false-positive physical findings pointing towards but facet joint pain are extremely crucial.

Last night I was talking to one of our own professors and he was saying that Lax don't forget the patient physical examinations mention that. So that is what I'm doing here as my professor told me.

The physical examinations and clinical assessment are strongly recommended with axial pain tenderness over the facet joints, reduced range of motion and pain reduction with rest and absence of radicular pain. However, this can only point towards potential diagnosis but not actual diagnosis. The imaging is not diagnostic. That is some evidence for a SPECT, but nothing else. Consequently, the we must do the rigorous beneficiary selection and inclusion criteria, that is, what improves the results rather than just going and sticking needles based on our instinct. So, examination, pointing towards that, and other management duration is extremely important.

Dr. Duerden Thank you, sir. So, the answer is to that is you're saying yes. Correct?

Dr. Manchikanti: Yes.

Dr. Duerden: And do you have a standard that is a that would be considered using the literature? That would be a rigorous standard for beneficiary selection?

Dr. Manchikanti: Just this thing, axial pain and if it is radiating, it should be somatic type of radiation, not radicular type. The tenderness over the paraspinal regions or facet joint tenderness mostly in the middle of the spine. That is not going to facet joint, they do reduce range of motion, pain reduction with the rest.

Absence of radical pain, these are the important ones, Extension is sometimes helpful. There is also a new sign called Kemp Sign. They are describing, but it is not clinically users that much. These are the ones we use, then, have been many descriptions in the past by other investigators, but they have been proven to me to be inaccurate, so we no longer use them.

Dr. Duerden: Thank you, sir, I'd like to move to question two as a way to build on Dr. Manchikanti and turn the time over to Dr. Maus.

Dr. Maus: Thank you. And I appreciate the invitation to be here. Question number two: Is use of non-specific assessment of subjective "pain reduction" reported by a beneficiary with nonspecific chronic axial spine pain not associated with radiculopathy or myelopathy a reliable and valid measure of improvement in pain following a facet injection or medical branch block injection?

I would score that four, referencing the medial branch blocks, no intra-articular injections. Here is my reasoning. The question addresses to the validity of patient reported responses to diagnostic block. Validity of a test should ideally be measured against a physical criterion standard, which is indisputable such as an observable pathologic finding. But there is no such criterion standard available. Practically the goals of interventional spine procedures are reduction of pain, restoration of physical, emotional, and social functioning and the reduction or elimination of consumption of health care resources. The subjective symptom of pain is fundamental. From chronic pain arises deterioration of physical. emotional, and social function and a demand for health care. The secondary measures are not amenable to measurement of the time of effect of a local anesthetic, but longer-term neural blockade is an area of active investigation.

Medical branch, block exhibit target specificity, in both cervical and lumbar spine segments, injectate reaches the nociception of the facet joint, medical branch blocks exhibit construct validity, the ability to discriminate a true positive response from a false positive response in both cervical and lumbar spine segments. The evidence is less robust thoracic region.

False positive rates, however ranged from 29% in cervical medial branch blocks to the 38 to 45% in the lumbar segments, hence the need for controlled blocks. The dual comparative paradigms is a practical solution with a sensitivity of 100% and a specificity of 65% in the cervical region; this is reduced in the lumbar region, where facet mediated pain is of lower prevalence.

It could be argued that in the absence of an actual criterion standards that the construct validity cannot be obtained, that one can only obtain credibility, i.e., how unlikely it is that the pattern of block responses expressed by the patient, is due to random guessing, or chance on the part of a beneficiary. And here, you might want to consider nonpainful patients seeking to create the fiction of a pain state. Bogduk and Engel elegantly demonstrated mathematically by two randomized comparative blocks that credibility as high as 75%.

The ultimate proof, which allays concerns regarding the credibility of patient responses, is predictive validity — does the block paradigm predict the response to the therapeutic intervention?

The literature endorses predictive validity of dual medial branch blocks in the cervical region since their inception. A recent systematic review of lumbar medial branch blocks and RFA by Schneider and colleagues, stratify the outcomes by rigor of the MBB selection criteria. As the rigor of selection is tightened from single to dual comparative blocks and the criteria for a

positive block is elevated from 50% to 80% to 100%, the proportions of successful RF procedures increase. At the most rigorous level of complete pain relief for dual comparative block the subsequent RF procedure results in complete relief of pain for at least six months in 55% of patients accompanied by restoration of function, return to work, and no need for other healthcare for a median duration of 15 months per treatment..

None of the above noted validation literature applies to intra-articular facet injections. As has been noted previously, these injections are subject to a higher technical failure, and may not remain as selective as the joint capsule is known to be fenestrated, and, therefore, are not the preferred diagnostic approach.

Thank you.

Dr. Duerden: Excellent. So, dealing with the Medicare Beneficiary Population you're saying is essentially that subjective pain reduction is, would be insufficient documentation to show efficacy of this patient, correct?

Dr. Maus: No, I am saying. that reduction of pain, reported by the patient, is the best documentation we have. We don't have an absolute criterion standard. And because of the predictive validity exhibited by utilization of patient reported pain responses to medium branch blocks. It is, indeed, the appropriate qualifying procedure for the definitive therapeutic procedure of radiofrequency ablation. It would be ideal, if we could measure functional improvements, but that's not possible at this time, due to the limited temporal duration of local anesthetic blocks.

Dr. Shwachman: I agree, you know what we do. I don't care how you cut the mustard. If the person says, my pain is relieved, that's where we really were going for.

After that, to suspect, other things that he can do. So be it. But the main thing we're going for is pain reduction, that if the patient is happy, the patient is happy, and we're ahead of the game.

Dr. Manchikanti: Pain reduction is the main issue, the main way we judge people, but there is also another component that immediately we examine the patient, and they should be able to perform previously painful moments with continued pain relief, otherwise, _it is_____ negative. So, a patient says 100%, or least in prone position, but they can't sit and stand and do anything, which was painful prior to that, then it will be considered as negative, in my opinion, and that is what literature says. And LCD already stated that they should be pain relief of the ability to perform previously painful . I'll address that in a subsequent question, which I am asked to address.

Dr. Duerden: Yes, there's going to be some bleed over. I appreciate that. I'd like to move to Dr. Simopoulos and his question number three regarding the numeric pain level.

Can you read that, please?

Dr. Simopoulos: Sure. Thank you everyone.

Lot of this has already kind of simple premise for the answer for this. Do you have an intermediate confidence that there is adequate clinical literature to support a minimal numeric pain value either NRS, VAS or similar threshold (6/10) to identify an individual's pain level before a Medicare beneficiary is eligible for facet joint injection or procedure?

I it's kind of complicated a little bit. At the end, I interpreted this as is there a minimum pain score, to which we would consider a patient for facet joint diagnostic procedure first. If we look at the literature, whether it's Dr. Manchikanti work, Dr. Bogduk in the past, Dr. Derby, all of these studies, patient says, Dr. Manchikanti alluded to earlier people who had long term pain and significant pain with movements, so there's always a mixture of factors.

And so in conclusion, I'm looking at the literature, there's not a minimal number, or a number that's minimum for doing this, that said, the patient has to have an adequate level of pain. You could then assess and get a degree of relief.

So, if I go, surely by the literature? There isn't a study that says, this is the minimum number, so, like, I had to say, no on the studies, if we go purely by science.

Dr. Duerden: Excellent. Thank you, sir. Going to move to question number four.

Dr. Schwachmann: Yeah, what you're saying on the one hand, what are the criteria for doing this?

And on the one hand you're asking about a number, and that's more like playing bingo very frankly. Other hand the approach to Dr. Manchikanti is taken. Now, I said pain relief, but certainly the degree of satisfaction in motion and where the patient stands, sits, and so forth, is what's really important. And there are various inclusion criteria, for example, and I, do have a contract with Cigna, but I'm just to contracted provider. Cigna got some very good criteria for doing this, and Dr. Manchikanti mentioned criteria for doing this. So, if you're going to do the blocks, I think you have to use inclusion criteria as Doctor Manchikanti does those rather than just pick a number like bingo out of the air. And there's not only inclusion criteria. There are also exclusion criteria on doing these cases, such as a fusion situation. So., I think that whatever those inclusion criteria are, you can pull them from various sources including Dr. Manchikanti.

Dr. Tracy: I'm a little bit disappointed that we've used numeric rating scale to assess pain for decades. So, we have to have a score to assess the pain. And what I do is explain to the patient, one is no pain, 0 no pain, and 10 is the worst pain you've ever had in your life, and you're in the hospital. So, we have to have something to be able to rate the patient pain. So, if I'm not understanding this right, please interject because what I'm reading here is a numeric scale, or visual log scale, a useful methodology. And I say yes, that it is.

Dr. Creamer: This Dr. Creamer. Just commenting on Dr. Tracy, I disagree. I think that the numerical pain rating scale is not useful. I think as a physical medicine and rehabilitation physician, I identify pain as it impacts a person's functions and I don't feel that the numerical scale really is able to reflect that. And I don't agree that we should be using the numerical rating scale for the determination of these types of procedures that should be based on a patient's discussion, of how this pain interferes with their functional activities. And pain ratings can vary, depending on whether they're sitting in our office or whether they're physically activity doing an activity. So, I think that that also has an impact, and it's, it's not very helpful to use a numerical scale.

Dr. Cohen: This is Steven Cohen there have been a whole bunch of studies, about 5 or 6 studies, and they've shown there's a high correlation between verbal rating scales, numerical rating, scales VAS scale. The same scale should be used with the same person don't switch from one to another. But this is the question that I think that you're getting at, and this is what the impact guidelines say. Right? That you shouldn't just look at pain in what Dr. Manchikanti said, is absolutely right. If people are sedated and they're just, you know, lying on a stretcher or go home and sleep for hours, that doesn't make sense, but this has been looked at, actually, by a podiatrist.

Guy McGarry published something in 2011and, there's, there's not a great correlation between pain and function , between patients. But there is if you're if you're looking at improvement in function within a patient, over again, a longitudinal study, or over in a given time period, it is very highly correlated. So, if people report 50% decrease in their pain, then they have improved function. So however, you want to do this, if you're talking about medial branch block, the problem with using something like _____ disability is there are questions on it.

Let's say, you know, how each year, know, how do you travel? so they're not driving or neck disability? You know, can you drive? There are questions about sleeping. There are questions about sex. And so, if you're using something, if you're using bupivacaine or lidocaine, that's going wear off in three hours or six hours or seven hours. You're not going to be able to actually have a very good index as to as to whether or not, you know, function is improved. So, there is, like you say, a correlation within a given patient between improved function and improved pain relief _____.

Dr. Scwachman: Your statement about, within the patient is appropriate and true, because I've had patients that, if I compare the before and after, I can’t get a number of those, Dr. Manchikanti, said It's more valid if you can get motion. However, if this question implies, that Medicare would say that you have to have a number five score, or seven score before you can have the block, then what you've done is you've compared patient A to patient B And as Dr. Kennedy pointed up, it, it doesn't quite work because one person will exaggerate the pain levels and another person's just shrugs off pain and so forth. So comparing using that system to decide whether or not you're going do, the block, I think is like playing bingo, the guys got to hit the right number or he doesn't get the block, as opposed to the inclusion criteria of what he can do,

what he can't do before and after an injection, or whatever, it is what if it's problems now, from inclusion criteria? And we have this from various people. Like, Cigna, for example, has a nice layout for that. And I'm sure Dr. Manchikanti, he also has a nice layout for who we would block, and we wouldn't.

Dr. Cohen: A three over ten pain in some people, is equivalent, 10 pain In, you know, in other people, any 0 to 10 pain scale is not linear, right? So, the difference between 8 to 6 is much easier to obtain than a difference between a four over a, two. So, you cannot have a cut off like this, and for clinical trials. If you look at Clinical trials FDA or NIH sponsored, it's four. Sometimes five is the cutoff. Six, definitely doesn't make sense.

Dr. Manchikanti: Here, the question was related to the diagnostic logs. So, how we select the patients are and how we assess, so that's correct. There may be about anything, about five in one, and one of the insurers says three on their policy. But they were investigating us, for not documenting 3 or 6. See what a document, an average pain. So, this issue has gone with a lot of understandings, but my comment was mainly related to medial testing of the patient.

So, a patient is lying down after the diagnostic block, so, we don't send them home, saying, that has been pain free, and don't document that it is 100% relief, rather than that. We make them to go through the various moments and then see then they come back. That is when we actually look at their work status, sitting, standing, walking, lifting, carrying mood, sleep patterns, all these other issues. That is more like a long-term relief if a patient gets 3 to 4 weeks of relief. That is the thing we're looking at it and after that eight weeks or 13 weeks, six months with radio frequency neurotomy. So those are the long-term ones. But for immediate evaluation that is what we were looking at, actually Cigna follows guidelines, old guidelines now than, I don't know what they're following now, but those are the same I understand, Dr. Schwachman

Dr. Schwachman: I'm just worried about situations where you're going to pick a number. And then after that, permit the procedures to be done. In my experience, some patients don't understand the numbering system. You try to explain it, as Dr. Tracy said. And it doesn't always come across with people. And now you've taken a particular number. I think you're better off in deciding whether this can be done. That Medicare will agree with that. Being done or insurance company agreeing that it will be done. That there'll be criteria to be that you could layout and at least give a little story of where they can, function can't, function, and then allow it to be done on that basis. The success of it afterwards is what Dr. Manchikanti's talking about, I think.

But whether or not the patient will be getting the treatment, I think should include inclusive criteria and exclusion criteria, and not just pick a number, like, we'll do it, but the number three, but we've also won't do it if the number six or vice versa, because that's just play bingo and the patients don't always understand it.

Dr. Duerden: Understanding that question correctly, so, Dr. Maus, go ahead. I just want to completely agree with the above-mentioned comments.

Dr. Maus: We have to be careful about discriminating the appropriate use of an NRS scale for measurement of a block response, versus here, where we are talking about a patient's eligible for a procedure where we want to look at not just pain, but also we want to look at physical, emotional and social functioning as well. So, looking at a broader profile, for example, the PROMIS profile, would be a much more useful, valuable tool to qualify patients for a potential procedure.

Dr. Duerden: Thank you.

I'd like to, move to Dr. Tracy on question five size. Perhaps, address the issue of conservative treatment as you can also go into some detail about that, and the duration of months.

Dr. Tracy: Well, I have to concur with Dr. Kennedy, and Dr. Cohen, and Dr. Manchikanti because it's very difficult to answer these types of questions and three minutes.

So, my answer to that question would depend on the intent of the question. Are you asking, does the clinical literature support conservative, for a minimum three months just prior to facet injection or median branch block, because most of us have patients who've been through rounds And so it's that, questions is, meant to support three months of conservative therapy just before

facet injection, I would have to say, no, I would, I would not be the case, but if they failed rounds and rounds of conservative therapy for greater than three months, then I would have to give that a high score. Now, in your literature, in your bibliography and trying to control time here. I just number the references in papers number two, three, five, six, and one they failed three months of conservative therapy. They didn't say if it was most recent, or after that. In papers number seven and 12, they talked about three months of pain or symptoms. In one of those was Dr. Manchikanti who did 12 randomized and five observational studies. And then in articles in 19, 20, and 7, it was greater than six months of pain. and in articles nine and 10, it was greater than 24 months of pain. So, you would have to clarify for me what you mean by the conservative therapy? Also, here, we're talking about the Medicare population. And, in one of Dr. Manchikanti his papers and in his draft ,outline on page 96, he says, there's a significantly higher prevalence of facet joint pain and patients over 65.

So, most of the studies in the bibliography, have patients of all ages in it and not over 65. So, I would agree with Dr. Manchikanti and the ASCIPP guidelines on page 96. I think you have this draft, and it'll be published tomorrow, that. It's more common in the population we're talking about, i.e., the Medicare population, but also on page 61 of the newly developed ASCIPP guidelines. It says that there is level two, and this evaluation level two is a high level. A level one is the highest in selecting patients for facet joint nerve injections at least three months after onset of failure of conservative therapy. So, you know, I'm not sure how to answer that. I think that anyone suffering for three months.

Some of my elderly is actually cry when I asked them to undergo physical therapy. There so debilitated, my practice is 90%, Medicare, eighties and nineties. So, I would prefer the three months of pain than, the three months of failed conservative therapy, with judgement factors added to that.

Dr. Duerden: So, it is more to the guidelines that you're alluding to when we were speaking a general term, the minimum of three months of conservative treatment prior to just someone coming in de novo without any prior treatment to get an injection,

Dr. Tracy: OK? So, you would say that years of conservative therapy greater than three months would be adequate in that question?

Dr. Duerden: Yes, OK, so then I would say yes, that would get a high degree, high score from me, and I would give that a four.

Dr. Manchikanti: Those three months of, Deborah did a wonderful job explaining her position there, and I agree with most of it, but why three months?

Why not one month? Why not eight months? Why not 12 months? There is no reason for that.

Why would you put somebody for three months of physical therapy if it is hurting them? They can't even go; they go to physical therapy. They don't want to go. And at the same time, if somebody is able to perform appropriate exercise program, self, or they have seen a chiropractor on and off altogether, they had failed conservative treatment our guidelines and LCDs. Always said that, three months after the onset of the pain, with a conservative treatment. That means conservative treatment did not work. It did not provide adequate relief, but once you've said that three months of conservative management, so a person has to have it have pain for at least six months, or even longer because they have to wait, see their doctor then go through the physical therapy. And everything else is going to take long time. So, I think that limit, maybe is a good idea to go ahead and remove it and then they nonresponsive to conservative your management in general terms, including physician ordered, physical therapy, chiropractic medication therapy. We can add all those things, but still it should be left to the patient and doctor and their financial situation. There are huge deductibles. These patients can't afford copays. I'm sure. We don't want to bring the cost here, but it is it is going to be a factor to them. There are my clients, she said, when you order them physical therapy already failed at so many times, why do you want me to go through that?

Dr. Kennedy: This is DJ Kennedy. I'm going to agree with Dr. Manchikanti, the number is somewhat arbitrary.

On the pro side, you know, the literature does support three months as a prerequisite purely because that is how the studies were designed in terms of their enrollment for subsequent enter

interventional procedures. If you take just flip side and ask, are there studies on conservative treatment that they require three months before they are shown to be effective? The answer is simply, no. The best studies we have on this are on some of the chiropractic treatments and it's somewhere on the nature of eight visits and if it's shown to be effective. So, no, I mean, if there is that literature showing that, yes, maybe three months waiting is what a lot of the enrollment criteria was, therefore, but again, that is not based upon any mechanism of action for the conservative treatments across the board.

Dr. Cohen: This is Dr. Stephen, I think my question is very related, so you can just skip over this, so I agree completely with what Lax and, and DJ said. So you should require conservative treatment. If you look at the randomized controlled trials examining , the set radio frequency ablation only two did not require it, the VanWick study and the LaClair study and both were negative. Guidelines from NICE guidelines from the Belgian Federation of Healthcare Institute, STEPCare Model for the VA, which is being adapted by a lot of military treatment facilities requires conservatives care. Finally, there's are validated instruments for evaluating epidural steroid injections studies. And there are a lot of people from all over the world. People have experts from Asia, Europe such as Van Dureink, who has a PhD and pulsed radio frequency Mark Entuned (?), who at the time was the editor-in-chief of ____ Concluded. It's called Aquarius, that three months should be required epidural steroid injections study. And the reason for this is that, if you treat people with epidural, steroids in a randomized trial, you're going to be more likely to not show benefit because these people will get better on their own. But it's the same thing with facet, if you are treating people with, you, know, most people who have back pain for five weeks, are going to get better, whether or not they're treated.

So if you treat them in five weeks with the facet innovation, and they get better, and let's say they get better for 15 months, and then they're pain comes back. What, what happens, in reality, is, they get treated again, and again, and again, and it's really difficult to know if they work. So, you need to require conservative treatment. Everyone agrees, but I agree with Lax and with TJ, that we don't know exactly what that is. It may not be three months, maybe it's, you know, maybe it's eight weeks, maybe, in some people, that should be more than three months. You can skip my turn, because I think it's almost the same question.

Dr. Duerden: Yes. You're absolutely correct, just as a slight variation of it, and I believe you addressed it very well. So, let me drop back to Dr. Barnhill to address some of the conservative treatments that would be considered in in a policy.

Dr. Barnhill Thank you. Can you hear me OK? Thank you.

My question is, do you agree the following modalities are considered conservative treatment? And the simple answer is yes.

When I look for evidence, that was a little bit more difficult to find supporting evidence. However, I did find protocols and guidelines, so I'd like to share with your comments on each of the modalities listed.

Current, low back and neck pain protocols by the North American Spine Society and regional insurance carriers recommend these modalities prior to pain specialists' evaluation, however, Cohen 2014, identified this practice as a fundamental medical principle in which you start with the less invasive interventions. This recommendation by NASS, and insurance carries is not supported by conservative therapy outcome studies. However, another problem identified by Cohen in his 2014 article relates to the timing of the proposed conservative therapy, either before or in conjunction with spinal interventions for low back pain. So as far as integrative treatments, I said, yes.

Acupuncture is considered an effective treatment for selective acute, and chronic pain syndromes and is therefore a reasonable referral option. Significant difference between true and sham acupuncture indicate that acupuncture is just more than a placebo. However, these differences are relatively modest, suggests that factors in addition to the specific effects of needling are important contributors to therapeutic effects of acupuncturist. And that's based on Vickers 2012.

Currently, the Academic Consortium of Integrated Medicine and Health Commentary to CMS acknowledges that acupuncture is recommended by the American College of Physicians, the National Institutes of Health, and the US Agency for Health Care Research and Quality for chronic low back pain and neck pain and is without serious pathology by the Global Spine Care Initiatives. While older patients were not excluded in trials that supported these recommendations, acupuncture for chronic low back pain, specifically in elderly, has not been adequately investigated. That's based on our Arya 2019.

Now as far as multimodal approach, including spinal manipulation therapy, other commonly used active interventions, self-management advice, exercise is an effective treatment strategy for acute and chronic back pain, with or without leg pain. A meta-analysis by Riddick et al in 2016 revealed that spinal manipulation was superior to sham therapy for non-specific low back pain. Smith 2019 considered osteopathic manipulation therapy as a great B level of evidence. For patients with acute low back pain, spinal manipulation therapy, results in similar outcomes to no treatment medication, or modalities. Periodically, short-term improvement is statistically better, but clinical significance is uncertain.

As far as physical therapy it is recommended by NASS and insurance curious prior to facet injections. However, the NIH care excellence and the Belgian Federal Health Cancer do recommend therapy in conjunction with low back pain protocol that includes RFA, not enough evidence to evaluate treatment results.

As far as medications, anti-inflammatories, anti-depressant recommend a three-month trial before facet interventions.

Others, nutrition, weight loss, sleep hygiene, Yes. Smoking cessation and stress management could be added to this list, of pretreatment conservative therapy. Also, may abolish some of the presenting symptoms and prepare patients for self-care after this bout or painful experience.

That concludes my comment.

Dr. Durhem: Thank you, Dr. Barnhill, and I appreciate that You took a very tough question. And you did an excellent job. We can move to question number eight with Dr . Creamer.

Dr. Creamer: OK, so the question number eight is, does the clinical literature support, at least intermediate confidence that history and physical examination can be used to identify painful facet joints as the primary source of pain?

Dr. Manchikanti in the World Journal of Orthopedics in May of 2016 a review that concluded "attempts to make the diagnosis of lumbar facet joint pain by history, identification of pain patterns physical exam and imaging techniques have shown low accuracy and utility."

In the article published in the Journal of Pain Physician in 2012 "multivariance analysis of the relationship between paid referral patterns and the source of chronic low back pain." This was authored by Ben Laplante. He concluded the presence, or absence of thigh pain possesses a significant correlation on the source of chronic low back pain for varying ages, whereas the presence of hip girdle pain or leg pain did not significantly discriminate among inter-discal disruption, facet joint pain or sacroiliac joint pain, as the etiology of chronic low back pain. He also commented a younger age was predictive of intra-discal disruption regardless of the presence of thigh pain. And I think the main indications are the main points that I took home from that was the varying impact of age. And that this disease itself may mimic or have a similar pain pattern, is what we would consider facet joint pain.

Another journal, the Journal of Physical Therapy, which I thought was interesting because it looked at physical therapists who we might assume have a good understanding of pain conditions. And this was published in 2007 and they reviewed the topic. And there are articles and title "Indicators of Lumbar Zygapophyseal Joint Pain: Survey of an Expert Panel with the Delphi Technique." And they went through various literature reviews and reported "following the three rounds, consensus was achieved, and 12 indicators were identified. Those that reached the highest levels of consensus were a positive response to facet joint injection, localized unilateral LBP, positive medial branch block, pain upon unilateral palpating of the LZJ, or transverse process, lack of radicular features, pain eased by flexion, and pain , if referred, located above the knee."

And then the referring back to Dr. Steven Cohen's article, "The Pathogenesis Diagnosis and Treatment of Lumbar Zygapophyseal Pain" concluded that that, "in summary no history or physical examination findings can reliably predict response the diagnostic facet joint blocks."

Then getting into the more recent article, the "Consensus Practice Guidelines on Interventions for Lumbar Facet Joint Pain from a Multi Especially International Working Group" in Regional Anesthesia Pain Medicine. Doctor Cohen, also summarized "no pathognomonic physical exam, or historical signs that can reliably predict response to facet joint blocks."

So I guess the question point of view, I felt that the clinical literature did not support intermediate content that his physical examination will be used to identify a painful facet joints as the primary sources.

Dr. Deurden: Thank you, sir. We'll move to Dr. Kennedy.

Dr. Kennedy: I have no conflicts of interest to be reported. The question is, Does the clinical literature support with at least intermediate confidence (≥ 2.5) a requirement for imaging before prognostic blocks?

I said no, but there is some evidence suggesting that the utility of the procedure imaging and there are additional concerns that drive providers to obtain these images. The most widely investigated imaging modality used to detect potentially painful is SPECT scanning, which does provide a measure of biological activity, does the potential to detect active inflammation. Some evidence exists about the ability of SPECT to provide predict a positive response to the medial branch block or intra-articular injection. Although, there's really no data on cost effectiveness of routinely ordering this test. This combined with the risk posed by radiation exposure has really limited its routine usage. There's also small study, specific MRI sequences for detecting inflammation that tend towards the positive predictive value. There are also additional studies on the presence or absence of facet arthropathy on MRI has been shown to correlate with a positive medial branch block. Meaning, if they have it, they're more likely to respond than if they don't have it. But the degree of arthropathy has not been shown to have a correlation.

Collectively it really is limited data that pre-procedural imaging enhances the outcomes from prognostic blocks on a population level. However, one study by Akuthota showed that 43% of procedures are changed based on the results of an MRI. It should also be noted that every practitioner, I know has seen a contraindication of a spine procedure on pre-procedure imaging. Also, advanced imaging is often obtained for other reasons. Specifically, by definition, by the time a patient is ready for an interventional procedure, targeting facet joint, hey generally met the criteria for advanced imaging due to the duration of pain, and typically failure of other conservative treatments, as we discussed above. Thus, while the procedure itself may not require pre procedure imaging, spine care, and the current medio-legal environment may mandate this.

Dr. Deurden: Thank you, Dr. Kennedy. That was a complicated question, that, I appreciate the breadth of which you addressed.

Dr. Manchikanti about question number 10 and objective documentation requirements, gets back to the original to some of the beginning questions was, is a subjective pain score, numeric,

analog scale, or should we be moving more toward more objective documentation? I'm going to turn the time over to Dr. Manchikanti.

Dr. Manchikanti.: I don't have any conflicts again.

Does the clinical literature support with at least intermediate confidence (≥ 2.5) objective documentation (e.g., a daily pain diary) should be required to measure the sustained percentage of improvement following facet joint injections to relieve pain and improve function? Answer is yes. So my answer is yes.

The clinical literature does support assessment of pain relief and improvement in functional stages, and it is mandatory in most of the jurisdictions. However, I do not feel that pain dairies are, that is the best way to do it. It only reminds the patient, the pain, the bad stuff, all the time.

and they do not complete on time. People have other lives other than just reporting the pain diary. They'll write down some kind of number, because that is what is required to get further treatment. So, in my opinion, and according to the literature available, the best way to assess improvement is, initially, their pain levels, along with the low back, or neck or disability index? But subsequent visits, we should look at not only where baseline pain was, but what was the average pain. And also, the pain during the time and that presenting to you. That could be 50% of what it was. Before or more than otherwise. they may not need further treatment. We need to assess the same things as I was talking before, their work status, sitting, standing, have they improved, somewhat improved are they functioning or the same? Lifting and carrying, mood and sleep patterns? These are the protocols we know of. Everybody has these things. So, you document routinely ask patients to questions and document routinely and move on with it. We can also evaluate how many of their goals have been met. We asked them, initially what goals they have, but some people are just going to taking, doing activities of daily living in our Medicare population is a major achievement, playing with the dog, grandchildren or going out about shopping. those are all important aspects. Again, they are participating in the structured exercise program or not. So, we would like to see that before proceeding with the injection therapy on the day of the procedure, we should document, for that day, that patient pain has returned to at least 50% of what it was, the baseline. So, we have average pain relief, and then on that day what the pain was.

Dr. Deurden: Thank you, sir, very well. Well go to Tim if you take on question number 11, please.

Dr. Maus: The question is: I am confident that there is at least intermediate confidence in the clinical literature to support the terminology of temporary pain relief, long-lasting pain relief,

and permanent pain relief is a reasonable, reliable, and meaningful health outcome terms to provide an objective clinical assessment for facet-mediated pain relief?

I would answer yes, but providing context to this, as I'm sure Dr. Simopoulos will want to address this with the subsequent question.

First, regarding temporary pain relief, this references response to a diagnostic block for the anticipated duration of a local anesthetic agent. The temporal duration of the effect, which is usually hours is subject to individual variability. Temporary pain relief in response to a diagnostic block should be complete or near complete, 80% for a block to be considered positive.

This is borne out by my previous comments on the predictive validity of medial branch blocks; when studies of RF neurotomy outcomes are stratified by the degree of temporary response, the responder rates for RF neurotomy significantly improve with more rigorous criteria for this temporary pain relief in the qualifying blocks. The patient response to queries regarding temporary pain relief also depend on how that question is posited and by whom. An independent assessor, not the procedural physicians should be utilized to assess this temporary pain relief. It must be made very clear to the patient, what is the index pain we're studying with this block procedure? And if that pain is precipitated only by specific positions or motions, then these proactive maneuvers must be performed and documented.

The subsequent question will address the definitions of long term and permanent pain relief following therapeutic, not diagnostic procedures. I think it's very important to make that distinction. I wish to add nuance to this by noting that patient reported pain relief by itself is a pretty blunt instrument and subject to misinterpretation. The literature for many years has noted that importance of multiple additional domains of physical, emotional, and social functioning, diminished consumption of health care resources, including opioid use. Such an assessment of domains beyond pain intensity is available using the NIH developed PROMIS system of patient reported metrics, which with computer adaptive testing also minimizes patient burden. This or other consensus agreed upon broader metrics, will improve and provide a better understanding of the overall utility of facet interventions, rather than simply a pain metric.

Thank you very much.

Dr. Deurden: Excellent, thank you, sir.

I would like to move with to Dr. Simpoulos I believe you’re up next in this complex. Next question is breaking down a little bit more and Dr. Maus will address it.

Dr. Simpoulos: Sure, I think that a lot of this is been addressed in part and leading up to the question. First, does the clinical literature support the definitions of the following terms?

And I think we've been through some of this: temporary pain relief is defined as pain relief, greater than 80% based on a minimum duration of action relief consistent with the duration of

the local anesthetic employ during the therapeutic zygapophyseal, joint injection procedure or medial branch. I think we went over earlier, the diagnostic value of facet clocks versus medial branch blocks. Right now, most of us including based on the literature find that the medial branch block is the way to proceed with the diagnosis for facet joint mediated pain.

The majority of the literature's gravitating towards 80% or more. And, finally, the idea of documents: you touched upon this, that this began by Dr. Boguk years ago. That, temporarily defined by the duration of the agent, was defined by either lidocaine or bupivacaine and typically the relief didn't last that long. Although, he actually pointed out that that's not the case in many situations, and it tends to move more towards the long lasting. So, I would say most of us would agree that very temporary or transient will be the duration of the anesthetic. So, then, I'll move to Part B. Long lasting pain relief is defined as pain relief consistent with greater than 50% or at least 12 weeks from the prior zygapophyseal joint injection procedure or medial branch block.

And, most of us would consider to be short-term relief. That's another term used for this, but it is longer lasting than the block and our chronic pain population. I think that given the mechanisms that were discussed, we kind of went into that, particular Lax, explained pretty nicely in our patients. So, I do think that something that exist long lasting been borne out multiple studies, both either epidural studies or facet joints interventions with either local anesthetic or steroids, that three months is not uncommon for patients, and do good. And, of course, as Dr. Cohen many and many do not, which brings us to the next area, which is, permanent pain relief, is defined as pain relief, that is consistent with greater than 50% relief, for at least 26 months. Typically, the six-month window here from the prior therapeutic zygapophyseal joint injection procedure and/or medial branch blocks.

A nice comparison was by the Lake Meyer study in 2013, looking at the six-month mark, or 4% detections and frequency of this small population with compared facet neck to neck. All seem to have the possibility that joint injections can render or enjoy long term pain relief. Facet joint injections can also be temporary or long lasting. A lot of these studies are small, and there's some of, that may vary a bit, and you see them. I think suffice it to say, these are reasonable definitions for what we do. We can't really go beyond six months. It's also called long-term pain relief and short-term. So, that's another terminology that I see commonly.

Dr. Cohen: This is Steven Cohen. So, the trend is not toward requiring 80% pain relief. It's actually against that, and I will tell you how. So, the IMPACT guidelines, which say 30% pain relief is clinically meaningful.

Almost every single FDA sponsored trial now, they look at responder analysis and they use 30%, or 50%, the ORC guidelines for osteoarthritis in general, even require less than 20%, less than 30% sometimes, they have criteria that sets, that's 20%. Second, facet degeneration, is really rare in the absence of disc degeneration. So, nobody has facet degeneration in isolation, there are

many studies for this. There is a systematic review by Brijisski in 2015 and it shows, know, by the time you're in your thirties, more than half of the people who never had back pain have disc degeneration, but that cutoff for facet degeneration generation in six years. And there were so many studies that have looked at this, this no cutoff threshold, and not just for facet there are many of those. We did one, with 92 patients with cervical facet, we've done a couple for lumbar facet. No difference between 50 or 80% or 1 or 2 blocks. It's been done for spinal cord stimulation. (Williams, it's done per pulse radio frequency (Jules Wang). It's been done for diagnostic procedures before superior hypogastric plication, celiac plisis neurolysis. Again, no difference between 50% or 80%. And there are studies that show that you get a higher success rate when you use 80% cutoff for radiofrequency ablation, But I'm going to very, very briefly go over these.

So, you have Rick Derby study, which had 51 patients, a retrospective study, and when he used 80%, which was how they classified a positive responder, the success rate was 84%, but, when he used 50 to 80% pain relief. So, these people, if you have an 80% cutoff, would never receive it, never receive radiofrequency ablation, and they may end up on opioids or getting spinal fusion or something else. The success rate was still 56%? So, in other words, you're going to deny access to care to people who have 50, 60% pain relief, which the FDA, NIH, and the IMPACT guidelines all say it is clinically meaningful. And there's only one prospective study that ever looked at that and this was our study published in 2012 in Clinical Journal of Pain and we designated cutoffs in 10% intervals. So, 50 to 60%, 60 to 70, 71 to 80, 81 to 90, and there's no difference at all, and radiofrequency outcomes. When, you know, between 50 to 60%, and 80 to 90, doesn't make any difference. We did do, there were six people we didn't expect this right? Ended up having radiofrequency ablation with less than 50% pain relief and only one out of those six got better. But that's even a statistical artifact, because this was a prospective study.

And so, we predesignated 50% pain relief and a positive global perceived effect in three months as the definition for positive outcomes. But these six people, they came in with 37 38 % pain relief, and they said I know I didn't get 50% pain relief, but, you know, I didn't have to take my oxycodone. I was able to play tennis, I slept better. And we did radio frequency on them, and

although only one got 50% relief, there were three out of six that that still say, I'm really happy, I feel much better. So, 80% relief is not where this is heading. That's really, really old data. That's from, like, the early two thousand or 90's when SIS was coming out with these guidelines. But, since then, you've had all of these organizations come out and say, that doesn't make sense, and it doesn't even mechanistically based, makes sense because, as I said, you never get to facet degeneration without significant degeneration and without significant myofascial pathology, and there's also a systematic review on that by Geiser in 2006.

Dr. Tracy: Yeah, I would like to strongly support Dr. Cohen's position and n refer you to Dr. Barnhart referenced in the beginning of the session, the Consensus Practice guidelines on Interventions for Lumbar Facet Joint Pain from Multi-specialty International workgroup and that was spearheaded by Dr. Cohen and on page 20 of that articles, it says summary, this committee recommends that greater than 50% reduction in pain be considered a positive block. Although we recognize that studies should be performed to determine whether lower cutoffs may prove optimal. And along with Dr. Cohen, here in Florida, our pioneers that move from other states, you get them back to golfing, and tennis being able to perform improves their functional ability, no matter how little you get there as happy as a clam. Thank you.

Dr. Cohen: Can I get 50% pain relief and is really, really satisfied treatment when there were no options and, in fact, there are other options, but they're not good options, surgery or opioids.

Dr. Manchikanti:. Yes. I think I'm not sure where Dr. Cohen is coming. We just completed a study, looking at 50% and 80% we did the study in 2010 and our last study was not that old. And they also published the 75% pain relief more recently.

And there are several studies which came with 80% relief too. There are also studies as we look at 50%, 80%. And they couldn't figure out what was happening at 50%. I'm not sure 30% is going to get them back the golf course. And it is not even worth doing intervention. And we are here, we are talking about radio frequency neurotomy. It looks like there's only treatment. There are other treatments these patients can respond to other than joint nerve blocks beyond moving more towards it, rather than less towards it.

We just have completed who papers, which will be published in the next few months, showing, again, the same amount of prevalence and high false positive rates with a single block.

Again, as I said before, we are looking at an acute pain model and chronic pain model, actually _____with the Philosophical Foundation, or diagnostic blocks and differences of opinion. There were three schools.

One was Boddy? school based on their own approach, which is 100% pain free, and duration of relief of less than seven hours, or less than 24 hours. The second approach he described was a pragmatic approach, by Dr. Cohen, we just talked about. The third one was the approach to described by me or us, which utilizes a different criterion, in reference to the duration of relief.

Only thing he didn't like is that we were compromising with a lesser effective treatment. It's hard, but facet joint nerve blocks do not provide, the same amount of relief as radio frequency.

So, we would offer less effective treatments, So, that is the only thing he did not like, but all in all, as we'll see as we move forward, there will be more requirements and more of literature on 80% and that will be more widely accepted than 50%.

Dr. Kennedy: I think part of the question, problem I have with this question is when we look at therapeutic responses. Which it says, Therapeutic zygapophyseal joint procedures, and/or medical branch blocks, and differentiating therapeutic outcomes from diagnostic outcomes. We wish they perfectly mirrored each other, but they don't always right, for a whole host of reasons. Dr. Cohen is 100% correct, 30%, 50%. therapeutic outcome is something that almost who wouldn't take that, right? I mean, that's still better than anything else in the literature for axial spine pain and by a long shot.

The diagnostic procedures, you know, it does change your predication in terms of where you're going and percentage of people that are getting a positive response. And, part of this is, when you, when we're looking at, you know, does 50, 60, 70, 80% change, it does not on a single block, right? It really doesn't. But if you start applying a more rigorous protocol, 80% and dual block, some of those, the literature trends towards a greater percentage of people having out positive outcomes.

However, there is a downside to this. And the downside is this pesky thing called a false negative, right, where someone can have pain that would benefit, and this is what Dr. Cohen mentioned. You know, in the Derby study that you would be denying care to a subset of people. And I really think that the question is the goal here to treat the majority of people that could benefit from this. Or to have something with a high response rate that is higher than anything else in the published literature? And, that's where you hear people arguing about 50, 80, 100%. I mean, these are all still significant cutoffs when compared to anything else in the literature.

Dr. Cohen: So, I think that is so perfectly said, and I want to tie this in because what Dr. Manchikanti said is also true.

And this is from his 2010 article, retrospective study, with 252 patients, and he looked at, this is the one-year follow-up and so he looked at 50% versus 80% pain relief. So, a lot of the patients who are on opioids, not all of them got radio frequencies. Some of them got just serial medial branch box but in the people, who are greater than 80% pain relief, he reported an astounding 93% success rate.

Which was higher than the 75% success rate when he used 50%, of less than of 80% relief. So, think about this. So, yes, as Dr. Kennedy says, and almost everyone agrees, that you will

probably get, a higher response rate if you raise threshold. But, these 75, 75% of these people, who got between 50 and 79% pain relief. That's amazing outcomes, 75%. And when people were thinking of this 80% or 100% cutoff, you know, this was a different world because the most common cutoff for a positive response was 50%. It was the 50%, 50% Club. If you got 50% pain relief you, it was great.

But now we know that that's not the case that 30% is, so even acknowledging that you may have better pain relief with medial branch block, 80% pain relief was coupled with the 80% pain relief during the diagnostic block was coupled with a 50% pain relief during radio frequency. So, those are the dual outcomes. Now, that we have 30% after radiofrequency ablation, used in the main trials using the main trials. And used in this huge NIH $16 million study that we have on radiofrequency ablation, 30% pain relief? Now, that you, you decreased it from 50% pain, relief to 30% pain relief, which everyone agrees with you still have this greater than 80% pain relief is a diagnostic cutoff. You know, tell a patient, they know, that, I'm sorry. You only got 75% pain relief. We're not going to do this procedure.

Dr. Deurden: I appreciate that vigorous interchange and I think that's exactly why we're having this type of discussion. Next, I'm actually going make it a little more complicated, now. We're going to have Dr. Shwachman actually even start addressing, some specific type of pain patients. And, trying to integrate that into the answer isn't the question

Dr. Shwachman: If I may, we basically answered because if you're going to have inclusion criteria, you're always going to have the opposite for everyone. For every pro there is a con. There is always exclusion criteria and various companies have put it together after good research papers cited the sickness situation before. There are exclusion criteria in Cigna does as well and as well as inclusion.

I would also add that one statement, Dr. Manchikanti inclusion and that is the idea of three months. I would say that using three months or any number like that, rather than a physician patient relationship, is frankly barbaric. Because you have someone who may not respond to conservative therapy and now, he has to wait three months. And a few exclusion criteria also have to be looked at, for example, in case of fusion, you wouldn't want to do it.

Dr. Deurden: Dr. Shwachman , I'd like to just press this, this question a little bit more as well.

What happens now that you have a patient that has axial spine pain, but they have confounding, additional diagnosis of widespread diffuse pain: do we need to have additional inclusion exclusion criteria that it includes or excludes that complex pain group?

Dr. Shwachmann: I think that you get complex situations.

For example, you're going to have a diabetic, have diabetic neuropathy, but it can also have disc disease as well. And sometimes you just treat the disc disease and these perfectly capable of

living with his diabetic neuropathy. I think that you treat what you can. And that's what you do. You don't necessarily just say well, this is the exclusion, and therefore, you have to suffer the other parts of the disease.

Dr. Duerden: I'd be interested in the rest of the panel, as well as providing some opinions regarding the complexity of overlapping low back pain etiologies.

I understand your point was diabetic neuropathy and degenerative disk disease, but those are typically different locations. What I think the question in the complexity of this is what has axial spine pain on top of fibromyalgia?

Dr. Schwachmann: Well, I'm trying to say that if you have a cause for treatment, regardless of what other issues have, you should try to treat it. I don't you have to look at each individual issue of them by itself. And you might look at the periphery situation, but I think you should look at treating what you've got, and you've got to facet joint disease. All that's been said today, should apply to treating that facet joint disease. And I don't think that necessarily having other diseases would be a contra indication of treating facet joint disease.

Dr. Kennedy: I'm going to partly agree with that and partly disagree.

I agree, completely this is on an individual basis, and you have to evaluate the individual patient to see what is being done. And the question about, does the literature support overlapping pain syndromes as an exclusion or inclusion for this.

I don't think the literature supports that one way or the other, meaning we don't have studies that specifically included this group, or excluded this group or controlled for that variable. And part of it is, as has already been highlighted. How are you defining it, right, because diffuse widespread pain could very easily fit with, you know, a peripheral neuropathy or fibromyalgia, or any other thing coming through. My clinical experience, and I am now into the realm of expert opinion, which is the lowest form of evidence, because there is not a lot of written evidence on this. So, I'm acknowledging that is when I do get people with overlapping spine syndromes in their back and I do, this kind of plays into the previous question. And I do a block and I get 20, 30% relief on them. Is not a primary pain generator, not a substantial restoration of function decrement and medication use the likelihood of me having a positive therapeutic response, that is notable to that patient, is not high? And, you know, I think that that's where it comes into the individual patient, because just because someone has widespread pain, they could have a major pain generator with functional restoration and decreased medication use with targeting an individual pain generator. Or. they could not and, you know, it is hard to tease that out based upon any data, patient, demographics ICD 10 code that we really have for these patients.

Dr. Deurden: Thank you, Dr. Kennedy, that was. Actually, Dr. Tracy, you're exactly who I was going to next because I want you to make the comment that I'm giving you the final statement to answer that last question as well as to opine on this current issue.

Dr. Tracy: Well, I would agree with Dr. Kennedy. Here in Florida our elderly has multi-factorial back pain, it's very common to see an MRI image that has facet deterioration inflammation, spinal stenosis, herniated, disk, bulging disks. And that's why we do a diagnostic injection.

Because If I see a patient that has a predominance of what Dr. Kennedy said previously, thigh pain and they have radicular pain but they say, not as much in it doesn't hurt is bad, then I'll go ahead and do the diagnostic block and get the answer to that. So, I would agree with Dr. Kennedy 100% on that, and I'm ready to move on except if there's any other comments.

Dr. Cohen: I have one. I have one comment. So, I mean, you know, involved at five o'clock, in fact, that I may have to cancel after calling from Australia. That's why it's five o'clock. I'm involved in this pain series with these people who are no neoplastic pain experts. So, one is for lancet.

And I'm just revising it now for, you know, for Pain.

And it's very clear that people who have a diffuse pain phenotype, fail all sorts of treatments. So, absolutely clear. So, Chad Brunmet's groups and Klasha? showed they have really widely average responses. We publish something last year in ___ the P value was there was a very strong trend. It wasn't, wasn't high enough and we have something coming out now in Regional Analgesia. And the reason is, because these people with diffuse pain phenotype, whether or not it's fibromyalgia, are called something else. The main thing next matter with them is that they're their nervous system is just hyper sensitized. So, they have knee pain. They have abdominal pain. They have pelvic pain. So that's a separate question.

So, they're going to be more likely to fail treatment, but I'm not sure what else to do, but in terms of, etiology is the same risk factors for facet degeneration, are risk factors for SI joint degeneration, that systematic review that I cited by Geiser, No matter what your cause of back pain, you know, people just have elevated myoelectric activity. They have, you know, increase muscle tension in their back. And there's work by Milan Stimnotowich (?) in that other systematic reviews, I pointed out. You know, these people are all also have, you know, stenosis, foraminal stenosis central stenosis in Milan 2010 article, he showed that there was an association between, you know, having spinal stenosis, an RFA outcomes not because you want to treat these people because they have real pathology, the same risk factors, People don't just get facet degeneration in isolation.

Dr. Deurden: Excellent. I'd like to move the discussion a little bit now on to Section three. Where we going to talk about the overlap of procedures and Dr. Barnhill, you are up.

Dr. Tracy: But doctor, I haven't answered question 14.

Dr. Duerden: Oh, I'm sorry, Dr. Tracy?

Dr. Tracy: OK, so, um, it is my opinion that studies are designed to exclude patients when it is thought that they would affect the outcome of the study or interfere with the outcome of the study.

So, in my opinion, these evidence-based papers are not real life, and it's difficult to use the evidence in the literature to exclude patients. So, when you were asking these questions, I was thinking are trying to exclude people with coagulopathy, If, so, the ASCIP? the guidelines published states that would continue coagulation therapy. You have that draft on page 2009.

As long as the INR wasn't greater than three. I believe and that literature would support taking people off their induced anticoagulation therapy. It's riskier than doing a facet block, especially that it's outside of the neuroaxis You know using pressure and pressure dressing. So, I would not exclude people with induced coagulopathy as 1 or 2 diagnostic blocks and then radiofrequency ablation would mean weeks of taking them off their coagulation medications and that would be very risky. Some of the papers in the bibliography excluded English speaking will certainly we've excluded person from getting a diagnostics facet block, or any facet injection, because they don't speak English. They cited inability to complete the forms and they did cite radiculopathy. I think Dr. Cohen and myself had made the case for multi-factorial back pain with facet joint being the etiologies.

They excluded rheumatoid arthritis, which I would not agree to, because these people have pain in many different joints, including the facet joints. They included psychological problems, which I would not include this because you're mentally ill, doesn't mean you shouldn't get treatment. A history of surgery, these people can often develop facet distractions from changes in the architecture of the spine, secondary to the surgery and can do very well with facet injections and get that 50% and also, they excluded lumbar spinal stenosis and herniated nucleus polposus. And I think that Dr. Manchikanti made a strong argument for patient selection criteria and that's what we use in that case. So, the only reason I could see that you wouldn't want to move forward with these types of injections, I do. By the way that that, metastatic prostate cancer responded very favorably to steroid injections and facet joint injections if there’s questions involved.

So, the only reason I can think of to avoid or exclude a patient would be if you wanted to avoid radiation. So, pregnancy if you had an acute neuropathy, which should be evaluated immediately by a spine surgeon. But we see patients that have foot drop for years, so that wouldn't be a contraindication. Infection, active infection would be an exclusion.

So that would be my recommendation, if you'd like me to clarify, I can.

Dr. Schwachman: I agree with Dr. Tracy.

This is what I was trying to say is that does exclude people because they've had some other disease, including, like diabetic neuropathy, which I cited before, or she cited rheumatoid arthritis or something like this. It's just incomprehensible.

There's no reason why there's only a few reasons why you would really back off facet joint disease. And so, I think that the fact that there's others, there's no reason to tell people you can't have at least a diagnostic procedure to see if they'll get some relief.

Dr. Hirsch: I made my disclosures earlier. So, I think the Dr. Tracy and the last speaker highlighted something in different ways, that is a pervasive problem through the LCDs. which is that the effort to be evidence based, which is completely appropriate exclusion, and inclusion are also matched to trials which, in no way, are, actually meant to mimic the real-world way patients present. And I mean, I could cite multiple examples beyond facet joints where that's true. I don't know the right solution as Medicare tries to move towards greater evidentiary basis. But I do think it reflects a real problem. And there's feedback on a recent coverage decision, where matching the real-world to what are exclusion and inclusion to make a clean trial has led to, I think. some real problems for patients. So, it's just something I think with this many of this level of talent, of CMDs, on the call to think about as we go forward.

Dr. ____I would build on that actually to say that, you know, when you when you exclude patients from treatment, and I think Dr. Cohen touched a little bit on it they're going to seek another treatment or another one, they're going, they're going go someplace else, and they're going get another treatment.

That might not be the best treatment, or the treatment that's the safest or best. So, you alluded to opioids, it was alluded to surgery. There will be some other place that they will go.

Dr. Deurden: In the interest of time, I'm going move to Dr. Barnhill to answer section three, question one, regarding other types of interventions at the same time as safe injection.

Dr. Barnhill: Thank you. The question asks, what is your level of confidence based on clinical literature, to support that the following procedures should not be used in the same or close location, and in conjunction with the Z-joint injection procedure to reduce false positive diagnosis, and or false, positive error rates in Medicare beneficiaries with spinal pain and facet joint origin?

It's very difficult to locate any literature attesting to the sensitivity or specificity of facet injections, either intra-articular, medial branch, that were concurrently administered with any other procedure. Prospective studies would have difficulty assessing efficacy in combined procedures due to subject variability and normal and abnormal pain pathology, placebo response, and other confounding variables. I did find in the CMS LCD or an older version that states and, I

quote, “Medicare does not expect that an epidural block or sympathetic block would be provided to a patient on the same day. Multiple blocks on the same day could lead to improper or lack of diagnosis. Coverage would be extended for only one type of procedure during one day session of treatment, unless the patient has discontinued anticoagulant therapy for the purpose of an interventional pain management.”

OK, I scored these, all one, due to the lack of evidence that I could not find.

Dr. Kennedy: I just have a clarification question? Meaning the question says, should the procedures not be used in close location? That level of confidence that they should not be used, so please score of a one versus a five, and answering that question to me and reading that level five is high confidence that they should not be used in a level. one is I have a low confidence that they should not be used. Is that correct?

Dr. Duerden: If you believe they should not be used together, that would be a low score, as opposed to a highest.

Dr. Schwachmann: I think you have two situations going. If what you're doing is a study, then you want to isolate exactly what your point of the study of the and eliminate as many variables as possible. If you're treating people in the real world, all you want to do is, you want to eliminate the pain and restore function. You don't care if it was the epidural that did it or if it was the facet joint block that did it. Because, for one thing, the goal is not to produce a beautiful study, is to get the person well and functional. And that's the goal.

Dr. Deurden: Let me press on that one just a bit.

So your position is that you should do them, correct together.

Dr. Schwachmann: Do them if you have inclusive criteria for doing that, for example, the support staff, for example, let me point out to you that the one of the descriptions of facet joint pain. Those pain. That's the low back pain that radiate into the lower extremity, but only along the posterior aspect. And no further usually than the knee, that can just as easily be a radiculopathy as the facet joint pain. So, what are you going do? Does the facet joint as a diagnostic thing and then send the patient home and then bring them back? And there's a cost factor in that. There's a risk factor within coming to the operating room. And now, you're going to bring them back. And now you're going to do the epidural. Why not do them both together and the patient gets better. You don't know which is which but, Hey, the guys better. He’s functional. He doesn't have pain.

Dr. Cohen (?): Then every single time they have pain, they're going to end up getting multiple procedures they may not need.

Dr. Schwachmann: It's better than going back to the operating room and taking that risk.

Dr. Kennedy (?): I question, you know, hard part is, I know, a very limited literature that combine those. And part of that is, as it was pointed out, and it was pointed out very appropriately. The studies are designed to be clean, right, that they are looking at individual patient population.

Yet, when we take the work of Mike DePalma, for instance, you know, the number of people that he's able to identify, a single pain generator, is actually fairly substantial. The number of people with multiple overriding theme generators that require all kinds of different procedures all at the same time was very low in his pain in his group.

And I recognized groups are different across the spectrum, but you know the number of people that need multiple procedures at the same time for me, based on after an examination of history, physical, and review of imaging, in my practice, is very limited. And we do outcome studies on all our patients with, keeping track of them by an independent registry, and we have literature are our outcomes are similar to what's reported in literature. So, I think that is a little bit tricky to do some of those things.

Dr. Schwachmann: Well, you point, if I can, you point it to studies, and I agree with you, if you're doing a study, you want to limited it and identify where the pain generator is, no matter what, and you want to have a clean study. In the real world, you're taking people back into an operating room, there's a risk there, there is an excessive cost there, and how much time do you do the other way around? And that's in the real world, in a study I agree with you and that was pointed out.

Dr. Kennedy (?): I'll agree. I completely agree that are the difference between clinical and real-world. I do practice in a real-world, and very rarely do multiple procedures at the same time and, you know, have good outcomes with my patients, which I monitor. And the question asked, specifically, what is the clinical literature to support the following procedures?

Dr. Schwachmann: I am concerned that Medicare will then stop us from, in the real world doing more than one procedure on the patient. And that's what I'm worried about, is they'll take the idea of what a study and graft it into the real world, and then were precluded from going further with it.

I think Dr. Manchikanti pointed out before, when he talked about three months, that there's a situation in which you should leave it up to the physicians and the patients. And there isn't a point for that, and there's a point at which you're told a patient that is part of a study, and that's the difference, there is very little literature on it, I agree with you, and one of the one of the previous speakers, for example, gave it a one for that reason.

Dr. Duerden: So, I'd like to move to the next question, which is number two with Dr. Cohen.

Dr. Cohen: To address the issue of the single medial branch blocks injections versus two. And I think I went over the 50 versus 80%. So, if you want to skip that in, in terms of timing. So, first, let me say, you know that if you have a definitive procedure, which is what RFAs should be, that's relatively safe, incomparably expensive to the diagnostic test. Then you really need to have a diagnostic test that has high sensitivity and negative predictive value. So, that people don't end up getting surgeries that won't help or put on opioids.

And, of course, the decision also depends on, on the prevalence rate, i.e,, no pretest probability, which, which DJ speaks about very eloquently. So, if you add a population with a very, very low likelihood of disease, like teenagers, then you might be able to consider two blocks. But here's the thing there's not a lot of studies that you can actually calculate sensitivity and negative predictive value, which is what you want high ones. But you can with Susan Lord's study in 1995 where they did placebo vs. lidocaine and bupivacaine injections in the neck, they found the sensitivity of 54% and a negative predictive value of 68%. And Rick Derby study in Pain Position, 2013, a retrospective study, which had a sensitivity of 55% and a negative predictive value of 53%. So, in other words, this is, this is saying, that you might not need any blocks. So, requiring two medial branch blocks is not consistent with other test before really invasive pain procedures. So, now you need to discography before disk replacement. You don't need to have it before, you know, before spine fusion. And I'm sure that they are accepting a paper in Pain a big huge multinational randomized trial, about whether or not you need a spinal cord stimulator trial before spinal cord stimulation, in delback (?) and they said you don't even need it.

Dr. Duerden: So, Dr. Cohen. can you drill that discussion down to your final opinion regarding two medial branch blocks?

Dr. Cohen: OK, so the literature does not support it right. There is there's 2 there's 2 randomized trials one by us that showed you a higher overall success rate and lower overall costs with less blocks than two blocks. And there's another study by Jack McCormick and the need was no difference between zero or one block and you know the whole point of doing two blocks is to reduce the false positive rate. But the more blocks you do, it's inevitable that you will have false negatives and the false negative rate is really important, right? Because these people aren't going get, treatment, and Rick Derby is the only guy with, with good information, and he found that there's a false negative rate of 47%.

When he put the cutoff at 50%, or the cutoff at 70%, and out of those people, eight of them had radio frequency, and six of them got better. So, in other words, you know, two blocks. Here's the bottom line. You will have an overall higher percentage of radio frequency ablation success rate. It will be higher. But overall, because you're withholding all of these, you know, holding well-being treatment from people who will benefit, you will have an overall lower success rate. And it will be much more costly. And almost everybody who has a second block. You know, it's, the second block is positive. Because, you know, people in private practice, they're telling patients, I'm sorry, Medicare is requiring a second block, and if you don't get 50% pain relief on here, we

can't do the procedure. It's definitely, it's inconsistent with all other, you know, prognostic procedures to blocks.

Dr. Duerden: I'm going to make the question a little bit more complicated and I'll turn it over to Dr. Cramer to discuss that issue of, actually you're not only getting the subsequent blocks, but how do you measure them?

Dr. Creamer: OK, well, again, this gets back to the question that we discussed before about even therapeutic facet at joint intervention.

So, the question is what is your level of confidence based on the clinical literature to support subsequent, therapeutic, intra-articular injections or medial branch blocks?

Previously injected facet joint or medial branch blocks, i.e. the same common site is expected to reduce pain and improve function? So, we're getting into issue with using it as a tool to determine whether a radio frequency ablation will be appropriate, but whether you would receive just nerve blocks or the intra-articular injections.

So again, getting back to Dr. Cohen's review again, there is weak literature to support therapeutic intra-articular facet joint injections or facet joint nerve block. But of course, there are studies that document the benefits of these interventions.

And of course, Dr. Manchikanti's review noted level two evidence for facet joint nerve blocks for long term improvement, and that's longer than six months. And he documents level three evidence for lumbar-sacral intra-articular injections for short-term improvement. So, again, I think the literature, I scored it as a three, in that regard.

And then we get into some other studies. Dr. Cohen's review in the Consensus practice guidelines also getting into the justification to repeat these interventions. The article questions, "what should the cutoff the for designating a block as positive and is there any benefit to using non-pain score outcome measures?" The authors in this report document that the question was focused on block success to proceed with an RFA. Again, their conclusions suggesting that 50% release combined with functional improvement documented and paid are would be reasonable.

Dr. Manchikanti reported in his findings back in 2008, "Cervical medial facet branch blocks for chronic cervical facet joint pain: a randomized, double blind controlled trial with one-year follow-up." And in his report the results demonstrate a significant pain relief greater or equal to 50%, and functional status equipment was observed at 3, 6, and 12 months, in over 83% of patients. The average number of treatments was approximately 3.5 in each group over. And duration of pain about 15 weeks. They concluded "therapeutic cervical medial branch nerve blocks, with or without steroids, may provide effective management for chronic neck pain of facet joint origin."

There was also report by Dr. Dong Gyu Lee in Spine, 2018 January article entitled “Comparison of Intra-Articular Thoracic Facet Joint Steroid Injections and Thoracic radiographs Blocks to the Management of Thoracic facet joints.” These results were assessed with the numerical rating scale concluding both intra-articular, thoracic facet joints, steroid injections, and therapeutic medical branch neurotomy reduce pain and persisted for at least six months after the procedure. They concluded that “both intra-articular facet steroid injections and therapeutic thoracic medical branch blocks are useful treatment options for managing thoracic facet joint pain.”

We're getting into the additional questions. Querying the outcome measures that would utilize to pursue with additional facet joints, intra-articular injections, or medial branch blocks. And what objective documentation will be required.

In question 3A the paragraph references, a minimum of 80%, just a relief for the first and second medial branch block with duration of relief being consistent with the agent used.

Dr. Cohen consensus guidelines since stated several times, in the absence of any reliable treatment options for patients who obtain, greater than or equal to 50%, but less than 80% believe that the least in this report, the Committee opted to maximize access to care.

So, again, I really feel that 50% mark would be more appropriate, and that 80% would set the bar too high.

And I know, at least in my review, I feel that the literature does not support a minimum of 80% sustain relief, the first or second medial branch block.

Then in 3B, I thought the literature supported a minimum of at least 50% sustained improvement in pain and then the ability to perform previously painful movements and activities of daily for at least three months. So, I gave that a score four the question 3B, score of three in the four question 3A.

Dr. Duerden: Thank you, Mike. You did a very good job with that focused response. I appreciate that. If I could turn to Dr. Manchikanti because there's a next question is also very complex and has multiple nuances to it.

Dr. Manchikanti:

I just want to apologize to everyone for Dr. Cohen for insulting him insulting on the private practitioners. Economy is the only thing we are involved with. In reference to the evidentiary is still coming, and you'll see, in a few days. My first question is, diagnostic injection should be a minimum of 28 days apart.

This probably will generate, again, significant controversy and discussion, some say that, if a patient is getting 45 minutes or one hour of relief, then they can go in and have a second block on the same day. And have a radio frequency the next day. There are other treatments for people

who cannot have radio frequency, and, again, 30 to 40% of the patients do not respond to radio frequency, and they want another treatment. Generally, we go with facet joint nerve blocks, but if they fail, because they do not respond to these things that they do have other things going towards. Epidural injection, for example, there are multiple studies. So, in my opinion, 28 did apart it reasonable.

If we take the chronic care model, if you take the acute pain model with the expected relief of 45 minutes to two hours, or less than seven hours, less than 24 hours as marked up as recommended, it may not be appropriate. Right now, it says two weeks, I believe, and this is going through the four weeks.

Dr. Duerden: The question is going to be on chronic pain models. Thank you.

Dr. Manchikanti: That's correct. So, that is what. So, this is a significant improvement to the pain and function. It does not have to be 80%, 80% relief lasts for several hours or a day or so.

We have shown that, it can last for two months. The second time, 6 to 12 days. The first time with the 80% and, but long-lasting relief is about 13 to 16 weeks. Again, I already discussed about this chronic pain model and extended relief. And I have given you the guidelines, the draft version, but it has table 16 and 17 shows that relief is much longer than what has been described. So that answer is yes for that. The next question is, therapeutic injection should be a minimum of three months apart. That is accurate. Some of the polices, because of the issues related to LCDs which vary wide. In the past, we heard a single, nice, beautiful LCD, but everything was changed. For unknown reasons. Now we have conflicting information like. Some of the LCDs standards there that there should be three months of relief. But they can have five injections in a year. That is bizarre, internally inconsistent but three months is fine and like CGS said it is four therapeutic in a year. This original is this all started with NGS when it covered Kentucky_____.

Then third question is: interventional procedures at different regions should be performed at a minimum of two weeks apart. I do not believe so. There isn't any evidence that to do so. This will only increase the discomfort of the patient and increases the utilization. We just did a study, and it is in publication. It showed that the age of sorts of radio frequency, neuroanatomy was performed in almost 44% of the patients. And more than two episodes of radio frequency per year were performed in 7% of the patient's lumbar spine, when you went to the cervical spine it was 20% and 5% increase. So, this increases the utilization patterns cause significant inconvenience. And especially in post COVID, we are looking at PPE so, we are using it quite a bit. So, we always believed that we have written always in the guidelines that we should try to do them in one setting to the best of our ability. If not, then we can go to a different level like Dr. Tracy brought that up.

Says, the patient is an anti-thrombotics, some people to stop them. In those cases, it really raises the risk. So, we should be able to perform the procedures in less than two weeks, and especially at the same setting, if not two weeks, four weeks, it doesn't matter. In the next question, in the

treatment phase, intervention and procedures should be repeated only medically necessary, not to exceed four times in one year. That is accurate. That is what CGS says, but other say five.

Facet neurolysis frequency would be only of medical necessity at minimum of six months apart. That is accurate, too. I agree with that, number five.

Dr. Duerden : That's not my question OK, thank you, excellent. Thank you, sir.

Dr. Kennedy, I'm going have you go to the next question and for the sake of time, I would like the additional answers to be focused as you can as best I can.

Dr. Kennedy: What is your confidence in the clinical literature to support facet injection or medial branch blocks being allowed for three (3) spinal levels per anatomic regions (diagnostic or therapeutic) in one session?

The published literature shows the two most common conditions causing facet mediated pain or osteoarthritis for the lumbar spine and whiplash for cervical spine. It really would not be consistent with our knowledge of either of these processes, to suggest that they could only affect 1 or 2 levels. However, there also is prevalence data that demonstrate three levels should not be the norm or routine. In the lumbar spine the highest prevalence for the purpose of facet is the L4/L5 or level followed very closely by the L5/ S1 level. Combine these two joints comprise around 80% of the overall prevalence for lumbar pain. Given their generally indistinguishable based on history or physical exam is reasonable to routinely target both the given the high prevalent, especially for procedures targeting medial branches which have overlapping innovations. However, in the lumbar spine, all the other levels combined have less than 20% prevalence. And there is no strong data on the prevalence of people with three or more level disease. So, the need for a three-level procedure should be well under 20% in the lumbar spine.

In patients with whiplash and neck pain or headache the C 2,/3 set joint was found to have a prevalence around 50%, whiplash patients with neck pain below C 2/3 the overall prevalence was combined around 60%, with the highest prevalence being C5/C6 joints, followed by C6/C7. These studies have not been replicated for osteoarthritis, but cadaveric studies have shown osteoarthritis to be more common in the image cervical region between C3-C5. Regardless, when compared to the lumbar spine, the cervical spine does have a more distinct pain referral patterns, as well as a higher reliability in the palpatory exam, will should help facilitate picking a particular level more easily than the lumbar spine. It very unclear how often three level disease occurs in the cervical spine, and we do not have strong studies showing you outcomes for 3 level procedures in the cervical spine.

Dr. Duerden: Thank you, Dr. Kennedy, we can to move to question six and Dr. Manchikanti could you address that?

Dr. Manchikanti: Thank you, sir. Question is: What is your level of confidence on a scale of 1 to 5?

The clinical literature supports that when subsequent thermal medial branch radiofrequency neurotomies at the same anatomic site are sustained considered medically reasonable and necessary if the facet joint denervation has objective documentation to show a minimum of 80% from diagnostic injections (with the duration of relief being consistent with the agent used) or objective documentation (e.g., a pain diary) to show a minimum of at least 50% sustained improvement in pain and the ability to perform previously painful moments and ADLs, for the last six months, This is, we may be able to, you may be able to change it to the same anatomical region, rather than. it does, then anatomic site. So, it has also set the painful moment that I was talking before. So, it is already in the policy. Now, there is good evidence for repeating the radio frequency in neuroanatomy.

I mean, there are multiple articles showing that the repeat radio frequency neuroanatomy does work. The level of evidence for lumbar spine is level two with moderate strength recommendation for: ablation with 11 relevant randomized control trials. There are two negative studies and four studies showing long-term improvement. When we come to cervical spine level of evidence is again two, with moderate strength recommendation. The inclusion of only one randomized controlled trial, there's only one controlled randomized control trial that was also published long time ago, but there are two observational studies showing improvement, and that one randomized controlled trial had only 12 patients in each group. The level of evidence is three, but it’s weak to moderate recommendation for thoracic radiofrequency ablation.

With inclusion of one relevant randomized control trial and three observational studies, the reason why we gave them higher Evidence in terms of recommendation because it is evolving subject and there is developing evidence on that. The question and that is: does the literature support repeat the support repeating imaging for repeat thermal medial branch radiofrequency neurotomy. Does the literature support a requirement to have repeat diagnostic injections prior to repeat radiofrequency neurotomies? No level of evidence, my vote is one.

Dr. Deurden: I am done. Thank you. Very well done. Thank you. Dr. Maus, could you go onto the number seven, please?

Dr. Maus: Question: Are there any evidence-based strategies to improve the safety and reduce complications associated with such joint injections and procedures?

The answer, yes. Facet interventions, inclusive of medial branch blocks, intra-articular injections and radiofrequency ablation procedures are safe procedures with very limited reported complications. Consensus Guidelines on interventions by Cohen and colleagues, categized adverse events on lumbar facet procedures as intra vascular penetration injury, procedure related pain or dysesthesias, injury to adjacent structures, consequences of muscle denervation, and the impact on implanted electrical devices. Each of these categories has a body literature describing

adverse event rate and strategies for minimization, which are nicely addressed in Dr. Cohen's guidelines. Very specific procedure related methodologies to minimize adverse events for certain interventions are also describe in the Practice Guidelines of the International Spine Interventions Society, now SIS. If one wishes to assess the effectiveness of these procedural guidelines this requires large cohort studies where those guidelines were followed. A large multi institutional (Mayo, Northwestern, Penn) study (Carr, et al) on 610 facet interventions where SIS procedural Guidelines were utilized found no major adverse events inclusive of bleeding or neurological injury. Most common, minor adverse events in those procedures are vasovagal reactions present in 1% of facet injections, 2.7% of medial branch blocks,3.4% for RFA. Other perceived the minor adverse events were orders of magnitude less frequent.

Answer is yes.

Dr. Deurden: Thank you sir. Dr. Simopoulos, question eight.

I'm going come back to it.

Comments submitted post call: What is your confidence in the clinical literature to support a limitation in the injection volume <0.5 ml for medial branch block and volumes <1.5 ml for intraarticular injections? Confidence level of 4. In order to improve the diagnostic specificity of medial branch blocks. volumes in the cervical, thoracic and lumbar have been 0.5 ml (multiple studies by Manchikanti et al and Derby et al, and less than 0.5 ml (in the cervical region, Cohen et al). Intra-articular injections have been on a trajectory of <1.5 ml for IA (Kim et al 2017).

Dr. Shwachmann: Question Number nine is, should these facet jointed interventions perform under fluoroscopy or CT the guidance?

My answer is, five. There was a study a number of years ago in which the epidural were done blindly and then checked up and the failure rate of actually appropriately placing the needle, I believe in that study years ago, was the failure rate was as high as 25%.

Originally, the epidural, I believe, were done under caudal, but as a move to anesthesiologists, they couldn't read the X-ray, and they needed an endpoint, and the inter-vertebral has an point, the loss of resistance. Now coming over to facet joint again there is no endpoint. Soo we'll be able to use an X-ray or a CT scan and to see where you're going, and then you're able to do it without the endpoint because you can see what you're doing.

So, I believe that it has to be done. It's mandatory that it'd be done under vision, and that's based on the history, the study that was done years ago of 25% failure rate is appropriately placing the needle when done blindly in spite of an endpoint. So, I believe that the answer to that is a number five.

Dr. Deurden: Thank you Dr. Tracy, would you like to please address 10 about ultrasound guidance?

Dr. Tracy: So the question is: What is your confidence that there is sufficient clinical literature to support facet joint interventions (diagnostic or therapeutic) can be performed under ultrasound guidance?

So I gave that a one. In all the papers in your bibliography 1 through 20 they all used fluoroscopic guidance. Dr. Manchikanti in paper number 12 mentioned a study done on ultrasound guidance that was mostly geared at placement. Blind vs ultrasound or fluoroscopy vs. ultrasound.

There's no thoughtful commentary in any of these papers on ultrasound however, the paper that was referenced previously the consensus paper in the international group, they had two pages, thoughtful commentary on the use of ultrasound and I'll read you the summary. The disadvantage for using ultrasound for lumbar spine injections include limited visualization of the field. In other words, we can't see as many segments as we can with fluoroscopy, lengthy learning curve and potential for inadvertent vascular uptake, which can be reliably detected using real-time contrast injection or digital subtraction angiography. Furthermore, visualization is impaired by body habitus of the target.

I also spoke to Dr. Andrea Chestscott who edited a book on its peripheral nerve entrapment using ultrasound guidance for nerve injections published in 2016 by Springer, using ultrasound experts all over the world. Concluding that facet injections would not be favorably performed under ultrasound, because there's limited evidence in the literature.

I also spoke to fellowship trained interventionalists, Dr. Rashad Juioa is trained in ultrasound and he does his blocks fluoroscopy.

So that one gets a one for me.

Dr. Deurden: Thank you. Doctor Barnhill, would you like to address

Dr. Barnhill: What is your confidence based on the clinical literature to support the use of facet joint cyst rupture to provide facet mediated, pain relief. I found quite a bit of literature on this one. So, I gave it a score of four.

Here's my rationale, although various interventional strategies for facet joints cysts have been suggested, most techniques involved disruption of the cyst itself via access. It can either be trans facet joints or modified epidural, aspiration and or distention, and injection (saline, contrast, corticosteroid, local anesthetic, or any combination herein). Via image guidance, and this is from the work of Boody and Savage as well as Shang and others in 2014.

In 2018, Jansen, Ogink and Schwab they found the prevalence of facets to be 6.5%. Of those, 46% were incidental, and 54% were symptomatic. Facets cyst presence was associated with increasing age and symptomatic cysts were found to be larger and more anterior in the spinal canal and based on the work of Janssen in 2018. Facet joints cysts may be a marker of spinal

segmental instability and may be predictive of the need for surgical fusion in symptomatic patients' cases. MRI can assist with differentiating thick wall cysts with heterogeneous signal that appear to be more difficult to treat.

As an alternative to surgical intervention, a 2014 meta-analysis, to evaluate the success rate of percutaneous resolution of lumbar facet joints cysts reveal satisfactory results as high as 55.8% of cases. This was Shuang in 2014. In a more recent systemic review or systematic review, RJ Campbell Mobbs and Rao and Phan 2017, the rates of symptom resolution for percutaneous approaches, to be lower than 58%, compared to surgical intervention, which is 90%. Of course, this must be weighed against the relative risk reach therapy.

Some authors have reported superior results with CT guidance versus fluoroscopy and CT superiority after unsatisfactory results with fluoroscopy. This is work of, once again, Boody & Savage; Chazen, Leeman, Singh & Schweitzer in 2018. In 44 patients who underwent CT Guided synovial cyst rupture and the steroid injections. Haider 2017 reported technical success rate of 84% improvement in measures of their pain, function and analgesic medication use over a one-year follow-up. However, successful rupture did not present subsequent surgery. More recently Shah 2018 report at a high rate of relief with facets cyst aspiration and fenestration procedure, resulting in complete or partial symptom relief in 86% of patients study had N=64. During a mean follow-up period of 49 months, 56% of patients reported persistent satisfactory relief, and 44% underwent surgical treatment. These results are comparable to the findings of Huang in 2017, who reported on long term outcomes in patients who underwent CT or fluoroscopy guided facet cyst rupture. "Over a mean follow-up time of 44 months, 12% of patients underwent repeat rupture and 46% eventually underwent surgery, whereas a majority of patients, an estimated 55%, experienced symptomatic relief and did not undergo surgery." There are no studies directly comparing an imaging modality, but relative consistency in outcome reporting.

Prospective cohort study by Lutz in 35 subjects underwent percutaneous, fluoroscopy guided facet cyst disruption in the treatment of low back and radicular pain, secondary to cyst presence. Subjects reported clinically, and statistically improvements in pain. They used the NRS, current, best and worst scales to measure, as well as function with ODI. At a one-year follow-up, 87% of the subjects reported continued satisfaction with their initial procedure, however, 40% went on have surgical correction.

Although some authors have positive facets cyst interventions, reduced surgical need, factors related to long-term success have not been explored. A proposed grading system (by the Neuronal Spines Surgery Research Group Grading Score) may be predictive of response to surgical intervention versus cyst rupture. There remains a need for further study to better define patient's response to facet interventions as well as optimal procedure technique. Therefore, a review of current literature suggests facet joints cysts rupture is a safe and reasonable approach providing relief of pain associated with the cyst presence.

Dr. Deurden: Thank you. Dr. Barnhill. Dr. Cohen, you get the last question and get to in a three-minute period of time.

Dr. Cohen: So I would, I would just refer something that we had a table in, in an article to 2007 December Anesthesia.

The cover article it's on you know the ability of blocks to predict operative results. So, I mean I would say that there is. I have no confidence at all so it's less than one in this.

So, you know, basically, you know, if you fuse the spine, So, if you do any kind of fusion or arthrodesis you have less motion and less stress on the facet joint. That's work by _____ and when they've looked at studies, there's a bunch of them in that table that I cited the Jackson in 1992 _____ in 1993 and earlier one by__ .You know, fusion doesn't work for facet joint pain.

And, in fact, as you know, you end up getting adjacent segment disease after a fusion. So, the rationale for, for these implants is that, oh, yes, it actually works for facet joint pain or fix that facet joint pain, but it's just so painful. You can think minimally invasive. The problem with these, these things is you're not actually you know, rendering that segment motionless, and, you know, they fall out all the time. It's very hard to put them in. So, there's just no data to support it, so you have to go buy this these older studies from the 1990s and they do not support the fusion.

Dr. Duerden: Thank you, Dr. Cohen. I'm going to turn the time back over to Dr. Loveless and concluding remarks and or statements she needs to make.

Dr. Loveless: Thank you, everybody, for that tremendous education and covering this large amount of material in such a thorough, an educational way.

We do ask our panelists to also submit their feedback and writing, and I remind our jurisdictional CAC members to submit their comments to their local MAC in writing with their voting within the next two weeks. They will also need to complete their conflict of interest form. The audio and transcript will be posted to the MACs website in the next 3 to 4 weeks.

I know some need to drop off because we're over time, but I do want to give an opportunity.

if any of our CMDs have additional questions for our panelists, while they're on the line, I have reviewed the question and from our audience and those appear to have been answered throughout the process.

Are there any additional questions from our CMDs?

Dr. Tracy: Yes, yes, I would just like say oftentimes when developing policy, indications and limitations, how you word: use an, and, or, have implications and we're left here to interpret it. I would just like directors, to know, as we're all sitting here to take a very specific approach to the development of the language and how it's going to be interpreted. And maybe even use some of

us to do that, because you can see in this session, many of us didn't even understand the question, so it's really important.

Dr. Kennedy: This is Dr. Kennedy. I'll echo the same thing.

That the, the questions were challenging to interpret exactly what, what we're being asked, which I know seems like a fundamental thing, but when you have a panel of experts that clearly we're having this level of difficulty, you know, there needs to be some more clarity and thought in terms of specifics of the question, and I'm happy to help with that, if that's helpful.

Dr. Loveless: Yeah, thank you. That's good feedback for us.

And then, also, once a draft of the policy is made, that draft will be posted publicly, It will go to the jurisdictional open meetings, and there will be a response to comment time, at which point, you can also make sure, we address any worry confusion as well as working collaboratively in the development.

And we also will ask for our panelists to turn in their comments and to make sure to complete their voting. You asked that voting should be completed today, if possible.

Any other questions or comments from our CMDs?

Dr. Lurvey: Thank you for all the hard work that you've done to make this work.

My pleasure to be gone on the call with everyone.

Dr. Cohen: Thanks. Thanks for putting this together. Thanks for including me with an amazing group.

Dr. Loveless: Thank you each of you. I know you're all busy, and your time is valuable, so thank you for being part of this meeting, and we'll look forward to continuing to work with you as we move forward with the development of this policy.

Have a great evening.