Multijurisdictional Contractor Advisory Committee Meeting Transcript

Moderators: Robert Kettler, MD, WPS GHA CMD

Marc Duerden, MD, NGS CMD

April 27, 2023

01:00 PM CT (02:00 PM ET)

Dr. Robert Kettler: Good afternoon everybody, and welcome to the Multijurisdictional Contractor Advisory Committee, or CAC meeting on Trigger Point Injections. My name is Bob Kettler and I am a Contractor Medical Director with WPS.

The purpose of today's session is outlined in CMS IOM Publication 100-08, Chapter 13, section 13.2.4.3 and I'll give some of the highlights of our process in a little bit. But basically the purpose of today's meeting is to convene subject matter experts in the area of trigger point injections and hear those subject matter experts evaluate the medical evidence regarding various issues related to trigger point injections. This is a public session, and we have over 300 registrants for the public listening portion of this session.

Now, we don't know yet, but an LCD or Local Coverage Determination may be a result of this process. That depends in large part on what we hear today.

Before we go any further, though, I would like to do a few introductions. As I said, my name is Bob Kettler. I'm a Contractor Medical Director with WPS and I'm going to be one of the co-moderators of today's session. I'd like my fellow Co moderator, Dr. Duerden, to introduce himself. Marc?

Dr. Marc Duerden: Good afternoon, my name is Marc Duerden. I'm a physical medicine/rehab doc, and it's my pleasure to serve today with Dr. Kettler.

Dr. Kettler: Thank you Marc. And then I'm going to ask my colleague on the Pain Management Workgroup to introduce themselves, starting with the chair of the work group, Dr. Loveless.

Rich Staley: Dr. Loveless, you are on mute right now.

Dr. Meredith Loveless: Now, it's on, thank you.

I'm Dr. Meredith Loveless with CGS administrators. I'm also a Contract Medical Director, and I just wanted to take a moment to thank our panelists for taking time out of their busy schedules to serve on this panel today.

Dr. Kettler: Thank you Dr. Loveless. Dr. Sandler?

Dr. Neil Sandler: yes good afternoon. I'm Dr. Neil Sandler. I'm also a contractor medical director with CGS, and sit on the pain management workgroup. And I want to thank everybody. Interested to hear what everyone has to say about this procedure.

Dr. Kettler: Thank you Dr. Sandler. Dr. Schaening-Perez?

And I don't see his name in the list that I have in front of me. Maybe he will be joining us later. Dr Volkar?

Dr. Judith Volkar: Yes, I am Judy Volkar. I am a contract medical director for Palmetto GBA, and thank you for having all of you here today.

Dr. Kettler: Dr.Stroud?

Dr. Jason Stroud: I think it might be now, are you able to hear me?

Dr. Kettler: Yes.

Dr. Stroud: Okay, I'm Dr. Stroud. I'm one of the contractor medical directors with Palmetto, GBA, and I'd just like to echo my colleagues in thanking everyone for being here today.

Dr. Kettler: And Dr. Moynihan?

Dr. Eileen Moynihan: I'm trying to unmute, sorry. Hi, I'm Eileen. Moynihan. Thanks to everyone for being here. I'm a contractor medical director for Noridian and also a rheumatologist.

Dr. Kettler: Thank you Dr. Moynihan. Now I'm going to ask the Subject Matter Experts to introduce themselves. I'd like, you to please give your name, your affiliation and just briefly

state any conflict of interest that you might have. You have submitted conflict of interest forms to us, according to CMS policy, so you don't need to go into detail. Just anything that you think that our listeners should be aware of today. I'll start with Dr. Argyriou.

Dr. Antigone Argyriou: Hello, my name is Antigone Argyriou. Thank you very much for having me today. I am a physician. I'm board certified in physical medicine and rehabilitation as well as pain medicine. I'm currently in private practice in Long Island, New York. I'm doing interventional pain management in an orthopedic spine group. I am currently serving on the reimbursement and policy review committee for the American Academy of Physical Medicine and Rehabilitation, or AAPM&R. I'm also the alternate CPT advisor for PM&R to the American Medical Association. Also, the former president of the New York state Society of PM&R. I'm the current treasurer of the society, and I serve on its executive board. I have no conflicts of interest related to this topic.

Dr. Kettler: Thank you, Dr. Argyriou. Dr. Bautista?

Dr. Alexander Bautista: Hello, I am Alexander Bautista. I'm an associate professor at University of [inaudible]. I'm the program director for the pain fellowship and I am a practicing pain management anesthesiologist, and I do interventional pain. I do not have any conflict of interest. I serve as a committee member for several pain societies, including ASA ASRA, and NANS. And thank you for having me.

Dr. Kettler: Thank you Dr. Bautista. Dr. Bell?

Alice Bell: Hello, my name is Alice Bell. I am a physical therapist on staff with the American Physical Therapy Association as a senior specialist in health policy and payment, and I'm pleased to be joining the group Thank you. I have no, I'm sorry, no disclosures.

Dr. Kettler: Dr. Freeman?

Dr. Pamela Freeman: I'm Pam Freeman, I'm a practicing Rheumatologist in Orlando, Florida; past president of Florida Society of Rheumatology. No conflicts to report.

Dr. Kettler: Thank you. And, Dr. Northrup?

Dr. Benjamin Northrup: I'm Ben Northrup, from the Mallinckrodt Institute of Radiology in Missouri, a section of Musculoskeletal imaging and intervention, also a CAC rep for the state of Missouri and no conflicts.

Dr. Kettler: Thank you. Mr. Rigdon?

Scott Rigdon: My name is Scott Rigdon, I am a nurse anesthetist. I am board certified in anesthesiology and non-surgical pain management. I work with our fellowships training fellows. I sit on the AANA Pain Management Advisory Panel, and I have no conflicts.

Dr. Kettler: Thank you. And Dr. Yoon?

Dr. Edward Yoon: Hello, my name is Edward Yoon. I'm chief of interventional radiology here at Hospital for Special Surgery in New York. Dual boarded and fellowship trained in interventional pain management as well as musculoskeletal imaging. And I have nothing to disclose.

Dr. Kettler: Thank you. And just as an announcement to everyone, Laurel Short, who was going to be one of our Subject Matter Experts had an unexpected conflict. She is going to be providing us with some of her comments in writing, so, we will have the opportunity to evaluate her input.

Prior to this meeting, the pain management work group, uh, has done a review of the literature and prepared a list of articles for review by our Subject Matter Experts. Subject Matter Experts will be commenting on these articles and any additional evidence that they are aware of.

The Pain Management Work Group has also prepared a series of questions to ask of our panelists. These questions, the answers to these questions should be based on the literature and we want to make sure that any Medicare coverage would be in alignment with good clinical practice and that's really our purpose here today. If the literature is silent or inconclusive on a particular issue, we would appreciate our Subject Matter Experts noting that.

We would like the subject matter experts to be able to speak uninterrupted in response to the questions that Dr. Duerden and I will be asking of them. If any of my CMD colleagues would like to have clarification elaboration or some other type of follow up, would they please use the "raise hand" icon and be recognized by either Dr. Duerden or me prior to asking the question. Likewise, if our Subject Matter Experts wish to either amplify or take issue with one of their colleagues, we would likewise ask that they use the "raise hand" icon prior to speaking and this is just so that we can have an orderly discussion this afternoon. Mr. Staley will also be helping us with recognizing when there are "raise hand" icons in effect. I would ask that all speakers please mute themselves when not speaking, so that we minimize any feedback. And when it is time to speak, you can either unmute yourself using that icon or press *3, if you're calling in by

phone. And then, finally, in order to have a productive discussion, we do want to have an expectation of civility and we would ask that all speakers speak to the issue and not to a particular person or type of practice. And again that all speakers, await recognition by the moderator before speaking.

With that, I'm going to turn things over to Dr Duerden for the first series of questions.

Mark?

Dr. Duerden: Thank you very much, Dr. Kettler.

So, the first the first question deals with the definitions for this potential LCD that is being developed on trigger point therapies and we would like - I'll turn the time over to Mr. Rigdon and Dr. Bell for them to they're going to co-answer these questions. So, I'll turn the time over to you to start answering, and start with trigger point, please.

Scott Rigdon: Dr. Bell, do you have anything to go first?

Alice Bell: No, thank you. I'll defer to you at this point. Dr. Rigdon.

Scott Rigdon: Okay, perfect.

Looking through the series of definitions, if you engage literature or if you look at these as a standard definition of the terms, there was no specific outliers here. I did not see anything that did not follow with current understood nomenclature or the definition. I will say I had some concern whenever I see the word “nerve block” and we discuss directing or injection – I’m sorry, injected directly into or around, I would associate that with around, although there are numerous articles of injecting, for example, the sciatic nerve directly. That is not a practice that we would train anyone into specifically engaging in. And I would open that up to the group to discuss. But I just don't like the word into the nerve.

Alice Bell: And Dr. Rigdon, and I apologize, I am going to just address just one item and that is the definition of dry needling. And there's two issues here that I'd like to address: one is the use of the term “thin needle,” simply because needle diameter can vary, and it’s kind of a subjective term in terms of thin and so I would recommend either to use filiform or solid filament needles or to use a diametric range, rather than just the term thin. And then the only other thing would be looking at the insertion of the needle into skin and underlying tissue, rather than isolating to trigger point as the dry needling can be used for both the evaluation and management of neuromuscular skeletal conditions, pain and movement impairments. So, we might recommend a technique that involves the insertion of solid filament needles into skin an underlying tissue to disrupt pain sensory pathways and relax contracted fibers, or for the evaluation and management of neuromuscular skeletal conditions, pain, movement impairments and disability and I’m happy to submit those comments following the meeting.

Dr. Duerden: And Dr. Bell, you went exactly where I was going to ask you to go. In writing, So we appreciate that.

Mr. Rigdon, let me drop back to the first issue because trigger points have been defined since the 1990's, or perhaps even before. But how would you differentiate that from a tender point? And would you recommend that definition be codified in a potential policy?

Scott Rigdon: Well, if we're differentiating between tender and trigger, specifically, we would – if you have a – their hyper-algesic in an area, you go in, you do your physical exam, you run your hands over that tight or taut band of muscle; If you can define that band of muscle, it's a primary pain generator for the patient, I would be able to differentiate a bit between tender – Tender to me is something that physical therapy and other modality may engage in – I would not put it in the same class as a trigger point, clinically.

Dr. Duerden: Dr. Bell, do you have a position?

Alice Bell: I – so, I apologize – I want to go back and, you're speaking specifically, Dr. Rigdon, to the taut band?

Scott Rigdon: Yeah, I'm going on and off mute, I apologize.

Yes, I'm looking directly at the trigger point definition in the form –

Alice Bell: Yeah.

Scott Rigdon: Did I [inaudible] it properly? Sorry.

Alice Bell: Yeah, I would agree that – I'm Not sure – I would agree with Dr. Rigdon.

Dr. Duerden: An additional question for the experts on – in regards to trigger point; Would you expect to see documentation of a trigger point to indicating these specific clinical criteria and, Well, let me stop there: this specific criteria.

Scott Rigdon: Currently, yes, I would use this specific criteria. I think we get a little bit historically boxed in when we come up with our diagnostic criteria. So, since we've utilized this for this amount of time, often times, this is what we use to create the medical necessity to move

forward with procedures or decide that this is not the right diagnosis for the patient and move them in a different direction.

Dr. Duerden: Dr Bell

Alice Bell: And I think when we are looking specifically at trigger point injections, then identifying that hyper irritable trigger point or point in the muscle would be a criteria.

Dr. Duerden: Thank you. Do either of you or any of the other panelists have any other statements you would like to make regarding question number one, the definitions?

Hearing none, we'll go to –

Dr. Freeman: Excuse me, this is Pam Freeman. I had my hand up –

Dr. Duerden: Oh, Sorry.

Dr. Freeman: - but wasn't identified. There is a letter being submitted by the Coalition of State Rheumatology Organizations to Dr. Kettler today, in comment to these questions, and the Rheumatology community represented nationally by the CSRO would favor a change in the trigger point definition to say "myofascial pain and skeletal muscle usually accompanied by other hypertonic muscle groups that is associated with two of the following: taut band, and hyper irritable spot, and referred pain." So the question is whether we can change the definition a little bit.

The other comment I would make is that I have reference from 2011, from two well-known rheumatologists who are managing chronic pain, are felt to be national experts, and their feeling is there's variability even in mind trained observers calling something a tender point versus a trigger point. So it is important to understand that there isn't always agreement on – even among experts, which is tender point, which is a trigger point.

Dr. Duerden: And, Dr. Freeman, let me follow up with additional question, then, relating to that. So, is it your position and opinion that it should include – this definition should include – at least three criteria, such as hypersensitive muscle, taught band and referred pain?

Dr. Freeman: No. It should be hypertonic muscle group with a taut band and hyperirritable spot and referred pain, two out of those three.

Dr. Duerden: And you said that was going to be provided in written format? And do you –

Dr. Freeman: Yes, I have a copy of the letter. It's dated today and addressed to Dr Kettler. It was submitted electronically this afternoon.

Richard Staley: This is Richard Staley the administrative assistant. I just want to confirm that we have received that letter. We will share it with the pain management work group after the meeting.

Dr. Duerden: Thank you.

Dr. Bautista: Hello? Can I add something to that? Can we also put like there should be distinct, localized pain on top of the referred pain because sometimes there might not be a referred pain, but it should be distinct and discreet in nature.

Dr. Duerden: So, Dr. Bautista, you bring up a good point and that's why, I guess, we're trying to make sure that we codify this. It is defined differently than a tender point. Would you see that that definition that you're proposing would be, or could be construed as a tender point, as opposed to a trigger point?

Dr. Bautista: The thing is, again, as what the other Panelists have said, it's very difficult to define between tender point and trigger point because in myofascial pain, it can occur alone or in combination with other pain generators, so it is very difficult of nailing it down, really. Because fibromyalgia may have focal and tender points, but they're not necessarily trigger points.

Dr. Duerden: Okay. Any other panelists? I don't see any other hands.

We'll go ahead and move on to question number two. And Mr. Rigdon, if you could read the question out, because even though it's on the slide, we'd like to have it in the transcript and then go ahead with your answer, please

Scott Rigdon: Sure. Do you agree the clinical history and physical exam requires: a taut band, a hypersensitive spot and/or nodule, and referred pain to diagnose trigger points?

We kind of were just rolling through those similar comments. And I do agree with the previous comments – and I apologize – It was a rheumatologist, but I apologize – the name I didn't catch – but I do say, yes, I agree with that. That falls in line with what we've been discussing. There

are some terminology differences where we're saying: it's an exquisite hypertonic band, there's other tender versus trigger, but I would say if we're speaking directly about trigger point injections or physical exam for trigger points, I would say yes.

Dr. Duerden: Just so that I'm clear and have the rest of the panelists opine as well, there has been some literature that has talked about sensitive areas or tenderness as a way to describe a trigger point. Would your recommendation, as an expert opinion, be that the terminology be specific, or more generalized as we've heard is already in some discussion at this point?

Scott Rigdon: If I was looking directly at this, and we use the terminology a hypersensitive spot or nodule, that sort of – there's a range in that. Some patients will let you get a hand on them, give them some reasonable amount of pressure with range of motion to elicit these trigger points. Other individuals, they're very hypersensitive on the skin, so the amount of force you put will sometimes delineate the difference between that if you're talking about sensitivity versus very sensitive, for example or hypersensitive. But I think the hypersensitive spot or nodule does kind of globally encompass those pieces.

Dr. Duerden: Dr. Freeman, I see your hand up?

Dr. Freeman: As a rheumatologist, we deal with a lot of chronic pain. Many of our folks with fibromyalgia hurt all over and so they are going to be sensitive to touch. For us to want to do a trigger point injection, it has to be much out of proportion to the rest of their pain, because if it's the same as everywhere, you would be injecting them with a blanket of needles. So, for us to call it a trigger point, it really has to be much out of proportion to everywhere else.

Dr. Duerden: Dr. Freeman, you also brought up an interesting term when you were answering the question and that you said "it is a chronic condition" should the term acute and/or chronic be incorporated into the definition?

Dr. Freeman: I don't think so. I mean, our folks, let's say, with fibromyalgia can have acute exacerbations that in someone without fibromyalgia would be called myofascial pain syndrome or cervical strain, et cetera. So, I'm not sure acute versus chronic makes much difference here.

Dr. Duerden: So let me ask and then this way: isn't myofascial pain syndrome really a chronic pain disorder?

Dr. Freeman: It can't – Yes, but for instance, if someone comes in with acute cervical pain from a muscle area, that's hyper irritable, I would usually call it myofascial pain but if somebody else wants to call it cervical strain instead, I guess you could do that.

Dr. Duerden: Which leads me to the really the next question and that is how do we differentiate trigger points from a contusion or strain, or of that area, that muscle or soft tissue and would it be reasonable to determine that a trigger point injection would only be limited or given if it has gone beyond [inaudible] of a muscle or acute injury?

Dr. Freeman: I did not hear the whole question.

Dr. Duerden: Okay, sorry it was it was a compound question and I apologize. So, would – maybe the question really is for both you and Doc – Mr. Rigdon here to say how soon would you [inaudible] these conditions, trigger points themselves, manifest?

Dr. Freeman: How soon, meaning…?

Dr. Duerden: After onset.

Dr. Freeman: I mean, that manifest, you mean, present to us? I'm not sure what –

Dr. Duerden: Yes, I'm sorry, let me – I'll clarify: when a trigger point develops with or without trauma, or associated with other conditions – I think Mr. Rigdon pointed out that it could be associated with other conditions as well – how soon would you determine that that is a trigger point, and that it is – that specific condition has now developed, as opposed to an acute soft tissue injury and even more to the extreme, delayed onset muscle soreness?

Dr. Freeman: I don't think there is a time frame here. I think it depends partially on the severity. So if someone comes in that has severe pain such that they cannot function, whether it's been a day, two days or ten days, we have to act on it.

Dr. Argyriou: Can I interrupt, I'm sorry, I had my hand up for a while. I'm not sure –

Dr. Duerden: I apologize.

Dr. Argyriou: I just wanted to be sure. This is Antigone Argyriou.

I think the key here would be palpation. And so I think the problematic term for me is the word "spot." So I like the idea of what rheumatology is proposing, where you would have two out of three criteria; so, you would have the taut band and then a hypersensitive nodule. So, to kind of answer your question "how do you know it's not a tear or some sort of sprain, where it's not necessarily a trigger point?" and I think palpation is key. So, if you feel the band, if you feel a specific nodule, and then you have the referred pain, I think that would be more likely a trigger point that would respond to a trigger point injection.

So, when we're looking at patients with fibromyalgia, where they have tender spots, but may not necessarily have any of the bands or the nodules, that would be a way to differentiate between generalized, diffuse myofascial, pain versus pain from actual trigger points that would respond to injection.

So, in summary, I think physical exam would be the most important determinant and I will say, as I see a lot of chronic pain patients, I'm in a pain management clinic; you can have patients with diffused, widespread, chronic pain that then come in and have developed a trigger point, which may not have been there before or which, as you suggested; when does it develop? I'm not sure what the literature, sort of, states. By the time patients have come in to see us, it's unclear when the trigger point actually developed after the inciting injury. But in summary, I think it's important to know the difference between a spot or just a tender muscle that could be something else, versus a nodule or a band that's palpable, that would be an actual trigger point.

Dr. Duerden: Thank you, Antigone. Sorry, I didn't see your hand up.

Dr. Argyriou: That's okay. Thank you.

Dr. Duerden: Are there any other panelists that would like to opine on this question?

Alice Bell: This is Alice Belle. May I just kind of reinforce what I think has already been said, and I would recommend that it would be that the clinical history and physical exam requires a taut band, a hypersensitive nodule, with or without referred pain.

Dr. Kettler: Excuse me, Marc?

Dr. Duerden: Yes?

Dr. Kettler: I just have a question that I'd like some clarification on it. I forget – somebody used the term "hypertonic" in regard to the muscle. As an anesthesiologist, I tend to use hypertonic

related to intravenous fluids and I just wondered if I could get some clarification on the meaning of hypertonic with respect to a muscle.

Dr. Freeman: Hypertonic, we would usually use in Rheumatology, as on palpation and a muscle is tighter.

Dr. Kettler: Okay, Thank you.

Dr. Argyriou: I'd like to add to that. This is Antigone Argyriou. Sorry. So, yes, I would say that a hypertonic muscle is simply a muscle whose tone has increased and that would be – it could be the entire muscle. So there are patients who may come in and, for example, the entire trap easiest muscle could be hypertonic, but you may not be able to feel a specific localized taught band or nodule. So, again, important I think, to differentiate between just a general muscle that is very tight and has gone into spasm versus a specific nodule or a band that has developed due to a trigger point.

Dr. Duerden: Is there any other panelists that would like to opine?

Seeing none, I may move on to number three, which is Ms. Bell. If you could read the question and provide an answer.

Alice Bell: Certainly, Thank you. Is there evidence/society guidance to provide conservative care prior to proceeding with trigger point injections (conservative care includes analgesics, physical therapy, home exercise and other non-interventional modalities)?

I would offer that there is strong to moderate evidence, depending upon the condition or diagnosis, and sometimes the individual patient.

And so we have some interesting data. I'll speak first to some studies that were done in relation to knee osteoarthritis. And the fact that many studies, many interventions were studied and of all the treatments, only physical therapy, NSAIDS and Tramadol were strongly recommended by the American Academy of Orthopedic Surgeons clinical practice guidelines for non-surgical management of knee OA. There was a study in the New England Journal of Medicine, finding a significant difference in WOMAC scores after one year, and more positive patient perceptions of improvement with physical therapy versus glucocorticoid injections.

We – I will say that there's also information to indicate that with something like adhesive capsulitis, that it may be very beneficial to combine a trigger point injection with physical therapy to promote increased mobility and work on strength and active stretching exercises. I think, in the area of chronic, low back pain, and we'll talk about that a little bit more, there's some evidence to indicate that early physical therapy in both low back pain and neck pain can often result in positive outcomes and the avoidance of injections, opioids or surgical procedures. So I

think there is variable evidence. And again, I would say dependent upon the condition, the diagnosis, and/or the individual patient presentation, and course of care.

Dr. Duerden: So Dr. Bell, on that variability of presentation, what is your professional opinion regarding that specific need to require conservative care prior to the administration of trigger point injections?

Alice Bell: Yeah, it's a – I think If we look at the evidence, I think if you look at something, like knee OA, there is strong evidence to support some physical therapy before injection. I think for other conditions, the evidence is not as strong. And I would hesitate to have an absolute because if the patient, in fact, is in need of an injection before they can effectively respond to physical therapy, it would be inadvisable to start a course of therapy that cannot be effective without the injection. And I know this is not a definitive response to your question. But I do think that we have to look very closely at the evidence. And I think for certain conditions, therapy first is clearly indicated. And I think, for other conditions, co- actually, injection and therapy managed concurrently is indicated, and for others, the injection may be necessary in order for the patient to effectively engage in therapy. So I would say for neck pain, low back pain and knee OA, there's very strong evidence that therapy fist, early access, may result in good outcomes without injection, but that is not an absolute. There are subsections, subpopulations in those patient groups. So I think it requires some good examination, diagnosis and often collaboration between providers.

Dr. Duerden: Dr. Argyriou?

Dr. Argyriou: Yes, I agree. And I just want to add that early identification and injection of trigger point injections may actually facilitate the rehabilitation process. So we prefer to recommend multimodal treatments so it does not necessarily have to be either/or, as many patients may feel better with physical therapy. If there is an identifiable trigger point, injecting the trigger point may alleviate symptoms, improve range of motion and decrease restrictions that were there before allowing them to advance more in physical therapy.

And I would also like to mention that there is evidence that trigger point injections cause decreased blood supply locally, and that can also cause some secretion of inflammatory substances, and these can, in several studies, sort of lead to development of central sensitization and the development of chronic pain. And there's one particular paper, it's Dr. Sadien's paper, should be on the list – I can provide it if it's not – So they suggest that there is evidence that the duration of pain will influence the duration of relief with a trigger point injection. They looked at the effect of trigger point injections and lumbar radiculopathy, with an emphasis on timely trigger point injections early on. And when trigger point injections were employed early in the treatment, there was a better prognosis with lower pain scores and even a full recovery of a positive straight leg raise test. And so this was thought to be development of central sensitization and increase local circulation with the trigger point injection would also decrease the production of inflammatory substances like calcitonin gene related protein. And

then this would absolutely improve outcomes and in this particular study, completely relieve a straight leg raise test.

Dr. Duerden: I would first like to turn the time over to Dr. Kettler, who's raised his hand and then follow that up with Dr. Freeman who has a – who'd like to make a statement.

Dr. Kettler: Yes, just a quick question; to some extent, I guess that was spoken to, just recently, but are there ways to predict which patients are going to maybe need the trigger point injections in order to participate in physical therapy effectively? How do people go about determining that?

Dr. Duerden: Dr. Freeman, I'll let you make your comment and also add an answer to Dr. Kettler's questions.

Dr. Freeman: My concern is that we also have shared decision making and look at the patient experience here. If someone comes in and has acute neck, pain, low back pain, but doesn't have discreet particular area that we would identify as a trigger point. Certainly we're gonna want to start with physical therapy. But there are some people that come in that are acutely uncomfortable and remember that we can't get them into physical therapy necessarily in a day or two, they have to get prior authorization and find a facility that can work them in. Usually, the first appointment, they don't do very much with them, except assess. So, we're looking at a delay in getting relief from physical therapy, just because of the logistics. And so, therefore, we would not want to make something absolute to avoid trigger point injections first, if the patient and physician feel that they are necessary to start, as the other respondents, have said, to help them participate in physical therapy.

Dr. Duerden: Before we go to Dr Bell, let me just, uh, have a follow up question. Are there any societal guidelines which are endorsing this position of not having it as an absolute?

Dr. Freeman: Certainly, the American College of Rheumatology does not have a statement one way or the other.

Dr. Duerden: Dr. Bell?

Alice Bell: Thank you.

I would just add a couple of things. I do think the point is well made that a delay is highly problematic, which is why there's some significant evidence around early indirect access to physical therapy to avoid these delays. And prior-auth is not always a barrier, it sometimes is.

In terms of identifying the patients who may, or may not require a trigger point injection in order to effectively engage in physical therapy, physical therapist may often be identifying the trigger point and may identify the, the patient's inability to respond to the prescribed plan of care for therapy and the need for trigger point injection prior to advancing. So, may actually refer the patient or work collaboratively with their other providers.

I do think that there's a fair amount of evidence and I will – we will share that after the call, particularly related to a low back pain and neck pain where an interaction with physical therapy may be indicated. first. But I think an absolute to say, for every patient, with a trigger point, they have to have physical therapy before they can get an injection would be inappropriate and prevent certain patients from getting the care that they need.

The other thing that I would say is this and this is, as it relates to dry needling, is in terms of continuing to gather evidence around how necessary the injectant itself is versus the effectiveness of the needling itself. And so we're continuing to gather evidence and information around that, when dry kneeling is a part of a physical therapy plan of care.

Dr. Duerden: And to the panel, I will present to you that recently an article by the American Family, or American Academy of Family Physicians, or at least published in the American Family Physician Journal, 2023, indicated that myofascial trigger point injections or trigger point injections in general should be reserved for refractory myofascial pain as opposed to being a first line of treatment. What is your opinion on that? Because I've heard something to the contrary and I don't know if that's personal opinion, or if it's societal guideline.

Dr. Argyriou: I think it's interesting to – I think we needed to define what refractory means. Does that mean they underwent a full course of physical therapy and did not get better? And then, at that point, you can argue, well, maybe had they had the trigger point injection earlier on, it would not have been refractory. It sort of proves the point that maybe if you had intervened a little earlier, it would not have been refractory in the first place. So if you identify a pain source, and the patient agrees that they're willing to proceed with that treatment. I think delaying – I think not offering the patient something where there is evidence that would allow them, even if it's short term, to at least participate in aggressive physical therapy and prevent something from turning chronic, I think that's unethical.

Dr. Duerden: Is there anything in the literature to substantiate end or corroborate what you're saying? Because, I'm not seen anything, and maybe Dr Bell can jump in as well, that You know, ASTM, or soft tissue mobilization techniques, or osteopathic manual techniques, and their efficacy, is there anything to show that that mitigates the development of a chronic pain syndrome, and/or is it is reasonable to do that treatment, that conservative treatment, prior to the initiation of injections and is that based on societal guidelines? Go ahead, Dr. Argyriou

Dr. Argyriou: Yes, well, I think that's why we require more specific definition of what refractory means. So then, that – you would need to take into account the duration of the symptoms. So then, not sure of any specific studies regarding – there are no studies where there's no trigger point injection offered. So again, you can't create a study where there's no control group at all and you're not offering an intervention. So, you can't directly compare that. Say a patient that didn't receive a trigger point injection versus one that did, that developed – that patient ends up having chronic pain. However, when we're using the word “refractory,” that, to me, suggests it's going to be a chronic issue, because they've already completed conservative care did not respond.

Dr. Duerden: Let me just back up because a statement in the answer about the duration of symptoms and that was kind of getting back to my previous question: What is the duration of symptoms that is been documented, or placed in the medical literature to help the practitioner determine a reasonable treatment out – a regular treatment path?

[Inaudible]

Dr. Argyriou: Dr. Bell, you can go ahead.

Alice Bell: So I, I'm not sure I'm speaking specifically to that question, but I want to go back to the definition of refractory and I would also just interject that it would be unlikely that a patient would go through an entire course of therapy – failed therapy – without the physical therapist considering referral back to other care providers if the patient is not responding to the therapeutic intervention. So, I would say, at least it is the responsibility of the therapist to identify that if the patient is unable to engage meaningfully in the episode of physical therapy, because we are not getting a response – a positive response – associated with a trigger point, and the patient is persisting with pain and restrictions in movement and not responding to those conservative techniques; that would be the point at which a therapist should be referring that patient so that they receive an injection that may be indicated, rather than running an entire course of physical therapy and letting the condition worsen and progress over time.

Dr. Duerden: How would you define “entire course of therapy,” and I'll let Dr. Bell respond first and then Dr. Argyriou.

Alice Bell: So, I would define the entire course of therapy as the anticipated duration of therapy. So, when a physical therapist performs an evaluation, part of the requirement of developing the plan of care is to establish the anticipated intensity of therapy; the frequency and duration with which we are going to see that patient, that we believe is necessary to produce the

desired outcome and to meet the patient's stated goals. We are, at every visit, assessing the patient's response to our interventions based on that duration of therapy, and the anticipated outcomes or goals. So it would be expected that a therapist, at each visit, would be looking at the trajectory of the patient in response to the interventions toward achieving those goals. And one of the responsibilities of the physical therapist is to make appropriate referrals when the patient is not responding to the interventions as he anticipated. I hope that answers your question.

Dr. Duerden: Dr. Argyriou?

Dr. Argyriou: The only thing I wanted to add is that there are several studies that have compared patients that have received either a home exercise program, or a supervised physical therapy program alone, versus physical therapy or exercise with trigger point injections, and the patients that did receive trigger point injections in addition to physical therapy did have superior outcomes. And there are several studies that do show that. So I am in support of implementing trigger point injections earlier on to allow the patient to advance in rehabilitation.

Dr. Duerden: But we may be running short on time, but you brought up a statement that I'd like to have that defined; when you say – brought up the injections should be done early on. What is your - ?

Dr. Argyriou: What that means is I don't feel it should be either/or, conservative care shouldn't be either/or. So we don't necessarily have to wait several months, or after they have completely completed physical therapy with no relief, to offer a trigger point injection. As we've discussed before, if a patient is not progressing, they come to you for the follow up and they're still not doing well and physical therapy, they feel they're not advancing. I think, at that point, having the discussion and offering that trigger point injection for symptomatic relief to the patient is appropriate. Don't necessarily think there should be this restriction, where it should not be offered until a certain point in their treatment.

Dr. Duerden: So, is that an opinion or something that comes from the literature? And I'm not trying to challenge you I just want to have full disclosure.

Dr. Argyriou: Sorry, yeah, well, as I mentioned, that's why I mentioned that study where we're looking at physical therapy alone versus physical therapy with trigger point injections. Patients that had physical therapy with trigger point injections tend to have better outcomes.

Dr. Duerden: Okay. Thank you for that, and I'll need to pull up that [inaudible] I will do that.

In the interest of time, we'll go ahead, Dr. Argyriou. Dr. Bautista, you're going to be up so on question number four, please.

Dr. Argyriou: Yes, so what injectant should be used during trigger point – is this number four?

Dr. Duerden: Yes.

Dr. Argyriou: Okay. What injection should be used during trigger point injections? Is there any evidence to guide the type of injectant used and if a combination (such as local anesthetic alone or in combination with steroids) is more effective?

So I will say there is high variability in both clinical practice, and in the studies. I'm going to try to make this short and brief and sort of summarize what the literature provided showed. So, in summary, regardless of the injected use trigger point, injections, relieve symptoms and the treatment of chronic head, neck, shoulder, and back pain as well as whiplash injury. There was some evidence that local anesthetics are superior to sterile water, and that sterile water may be better than saline. There was one study suggesting that 5HT3-receptor antagonists may be superior to local anesthetics. Botulinum toxin is significantly more expensive and not more effective than saline or lidocaine in most of the studies. However, both lidocaine and botulinum toxin provided greater symptom relief versus dry needling alone. They did mention in several studies, however, that the use of local anesthetic can reduce the pain and the irritation associated with the needling or the actual procedure, making the injection more tolerable for the patient. There was also no evidence to, or no strong evidence to suggest that corticosteroids alone or used in addition to other agents, like local anesthetics, would improve outcomes. Specifically, a narrative review by Bautista et al., they examine the role of intramuscular corticosteroids and trigger point injections in four clinical trials. They demonstrated no benefit from the addition of corticosteroids. One paper did report improved outcomes but was limited in the overall study design. And there were several side effects associated with the use of corticosteroids that included hyperglycemia, weight gain, hypertension, bone mineralization, mood changes; so in conclusion, given the lack of added benefit and the potential for side effects, currently, there's no evidence to support the use of corticosteroids in trigger point injections over other agents. And I think, based on the medical literature, sterile water, sailine or local anesthetics are all readily available, effective, safe and low cost options for injecting trigger point injections, with, I believe, local anesthetics being the most supported overall.

Thank you.

Dr. Duerden: Dr. Bautista? You're on mute, Dr. Bautista

Dr. Bautista: Hello? Well, I think she summarized everything and cited one of our papers, so I agree to what she said. Currently there is really no data that supports the use of steroids for trigger point injection. And other drugs are more expensive when, true enough, like lidocaine,

which is cheap or even sterile water are already available to be used and still helps with relief in the trigger points.

Dr. Duerden: So, for the panel, if the literature is showing it, as Dr. Bautista pointed out in his article, that steroids are not effective, should the policy then articulate that since steroids have no benefit, they should not be co-administered?

Dr. Argyriou: I support that. This is Dr. Argyriou.

Dr. Duerden: Any of the other panelists have an opinion?

Dr. Bautista: Most of the steroid effect that the patient would feel is not due to the injection of a steroid to the trigger point area, but the systemic effect of the steroid, and giving steroids long term can cause more side effects than benefit.

Dr. Argyriou: So, I'll also like to add many of these patients have chronic pain, may require other corticosteroid injections, joint injections, nerve blocks, or any other procedures. So I try to limit the corticosteroids that I'm using and so when trigger point injections are used as adjunct treatments for other muscular skeletal complaints, I tend to avoid using corticosteroid in the trigger point, and reserving it for other conditions that would respond better to corticosteroid.

Dr. Duerden: I'll open it up to the rest of the panel for any final comments to make about this question.

Dr. Loveless: Hey, this is Meredith Loveless. I just was wondering: what do you think the mechanism is for saline or sterile water to work and how does it compare in that case to dry needling without any injectant?

Dr. Argyriou: I think the true mechanism is unclear to us. There are several theories. Now, any sort of needle into the skin will elicit an inflammatory response. And so, it is believed that cascade will sort of lead to healing of that area, increase local circulation, decrease any sort of these substances that cause inflammation and you sort of trigger this healing response, regardless of what you're injecting into the muscle. If someone has more specifics, I'm happy to allow you to elaborate.

Dr. Bautista: I think there is one mechanism regarding deactivation of a trigger point injection by direct stimulation of cutaneous A-Delta fiber and it was published – the mechanism was published in 2001, by Baldry. But again, nobody really knows why it – even dry needling, even without putting anything there, sometimes they get relief, but nobody knows why. But that is a proposed mechanism; deactivation of a trigger point area by stimulation of cutaneous A-Delta fibers.

Dr. Argyriou: I will also like to add, specifically, when dry needling, the goal is to elicit a twitch response. And then, typically, when you elicit a twitch response, the muscle is actively relaxing, and they tend to have better outcomes. So, sometimes just eliciting the twitch response and having this mechanical relaxation of the muscle will cause improvement of symptoms. Which could explain why dry needling could still be effective especially if twitch responses are elicited.

Dr. Duerden: And, Dr. Argyriou, you bring up a good point and that goes back to the first question again, which is definition. Should the twitch response be part of the definition for the trigger point injection? That it has to elicit the twitch response?

Dr. Argyriou: This is going to be opinion, because I don't know of any data or research on this. Sometimes it's difficult to elicit the twitch response and, very specifically, going back to that term "hypertonic." If the entire muscle is very hypertonic I find it difficult to elicit a twitch response. And then if I bring the patient – this again, this is truly experience, and I understand this should be evidence based – but this is just to answer your question; when you repeat it and the muscle is not as hypertonic and you're able to inject the trigger point we usually are able to then elicit an actual twitch response.

Dr. Bautista: Also, this can make more confusion; a lot of key trigger point and satellite trigger points too. So that is like, when you try to press in a particular muscle and induce this activation of other trigger point areas.

Dr. Argyriou: And I think currently, in the literature we have not compared any injections with twitch responses versus no twitch responses. We have evidence here that even regular trigger point injections, all the studies that we examined today, there was no mention of twitch responses and there was still a positive effect. So I agree, including that in the criteria, I don't think is necessary because here's still some dramatic improvement of pain and in function. I don't think it's necessary to be in the actual criteria.

Dr. Bautista: And also, most of the time, it just boils down to subjective experience of the physician.

Scott Rigdon: I would also agree with these statements. I would also say that when you evaluate these trigger points with ultrasound, you will sometimes find hyper-echoic bands of muscle. I haven't noticed a qualitative difference in the jump sign or the twitching that we see when we inject them and similar patients, and the same patients, at different encounters will sometimes have a jump that sometimes not have a jump or a twitch. So I wouldn't say that it would, from a clinical standpoint, be a form of diagnostic criteria.

Dr. Duerden: Thank you Dr. Rigdon. Does anyone else on the panel have an opinion?

Seeing none, we're going to move on to question number five. Dr. Argyriou, you're back on, if you could read number five and provide the literature.

Dr. Argyriou: Sure. What is the expected duration of relief from trigger point injections? Does it vary with the agent used or the underlying disease process?

This is kind of a loaded question. Again, I'm going to try to stick to the data and the literature. So, the duration of relief from trigger point injections can vary and that obviously depends on several factors we just discussed; the specific condition being treated, the severity and the duration of the pain, and then individual patient factors. But overall, the body of literature suggests that there is relief of pain from trigger point injections which can last anywhere between one week post injection, to as long as eight months, after injection, depending on the study design, and the study that you're looking at.

And so, the duration of effect, this is sort of a tricky question, because it's limited by each study's follow up protocol. So, most of the studies are not examining the duration of effect past three months. Most of the studies are three months or less. So, it's difficult to say what is the expected duration of relief based on the evidence. I say at least three months, because most patients are evaluated up until that point. Again, it would depend. And then studies with observational findings suggest that trigger point injections can provide relief of myofascial pain from one month to four months. So, overall, that may not be the duration of relief, that just is that that's what we're examining. We're examining them and around this period with no further follow up. So it's very difficult to make any conclusion about that. The longest follow up period in a systematic review of 15 peer reviewed, randomized, controlled trials, this is from Scott [inaudible], Was eight months. And of those 15 studies, only three were evaluating patients longer than three months. So, again, we only have that time frame in terms of the data. Most of the studies had small sample sizes and high interest study heterogeneity. So it precludes a definitive summary of the data specifically with duration.

So, I have a couple of other studies here. One follow-up with one week with no further follow up thereafter. The longest, again, was eight months that's Burn, et al. Another follow up, sorry, another study Curup [inaudible] et al., it was six months and that was evaluating pain and intensity immediately after trigger point versus laser treatment for neck pain and that was at six months and there was no difference in degree of improvement between the two treatments. But again, no analysis of the actual duration of relief.

So, it's unclear how long the effects last in the patients who do have a positive response; weeks or months after an injection, because that's where the studies are ending.

That's all.

Dr. Duerden: Excellent.

Dr. Argyriou: -For the first part; I'm going to go into the agent, but I'm going to give everyone a chance to comment before I answer the next part.

Dr. Duerden: Okay. I'll open it up to the panel for comment/opinion.

Dr. Argyriou, there's no one else's [inaudible] opinion, so go ahead.

Dr. Argyriou: Sure, so, regarding any variance and duration of relief with specific agents; so, again, there's a lot of variability in the studies. There are no studies specifically comparing the duration of relief between specific agents. The literature suggests that some agents may be more effective during a particular set, follow up period, but its – they're not examining whether one agent will produce a longer duration of effect compared to another. So they're usually comparing the degree of effect, not the duration of effect. So I don't feel we can adequately come to a conclusion based on the literature regarding duration of relief.

And then the last part; there were three parts of the question in the original agenda. I apologize. The last one is any variance and duration of relief with different underlying disease processes. And then similarly, no, there's no evidence with specific underlying disease processes.

Dr. Duerden: So, for the panel, let me ask then, another question. Things need to be reasonable, medically reasonable and necessary. And as Dr. Bell pointed out, one of the criteria, or some of the criteria that they do – particularly in physical therapy – is that you determine the frequency, the duration, intensity of the services. Should there be some codified criteria for the expected duration of relief from a trigger point injection?

Dr. Argyriou: There was a follow up question, which was number nine on the original agenda, that was also addressed to me. So I touched upon this. If I may, I can sort of answer that.

Dr. Duerden: Certainly. Go ahead.

Dr. Argyriou: And so the question was specifically for what duration should trigger point injections be utilized. So, based on the evidence, what should be done. and then the second part of that question was what evidence or societal guidance supports this and so, after examining all the research and the literature, trigger point injections should be utilized

throughout the course of a patient's active rehabilitation program. And so, the duration of use in the literature once again, dependent on the follow up intervals of each study and that vary from days to months.

So, I don't think we can rely so much on these studies to dictate the duration of treatments – oh, sorry – the duration of relief, because we're not comparing the duration six weeks versus three months versus six months versus one year. There's no data to my knowledge that assesses that. However, most studies evaluated improvement at the three-month mark. And that's where our data is.

So, I think it's fair to use the three-month mark as sort of our baseline, because that's where most of the studies are evaluating the response to treatment and that's also similar, like, after several weeks of physical therapy, and a follow up with a physician that usually falls within the three month timeframe. So, if I'm going to define an active rehabilitation program, I would say that would be up to three months.

And so, in addition, the duration should depend on the patient's response to the treatment. So we should be including the patient in this. If they're receiving symptomatic relief and they're getting better, to deny them this is just, again, it's unethical. So, if they're responding very well and they're continuing to be active in a rehabilitation course, I think that's typically what influences the societal guidance in clinical practice.

I do have here some practice guidelines, put forth for chronic pain management by the American Society of Anesthesiologists. They recommended using trigger point injections for myofascial pain as part of a multi-modal treatment strategy, but do not provide recommendations for what duration they should be used, suggesting the treatment should be predicated upon response with an I quote, “periodic follow up evaluations” end quote, once again, no specific time frame. So, in summary, I believe since most of the data is three months, and that's typically when a patient would be actively involved in a rehabilitation program, I think three months is fair for assessment.

Dr. Duerden: Okay, so, let me just make sure that I'm understanding this correctly and articulating if there's a nuance between question number five here, which is the expected duration of a trigger point injection, in that context I would say – that single injection – I think the question, the next question that you were also going toward was the duration of treatments and how many injections should be given in a duration. So not necessarily a single injection, but during a course of treatment of injections, what is reasonable?

So, I'm going to I'm going to pull that second question back again, just to allow you to present that when it comes up again, but for the single injectant, that is provided, a single procedure that is provided, it sounds like the current literature is endorsing about a three month period of efficacy from the injection itself. Correct?

Dr. Argyriou: That's correct. And I'd like to say, depending on the study design, some patients receive multiple trigger point injections, more frequently. And so there's so much variability and how many trigger point injections were used and how often it was done. So, I think it's very

difficult to establish clinical guidelines based on those studies, unless someone else has information that may address that.

Dr. Duerden: And I will open that up to the panel; if they're aware of any other literature that addresses that issue.

Dr. Bautista: I don't think there's any societal guidelines regarding the frequency that you need to do trigger point injections, and agree with whatever Dr. Argyriou had said a while ago.

Dr. Duerden: Thank you Dr. Bautista. Seeing no other respondents for this question number five, I'm going to turn the time over to Dr. Kettler for the presentation of the next series of questions.

Dr. Kettler: Thank you Marc. And this next set of questions is going to be for Dr. Freeman. And the first is: what assessment should be done before and after trigger point injections? Dr. Freeman.

Dr. Freeman: Again, this is from the Rheumatology standpoint. I don't see a lot of literature help in this regard, but we consider from the Rheumatology standpoint that we have a pain score. We would also have a functional assessment, such as their activities of daily living and ability to sleep, et cetera. Because that would help us understand whether they are impaired enough that an injection would be worthwhile. And then afterward there would be a question as to did they get immediate relief. And then, did they get sustained decrease in pain and improvement in function.

Dr. Kettler: Now does this change if, for instance, you're just doing maybe a short-term treatment for an acute problem; something that might be just a matter of a few weeks versus patients who have a long standing myofascial type of syndrome? Does your assessment and approach to those patients differ?

Dr. Freeman: Again, if it's a chronic problem, and we are thinking about an acute intervention, such as a trigger point, we have to have a change in pain and decrease in function compared to their baseline.

Dr. Kettler: Okay, thank you. Do any of the panel have any comments on the question?

Dr. Bautista: I think your question will follow the question for me. Like, what do you think is a meaningful pain relief after a trigger point injection? And truthfully, if you look at all the studies, so, a two-point decrease from the baseline pain score is considered significant. How significant is it clinically, it's really very, very hard to tell. So you have to use some target markers as to whether patient have improvement of sleep, patient had increased functionality or improve their ADLs as a recorded metric to evaluate efficacy of the procedure. And also, be mindful that placebo response is between 20% to 40%, which is very, very close to 50%.

Dr. Freeman: I agree. Part of this is just in does the patient feel that the improvement is significant enough that they are satisfied with the effect of treatment.

Dr. Bautista: So I think it should boil down to what is the documentation tells us.

Dr. Freeman: So again, if their function improves, quality of life, ability to sleep and function with their families or at work, then we would feel that that is successful.

Dr. Bautista: True like currently right now, I don't really rely much on fast scores, because pain scores is very subjective in itself. There's no objective way of knowing. So, my perception of eight out of ten may be different from anybody else in this panel or in this call.

Dr. Freeman: Yes -

Dr. Kettler: Dr. Bell – I'm Sorry.

Dr. Freeman: Yes, I agree. I mean, as I tell patients, I care about their pain, but I care more about their function.

Dr. Kettler: Dr. Bell has her hand up. Dr. Bell?

Alice Bell: Thank you. And speaking more broadly not specifically to only the injection, but to patients who may present with conditions requiring injection. Similar to what's been said, we would look more at pain interference measures than pain scores. So, understanding the patient's ability to engage in whatever they need or choose to do versus simply a numeric scale. And additionally, looking at movement, mobility, quality of movement, as well as sustainability of pain control while re-engaging in levels of activity that they may have been restricted from as a result of the pain associated with the trigger point.

Dr. Kettler: You know, you sort of spoke to something that that I often felt when I was in pain management, and it's been a long time. I seem to remember that, for instance, the visual analog scale, while it was a useful research instrument, wasn't particularly effective on clinical grounds. And I tended to have the patients set goals and then looked at whether they were progressing to those goals or not. Do you think that we should be using a visual analog scale at all in clinical practice?

Alice Bell: I can only speak to the practice of physical therapy, and I can tell you that we have moved largely away from visual analog scales, in most cases, to more standardized objective pain interference measures, because it just informs us more around what – where - pain is pain, right? And an individual's perception of pain is their perception of pain, and that pain is a reality. But very much – what's much more important to us, and where we're kind of measuring effectiveness and efficacy, is what is the impact of that pain on an individual's life? And when we see individuals being able to resume important and necessary activities while managing pain, it may not mean that we zero pain out. But the level of interference of that pain is less. That is often, much more meaningful information. And I think too, there's been some speculation that a focus on a visual analog scale can sometimes actually reinforce some pain catastrophizing and kind of limit an individual's perception of their level of improvement, when all they're thinking about is that number.

Dr. Kettler: Dr. Argyriou?

Dr. Argyriou: I agree, and I would also like to add that some patients the VAS portrait for several reasons is problematic, but I think it's quick and an easy baseline. Rather than telling them “what is your pain right now?” Sometimes, if you tell them - what I tell them – you had an injection and this was your pain score before the injection, what would you rate your pain score now? So sometimes when they realize that we're trying to compare their pain before to their pain right now, you get a more realistic number. And then some patients also feel giving you a higher number, will give them greater attention or that you will you'll treat them more aggressively because your number is so high. And so, for those reasons, I think the patient's not able to provide a comparison. The VAS is not a comparison. However, if you ask the patient “what percent better are you compared to before the injection?” They're able to give you, I think, a more accurate number and so if we're using percents, you can also use the VAS. Before the injection, you rated your pain and eight out of ten. What is it today? Oh, well, okay. It's a three out of ten, or something. So sometimes, giving them that context can make the information from the VAS score a little bit more valuable despite it's problematic.

Dr. Kettler: Thank you. Any other panelists on the issue of assessment?

Dr. Freeman a related question; I don't see it up on the screen now, but it was, I think, in the original packet with this, is the issue of fear avoidance behaviors and also pain catastrophizing.

Somebody's mentioned pain catastrophizing, but do you have any thoughts on how those two issues impact the assessment of pain and pain relief?

Dr. Freeman: Well, I think that certain people have an un – as one of my patients daughter once said, she said her mother was allergic to pain. So I do feel that different people have different ways to assess it. And I think you do have to look at the total patient, and what they're underlying baseline is in that regard, but I'm not sure that that should be part of a guideline to say whether they could get a trigger point injection or not. Because I think it makes things too complicated for documentation. Certainly any good physician would take a look at the baseline personality and characteristics of the person that you're seeing and decide whether an intervention would be worthwhile or not.

Dr. Kettler: Marc? You have your hand up.

Dr. Duerden: My question is to the panel. After a trigger point injection is performed, and it is presumed that the trigger point was the pain generator, wouldn't it be both diagnostically and therapeutically accurate to say that the pain should have been mitigated to define that that was indeed the pain generator?

Dr. Freeman: Agreed.

Dr.Bautista: Agreed

Dr. Argyriou: Agreed.

Dr. Freeman: But again, the overall pain score may not have been too much different, if they already had a high degree of pain anyways, if they were a chronic pain patient. But their degree of pain in the area of interest for the intervention should have been significantly improved.

Dr. Kettler: Any other comments on assessments, or pain avoidance behavior, or catastrophizing?

Dr. Bautista: So, during those assessments, the patient can barely fill out their actual intake form on a regular basis. And having them fill out those questionnaires would, number one, put a lot of time for them to answer. Second of all, the understanding of the questionnaires may be a concern. Sometimes they don't know what they're really answering. And it's a good thing for

research purposes, but for clinical purposes, and for documentation purposes for clinician, I think it would be very, very taxing just for a trigger point injection to be approved or not.

Dr. Argyriou: I also want to say that most patients do not present with these issues, especially in a new injury, or a new set of pain so if we're looking at trigger point injection, I don't think underlying catastrophizing should be something that would otherwise prevent treatment for patients. This is a small subset of patients. I think we're looking at two different things. We're looking at myofascial pain and now you're bringing up, sort of these patients in a chronic pain state. That may have central sensitization and the other psychosocial issues. And so you're sort of complicating an issue. I think it's irrelevant. It may be relevant to that specific population to say, hey, trigger point injections may not be the best option for you because of these other conflicting psycho-social factors that we've identified in the way that you're processing pain. But I think this discussion is different than patients who are presenting with musculoskeletal pain due to a trigger point.

Dr. Kettler: Any other comments?

Dr. Freeman: I agree and part of the thing here is you don't want to deny access to somebody for a procedure they need just because they have underlying problems with chronic pain and psychosocial problems.

Dr. Argyriou: You could still have a trigger point and struggle with pain catastrophizing, so –

Dr. Freeman: Right, right. I call it fibromyalgia plus.

Dr. Argyriou: Or acute fibromyalgia.

Dr. Freeman: Exactly. Exactly.

Dr. Argyriou: You can still get them through it and get them to improve.

Dr. Freeman: Absolutely.

Dr. Kettler: Okay. The next question number seven, Dr. Bautista, you've to some extent already spoken to this. Do you have anything to add?

Dr. Bautista: No. Most of the studies have shown, like, 50% improvement or decreased with their pain score two standard deviation from the original one. So, I and anything in pain right now is 50/50 for the most part, except for some interventions like facet that they are wanting 80%, but I think 50% relief would be adequate.

Dr. Argyriou: I agree.

Dr. Kettler: Then, is there specific evidence or societal guidelines that support this principle?

Dr. Bautista: There's none I can think of, or I've read. But most of the studies that were done for a trigger point injection, they look at 50% improvement.

Dr. Kettler: Other comments?

Okay. The next question is for doctors Yoon and Northrup. This would be Question number eight, and it has to do with; is there any evidence for or guidance on repeating the injection in the same area? And then if there is, how frequently should those injections be performed?

Dr. Northrup: This is Ben Northrup, I'll take this one. So first, thank you to Dr. Bautista and Dr Argyriou for articulating the answer to this in their duration question. I believe that was kind of mentioned in that secondary discussion there. So, yes, I agree with them. Much like with their societies, with our societies in radiology there is no specific guidance as to how often, or how soon these should be – how frequently or how soon – they should be repeated. Reviewing the literature that was sent, and a few other papers as well, it is really quite dependent on the study design, how frequent these are done. I've seen everything in the studies from several days, four days plus, several weeks up to a month, and then as Dr. Argyriou pointed out previously, most of the studies have a final end point around three months. So, yeah, quite a bit of variability and mainly due to study design.

One other thing that was mentioned in there, and this is one I'm personally less familiar with; we do not in my practice do these PRP injections. But one study did note that PRP injections should be repeated in the masseter muscles until a sufficient therapeutic effect is achieved. So, that didn't give an exact number, but it gave more of true guidance than some of the others did.

Dr. Kettler: Dr. Yoon, do you have anything to add?

Dr. Yoon: No.

Dr. Kettler: Okay, any comments from the rest of the panel?

Hearing none, I'm going to turn things back to Dr. Duerden. Marc?

Dr. Duerden: Thank you very much, Dr. Kettler. So this next question is again for Dr. Yoon and Dr. Northrup, if you could read the question, and then provide your answer in your opinion.

Dr. Yoon: Can we – Yeah, so I'll take this one.

Is there a limit to how many trigger point injections can be performed during the same session? What evidence or societal guidance supports this?

And again, just like the previous question, there isn't a whole lot of societal guidance in terms of how many trigger point injections can be performed within the same session. And upon me kind of looking into if there are any additional papers that specifically looked at how many trigger point injections should you do in a specific muscle? Or if there are two different body parts that we're treating, is there specific guidelines as to okay is one better than two, or two versus the three? And I didn't find any studies regarding that either.

Dr. Duerden: Dr. Northrup?

Dr. Northrup: I agree with Dr. Yoon. No further comments.

Dr. Duerden: Okay, and I'll open it up to the panel. Is there any other opinions and or discussion.

Seeing none, we'll go ahead and move to question number ten. And Dr. Argyriou, you're up, please. Number 10.

Dr. Argyriou: I think we sort of already touched upon this. We kind of briefly tried to answer this. So, for what duration should trigger point injections be utilized? and what evidence or societal guidance supports this?

And so, once again, I – they should be used throughout the course of a patient's rehabilitative course as long as they are actively engaged in rehabilitation, and as long as they are responding to the treatment. In terms of evidence; the studies are so variable, so they heterogeneity in terms of how often the injections were offered and how often the follow – how frequently they were followed up – all varied I think in terms of societal guidance, I didn't find anything published in any societal guidelines where there was a specific time frame. I mentioned earlier the American Society of Anesthesiologists, they recommended periodic follow

up evaluations, but no specific timeframe. So, I think this is based on clinical judgment. Most of what I do, and my peers, usually the injections are performed about four weeks apar, because that's typically when you would see a patient for follow up and it's usually like we mentioned before, the time frame would be three months. So, as long as they're responding, and you see them at follow up, and there's been a certain amount of improvement, as someone mentioned, usually 50% or better, and they report improvement in function, it's fair to say you would repeat and offer that injection to them once again.

So, In terms of clinical practice, usually a series of three as needed, About four weeks apart and then re-evaluate at that three month mark. But again, this should be a clinical judgment based on the patient's response, and any objective findings that we have to know that there is an improvement. I think if there is an improvement, and we're denying patients access to something that is so safe and low cost I think it's very unethical. So, if the evidence is there that even if their short-term improvement allow them to proceed with rehabilitation, I have this issue with restricting what we can offer patients because the guidelines don't – the guidelines, excuse me – the medical literature does not support any caps. And so placing these restrictions, which I see often times with certain insurance companies; I want to treat the patient, the patient wants to be treated, and then you have these guidelines from the insurance company, which are not based on medical evidence. So, at this point, we're trying to see how frequently is appropriate. But I also feel that everybody is different and based on clinical judgment, we should have the freedom to have this discussion with the patient and sort of, as physicians, tailor the physical the- the rehabilitative course – and offer something that can be safe and effective for them.

Dr. Duerden: So building on your answer, you articulated that there's limited evidence for the long duration of treat – for a duration of treatment. So, in a superlative, should you continue this for years?

Dr. Argyriou: That's a great question. And for patients with chronic pain, I guess that's controversial. Now, some patients may have a specific trigger point in one part of the body, and at follow up, they continue to have pain, but that initial trigger point has resolved or improved. And so, at that point, this will bring up another discussion which is: body parts. So are you injecting the same trigger point? What if there's a new trigger point? So we're opening up an entire new discussion here. So sometimes, it's not that you're repeating the same trigger point, they may have developed another trigger point. So that's difficult to answer because again, when we're looking at duration and we're looking at studies, there's often a time limit. When the study ends, the evaluation ends. So we don't know at one year, do these patients continue to have relief? Somebody might be able to tell you that based on their clinical practice, but the evidence doesn't answer that because most studies end at three months. So it's hard for me to answer that based on the literature.

Dr. Duerden: Okay. And one of the other components in your answer was that there had to be – and it has been alluded to in the other answers by others – that there has to be a functional improvement. And while it's – there may be some value in subjectively determining functional

improvement, is there any evidence to show that we should be, and clinicians be, looking at objective and functional improvement?

Dr. Argyriou: That's a great question. I'm a physiatrist; we love function. So typically you can ask patients if they're working. If – I like to ask them at work, if they're able to sit longer, stand longer, do better at work, if they need less breaks. Or in patients who don't work can they do activities of daily living with more ease; "Oh, I was able to wash my car, which is something I couldn't do before." So bringing up specific examples of day-to-day activities that couldn't be done before, and now they can be done. Sleep is also really important. I always ask patients about their quality of sleep. And we know adequate sleep can overall improve pain tolerance anyway, so all these lifestyle factors are something that we should be asking patients about.

Dr. Duerden: Dr. Kettler?

Dr. Kettler: Yes, this is Bob Kettler and I've been asked to remind everybody that when you begin speaking, briefly identify yourself. For instance, "this is Dr. Kettler" and then proceed on with your answer. That's for purposes of both the transcript and the recording that we have to post. That's all, thank you Marc.

Dr. Duerden: Thank you. So, we have unique members on our panel, such as Dr. Bell and Dr. Northrup, Dr. Yoon as well. Mr. Rigdon, you've – I'd be interested because of your unique backgrounds, if you have an opinion regarding this question; number ten.

Scott Rigdon: This is Scott Rigdon. If we're speaking specifically to providing this as a sole procedure or in conjunction, we oftentimes provide incidental, is what we discussed, it's not a billable service unless we're using separate imaging modality. Trigger point injections, for example, a cervical RFA for performing an ablation on a cervical facet joint, there's oftentimes associated trigger point injections in the splenius capitis, and semispinalis capitis, proximal trapezius, those areas. And we will provide these incidentally to calm down the zone after we've worked through medial branch blocks and other testing procedures to get to the final procedure. And this does help significantly when performed versus not performed in the right particular patients. There's an index of clinical suspicion that you have to implement. So, I would say that it is performed in conjunction with other procedures, and I don't think it needs to be an isolated procedure in certain patients. But I would say in general, we do use them in isolated instances to address trigger points.

Dr. Duerden: So, Mr. Rigdon, you're a step ahead of me. And so that's okay. But I want you to opine when we get to number 11 on that specific issue because I have a [inaudible], but staying with question number ten at this point, Dr. Yoon, Dr. Northrup, any of the other panel members, any of the other CMDs want to render an opinion?

Dr. Yoon: Yeah, I think I – my practice kind of, obviously there's – we've talked to extensively regarding – in regards to the level of evidence there is and the studies duration and all that. And I kind of, because I work very closely with the physiatrists here at my institution, I kind of go towards the same kind of logic that Dr. Argyriou was using; in terms of as long as the patient requires it, and it's helping with their physical therapy, we continue to utilize this so that they're able to kind of get up and moving; which is what is kind of the ultimate goal. Cause I perform a fair amount of kyphoplasty and patients get kind of paraspinal pain, even after the acute pain phase is over. And I routinely utilize it and at least when it comes to material compression fractures, it seems that it's more of an acute stage thing. So they don't require as, long of a duration in terms of treatment. But when it comes to chronic myofacial pain, I assume that it's more of a prolonged process, rather than an acute disease. So, that's kind of my take on it.

Dr. Northrup: This is Ben Northrup. Yes, my experience with it is quite similar to Dr. Yoon's with one addition. Here at our institution, we do perform – me personally, and several others in our section – perform quite a few vertebral augmentation procedures. After which, this is sometimes used as adjunct therapy to help patients with myofascial pain afterwards in that setting. Also, our neurosurgeons find this is a common issue after instrumented posterior spinal fusion, and they ask us to perform these after those. So those are two common times that we would perform it. In that case, it's often just a one-time deal. So, duration does not become as much an issue for that indication. Nor does it for the other indication for which we are commonly asked, which is patients with cancer pain. Certainly, if the cancer pain itself is due to metastatic disease to the bone or the tumor compressing a nerve, this therapy would be ineffective. But if those – on top of that – might have some other myofascial pain, sometimes we'll treat that as well. Again, with cancer patients, duration doesn't become as much of an issue but those are the, those are the common indications that we deal with.

Dr. Argyriou: This is Dr. Argyriou again. I'm also going to say that my – I think what we experience at clinical practice is often dictated by insurance guidelines. So, while we may have different results with increased number of injections, that's something that's not an option based on insurance restrictions and guidelines. So sometimes it's hard to know if I did perform injections more frequently, would there be a different response? So, even in clinical practice, it's very difficult because we're often abiding by the guidelines of the insurance companies.

Dr. Freeman: This is Pam Freeman. I have a question about duration: for instance, I have someone who has chronic pain, but also cervical degenerative changes and does have myofascial pain to go along with that. And she comes in maybe every six to 12 months for a trigger point injection. So when you're talking about duration, are we talking about duration for an episode of, let's say several months? Or are we talking about duration in general during their lifetime for these injections?

Dr. Duerden: The latter.

Dr. Freeman: So I would say that for somebody that's doing, let's say, home physical therapy and whatever medication they should - they can do, if they are needing infrequent trigger point injections, we shouldn't deny them access to those services.

Dr. Duerden: And I think – correct me if I'm wrong, Dr. Freeman, but does that kind of go with Dr. Argyriou's point of saying that, during the rehabilitative course, the injections are beneficial, maybe not – and I'm speculating now that – and then maybe not after that end of the rehabilitative course or am I just misreading it; the opinions that have been rendered?

Dr. Freeman: I think that she can speak for herself, but some of these people are going to have lifetime problems so that they may periodically have a flare. And, in my opinion, that is a new episode if these are widespread.

Dr. Duerden: Dr. Argyriou, we've got you on the spot.

Dr. Argyriou: Yeah, no, no, no, I absolutely agree. What I want to clarify, they should absolutely be offered during an active rehabilitation course, and then there should be revaluation. So, if somebody goes to physical therapy and at some point, they do better with trigger point injections and then they complete the physical therapy course, and then they return. At that point is where you have that discussion with the patient. If they are helpful, you can continue that. Sometimes the patients don't want the trigger point injections. And at that point, they want to discuss other interventions maybe spine injections, maybe other treatment options.

And so, I think, to clarify, this is something that you should discuss with the patient. And so, like, I mentioned before, I think clinical judgment is important here. So, while there's an active rehabilitative process going on, there should not be a cap to these injections. I think we should offer it to the patients. I think it's unethical not to, based on the fact that we know it's effective and can improve function and pain, and that they're safe. So I don't think we should be denying patients the treatments throughout an active rehabilitative course, but I believe they need to be reevaluated thereafter.

Dr. Duerden: So, building on that, because you're talking about the duration of treatment and being reevaluated thereafter, are there any prognostic indicators to indicate that repeat injections – trigger point injections - have benefit? Not just that it's helpful, but are there any specific prognostic indicators in the literature that shows us that someone is going to benefit, or more likely than not will benefit?

Dr. Bautista: This is Alex Bautista, I – [inaudible]

Dr. Duerden: Dr. Bautista, you dropped off.

Dr. Bautista, you're back on mute.

Dr. Bautista: [inaudible] – Setting goals and expectations are very important throughout this process. So I agree with Dr. Argyriou that we should not deny this patient's therapy if they need it to allow them to be more functional.

Dr. Duerden: So, how would you objectively place that criteria on your patients? And what is the literature show that we should objectively be doing to assess this?

Dr. Bautista: Again it all – This is Dr. Bautista – again it all depends on your history and physical examination. So, if you – going back to the definition, do they have recurring taut bands again? Or do they have hypersensitivity and they responded to the trigger point injection? Then you should not deny those patients if those symptoms come back.

Dr. Argyriou: Or if they – This is Dr. Argyriou – or if new ones develop in a new location. So, if we're capping the injections in general, I think that's unfair. So they may have responded to treatment and now they have a different problem, and I don't think it's fair to say "well, you've already had X number of trigger point injections and X amount of time, you cannot have anymore." Even though in the past, they've responded and have done quite well.

Dr. Duerden: So, let me clarify the questions: I'm not suggesting that there's a policy, or anything, is being discussed to determine if there's a cap on the procedures themselves. Rather, what are the mechanisms that we should be encouraging in a codified policy, and based on the literature, to show that these injections are quote helpful end quote?

Dr. Bautista: So, Again, just the – It's documented that they have, like, more than – at least a 50% pain relief with improving functionality, with improvement of sleep.

Dr. Duerden: And I'm sorry Dr. Bautista, I appreciate that, because that's exactly what I'm asking. When we say that there's an improvement of sleep, how are you objectively determining that? And if there's an improvement of function, how are they being objectively assessed?

Dr. Bautista: So, again, this Alex Bautista. So for improvement of sleep, you normally ask the patient the quality of sleep and the duration of their sleep. If the quality of sleep is initially poor, then it becomes better, than you take that as a success. For improving a functionality, before the trigger point injection, It's hard for them to stand up from their chair and walk to the bathroom, and now they're able to do that. So that's improvement in ADLs. Does that answer your question sir?

Dr. Duerden: It Does.

Dr. Argyriou, your hand is up?

Dr. Argyriou: Just to answer your questions about more objective findings; I usually ask them the number of hours that they're sleeping and the number of times that they're waking up at night. And so, when I say, are you sleeping better? Are you sleeping through the night? How many hours are you sleeping now compared to before? And the second question I ask is, do you find your waking up less frequently? and due to pain? Because some patients get up frequently to use the bathroom. And so if – are you waking up less often due to pain? And are you sleeping longer hours? So those are two objective questions I'll ask regarding sleep.

Dr. Duerden: And it was articulated by the panel that there are goals and expectations. How are those objectively measured?

Dr. Argyriou: I think that depends on the patient's lifestyle. So you take that into consideration. In terms of older patients, community engagement, ambulation, they're able to complete grocery shopping with stopping less often, or even they're sitting and their walking tolerance is longer. So those are questions you can ask. And patients who are working, you can ask them throughout their - throughout – while they're performing job duties. Find out, depending on what they do if they're able to perform certain things with more ease, driving longer. It's sort of day-to-day activities. You can start to get some specific information on how they have improved compared to before. And everyone's lifestyle is different, so I think that is going to be very patient specific.

Dr. Duerden: And is there anything in the literature to help guide the clinicians in formatting their assessments in that regard?

Dr. Argyriou: There are multiple validated scales you can use for functional improvement. I'm not sure specifically not specifically for trigger point injections, but in physiatry and rehabilitation, there are various functional assessments that can be performed, and surveys that you can provide.

Scott Rigdon: Some of the literature that I reviewed in the ultrasound utilization category, they use the shoulder pain and disability index as well as the neck disability index. And we've used the neck disability index in our practice.

Dr. Duerden: Thank you Dr. Rigdon.

Dr. Freeman, I see your hand is up?

Dr. Freeman: In Rheumatology, we have the rapid three score, which has modified health assessment questionnaire, but these things are relatively gross measures, and for people that - particularly those who have chronic pain – their improvement can be more subtle than what these documents show. So, I think, as Dr. Argyriou said, this is very patient specific. And they just need to be able to articulate a way in which they improved significantly compared to their baseline after these injections. And for them, that may just be improvement in ability to do something like childcare, et cetera, that would not necessarily be on these standardized documents.

Dr. Duerden: [inaudible]

Dr. Bautista: This is Alex Bautista. So, with regards to literature, there's a lot of outcome measures that we have used so far, and it varies. So there are like, McGill Pain Questionnaires, as what the other panelists have said, the neck disability indices, bass scores, SF36, osseous disability indices, brief pain inventory indices, so there's a lot of them that have been used in research, but the thing is, how do you translate that into practice? You cannot document every single indices in your in your charting. So, I agree with the other panelists that it depends on the patient's baseline status, and again, their goals. If they're meeting their goals, I think you're treatment plan, whatever it is, is efficacious.

Dr. Duerden: So, I'm – let me build on that point that you're making. Certainly no one would expect That all indices would be used. But is it unreasonable to use at least one indices, isn't that how the oswestry is measured anyway? It's based on change and it actually has a minimal clinical significant difference in those scores. So, shouldn't we be assessing for those? That minimally clinical significant difference?

Dr. Freeman.

Dr. Freeman: I just think it's very difficult to choose a document that all specialties are going to agree on and to add to the documentation burden when there is individual variation in what improvement in quality of life there's going to be. And so, I think it just needs to be something where you can have the patient verbalize a degree of improvement, which has functional correlates to it.

Dr. Duerden: Okay.

Alice Bell: This is Alice Bell. If I could just offer, I would also just say in the situations where we are working under a collaborative care model and the patient is also receiving physical therapy, physical therapists are routinely administering standardized objective tests and measures as a part of their course of treatment, and there's no need to necessarily duplicate efforts. And I would just encourage that that data be shared and it can be incorporated into the patient's record. That information should be readily available.

And then I just wanted to ask, or, I wanted to make two other points: One, in terms of duration and need for repetitive injection. I think the other part of that is understanding the underlying pathophysiology, and what is what is triggering the trigger point? And so part of the collaborative model of injection with physical therapy is hopefully getting that trigger point under control, so that the patient can engage in meaningful prescribed physical activity that not only addresses the presenting issue, but hopefully addresses sustainable performance without recurrence. Now that's not going to be the case for every patient, depending on underlying pathophysiology, but certainly for many, that should be a measure of the combined efforts of the injection and the therapeutic intervention.

And then the last thing, and this is more a question for the group, because I am not the expert in trigger points injections, but there's been a just got a lot of discussion about having to have some sort of a functional outcome. And my only question to the group is: is function always is it 100% of the time the goal? Or is there a subset of patients for whom the injections are palliative in nature and may or may not be associated with a functional change?

Dr. Argyriou: This is Dr. Argyriou. I think that you go hand in hand. So with pain, there's often dysfunction. And I think when one improves the other one, naturally, also does as well. And so I think it does make sense to address functionality. Some patients are in pain, but they're still able to function. And so, I think getting the patient experience is very important. And that's where specific questions about lifestyle come into play, because every patient, as somebody mentioned before, is going to have different goals. Whereas it's, you know, "I can't sleep through the night" versus "I can't pick up a ton of bricks at work," these are two very different goals. Or "I can't go to the supermarket without having to stop 100 times." And so I believe every patient is going to be different, but usually pain and ability to function go hand in hand.

Alice Bell: I agree. Thank you.

Dr. Duerden: So, I'm going to move on to the next question, which is question number 11. And Dr. Bautista, if you could read that question and please answer.

Dr. Bautista: Do you agree – this is Dr. Bautista – do you agree that trigger point injections should be performed as a sole procedure and not in conjunction with other procedures during the same session? Please explain and why.

So, it boils down on your history and physical examination and the circumstances. That's what, Mr. Rigdon has said a while ago, when you do certain procedures, and you feel, like, spasm along – or trigger – along the other part of the muscle, that gives you a trigger point injection, and that relieves the pain. So, again, it depends on the situation, the circumstances. And I don't think we should limit that if – [inaudible]

Dr. Duerden: We lost you again, Dr. Bautista.

Dr. Bautista: I'm Sorry?

Dr. Duerden: We lost you.

Dr. Bautista. Oh. So, I would say that it depends on your assessment in your History and Physical Examination, if a trigger point is needed, in conjunction with other procedures. So we should not limit trigger point injections if it's absolutely necessary at that particular moment.

Dr. Duerden: Okay. And Mr. Rigdon, I think you had a – you want to build on this one because you addressed this, and then I have some questions for the panel on that as well.

Scott Rigdon: I apologize, I just sent you a message. My sheet when I printed it out, I have number ten, because when you were asking me the question, you mentioned ten and we were on nine, but I was, like, okay, I guess we'll start on ten. So, I apologize right now, what I'm looking at is my numbering is off by one. So, I have a 13 on mine, so sorry about that. That's why I jumped ahead.

Dr. Duerden: No worries. Go right ahead. Sir.

Scott Rigdon: I sorry, I kind of said what I had to say at that time. I didn't have much more to add. I do find that it is, oftentimes, I wouldn't go to the level of saying the word necessary, but I would say that we oftentimes add these in conjunction with other procedures to globally calm down the zone where we're working because often times trigger points are somewhat of a secondary pathology, if you will, to the primary issue and we, in order to get patients under control pain wise, we will add the trigger point injections as well.

Dr. Duerden: So, in my review of the literature, there's, it's sparse on this issue of dual or multiple injections. So, I'm going to address it in two points. The first is, is that there is some indication in the medical literature that demonstrations when you are doing an inter-articular or maybe even a peri-articular injection of the cervical facet joint, that you can mitigate the pain of a myofascial trigger point in the upper trapezius and shoulder pain. So, if the treatment – the primary treatment – of the facet problem is being treated, why would we want to continue to do other injections for myofascial pain, if indeed the primary pain generator should be able to mitigate that?

Dr. Bautista: This is Alex Bautista. So there's also a concept about a primary trigger point, or a active trigger point and a satellite trigger point. Most often than not if you treat the primary trigger point, it resolves quickly. However, if you just treat the satellite trigger point, then there's a possibility it may not be able to provide significant relief. Does that answer your question?

Dr. Duerden: Yes.

Dr. Bell? Did –

Ah, Mr. Rigdon, I see you raised your hand.

Scott Rigdon: I would – So, kind of following along that line of reasoning; I do, and we do as a group, discuss with patients primary and secondary pain generators. I find clinically that it can take quite some time for a myofascial pain, not a syndrome, but a trigger point, or pain in the muscle, to calm down post-intervention, whether that is an intra-articular set, or whether that would be other facet work. When we perform radiofrequency ablations, for example, we are giving a concentrated local anesthetic prior to the ablative process and there are times where post procedure, if we manually palpate the zone where they had pain prior, if their pain is relieved, we don't add the trigger point. If their pain is not relieved, then we generally add the trigger point.

Dr. Duerden: And is there any clinical literature to substantiate that process that you've developed?

Scott Rigdon: Not that I'm aware of.

Dr. Argyriou: This is Dr. Argyriou. I think similar experiences have been documented, but not evaluated in a trial. So I have read and have come across similar experiences in other physicians, I don't know of any study specifically, but I will agree in clinical practice similarly; I have been seeing the same thing.

Dr. Duerden: Thank you very much to my – express my appreciation to the panel. I'm now going to turn the time over to Dr. Kettler for the final questions.

Dr. Kettler: Thank you Marc. The next two questions are going to be for Doctors Yoon and Northrup. And the first is: Are there circumstances where image guidance is necessary for trigger point injections?

Dr. Yoon: Yeah, I'll take this one.

So, essentially there have been some studies that use fluoroscopy, CT and ultrasound as well. And there have been kind of scarce literature regarding potential ultrasound findings of what a trigger point is. But without a definitive confirmation of okay, there is a trigger point here for certain. But I think, just for safety reasons, when you're doing paraspinal work in the neck, or the thoracic spine, especially in the thoracic spine, if you veer too deep on a thin patient, that could certainly cause pneumothoracies. And also, if you really don't know what you're doing and the patient's really small, you can get intrathecal with the needle, even if it's a short and a thin one that you use to dry needle or whatever. So I think when it involves specific anatomic regions where there are vital structures superficial to where you're working, then I think ultrasounds specifically can certainly aid and not causing the patient's any harm.

Dr. Kettler: Thank you. Any other comments from the panelists on this question?

Dr. Argyriou: This is Dr. Argyriou. I think it simply depends on what region you are injecting, and the underlying structures as mentioned. Most studies have shown that this is safe, not very many complications. A couple of case reports of unusual adverse reactions to trigger point injections; and part of that is if you are performing trigger point injections, you usually know the high-risk areas and if you don't have any image guidance or less likely to go ahead and perform those injections. And so, in those instances, especially, for example, pneumothorax, anything in the thoracic area or anywhere where we have a high concentration of blood vessels, image guidance would be necessary just to prevent adverse reactions in addition to ensuring you're in the proper location. So there's a dual need for image guidance. One for safety and one for accuracy.

Dr. Kettler: Other comments?

Dr. Bautista: This is Alex Bautista.

Dr. Kettler: Yes.

Dr. Bautista: I agree with what you have said. However, if you're looking at these, there's very limited studies on the effectiveness of image guidance for doing trigger point injections. And there's no comparison that doing blind technique with image guidance and guidance improved efficacy. However, again, that's what Dr. Argyriou said; if you are dealing with trigger point areas where it's close to a vessel or close to the lung, that can potentially be helpful.

Scott Rigdon: [inaudible] add that, with imaging that it does make for a more robust injection if you will, from the perspective of seeing the entire muscle belly; seeing the facial planes and being able to bring the needle in play into the mid portion of the belly; inject; see a little bit of hydro dissection; see if it's a little much; move it around a bit; control your volumes. There's quite a few things that are very efficacious with imaging. But it's also having it close, because a lot of these procedures are a very quick, easy to perform on patients, and they have a low risk/high benefit to them. Certainly as stated previously, anything in and around the thoracic zone should be done with image guidance. So I agree with all of that. This was Scott Rigdon, by the way.

Dr. Kettler: Okay. Further comments?

And the next question, again for Doctor Yoon and Northrup: What absolute contraindications are there for trigger point injections?

Dr. Northrup: I will take this one, this is Ben Northrup. So the absolute contraindications; so first off, these procedures require informed consent. So if the patient is either unable or unwilling to sign the informed consent or refuses the procedure thereafter than that is an absolute contraindication. If there is active infection, or an open wound directly over the target site; and then also, if the trigger point is not safely accessible by needle. Now we just spoke of imaging guidance. You can help out with that a little bit if you're worried about a vessel or a sciatic nerve in the way, something like that, you can certainly avoid that with imaging guidance but sometimes, even with imaging guidance it will be inaccessible and therefore would be contraindicated. Or if you don't have imaging guidance available to you. So, for those safety concerns, certainly that would be an absolute contraindication.

There's several relative contraindications to if you happen to be using a local anesthetic with your technique and if there's an allergy to that. That's a relative contraindication, depending on how bad the allergy is, you might need to use an anesthetic in a different category. And then other very unique situations, such as a cancer patient with severe leukopenia, severe coagulopathy that's not correctable. So, several other relative ones that we could go over a great length if need be. But those first four are the main absolute contraindications.

Dr. Kettler: Thank you. Further comments?

Just a follow up question I have on the preceding question number 12 that I forgot to ask at the time: Are there any professional society guidelines that either recommend or require some type of imaging guidance for trigger point injections?

Dr. Yoon: This is Ed Yoon. There's no societal guidelines that require it, but it also doesn't prohibited from using. I think the individual provider is free to use whatever is comfortable and feels it's safe for the patient.

Dr. Kettler: Okay, thank you.

Anything else than on either 12 or 13: Imaging guidance or absolute contraindications.

Okay, Rich, if you could display the grid.

What we're going to do now is run through the last question, which is going to provide a series of conditions where I'm going to ask the panel to comment on whether a trigger point injections are helpful or not. And I would like for the panel to frame their answer in terms of their assessment of the literature and their confidence in the literature: high, moderate, low, and there are some phrases here that describe the level of confidence or finally that they're, they believe that the literature is insufficient to make a recommendation. So, again, these are the benchmarks that we will use.

And Rich, if you could then go to question 14.

Rich Staley: One moment.

Dr. Kettler: No problem.

But we are around in the final turn and coming down the homestretch here. So we're getting close.

Okay, so, as the question says, we would like the panel to rate the strength of evidence to support the effectiveness of trigger point injections to relieve pain for the following conditions. And again, using the terms insufficient, low, moderate, or high quality, to describe the supporting evidence. Now for our first category here, Ms. Short was assigned this particular assessment. She has said that she will email her assessment to us. So we will get that. I don't know if it's come in yet. But would any of the panel members like to comment on the strength of evidence supporting the effectiveness of pointing in myofascial pain disorders?

Dr. Argyriou: This is Dr. Argyriou. I'd say most of the evidence is examining trigger point injections for myofascial pain disorders. And obviously there are, there's a lot of work to be done. It is a difficult topic to study. There is a lot of variability, but overall I would say there is moderate evidence to support the use of trigger point injections in myofacial pain disorders.

Dr. Kettler: Thank you. Anybody else?

Scott Rigdon: This is Scott Rigdon. I concur with that.

Dr. Freeman: This is Pam Freeman. I concur as well.

Dr. Bautista: Alex Bautista, I concur.

Dr. Kettler: Anybody else?

All right, Dr. Bell,, the next one is for you; chronic low back pain.

Alice Bell: Thank you. Based on a review of the evidence, it would indicate that there is insufficient evidence to support the use of injections for chronic low back pain, and moderate to high evidence to indicate that other interventions should be attempted first. And that there may be a subset of patients for whom an injection may be appropriate, if they are unable to respond to other interventions.

Dr. Kettler: Thank you. Any comment from the panel?

Dr. Argyriou: This is Dr. Argyriou, I agree with that.

Dr. Bautista: I agree with that. Alex Bautista.

Dr. Freeman: Pam Freeman, I agree.

Scott Rigdon: This is Scott Rigdon, I agree.

Dr. Kettler: Okay, thank you. The next was, again for Dr. Short, migraine and other headache disorders. Do any panel members wish to comment on this one?

Dr. Bautista: This is Alex Bautista. There is moderate evidence that it can be used for some headache disorders that is associated with myofacial pain. And trigger point injection may prove to be beneficial in those situations.

Dr. Kettler: Any other comments?

Okay. Dr. Bell: d. Non-radicular neck pain?

Alice Bell: So, for non-radicular neck pain, some similar indication that a course of physical therapy or other interventions may be indicated first, but also some evidence that injection of lidocaine may address non-radicular neck pain effectively.

Dr. Kettler: Thank you. Other comments?

Dr. Bautista, anterior cutaneous nerve entrapment syndromes?

Dr. Bautista: So, the, it's just limited to case report, and case series and patients who have trigger points over the abdominal wall that may be associated with the- [inaudible]

Dr. Kettler: I didn't catch the last part of what you said. It seemed to drop off.

Dr. Bautista?

Any other comments from the panel on anterior cutaneous nerve entrapment syndromes?

Dr. Argyriou: This is Dr. Argyriou. I would agree; there is much insufficient data on that.

Dr. Kettler: Okay, Thank you. Dr. Freeman, chronic pain syndrome?

Dr. Freeman: The evidence for this, I think, is relatively low quality in the literature, although I think we all in practice, think that they're individual patients who can improve and the practice guidelines for chronic pain management from the American Society of Anesthesiologists does list a table where they hold members who did overall feel that there was benefit.

Dr. Kettler: Thank you. Other comments?

Dr. Freeman; again for fibromyalgia?

Dr. Freeman: Again, in this regard, there have not been a number of studies that are randomized controlled studies. However, I did find a study of tender point injections beneficial to fibromyalgia from Knight – Let's see – from 2000. This is a relatively small study, and was open study that showed tender point injections were a benefit in fibromyalgia. But again, this was very small and was an open study. So I would say that from a literature standpoint, the evidence is low or insufficient.

I would also say that we found a study from 1996 that compared tender point – or excuse me – trigger point injections in people with myofascial pain syndrome to injections of the same sort of people with myofascial pain syndrome and fibromyalgia, finding both were helpful. The advantage of this was that they injected the upper trapezius in all of these people, and for all of them used 0.5% lidocaine, but again, this was a relatively small study. So, I'd say again, low evidence, but common in clinical practice.

Dr. Kettler: Thank you. Other comments?

Mr. Rigdon, Neuropathic pain?

Scott Rigdon: Yeah, this is Scott Rigdon. With neuropathic pain, the evidence is insufficient. Some might be able to argue low, but I believe that it's insufficient. There was a article in the Journal of Pain in 2017 and the best way they could summarize this was limited evidence. When you look at the underlying mechanisms for neuropathic pain and neuropathic pain and with types of neuropathic pain that we attempt to mitigate and treat. I believe that the evidence is essentially insufficient.

Dr. Kettler: Thank you. Comments from the panel?

Dr. Bautista: I agree.

Dr. Argyriou: I agree as well. It's Dr. Argyriou.

Dr. Freeman: Agree, Pam Freeman.

Dr. Kettler: Okay. Dr. Argyriou; non-malignant musculoskeletal pain?

Dr. Argyriou: So, there is moderate evidence. Most of the studies that we have, once again, are looking at either myofascial pain or non-malignant musculoskeletal pain. So, most of the studies are looking at this particular type of pain. So I would rate the evidence as moderate.

Dr. Kettler: Thank you. Other comments?

Dr. Bautista: This is Dr. Bautista. I agree with – [inaudible]

Dr. Kettler: Thank you. Dr. Bautista; lumbosacral canal stenosis?

Dr. Bautista: I don't think there's any evidence that supports the use of trigger point injections for spinal stenosis, unless there is an existing myofascial component of the low back pain that may benefit of a trigger point injection. So, for this diagnosis alone, there's no evidence that supports trigger point injection.

Dr. Kettler: Thank you. Other comments?

Doctors Yoon and Northrup; cancer pain?

Dr. Northrup: This is Ben Northrup, I'll take this one. So, I would rate the evidence on this as low. There are several small studies, essentially case series that do discuss this. It's essentially for patients that have pain that is myofascial pain, That is, are related to, or in addition to their specific cancer pain that might be causing pain via the bone or compressing an adjacent nerve. In terms of what the studies show, it's most effective in cancer patients that have fewer myofascial trigger points and those that are located not in the lower back or the hips. But again, all fairly limited studies. So I read it as low.

Dr. Kettler: Thank you, Ben. Other comments?

Okay. The next, again for Doctors Yoon and Northrup. Hemiplegic shoulder pain?

Dr. Yoon: This is Dr. Yoon, I'll take this one. I would rate this as low. Just like the cancer pain, they're very small amount of literature to support this. There has – and in the literature that has supported it, I think the one biggest, or the largest cohort of patients they use actually botulism toxin, which I know we're not discussing today. So.

Dr. Kettler: Allright, thank you. Other comments?

Okay Dr. Argyriou, pelvic floor myalgia and/or sexual pain.

Dr. Argyriou: Most of the evidence we have for this are small case series or case reports. So, while promising, there's just not enough. There aren't enough quality studies, or there are no – to my knowledge – no randomized controlled trials that are looking at this. So, in the small number of case series, most of the underlying causes of pain in pelvic floor myalgia or sexual pain are myofascial. So, once again, it's sort of looking into myofascial pain disorders and non-malignant musculoskeletal pain. It just happens to be in the pelvis. So while there is potential for effectiveness we simply don't have the evidence for it. But we do have several case reports that do look promising. So I'm going to read it low.

Dr. Kettler: Thank you. Other comments from the panel?

Okay, and then finally, are there any pain conditions that the work group neglected the list? And if so, is there evidence to support the effectiveness of trigger point injections in managing those conditions?

Dr. Argyriou: This is Dr. Argyriou. I would add whiplash injury. There were several studies in the literature that addressed whiplash injury with improvement and symptoms. So I would include whiplash injury here.

Dr. Kettler: Thank you. Any other conditions?

All right. And that does conclude the multi-jurisdictional CAC on trigger point injections. First of all, I do want to thank the subject matter experts who participated today. In addition to your expertise, which I think you expressed very articulately, it does take a certain amount of courage and commitment to provide this kind of input publicly in a public forum like this. And on behalf of the work group, we do appreciate it and we will be taking the information that you've given us into consideration as we consider our next steps moving forward.

I also want to thank my colleagues on the work group. They did a considerable amount of work, putting together the questions, reviewing the literature and participating in the event today.

I want to thank my colleague Marc Duerden, who helped me co-moderate this session. It was helpful to be able to take a bit of a break here and there. And so I do appreciate that, Marc.

Also Dr. Loveless, who chairs the pain management workgroup and really provides a lot of the inspiration for all of these activities.

And then, finally, I do want to thank Mr. Richards Staley. He does a lot of the behind the scenes work on this and does make this CAC and other events that we hold here at WPS to be a success. So, thank you very much Rich.

And with that, we are adjourned.

[Panelists]: Okay, thank you so much. Thank you. Thank you. Thank you. Thank you.