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J15 Contractor Advisory Committee (CAC) Meeting Regarding Platelet Rich Plasma Injections

Meeting Date and Time:	March 10, 2020 3:30 p.m. EST
Facilitator:	Dr. Meredith Loveless, CMD
Location:	Teleconference
Attendees:	Not to disclose

Dr. Loveless: Good afternoon, everyone and welcome to our LCD session today on Platelet Rich Plasma injections.

Juan Lumpkin: My name is Juan Lumpkin with the Provider Outreach and Education Department. Before I turn it over to Dr. Loveless to get us started, I just wanted to let you know if you need to look at the actual voting questions that were submitted, you can go to your handouts panel. So, if you're looking at your GoTo Webinar control panel, you'll see a window there. If you click on that drop-down box, you will be able to download the PDF version of that document. So, feel free if you want to follow along today. I'll go ahead and turn it over to Dr. Loveless.

Dr. Loveless: Thank you, Juan. Welcome everybody. Thank you for joining us today for the evidence review regarding platelet rich plasma for non-wound indications. We have our panelists with us today, so, I want to thank each of them for their time.

Just to make sure, we're clear, today's discussion is to review the evidence surrounding platelet rich plasma into tissues for non-wound indications.

We asked our panelists to focus on the review of evidence, and we will ask you to rate that evidence on the scale of one to five. One being low, confidence to five being high confidence for the different for the different topics.

This meeting is recorded, and we will have a transcript. All of that will be posted onto our website in about 3 to 4 weeks.

And without further ado, I want to introduce our panel. So, I'm going to say each panelists name, and if they can get a brief introduction..

Dr. Loveless: Dr. Bhatia.

Dr. Bhatia: Hi. My name's Animas Bhatia and I am from Columbus, OH. I've been in practice here for about 24 years, in private practice and I am a podiatrist.

Dr. Loveless: If you have any conflicts of interest, just please state your conflicts of interest.

Dr. Bhatia: Sure, no conflicts of interest.

Dr. Loveless: Thank you.

Dr. Block: I am a podiatrist also in Columbus, Ohio. I sit on the Board of the American Medical Association, and I'm a clinical Assistant Professor at the Ohio State Department of Orthopedics and I have no conflicts.

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Dr. Loveless: Thank you, Dr. Ryan.

Dr. Ryan: This is Andy Ryan in Lexington, Kentucky. I am representing the Kentucky Orthopedic Society.

I left Columbus, Ohio, in 1996 to come down to Lexington, Kentucky, and over the last few years, I've been doing private practice and starting to do some teaching at the VA Hospital, but again, I'm representing the Kentucky Orthopedic Society.

Dr. Loveless: Thank you, and any conflicts of interest.

Dr. Ryan: Not that I know of.

Dr. Loveless: OK. Thank you, Dr. Moore.

Dr. Moore: Yes, good afternoon. My name is Jonathan Moore, and I'm just south of Lexington. I'm in Somerset, KY. I'm a podiatrist, and managing partner of the Cumberland Foot and Ankle Centers of Kentucky and clinician, teacher, and I think that's it, thank you very much. Glad to be with you.

Dr. Loveless: Thank you, and any conflicts of interest?

Dr. Moore: No conflicts.

Dr. Loveless: Great, and Dr. Buenaventura.

Dr. Buenaventura: Hi, my name is Rick Buenaventura. I have no conflicts. I'm an anesthesiologist of pain management physician. I did do my Fellowship at Ohio State. I am based in Dayton, Ohio and I have a solo private practice.

And I do use prolotherapy and PRP. I've been using it for 10 to 15 years, and I performed all of these procedures that we will be discussing here today.

Dr. Loveless: Thank you, Dr. Coleman

Dr. Coleman: Yeah, the Kirk Coleman and I'm from Lima, Ohio. A physical medicine and rehab physician out of Ohio State and I have been in private practice for 25 years. And I do a little bit of a little bit of everything and have no conflict of interest.

Dr. Loveless: Thank you, Dr. Phillips

Dr. Phillips: Sure. So, let's I am a practicing rheumatologist in Paducah, KY. I've been here for about 10 years. I chair the Insurance subcommittee for the American College of Rheumatology. I do not have any conflicts.

Dr. Loveless: Thank you and Dr. Douglas

Dr. Douglas: Yes, ma'am. This is Dr. Douglas and I am in Louisville, KY. I am the Chief of Sports Medicine and Orthopedic Surgeon for U of L Health. I have no conflicts.

Dr. Loveless: Thank you. Thank you, each of you for taking the time to join us today.

As you can see, we aim to try to have a variety of different sub-specialties that may be impacted or that would have a knowledge and background in terms of platelet rich plasma. And so, without further ado, I'm going to move forward with our question.

The questions are posted in the handout, and you should be able to see them on the screen. As far as the format, if a panelist, who wants to begin the questions, can answer the questions, and then we will just have an open discussion regarding the topic, being aware of time, for any reason you do not have the opportunity to discuss any additional comments. I will be happy to take those in writing as well, but I think we'll have ample time to go through this material.

So, the first question is in regard to the safety of platelet rich plasma joints and tissues for non-wound conditions. And breaking that down, we're interested in their evidence to demonstrate safety, both short-term and long-term. And so, we'll start with that.

Unknown: I apologize. This is my first go around. This particular panel, position is open, open answer. Anyone pops off?

Dr. Loveless: Yes, and if you could please state your name when you begin to speak, that helps our transcriptionist to know which panelist is speaking.

Dr. Douglas: I don't see any evidence of any lack of safety, across the literature. I don't see in particular a risk greater than greater than normal controls anywhere.

Dr. Rick: I agree with that. All these studies mention that very few, if any, patients that participated in all of these randomized controlled trials, had any, complications. So, I think there's good evidence that this is a safe procedure, and in fact, I would say there is evidence that it is very safe to proceed and allow this in the future.

Dr. Moore: I'm sorry, I know we're talking on top of each other and I apologize. Having done many of these over the years, like many of you on this call and having reviewed the medical literature, I think that there's really good systemic reviews and meta-analysis studies. The most recent study in 2019, that I'll refer to, maybe over the course of this talk, but there, but this is the systemic reviews and meta-analysis. Many of them actually refer to studies comparing the use of corticosteroids to PRP. I believe that that there are far more complications from corticosteroid use within PRP and there's really none mentioned in the middle meta-analysis systemic reviews that I've seen. Thank you

Unknown: Actually, this is ……., to pair on that statement. Thank you. We were clearing hyaluronic acid for a very similar purpose. I will tell you, hyaluronic acid has a far higher rate of adverse events than platelet rich plasma does. We approve that so, I think we should proceed with at least that in our minds.

Dr. Coleman: I agree with everyone else that's noted this. In reviewing the literature as well as personally doing a lot of these procedures. I believe the PRP is considered very safe, relative to other similar procedures.

Dr. Phillips: I admittedly don't do any of these procedures. So, I'm just objectively reviewing the literature as a rheumatologist. I would say from the literature, it does to be safe. I guess my only question is that the studies themselves, whether they demonstrate long term safety or more so, short-term safety? I don't have any reason to think there would be a long-term safety signal. I'm just questioning whether the evidence is firmly there for that or not.

Dr. Loveless: That actually fits very well into the next question on this. So, to open to that, what about repeat injections? Is there any we have any evidence to say that repeating the injections into the same joint is safe and how many injections is there? Is there any evidence to say a limit on how frequently these can be done and if they're done perhaps too frequently, does that potentially create any harm?

Dr. Coleman: For my review of this, it indicates a one to four injections are commonly done. Two to three is probably the most common and when it's done in that manner, separating this by a month each checks each injection is quite safe in that particular manner.

Dr. Buenaventura: I would agree following up what he just said. In term of long-terms safety with Dr. Phillips commented about the question of long-term safety, while several of these studies follow patients for a year.

They didn't note any increase in complications on them relative to other patients. In terms of repeated injections, several of these studies did do you repeat injections. Two or three or one or two follow up injections.

Again, there none of these studies show any increase in complications. I feel that it's a safe procedure. As far as how many injections, there's really no evidence to say, what's the number or what first number ideal number:

Dr. Douglas: I concur with everything you said. No greater risk of injection infiltrating until the first place for other type injections.

Dr. Moore: Ultimately, I would agree. The only thing that would be called into question is technique. As far as injecting around an insertion site, if the if ultrasound guided, if there's going to be going to be irritation of the tendon. Too aggressive approach, in that regard, and too close to the interval may be an issue. As far as the PRP itself, it's from the patient's own blood is, I think that there's little to no risk in that respect. The only risks could be technique if I may put that forth.

Dr. Douglas: I agree with my colleagues. You got to do it right. We can't discount for that, but the technique itself is sound.

Dr. Loveless: Dr Douglas, you touched on this briefly, but the final safety question would be, how this compares to current standard treatment in terms of safety? We can elaborate on that a bit further.

Dr. Douglas: That would be tough to do at this juncture, because talking about platelet rich plasma is like talking about fruit. All right? "we're talking apples to kiwis. Can't lump it all into one gross category. So, we would probably have to look at safety from a safety profile. It's a very safe procedure, you're essentially introducing the patient's own plasma elements into their own body again. All right, so, it literally is the risk of an injection at its baseline with any other procedure. The differences between the preparations and the applications for plant rich plasma is a big spectrum here so you can't lump them into one. In general, is it safe? Yes. There were some allusions as to the efficacious of it, but I'm sure we'll get into that as we continue to talk.

Dr. Buenaventura: I'd just like to say in terms of comparing it to current standard treatment, steroids, or anesthetics. I'm going to say, it's much more safer. Steroids overuse can lead to osteoporosis or earlier onset of cataracts. It can lead to tissue atrophy at the site, whether it's just scan that atrophies and loss of color or eventual rupture of a tendon and of course anesthetics. It can lead to local numbness and weakness if it spreads onto a nerve. And if a person were to inject too much local anesthetic while the toxicity of local anesthetic, leading to seizures. So, certainly, PRP is far more safer than steroids or local anesthetics.

Dr. Moore: This may be jumping ahead too far, but if we really identify the etiology of what plantar fasciitis, we can talk about what that really is. There's a lot of different, obviously, a variety of different musculoskeletal conditions upon which this will work. But speaking specifically regarding, the breakdown or overstressed of these types of tissues. We are talking about, in many cases, conditions that are not inflammatory and because you're talking about the degenerative conditions of these tissues, there has to be the introduction of some type of cellular regeneration using static growth factors.

So, just considering the fact that we are talking about more than just an inflammatory condition for which corticosteroids maybe more indicated. We are talking about degenerative conditions of tissues for which PRP is really introducing growth factors that that promote regeneration. So, I think that's important maybe to bring that up.

Dr. Loveless: I think that's a very good headway and if anyone has additional comments on safety, I welcome that. I think that the mechanism is a good opening into beginning a discussion about the efficacy. And so, if we look at that question, we're looking at the quality of evidence, how would you rate the quality of evidence for the efficacy of platelet rich plasma injected into joint care tissues for non-wound indication?

Unknown: I hate to ask a question in response to a question, but that seems to be an overly broad question. Which joint, for which tissues, and for what region?.

Dr. Loveless: So, if each specialist can focus on the indications that would align with your specialty. So, osteoarthritis of the joint plantar fasciitis, tendinitis and looking at the short term and long evidence regarding short- and long-term benefit associated with the platelet rich plasma or lack of evidence depending on your analysis of the literature.

Dr. Buenaventura: It seems like question four, kind of goes along with each, breaking it down by each condition. But in terms of getting back to number two, in terms of the evidence, I would say yes. Several of these studies there were recommended in the syllabus or list of articles, randomized controlled trials, show that there was efficacy. Benefit is short-term and long-term, some are pro or some are con, but I'd say there were several particularly strong with certain conditions like the knee in particular. I thought almost all of them, that I saw were pro or supportive of that. Is there evidence that repeat injections in the same drawing improve efficacy? I'd say the jury's out on that, some studies did one injection and the patients had improvement for a year. That's going to depend on the joints and will probably need more evidence there. Is there evidence of effectiveness as compared to current standard of treatment of steroids anesthetics? I'd say yes. Several other studies show that there was improvement with PRP in terms of pain and functionality in the short-term and the long-term, compared to steroids, saline or hydraulic acid, dependent on the joint involved.

Dr. Coleman: Yeah, I sort of agree with everything you just said. I think there is evidence of short-term and long-term benefit. For most of these conditions, by far, I thought the knee had the most evidence to support that. It seems like two the three injections are probably better than one injection. PRP for the knee has been shown to be better than steroids and hydraulic acid and placebo.

Dr. Phillips: I would agree with most of those comments as well. If I focused on osteoarthritis, I thought the data was most promising for the osteoarthritis of the knee. I definitely thought that the majority of the studies were favorable. As someone who does not use these products, I guess my main question or concern would be heterogeneity of the preparations, whether it's being used in early or advanced osteoarthritis. So, some questions regarding PRP preparation, number of injections, overall study quality are my concerns, but I definitely thought the data was favorable.

Dr. Moore: I know I have several esteemed colleagues that could probably follow me with regards to plantar fasciitis. I have experience primarily with plantar fasciitis, some with Achilles Tendinitis.

But there's a considerable amount of evidence supporting the use of PRP for plantar Fasciitis.

I could cite the studies, but I will tell you that there's a number of double-blind trials, randomized controlled trials that that demonstrate improvement.

But I think that one of the most powerful studies that's recent is a meta-analysis and a systemic review that was published in 2019. Which, again, reviewed all of the higher-level studies that were that were available demonstrating that PRP provided long term effect, and relieving these types of patients.

So, you're going to typically see corticosteroids helping in the short term and PRP helping more significantly in the long term. Because I think you are seeing more of a healing of the underlying etiology of the problem.

This particular systemic review, which I think is a very good one, most all of the randomized control studies suggest significant improvement with plantar fasciitis specifically.

Dr. Douglas: I agree with the statement, a couple of minutes ago that it is very difficult to draw hard conclusions based on meta-analysis that are based on studies that are as heterogenous as you can possibly imagine.

Very few of the state of research in platelet rich plasma, right now is still very much like the Wild West. We have some standardization and protocols, but I made the apples and kiwis analogy earlier.

Platelet rich plasma is not platelet rich plasma. The preparation, the activating agents and where it is actually applied and under what terms, makes all the difference in the world. It turns an apple into an orange very quickly.

That being said, in the knee, I was actually surprised by the meta-analysis. I do not, for disclosure, I do not use platelet rich plasma. I don't give any cash paid procedures in my practice, but I have a number of young patients that ask about it.

I was surprised by the level of efficacy and the consistency in the positive results for osteoarthritis of the knee, especially in younger patients.

Some of them had a BMI that's not compatible with Kentucky on average and it was very eye opening. And I think that I think the evidence there is very strong.

For patellar tendonitis and achilleas tendinitis, I felt the evidence is quite weak.

Which actually makes sense, given the underlying biomechanics. Plantar fasciitis holds some promise, and also, for …but not as much as I would like.

But for the need, and also, for healing rates with rotator cuff tears, which, again, is a terribly mixed group.

I mean, not all cuff tears are the same, nor are all the patients, but considering these wide variations, variables still seem to have good efficacy.

Dr. Ryan: I'm not supposed to say too much about this. I was on the American Academy Orthopedic Surgeons Committee updating the clinical practice guidelines for knee osteoarthritis.

When we got to the subject of PRP, we're probably going to come out with a limited support based on the evidence. So, there's not a lot of great evidence for knee arthritis in terms of outstanding evidence, as much as there is for short-term treatment with the osteoarthritis.

That said, I think, looking at the reviews in terms of should it be covered for Medicare or not?

I would think that it works so much better than the hyaluronic acid that if we're going to have Medicare payments for the hyaluronic acid, we should be doing it for the PRP for the knee arthritis.

And then all the other things will go in, but I wanted to get my 2 cents in on that.

Dr. Block: To your point., I agree with you wholeheartedly. From an AAOS standpoint, this almost I feel like I'm sacrilegious.

At the same time, when the evidence for hyaluronic acid came out, it was not quite so strong. It was also industry funded, and we still don't understand why the devil it actually works when it knocks.

And to that point, I came into this biased against PRP, but reading through this, especially reading all of the source references. I can't deny that there is potential value there. So, I'm glad you said that.

Unknown: We really didn't like the hyaluronic ironic acid at our latest review, either. But that's consistent with what we said seven years ago.

Dr. Block: Just going back with what Dr. Moore said about I used it a lot on Achilles tendons and I found out the sooner I gave it a call instead of waiting until the patient has had problems for years, they did much better.

And of course, you don't want to put a steroid into an Achilles tendon, different than plantar fasciitis and it gave a patient an option.

The problem with it not being covered is, that we do this in the office, we would … it in the office. We have little procedure room.

But the problem was, it's not covered and taking the patient in the hospital left them with a huge bill because you have obviously have anesthesia.

That was the problem. I like the idea of injecting in my office to be honest with you, for that reason. But again, for Achilles tendon, by the way, Achilles is spelled wrong for Achilles tendinopathy on the handout.

But I've had great results, and I did also with plantar fascia. And then I started doing with posterior tendons. There was a really good study back in, I think, 2017 that got me interested in doing that. And they were doing a rotator cuff tears. And they found out as three centimeters or less in the tear, patients tended to do better, and so I was more apt to do this quicker.

And the patients that I wouldn't normally open when I was doing another procedure, I would go ahead and supplement surgery with action.

Dr. Moore: I to do these now in my office and patients do pay cash for this. Unfortunately, that 10 to 15% of people to end up with recalcitrant plantar fasciitis or Achilles tendinitis.

Because there's a lack of coverage for this, it really unfortunately, puts these folks in a position where they have to go to the OR for an endoscopy plantar fasciitis release, or some other type of procedure.

There's a really good study that was done not long ago, I think, 2015 that compared the efficacy of plantar fasciitis release versus the PRP.

There was a fairly significant improvement that was seen in both groups, but you've obviously got, you know, a surgical procedure done in the operating room. The costs have to significant more significant to go to the operating room. So, I would love to see this available, to be done in the office.

I think the evidence supports it has been for, probably 10 years plus. And for heel pain for Plantar fasciitis, specifically limits people in their activities and their work.

We do the endoscopy plantar fasciitis release and have good success with it, I think we would get people back to work much faster, have significantly less complications with PRP.

Dr. Douglas: I agree. One of the problems that we have with these types of procedures when there is evidence to support, that they can have clinical benefit.

When they are not paid, what that does is it pushes these procedures to the periphery, and to the French, where it is strictly cash paid.

In which case, at least, if it is a covered procedure, a provider still has to provide preauthorization. They have to demonstrate that they're doing the right thing for the right reason.

And the patient expects it to be paid if it's not in their questions range.

When it's not paid, its cash pay only. It becomes a carrot on a stick and saying, Hey, you want to pay for this?

There's not that same level of oversight and there's not a control that goes with. So, I think, for the things that we can agree on, where it's a reasonable expectation of results.

It would be far preferable to have them pay, because the backup option, which is surgery, is not necessarily cost effective.

Dr. Loveless: One of the challenges in Medicare policy, with 21st Century Cures, is the need for robust clinical evidence to support policy decision making. And one of the challenges is that evidence is there's a lot of variability.

So, if you look at Question three, I think that addresses some of the challenges, what patient selection preparation protocol, concentration of platelet injections combination with other agents, number of direct injections duration, preparations, use of local anesthetic that damage. Does that cause any problems and are they effective?

So, there's just so many different pieces that I'm not sure the evidence answers.

So, for answering this question, if we can focus on where there's evidence to help guide these things, and where there's a lack of evidence, I think that would be the most useful in terms of helping to analyze the technology.

Dr. Douglas: This particular topic is more problematic than most. Just as you said, variability in the research protocols, makes it near impossible to really analyze and compare like to like.

If there were going to be anything, there are a million different preparations. You see it, looking through these different studies.

There are countless different collection techniques, different instruments used to distill the product. There are different preparations, they're different activating agents. They're placed in different places.

Probably, if a person, for uniformity sake and for future research to protocols.

At minimal, to have protocols that evaluate leukocyte rich versus leukocyte poor platelet rich plasma. Everything is platelet rich except for the platelet poor, which is an anomaly.

The concentration of leukocytes, the leukocyte core therapy is kind of like water and you kind of trust, put the fire out.

Leukocyte rich is more like kerosene, it tries to start a fire. That at bare minimum, those two have to be differentiated.

Beyond that, the specific procedures performed, or at least the location that is injected.

There are sorts of different variables here that one can could try to control for, but at least boiling it down to leukocyte poor or rich would give us some sort of insight as to the right preparation because right now, it's all over the map. It's, it's literally provider preferences.

Dr. Phillips: I would agree 100%. Again, as an objective observer, never used this stuff.

I heard someone else, earlier say, was more skeptical at first and was fairly impressed by the data, especially for OA.

But I really think the Achilles heel no pun intended, is, is this variability and heterogeneity of the preparations, leukocyte rich versus poor, different activating agents, degree of their arthritis, different locations.

And I feel like that is going to be the major limiting factor to covering it. What exactly are you covering? Are you covering a certain preparation? It's the lack of standardization is the most troubling thing to me.

Dr. Douglas: Dr. Philips, I left one thing out. The other thing is it needs to be compared against historical controls.

In the patella tendon, for example, there was no control for dry needling, but they injected PRP five times. All right, so what was more beneficial?

The fact that you stab the tendon five times or the fact that you inject PRP five times, it really need to be compared against historical controls or, else it's very difficult to have valid data.

Dr. Coleman: I certainly agree with that, I guess, just my review of these literature.

You know, for joints such as knee? the leukocyte poor, is probably better than leukocyte rich.

For the tendon, the leukocyte rich is probably better than the leukocytes poor.

For Carpal Tunnel Syndrome, the leukocyte rich may actually increase symptoms.

Other things with this in question three is probably 2 to 3 injections is probably better than one injection for long term benefit.

Low dose local anesthetic is probably better than high dose local anesthetic. Ultrasound guidance is probably better than doing it blind.

Certainly, the higher concentrative platelets is probably better than not.

That's the sort of things, I guess, that I saw with this particular question. But I agree. It's, there's way, way, way too many protocols.

And I think they're going to have to get this leukocyte rich and poor thing down to the T first.

Dr. Buenaventura: I just wanted to follow up with what's been said.

As far as the injection technique. Certain joints, shoulder, there's too many targets. And yeah, it's all over the map. People are injecting into the tendon, into the joint into the muscle.

But actually, what articles for the needs.

A lot of these injections on these studies were just intra-articular. Some people over intellectualized and overthink it and they start injecting into the patella tendon or though lot of collateral ligaments, …, ACL. But these studies, they just injected into the into the joint, so they kept it pretty simple.

And they compared that to steroids, placebo, Celebrex and they showed benefit.

So, that's good in the sense of the knee studies. I read about 6 or 7 of them, and they were all very simple. I use fluoroscopic guidance in my clinic and I get a little bit more sophisticated.

I'm injecting around the tendons. I just might just stick a needle in the joint and do it intra-articular. So, at least on the knee, I think there's good evidence for that.

It was just a simple injection. There wasn't too much heterogeneity, so that's what the price of injections that they were doing. I agree, yes, leukocyte rich and poor, or how many objections, it's a little harder. Other ones, they went ahead and looked at some other injections that I do. There weren't in the bibliography.

Hip arthritis was very similar to the knee. I think the studies were very good.

Then they just did a straight shot into the hips, are using fluoroscopic guidance or ultrasound guided, and they got good results.

Similarly, for back pain, pelvic pain, ultrasound guidance, and right into the joint where I'm messing around with injecting into the ligaments. And I think there's some good results there.

So that's something to consider with the knee if we are going to consider recommending it. I think, at least the injection into the joint is pretty simple.

These people that were doing this, some of them are family practice and family medicine. They were doing a blind, and they got good results, so that's something to keep in mind.

But I agree, images, you should use some type of image and guidance. I use for fluoroscopic. Lot of people with ultrasound can just cheaper and there's no X-rays.

But I think I think both would work. I don't think you need to limit it to just ultrasound.

I just recommend both, if you're going to use it one or the other, in other words.

Dr. Moore: There's no question that there's variability in the composition and the concentration of platelets here, even white blood cell count and other things. There's no question about that.

But, I think that the market has not allowed this to really grow and kind of become sophisticated in a lot of respect, because it has been pushed the periphery, is experimental.

And you know, I take orthotripsy. I think orthotripsies are extremely beneficial for a lot of different conditions. Medicare has said: OK, we're going to cover orthotripsy under these conditions, which make it almost useless.

In order to get orthotripsy covered, I have to put some under general anesthesia and use high energy orthotripsy and I can go off on that for a long time.

The bottom line is that I think there can be standardization, just like there is for durable medical equipment and other devices that have to meet specific criteria.

And, certainly, I think that some standardization can take place without waiting another 10 to 20 years for the studies to develop, in order to make this available for patients. And so, I would, I would hate to throw out this very useful and very valuable tool to wait for another 10 to 15 years for more studies to standardize this.

I think that standardization will take place and can take place with some clinical guidelines that at least highlight the components of the PRP that are most clinically significant, if that makes any sense.

Dr. Loveless: It does. I can certainly understand as a clinician and as a provider, which I've practiced, you know for quite a while. You have a products that you see is safe and that you see a benefit when you use it in your patients.

So, it makes sense that you would want that to be something to use if you have evidence and you have safety.

I think that at the same time, if you put yourself in the position of policy development with the necessity that is evidence based, I think one of the biggest challenges is this lack of clinical guidelines, lack of societal support.

And so, in reviewing the different condition, if you could focus on anything that helps to standardize, helps to address the areas that there is a lack of clarity. That is the most useful in terms of helping to resolve those issues. Unfortunately, there are areas that remain unknown and that's certainly a challenge. So, it's really a conundrum in terms of trying to answer the questions.

Dr. Douglas: One of the things that makes it very difficult is, if you rely on meta-analysis to render these judgements, if there's you, pardon me, there's an old saying, If you take a big, old load of **** and you distill it down to the best **** you still have ****

It's not terribly useful data to perform a meta-analysis on wildly varying protocols.

And this is one of these things that will likely have to evolve over time, and the industry does a reasonably good job on narrowing down on the ones that are more efficacious than not, and for various conditions.

With the literature that was presented, and only one, like I said, I was surprised but for OA in the media, I really didn't think that was going to turn out the way it did. Especially, with a lot of different studies with a lot of different conditions.

But in general, it's very difficult to really nail down a real scientific consensus when you're when your data points are all over the map.

Dr. Loveless: Yes, that's a challenge. So, as we review these, if you have any specific evidence that can help guide that or any societal guidance. That's what I think is the most useful.

I do think it's hard because I think it not been clarified. But, but as the experts, and for those that are using it, if you have any specific references or input, I'd appreciate if you could bring those up.

We're trying to figure out what the right patient, the right preparation is, how often they should be getting those sorts of questions. What, does the literature telling us to be able to try to answer those questions?

Dr. Moore: I think that from a podiatric standpoint from the clinical guidelines. We know, most of us practice using clinical guidelines.

I think certainly has been a lot of studies, but I know PRP because it hasn't been covered. It has been kind of putting the category experimental.

I think that some of those pathways haven't been fully developed just in its name. There are good studies going back a considerable amount of time over 10 years indicating its efficacy.

I think that the question is, is, you know, can you expect really good clinical guidelines using PRP with no coverage?

I think that may be tough in our world. I don't know about in the orthopedic world, but it may be tough to have a consensus in that respect because it's considered experimental.

Dr. Douglas: I would second, Dr. Moore and, say, I think what you're asking Meredith, is a chicken and the egg question.

Dr. Loveless: It is a challenge, that's for sure.

Unknown: In our clinic, just from perspective, we order a smart prep kit from harvest. They've been around for a long time.

We order those kits, we buy them, we have the machine here. We anesthetize the patients I will tell you the numbers that the improvement that we get in that respect, is pretty significant, and those patients literally are able to leave here and get back into their daily lives.

I don't think that the risk for Medicare is that high, being that these kits are not enormously expensive. What's expensive, of course, is doing this in the operating room and clearly when you're doing some of the orthopedic procedures, that's going to have to be the case.

But in our case, as one of my colleagues already pointed out, these can be done in the office very effectively with good results. Again, I would say that that from our perspective, we've been doing this for so long we know the proper technique. We do, we do have a level of trust with this particular vendor.

But I think it's not like we're getting an implant. These kits, I think cost around 200, $250 somewhere in that range and it's just, it's not a huge cost that could. And again, I would just compare that or consider that in comparison to endoscopic or some other type of procedure surgical procedure, in that respect, in the operating room.

Dr. Douglas: Along the same lines. I know that the desired outcome from a panel like this is to come up with a matrix and sort of an algorithm. Something that is very clearly quantifiable.

We're not at that point yet. Not with literature, we're not, but I will tell you that, for example, for osteoarthritis, now I've got a 45-year-old. I'm talking about doing a partial knee for isolated osteoarthritis of the knee. It be far better if I could put them off for 5- 10 years, with rich plasma or anything, quite frankly, that would be far preferable to a surgical procedure that will inevitably lend themselves to at some point down the road.

A lot of times, these are procedures not meant to generate income. They're meant to prevent a surgery procedure, which is not good for business, but it's the right thing to do.

There's not a great way to put that into a presentation. So, I wish we could come up with great profound answers here, but I'm not entirely sure, I'm going to be able to for this particular topic.

Dr. Loveless: Yes, it's these difficult ones that we end up having these meetings on, because if the evidence answers the questions clearly, it's straightforward and it becomes a standard and there becomes guidelines.

And when the evidence is not clear, it becomes much more difficult to create those guidelines or standards, and so I think that's the challenge. And I think it's particularly challenging when, you know, as a clinician, you see a benefit, but it's hard to get the supporting evidence behind it.

If we go through the box below of the different conditions, I think we can skip the safety, because you've all addressed the safety concerns, but for the different condition, If you could highlight any particular support for that particular condition, or lack of from your review of the evidence, I think that would be helpful in terms of helping to identify areas that we have strengths or weaknesses in what we currently know.

Dr. Moore: I have 15 articles, some of which are randomized studies, some of which are meta-analysis systemic reviews, specifically with plantar fasciitis that demonstrate benefits.

So, I can at least speak for plantar fasciitis that I've done my own research and have what I think is probably the latest information regarding that and would be happy to pass that along. So, I'll speak to plantar fasciitis in that respect.

Dr. Loveless: And if you could, send me those or just the name of the citations, I can get the article. That would be great.

Dr. Moore: I can send it on the zip file and get all these to you. So that's not a problem to send you the real articles.

Dr. Loveless: Thank you. Anyone want to speak on osteoarthritis?

Unknown: I don't, because I didn't like it to begin with, but I will.

So, most of the review articles that were provided. I thought ahead, 5 out of 5 one evidence that this is at least a worthwhile adjunct corticosteroid use in trying to delay totally arthroplasty or partially or via departmental arthroplasty, especially because the results were superior to hyaluronic acid which is already been approved.

Dr. Coleman: Yeah, I thought the same thing. I gave this a 4.5 for efficacy and a 5 for safety, but this is very safe. The articles indicate it's definitely better than steroids, hyaluronic acid, and placebo.

They're seeing benefits from 3 to 12, sometimes even 24 months on some of these studies. Leukocyte poor seem to be better than Leukocyte rich.

2 -3 injections generally were better than one for long term relief. In general, this was better if it was mild to moderate OA.

Dr. Ryan: Part of my hesitation about giving it more than a four for osteoarthritis of the knee, is that I don't see a lot of studies that graded out into 0, 1, 2, or 3 graded in those different strata.

Showing us, like we have with the hyaluronic acid that works better with the lower grade arthritis as opposed to higher grade arthritis, but I would give it a four out of five.

Unknown: I actually agree with Dr. Ryan. I say five, just because it was better in HA. I don't like HA either. But, no, I agree, yeah, I think clearly for lower grade osteoarthritis. The biggest problem we have right now is that we can only get HA approved for severe track departmental arthritis, which is exactly what it's terrible at, its early stages of disease.

Usually our folks that are forties, or what not, my age group, that we're desperately try to avoid surgery that will not be paid. So, in that regard, I just want to make a note, but, yes, I agree with him, and you're exactly right.

Unknown: Yes, I agree with the last two speakers. I was going to give it between a 3.5 and a 4 on efficacy for HA. The main limiting factors being quality size of studies, heterogeneity of preparations, et cetera, the data clearly sees. Thanks.

Dr. Buenaventura: I also would give for osteoarthritis and the efficacy of four. Certainly, five preferably would be if you have better ideas of protocols and types of injections and such safety as five.

Dr. Loveless: I appreciate your rating the evidence. If anyone has not yet rated for osteoarthritis of the knee. I go through and vote on, while we're on the call. I think that it is helping the discussion, as well.

Unknown: Are we supposed to vote?

Dr. Loveless: After, for the voting, but I think it's useful to hear how you're rating it. OK.

Dr. Loveless: Does anyone else have any further discussion on the plantar fasciitis?

Unknown: I would say that just the safety five efficacy based upon the studies, I would say, somewhere between 3.5 and 4.

Dr. Block: I would agree with that.

Dr. Douglas: I've got no problem.

Dr. Ryan: My comment is that I would rate it somewhere between a 4-4.5 for efficacy and the 5 for safety. But I've had plantar fasciitis, I've never had steroid injections.

But I almost wanted to have another episode of it so I could try the PRP to see how well it worked.

Dr. Bhatia: Safety, I would rate it as a 5 and efficacy 4.

Dr. Coleman: I thought safety was a 5 in efficacy a 3.5.

Dr. Loveless: Moving on to the Achilles tendinopathy.

Dr. Moore: Safety 5. Efficacy based upon the limited medical literature somewhere between a 2-3.

Dr. Coleman: Safety-5 and efficacy 3.

Dr. Bhatia: Safety-5 and efficacy 3.

Unknown: You guys, I don't mean to be a ****, safety 5 and efficacy 1, based on what I saw.

Dr. Buenaventura: Same efficacy safety 5 and efficacy of 2.

Dr. Ryan: I graded safety 5 and efficacy 2. I just couldn't see anything that stands out as if it's better than anything and then a large dose saline injection.

Unknown: I agree with the efficacy of 2, just based on data being very poor.

Dr. Loveless: Thank you. Patellar tendinopathy.

Dr. Coleman: I gave it the safety of 4.5. There was some adverse events noted with that at all on the patellar attendance of thickening and efficacy 3.5.

Dr. Douglas: All right. I'm the bear, I gave it a safety 5 of and efficacy of 1.

Dr. Buenaventura: I gave it a safety of 5 and efficacy of 3.

Dr. Ryan: I gave it a safety of 5 and efficacy of 2.5.

Dr. Loveless: Moving on to lateral epicondylitis

Dr. Coleman: I gave it to as safety of 5 and efficacy of 3.

Dr. Phillips: Efficacy of 3 and safety of 4

Dr. Ryan: I was going to vote safety of 5 and efficacy of 4.

Dr. Buenaventura: I say similar safety of 5 and efficacy or 4.

Dr. Douglas: Safety of 5 and efficacy of 3.5

Dr. Loveless: Someone mentioned with this one that the difference in the leukocyte rich vs leukocyte poor could be a factor.

Unknown: It's a difference in every single one of them.

Unknown: Leukocyte rich, PRP for this.

Unknown: Only Leukocyte rich

Unknown: It's Leukocyte rich for tendinosis, but not tendonitis. Any other inputs on this one or discussion? So Carpal Tunnel Syndrome.

Dr. Coleman: I gave this safety for 5 efficacy a 3.5. This should be leukocyte poor, usually 1 to 3 MLs with guidance for mild to moderate carpal tunnel. And that seemed to be as good as you know, splints and steroids and sailing.

Dr. Loveless: Is that from your experience or do you have evidence to go with that?

Dr. Coleman: That is reviewing the one article. I do carpal tunnel studies, probably two every day. I do a ton of these. And I've not used PRP specifically for this but I've certainly done the steroid injections.

Dr. Ryan: I was going give it a safety of five, but the efficacy of only three. I can't find anything that stands out that it's closer to surgery or that it's a better long-term relief.

Unknown: I would agree 100% with that, but there are that that subset of people who don't want to have surgery, but in general, surgery is going to be better than anything I think without a doubt with Carpal Tunnel Syndrome.

Plus, the surgery is relatively easy, as far as surgeries go, but there's that subgroup of people who don't want to have any surgery done, and then this may be an option for them.

Unknown: I won't disagree on that.

Dr. Buenaventura: I say safety of 5 and efficacy 3, for carpal tunnel. Yes.

Dr. Loveless: I know there was some discussion on rotator cuff tear. So, if any, let's go to rotator cuff care. Any discussion on that one, particularly?

Dr. Douglas: I do know, at least both from the literature and personal experience that biologic adjunct of some sort is beneficial.

The problem is, how do you quantify that? Right, because all rotator cuff tears aren't created equal. You've got different age groups, different qualities of tears, different quality of patients.

The literature that we were given does show a lack of retear over time. Now, something that's interesting, is the patient pain after surgery.

Well, let's use patients whose leukocyte poor, you would think there would be the last thing, rich, but there's going be more thing: because you have more things to bring in inflammatory mediators.

Nonetheless, the only thing is the literature actually shows, is a marginally decreased rate of retear over time, and so I cannot advocate for that trauma.

I can't, but I think it's better than not using it, but that's the extent of it.

Dr. Coleman: Yeah. I gave this a 5 for safety and probably 3, 3.5. for efficacy, it seems like it helps a little.

Dr. Buenaventura: I gave it a 5 for safety and efficacy for 3. I just think like Dr. Douglas said, it just so many muscles and tendons that make up the rotorcraft. There's no great study that there's not enough work on that one.

Dr. Phillips: I give it a safety of 5 and efficacy of 2 for the reasons mentioned before.

Dr. Ryan: I'd give it a safety of 5 and efficacy of 2. I haven't seen anything that would make it stand out as this is a preferred treatment over physical therapy or useful at the time of surgery, but I'm not sure that we can justify using it for a run of the mill someone coming in with a rotator cuff pain in the clinic.

Unknown: Oh no, I wouldn't suggest something to give someone in the clinic with a rotator cuff tear. You, got a tear, you have to fix it. As an adjunct to surgery, even me, Meredith, I'd give it a 5 for safety and a 3 for efficacy.

Dr. Loveless: Thank you, everybody. The last one on the list is chronic low back pain.

Dr. Buenaventura: As an Interventional Pain Physician, I treat a lot of back pain. So, I do lot of injections, and I've done PRP for the spine, SI joints, intradiscal injections.

I pulled out several studies, a couple of extra ones, plus, the ones that were recommend as far as control studies and such. Especially the ones I pulled about 6 of them were all positive. So, this was for intradiscal injection with Dr. …..I outside of New York in 2016.

There was the epidural, which I don't do epidural PRP, but that was a positive one. Then three SI injection ones that I pulled separately, which weren't part of the syllabus. There all positive. So, I'm going to say with little complications.

I'm going say safety of 5 and efficacy of 4.

Dr. Loveless: If you can send me those references, that would be great.

Dr. Buenaventura: Sure.

Dr. Coleman: I gave it a safety 5. And just based on the literature that we had to review, I gave that a 3, seems like it helps a little. But there's just so many different conditions that you're evaluating with that.

Dr. Ryan: Safety of 5 and efficacy of 3 also.

Dr. Phillips: I would go efficacy of 3 and a safety of 4

Dr. Loveless: So, I'll follow up with a link to have the official voting, but I appreciate your sharing that on the call.

And with a little bit of time that we have left, just a couple of questions that come to my mind that you might be able to provide some insight. In the osteoarthritis group, what about the obesity risk? Is there anything that would affect patient selection based on certain risk factors or clinical features of the patient, like obesity or duration of time that they've had their symptom, or what other things they've tried and failed?

Dr. Ryan: I'm not sure that we've got good literature differentiation between a higher BMI patient or lower BMI patient for the PRP in arthritis.

Dr. Loveless: For those of you who are using these injections or what you've seen from the literature more specifically, what would be the timing of that for something that failed Conservative treatment? And really, what does the evidence say in terms of when we it should be used?

Dr. Coleman: The review literature that I'm seeing, indicates this is probably better for the mild to moderate arthritis. Once it's severe arthritis mean, nothing is probably going to work. So, I would not think you would have to fail multiple things first before you do this, with respect to the obesity patients. I mean, that's who gets knee arthritis so I think you're going be stuck with that patient population.

Dr. Ryan: There's been a lot said and written in the orthopedic literature over the last few years about the cost of non-operative care for knee osteoarthritis in the last year, up to the replacement surgery. And I think the, the big move is going to be, how do we optimize that care so that we're giving people a chance to get better without spending in order amounts of money? Again, it's more of a big picture comment. I'm not sure any closer to actually solving that problem or that dilemma, but that's really the perspective we need to be having on this, I would think.

Dr. Loveless: Thank you. And does anyone have any other comments that they didn't get to share on any of the questions or topics, before we wrap up? Well, I want to thank all of you for your time, sharing your expertise, and taking the time to review the literature. I will send a voting link to get the voting, and if you have additional articles or literature, that would be very helpful for us to review.

I think that we'll take a look at all of that, and evaluation and trying to sort through all of the different aspects of this complicated topic. So, I, again, really appreciate all of you for participating today. You're welcome. Thanks for giving us an opportunity. Thank you. And have a great evening.