CENTERS FOR MEDICARE AND MEDICAID SERVICES

Medicare Coverage Advisory Committee (MEDCAC)

Devices to Manage Tremor in Parkinson's Disease and Essential Tremor

Clinical Endpoints

Virtual Subcommittee Meeting

March 26, 2025

Attendees

Chairperson

Joseph Ross, MD, MHS

Vice-Chair

Sanket Dhruva, MD, MPH, FACC

Voting Members

Pooja Khatri, MD

Timothy Barreiro, DO

Patient Advocate

Amy Goldsmith, MA, CCC-SLP, RAC-CT, CMAC

Industry Representative

Laura Mauri, MD, MSc

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SUBCOMMITTEE PROCEEDINGS

(The meeting was called to order at 10:00 a.m. EDT, Wednesday, March 26, 2025.)

MS. HALL: Good morning and welcome, committee chairperson, vice chairperson and panel members. I am Tara Hall, the MEDCAC coordinator. The committee is here today to discuss devices to manage tremor in Parkinson's disease and essential tremor. The MEDCAC panel will consider which clinical endpoints the studies of devices to manage tremor in Parkinson's disease and essential tremor should be of interest to CMS. Assessments of new medical technologies frequently have evidence gaps with respect to essential health outcomes that are clinically meaningful for CMS beneficiaries.

The MEDCAC panel will consider a review of the relevant clinical research and professional guidance literature along with expert commentary.

By voting on specific questions and by their discussions, MEDCAC panel members will advise CMS about the ideal clinical endpoints to measure in research studies on this topic,

as well as appropriate measurement instruments and adequate follow-up duration. This input will help provide clarity and transparency in future national coverage decisions.

For the record, members present for today's meeting are Dr. Ross, Dr. Dhruva, Ms. Goldsmith and Dr. Khatri, and Dr. Mauri. We ask that everyone state their name each time they speak, speak slow and concise so everyone can understand. Speak directly into your computer mics and do not use your speaker phone to achieve the best audio quality, to assure the transcriptionist accurately transcribes. Please assure your devices are on mute if not speaking, and please place ringers on silent.

This meeting is being held virtually in addition to the transcriptionist. By your attendance you are giving consent to the use and distribution of your name, likeness and voice during the meeting. You are also giving consent to use and distribute any personally identifiable information that you or others may disclose about you during today's meeting. Please do not disclose personal health information.

In the spirit of the Federal Advisory Committee Act and the Government in the Sunshine Act, we ask the advisory committee members take heed that their conversations about the topic at hand take place in the open forum of the meeting. The committee is reminded to please refrain from discussing the meeting topics during breaks or at lunch.

And now I would like to turn the meeting over to Dr. Steven Farmer, our chief strategy officer.

DR. FARMER: Good morning. Thank you so much for joining us today to talk about this topic.

I just wanted to give a little bit of a background and framing for why we're conducting these meetings and what role we hope that they will play for both Medicare beneficiaries and also many factions that hope to develop evidence to support coverage of items and services in the future.

So we have heard for years a desire from the public to engage more extensively with manufacturers in the premarket phase. Given staffing limitations and the number of

companies and the early stage at which manufacturers desire that input, we feel that the most efficient and effective way of conveying our expectations for manufacturers when developing evidence for new products or services is to conduct meetings like these where we review the existing endpoints that were used within therapy areas, and consider their applicability and particular nuances that may be appropriate to consider for Medicare beneficiaries. What we have or are exploring at this time is developing a library of therapeutic areas so that the public will have an opportunity to see what our expectations are across a range of topics.

We've conducted one to date on devices for treatment of type 2 diabetes, this will be the second in the series, and we hope to publish a number of others, as well as clinical endpoint reviews, and post them publicly so that manufacturers and the public can use those.

We also believe that as we're reviewing national coverage analyses that a library of clinical endpoints that are

pertinent to particular therapeutic areas will be useful to our review teams because we have a reference that has been, that has gone through an open and transparent process which enumerates the available endpoints, their clinically meaningful differences, and has at least a discussion of what kinds of durability assessments are appropriate in various different contexts for those endpoints, because we believe that will make our reviews more consistent, more predictable and generally make the whole process more effective.

So that is the background of what we're hoping to achieve here. So what are we going to do today? So firstly, you have had an opportunity to review at this point a review of endpoints for this topic that was conducted by our contractor that identified all the major research studies over a certain timeframe, and looked at the endpoints that they used. And then we researched what are any published clinically meaningful differences for each of those endpoints, and identified those in the literature review where they are available.

We've also, we also are hoping at this

meeting to discuss, or at least have some kind of back and forth about what might be an appropriate duration of followup for those endpoints in various different contexts during this meeting. What this meeting is intended to do is allow a wholesome discussion of the topic that is not that often available to us in a public meeting where the public has an opportunity to comment, and we're deliberating on specific voting question. So we're going to have that broader discussion during the meeting today and then all of these comments will be made available to the public so that they can review those ahead of the meeting if they want to incorporate those into questioning.

But the other point of this meeting is to identify the voting questions that we're going to pursue in that public meeting. And there's a balance when establishing the voting questions between efficiency and specificity. It's possible that you could vote on every single individual endpoint, but there could be dozens of those endpoints that you might want to vote on and that could take a very long time and be very tedious.

I believe that it may be more appropriate for us to think about domains for those voting questions because it's more tractable in the sort of time frames that we have available in a public meeting, but we can also make use of the deliberation and the comments in the transcript as we're reviewing where to turn in the future, and that also again, will be available to the public.

So this is just a framing of what we're hoping to accomplish today and again, CMS thanks you for your contribution and service to the public here. Thank you so much.

MS. ROGSTAD: I will begin sharing my screen and make the presentation.

MS. HALL: Teresa, could you turn on your camera?

MS. ROGSTAD: Do you see my screen now?

MS. HALL: Yes.

MS. ROGSTAD: Okay. Let me start the slide show. Good morning. I will be presenting a high level summary of the clinical endpoint review report that is the basis for, or will be the basis of the MEDCAC panel's

deliberations. I'll also give a summary of the feedback we received from three external subject matter experts.

So the primary objective of the CER report was to identify the most common clinical endpoints that are used in studies of devices for the management of Parkinson's disease and essential tremor, focusing on tremor and related motor symptoms. Secondarily, the objective was to identify the instruments or tools commonly used to measure those endpoints and to look for definitions of clinically meaningful differences for each of those instruments.

First a little bit about the two disorders. Parkinson's disease is a progressive loss of dopaminergic and other types of brainstem neurons leading to impaired motor function. Patients exhibit slowness of movement, muscle rigidity and tremor that is worse during rest and during active use of the muscles involved in that tremor. A number of non-motor symptoms also characterize Parkinson's disease.

First line treatment is pharmaceutical

with levodopa and other dopaminergic drugs. These drugs promote, or rather stimulate dopamine receptors in the brain. However, long-term use of these drugs leads to motor complications. Motor complications include loss of or wearing off of the efficacy of the drugs or what's called, those are called motor fluctuations. The other thing that has happened is the development of dyskinesia; dyskinesia involves erratic involuntary movements of various muscle groups. It's not a symptom of Parkinson's disease itself, but rather a complication of treatment. So for these reasons, nonpharmacologic treatments or devices have been developed to treat refractory Parkinson's disease and essential tremor.

A little bit about essential tremor. It is also progressive, the main symptom is tremor, but unlike with Parkinson's disease, the tremor occurs with voluntary movement. The other types of motor systems and non-motor symptoms are less extensive than they are with Parkinson's disease.

So the goal or nonpharmacologic treatment is to reduce motor complications in

Parkinson's disease and/or to provide an option for treatment in essential tremor. The examples of nonpharmacologic treatment that you see on this slide were all represented in the CER report. Deep brain stimulation was by far the technology that appeared most frequently in the research literature. Other technologies include other types of stimulation, surgery and external devices.

The CER methodology began with a systematic search of the published literature and also involved a search of the gray literature. The report collected systematic reviews of any device for the treatment of tremor associated with Parkinson's disease or essential tremor. The report also collected professional guidance documents as a source of clinical endpoints that would be considered important for monitoring patients for these disorders.

From 30 collected systematic reviews the report abstracted all the clinical endpoints for the included studies in each systematic review. Then the total list was subjected to a prioritization rule that was

based on a certain threshold of citation volume. In other words, the report identified endpoints as being important if they were used frequently in the studies represented by the collected systematic reviews.

Then looking at the professional guidance documents, the report selected endpoints that were emphasized either through implication or by explicit recommendation. In the ensuing analysis the focus was on the endpoints that were implied or represented by at least two of the five selected documents.

Then after the CER report was completed, it was sent to three external subject matter experts in academia, two neurologists and one neurosurgeon. The purpose of their review was to supplement the completed CER with a clinical perspective and to fill in some of the information gaps in that report. The version of the CER report that was reviewed by these experts is exactly the same version that was sent to the subcommittee prior to the March 10th pre-meeting. In other words, the expert input has not yet been incorporated into the CER report, but it is reflected in the Word

document that we provided that has a summary of the CER.

So in the next several slides I will be providing a condensed version of the information in the tables that appear in that Word document that I just referred to, the file name is found on this slide, and as we move on and the discussion begins, it might be helpful to have that document open on your laptop or a print copy close at hand.

So most of the clinical endpoints that were deemed important by the CER report and/or recommended by the expert reviewers fell into the domain of clinician-assessed health outcomes. These endpoints are either measured by a clinician or they are assessed in the context of a clinician-administered questionnaire. The endpoints that are in black font are the ones that are prioritized in the CER report. The expert reviewers all agreed that these were important, and they recommended additional endpoints and measurement instruments which appear in red font.

MCIDs were identified for most of the instruments. One of the questions that was

posed to the expert reviewers was whether the importance of endpoints would vary according to device type or patient subpopulation. The response was that it would not, the device type would not matter but that for a couple of patient subpopulations certain clinical endpoints were especially important. So for example, if the disease duration was greater than five to seven years, then it would be especially important to measure motor complications. And then in older adults, it is critically important to assess cognitive function and motor symptoms involving gait, balance and falls.

One of the reviewers pointed out that positive function and mood can be adversely affected not only by a Parkinson's disorder but also by some treatments, so that particular clinical endpoint also appears in the safety domain on the next slide.

Just a little bit of information about the UPDRS instrument. That stands for the United Parkinson's Disease Ratings Scale. The currently used version is a revision that was published in 2008 by the Motor Disorders

Society, MDS. So this scale includes four parts, each of which has been validated and each of which has an associated definition of minimal clinically important difference, MCID. The first part deals with non-motor symptoms, part two with motor-related activities of daily living, part three motor symptoms attributable to the disease, and part four motor complications.

I can't remember if I explained -- I did, never mind. I couldn't remember if I explained what motor complications were.

In the patient-reported outcomes domain the CER report identified disease-related quality of life as an important clinical endpoint, the expert reviewers agreed with that, and also advised that sleep quality being assessed and identified instruments for that measurement.

In the device-related safety domain, no clinical endpoints were prioritized in the CER report. They just weren't frequently discussed by these collected systematic reviews.

The expert reviewers advised that

measuring or assessing adverse events related to the devices being used would be very important. One of the reviewers differentiated between relatively serious adverse events that can occur with a more intense form of treatment, and less serious events attributable to the noninvasive variables, and that would involve mainly just comfort or skin issues.

So for essential tremor, the CER report identified a handful of tremor-related clinical endpoints with corresponding instruments. No MCIDs were found for any of these instruments. The expert reviewers did not have anything to add to this information other than to say that device-related safety should be assessed in the same manner as that for studies in Parkinson's disease devices or studies.

So in addition to prioritizing clinical endpoints that appeared in the clinical research literature, the CER report also looked at professional guidance documents. No relevant documents were identified for essential tremor but five were selected for Parkinson's disease. These included four sets

of practice guidelines. The most comprehensive was a set of guidelines produced by two organizations in Europe. A fifth document proposed ways of translating the data from wearable sensor devices to clinically meaningful endpoints.

Then moving to the right-hand side of the slide, that bullet list should look pretty familiar because it is almost the same as the clinical endpoints that were considered important in the CER report and/or recommended by the expert reviewers. The one exception is behavioral and mood changes.

The single and double asterisks refer to labels that were applied by those broad scope European guidelines. The European guidelines produced a list of recommended clinical endpoints slightly longer than the list on the slide and labeled each one as either critical, that's the single asterisk, or important but not critical, that's the double asterisk. And all of the endpoints that were considered critical by those European guidelines were also considered important by the CER report or by the expert reviewers, so

there's just a lot of good corroboration there.

Another source of corroboration of this list comes from a study that was cited in the CER where participants in two upcoming trials of Parkinson's disease treatments were asked to specify what should be measured in those trials, and the patient list also was the same as the list you see on the slide, with the exception of behavioral and mood changes.

As for cognitive decline or cognitive function, it's my recall this was a clinical endpoint that was considered important in the CER and endorsed by the expert reviewers, but it was only mentioned by the European guidelines, it didn't come up in the other practice guidelines.

So, the CER report was not able to provide information on follow-up duration that was specific to different clinical endpoints, so that question was posed to the expert reviewers, and their response was somewhat inconsistent. One of the reviewers differentiated follow-up intervals according to the device that was being studied, and also according to the clinical endpoint domain.

Applicability or generalizability to the Medicare beneficiary population is of course important to CMS. No systematic reviews or professional guidance documents that were covered in the CER report focused on older adults per se. However, the mean age across the systematic reviews were for the included study populations was 54 to 77 years, so that body of evidence was representative of an older population.

There was also a mix of disease severity across the systematic reviews. However, there was insufficient information to allow the assessment of applicability according to demographics other than age.

So as I said before, please refer to that Word document that includes the CER summary and review questions that has more detail than I presented here.

And I believe we are scheduled to go on break now, but I will turn the meeting back to Tara or Dr. Ross.

MS. HALL: I was going to say, do you want us to take a break now or do you want to just start with the discussion questions?

DR. ROSS: I just want to -- Terry's camera wasn't on and I wanted to inquire if it's necessary that we all have our cameras on like we would in any typical public meeting, so I just wanted to -- okay.

MS. ROGSTAD: My apologies. I just noticed that myself.

DR. ROSS: Okay. Before we go to the discussion questions, I wonder if anyone on the committee, and I'm just going to introduce myself briefly, and the first time that you speak, please introduce yourself so everyone knows who everyone it.

My name's Joe Ross, a general internist at Yale School of Medicine, School of Public Health, and I'm also the chair of MEDCAC.

But I wanted to see if people have questions for Terry on the, just on the review before we go into the sort of specific question, on some of the material she presented.

And I do have one, Terry, which is that I think because I'm a general internist and a little bit less familiar with these, I

notice that these are bucketed as clinician assessed, the vast majority of the endpoints, and there's only a couple that were patient reported. But I was wondering if you knew among the clinician assessed, if they do seem often that they're scaled where the clinician is asking the patient for responses. So there's sort of a blurry line between whether they're patient reported versus what I think of as a clinician-assessed outcome, in that they're making the determination without the patient's input, and I'm just curious if that came up at all in the reviews?

MS. ROGSTAD: That's exactly right. There are questions on those scales that were in that clinician-assessed bucket that can only be answered by the patients. Some of them were just flat out patient reported, and in other cases the instructions in the scale is such that a clinician to kind of make an assessment, taking the patient responses into account but making their own judgments as well. It's really a mixture.

DR. ROSS: Okay. To me that just helps us get a sense of what's the direct

measurement of the patient's experience in some of these functions.

Other questions, and for clarification, these are questions around the CER review?

DR. BARREIRO: Yeah, this is Tim Barreiro. One of the questions that I had is when I was reviewing some of them, they didn't put any timeframe on any, like how long does it take each one of these, and the practicality. I know that it's, you know, I'm a pulmonologist, so a six-minute walk assessment is pretty simple to do and that's why the utility of it is so helpful, and then the literature supports it.

Some of these were interesting at best. So did they put any consideration into the laborious nature of it or the practicality from a time and resource-related aspect of people seeing multiple people in the office on a regular basis?

MS. ROGSTAD: Not that I noticed either in the report or in any of the supporting literature that I looked at. Keep in mind that what we're thinking about are

clinical endpoints to be measured in a clinical study, not necessarily to be measured in every patient encounter, you know, in clinical medicine. But yeah, if you went through the whole UPDRS, it would take a long time I would think.

DR. MAURI: This is Laura Mauri. I think that clarification is really helpful since our intention here is to talk about endpoints in clinical studies rather than clinical practice guidelines per se.

I had two additional questions. One was to clarify that the source documents that were included in the review, while they started at a certain time point, I think it was 2014 --

MS. ROGSTAD: 2018.

DR. MAURI: 2018, sorry. But they referred to trials that occurred earlier than that. The reviews occurred at that time but they referred to trials that occurred earlier than that; is that correct?

MS. ROGSTAD: Absolutely, yes.

DR. MAURI: That's helpful, because there's a large body of randomized trials published in high profile journals that goes

back at least a decade or two before that, so that's very helpful to clarify.

There was one other comment that you made in summarizing the reviews from, that happened by the physicians after the CER was prepared, and I noticed there was a question about what if there was a variation of endpoints according to device type. And I saw that the responses came up, or conclusions came up in multiple different categories and maybe not all pooled into one direct question on that topic. And so for example, the response from, I think it was Dr. Samachano (phonetic) on the safety endpoint pertained to both efficacy and safety, and thinking about the range of these devices have different expected effectiveness outcomes as well as potentially different safety related outcomes, as well as the question of, you know, which outcomes are truly safety versus efficacy.

I think it might be important to call out some of that and maybe we will more so in our discussion, so I just wanted to point out that the conclusion that I drew in looking at the summary of the reviews was not that there

was no variation across the various devices aside from the age variation that you mentioned, but rather that there might be different mechanisms that applied for both safety and efficacy. Does that fit with what you, how you interpret the overall answers to the questions that the clinicians provided?

MS. ROGSTAD: I guess I'm not sure when you mean about differences in mechanism by device.

DR. MAURI: Like for example, Dr. Samachano talks about you might have a sensor that's placed on the wrist that you want to measure, and is there any difficulty with the wrist and any potential discomfort or complications related to the wrist, whereas if you have an eclantic (phonetic) product that goes into the brain or if there's an ablation or a stimulation in the brain by other mechanisms, then we need to measure the difference in outcomes (inaudible, static)

MS. ROGSTAD: Right. Yeah. There was some explicit feedback on the differences in the kinds of safety outcomes that could occur from different devices. And obviously the

example that you just pointed out, you know, robotic gait training or gait split is not going to lead to a difference in time probably. That just didn't come out explicitly in the reviewers' responses, at least from what I received.

DR. ROSS: Sanket, I see that your hand is up, so I appreciate that you're using that, but Tim, you put into the chat that you had a question about the a point Laura made. Just for everyone to know, we should say everything out loud, we shouldn't be using the chat for communications. But Tim, if you want to follow up on a point that Laura made, why don't you go first, and then Sanket, we'll go to you.

DR. BARREIRO: Yeah, thank you. I was just reading the initial thing and that's why I wanted clarification on it. So it says that well-developed CMS developed guidance on important clinical endpoints and studies of devices for the management of tremors in patients. Are we based on -- my question then, are we just looking at the safety of the device and what should we be approving, or if the

device doesn't have a clinical presence, I don't know if I can separate the two. So I just, and I apologize but I'm just looking for clarity, because there's lot of devices of which, if you're just looking for safety, they can get by, but they actually have no clinical endpoints to say they're improving the patient.

DR. ROSS: I think -- oh, Terry, do you want to answer the question?

MS. ROGSTAD: Well, the intent was to capture clinical endpoints that relate to both efficacy and safety, and that's why they were, you know, they were categorized according to those different domains.

DR. BARREIRO: Okay. I don't know if I'm more confused or less, but nonetheless, I'll just follow.

MS. ROGSTAD: Well, you know, all of this is to support future national coverage determinations, and those of course are based on both efficacy and safety.

DR. BARREIRO: Okay, thank you.

DR. ROSS: Tim, if I could help perhaps, I think Steve's directive to our group is to help identify the endpoints that are most

important that should be evaluated as part of clinical studies for treatment of these conditions, for medical devices treating this condition. So then we can be sort of signaling kind of, what are the most important types of information that sponsors should be generating in order to bring this sort of to CMS as part of our coverage determinations.

DR. BARREIRO: That was helpful, thank you.

DR. ROSS: Sanket, your hand had gone up.

DR. DHRUVA: Thanks, Sanket Dhruva, UCSF cardiology. One of the questions that I had is a little bit more methodologic, Terry, is the CER goes up to August of 2023 and is prioritizing citations. And we know that it takes time for citations to accrue, that is, a paper that was published in early 2023 is likely to be cited only a couple of times, whereas one in 2013 or 2018 is going to have a much higher rate of citations.

I'm wondering if -- I realize that the systematic review seemed very robust, but I'm wondering if that's something that we need to

grapple with, because there are other ways to kind of get at that, you know, citations per year or something to that effect. And I guess, although coming in it seems pretty comprehensive, we may be biasing towards older instruments that have been around for some time, and I'm just wondering your thoughts on that, if there might be any considerations that we should have as we think about that.

MS. ROGSTAD: That's a good point. I suppose we could do a couple different things. One is to request, when we start these reviews, is request some sort of analysis of a trend over time, you know, for clinical endpoints studied a lot in the past and not recently. The other thing maybe, although this is a resource question, is whether it's worth doing a quick update search, you know, right when we get ready to post something or present it to the MEDCAC panel.

DR. FARMER: Just one additional point of clarification. While CMS might review endpoints that are pertinent for particular therapeutic areas and publish those and speak about the various domains, but there's no

requirement that you must submit any or all of those. If you have a relevant alternative measure that you would like to submit, you certainly can do that and those will be reviewed on their own merits.

What we're trying to do is say this is what we've identified in the literature as most important endpoints, and have some discussion of relevancy specific to the Medicare beneficiary population.

DR. DHRUVA: Got it, thanks. So Steve Farmer, do I understand correctly that what we are working on here as a MEDCAC is to get some general guidance, here is what we're finding, but by no means is that exclusive. If a device manufacturer is developing a device, they do not necessarily need to do one of these. This is a vetted list at the end of the day, but not necessarily a comprehensive or exclusive list.

DR. FARMER: That is correct.

DR. DHRUVA: Thanks.

DR. ROSS: Terry, I was going to ask you, I was trying to pull up the -- we'll get into the sort of specific questions we've been asked to I think pretty soon, but I just wanted

to ask one other question, which is, I notice that this evidence review was focused on the endpoints that were identified in clinical studies of devices and I wondered, again more out of my lack of expertise, how common would these endpoints be if we were looking at pharmaceutical therapies? As in, I know the safety endpoints would likely be quite different for a procedure versus, you know, medication taken, but in terms of the effectiveness of outcomes, both clinically assessed and patient reported, would there be a substantial amount of overlap or would there be different endpoints that might have been identified?

You may not actually know this because that wasn't what the review was.

MS. ROGSTAD: Well, the professional guidelines were introduced to that question indirectly, because they were not necessarily restricted to recommendations regarding device treatments. So they included, you know, some of them included pharmaceutical treatments as well, and there didn't seem to be much differentiation, much difference.

DR. ROSS: Okay, that's helpful.

MS. ROGSTAD: Of course, well, one difference would be motor complications which are, you know, an adverse event of the drugs, but then with, if you're looking at a device, you would want to see if those diminish.

DR. ROSS: Right, like the motor fluctuation.

MS. ROGSTAD: Right.

DR. ROSS: Any other clarifying questions before we go into the discussion of the questions that have been posed to the group? Yeah, Laura?

DR. MAURI: I apologize, I'm not -- maybe I can figure it out at a break, but I'm not using the hand.

DR. ROSS: It's okay, it's a small group. We can manage.

DR. MAURI: Well, this relates to a couple of the questions that you asked, Joe. I just wanted to follow up and it relates to, and maybe we can discuss more but I'm interested to hear, Teresa, your thoughts around this, and it's the balance between clinician-reported and patient-reported outcomes, and understanding

their attendant discrepancies.

So it's a little different than Joe's original question about what's assessed by the clinician, but rather for example, I know that one of the endpoints that's been used in studies in randomized trials is the patient motor diary to look for the on time dyskinesia as an outcome for DBS is one example that is patient reported. And at the same time it reflects the perception of the patient and it seems that it could cross over into device studies.

Two question about that I suppose. One is that that's not included in the list that was circulated, so I wonder if that's one that we should look into because it has been used in randomized trials.

But the second part of it is getting the thoughts around how you weigh clinician-reported versus patient-reported outcomes in this space as we go into our discussion.

MS. ROGSTAD: I'll have to double check to make sure, but I think that those European guidelines that I talked about, they

specifically recommend a patient diary of motor fluctuations. I'll look that up and provide the information, or I'll look it up during the break.

And then as far as the relative importance between clinician and patient-reported outcomes, that just, that was beyond the scope of the report.

DR. ROSS: Laura, if I can jump in, this is Joe again. To absolve Terry of having to answer that question, actually part of what we're going to be asked to do is vote on that when it could comes time at the next meeting. So we will be sort of looking at blocks of endpoints by domain, and I haven't looked forward at the way the voting questions were asked, but in the last time it was, you know, among the surrogate markers, how important were they, which were the ones that were the most important among the clinician assessed, which were most of them. So we will be giving feedback to CMS on our perception of the relative importance of a patient-reported outcome versus a clinician assessment endpoint.

DR. MAURI: Okay, thank you.

DR. ROSS: Pooja.

DR. KHATRI: Hi. Pooja Khatri, Yale neurologist. So I just wanted to clarify one thing that I'm trying to understand, that the goal here is coverage decisions. So for example, we might have device trials that are trying to prove a concept, in which case to Dr. Mauri's point, that might be something that, where we want to measure the impairment that's being assessed as opposed to, you know, more of a patient-centered outcome that's, you know, quality of life being more heavily weighed. So I just wanted to make sure for my own framing that I understood that overall our goal here is to talk about endpoints for its clinical use in sort of the development pipeline necessarily.

MS. ROGSTAD: Actually, I'll let Steve just comment on this as well, but I think we are talking about clinical endpoints that would be measured in evidence development, because the audience for this information is manufacturers and sponsors of clinical trials that would then serve as the evidence base for a coverage determination.

DR. FARMER: So just to comment on that, there's an arc of development of both drugs and devices where during the early state of development there may be a greater emphasis on surrogate endpoints because they may have greater change, might have allowed for smaller numbers, shorter followup. But if you rely solely on those surrogate endpoints with short durations of followup, historically CMS has found gaps in the evidence base to find the authorization relative to our assessment as reasonable and necessary, which is our legal obligation to assess when making coverage determinations.

So what we're trying to do here is to express the type of endpoints or RNN that would be relevant. Again for manufacturers, if you're thinking about the fertile public life cycle in your development effort, you might want to commend on both short-term surrogate endpoints of developmental endpoints that are emphasizing your FDA review process, but also be thinking longer term as well at the same time in building in those clinical endpoints that demonstrate improved health outcomes so

that your full fertile public lifestyle development is more efficient.

DR. ROSS: Tim?

DR. BARREIRO: Yes, thank you, although Steve, maybe it's just me, I'm having a hard time hearing you. I don't know if that's your soft voice or just my bad computer, but nevertheless, I think I got the gist.

My question, then, is around these last comments. None of these papers told us how much the device costs, and is that something that we are considering in this evaluation, or just looking at it could cost whatever at a minimal output or clinical benefit. Because none of this information has provided the cost of the device in and of itself, and I'm sure that has to weigh into a coverage benefit plan.

DR. ROSS: No, no, we're actually completely device agnostic here. We're only talking about the endpoints. So whether, whatever this is, we don't know which devices may come to CMS for purposes of a coverage decision that are being used to treat Parkinson's disease or essential tremor, so

we're just focused on the endpoints.

DR. BARREIRO: Okay.

MS. ROGSTAD: And also, CMS is prohibited by statute in considering costs in a coverage decision, so we don't capture any kind of, in the CERs, we don't capture any kind of cost measurements.

DR. ROSS: Sanket?

DR. DHRUVA: Sanket Dhruva, UCSF. I just wanted to emphasize, when I was reading for example the U -- I'm forgetting the title now -- the UPDRS this morning, so I just wanted to emphasize, just getting to Joe's initial point, a lot of the domains, although this is clinician assessed, a lot of the domains say for the clinician to ask the patient how often in the past week have you had X, Y, Z, hallucinations, non-motor symptoms, et cetera. So I do think that for the clinician or the observer, I don't know, the researcher I suppose when conducting the research studies is engaging directly with the patient, so I do think that the line is a little bit more blurred here where we are asking, instead of having the patient directly check off a box or

put a number into a, into a survey for a PRO, that they are telling a clinician, but the lines are a bit blurred, as opposed to a clinician necessarily assessing.

But there are some domains where the clinician is actually examining the patient and looking at their tremor, looking at the rigidity, so it's kind of a hybrid assessment tool but one that is, that has some clinician and some that I would argue are a bit more patient centered, but obviously that can lead to potential bias, what does the patient tell the observer or the researcher, and would that be different than if the patient was checking of a box himself.

I just wanted to make that point of clarification.

MS. ROGSTAD: Yeah, and maybe when I present the CER to the panel, I will make that point.

DR. ROSS: Yeah, I do think actually that could be useful, if there are just, to even identify which measures are hybrid and which measures are solely clinician assessed.

MS. ROGSTAD: Okay.

DR. ROSS: Pooja, I don't know if you feel that you could speak to this as a neurologist, in terms of have you used these terms in the past, I don't know. It would probably help all of us who are here about your experience, you know, working with these measurement tools.

DR. KHATRI: You know, offhand, I am a stroke specialist so I remember them, you know, in residency, and I actually was involved in one study where I used the UPDRS maybe 20 years ago, so I'm not that much of an expert. I think the experts there are better, but I am familiar enough with them to just speak to sort of their reputation and base validity.

DR. ROSS: Okay. Laura, were you going to say something?

DR. MAURI: Yes. I was going to ask about the MCID topic, because I recognize that the MCID was not able to be ascertained from the systematic reviews, but then there are specific references if you search for the MCID of the different scales. And I was wondering about how that could be incorporated for the panel discussion.

MS. ROGSTAD: We did include a suggestion or example of a voting question on that issue, I think. That's the sort of thing where discussion is particularly helpful. Where there are no MCIDs, the expertise that panelists have to offer on that issue is helpful to CMS. I'm not sure what you're asking for exactly.

DR. MAURI: I guess my question is for example, if you look in the published literature aside from the systematic review you can find, for example there's a paper that recommends an MCID of five, and it could be something that's useful to provide to the panel for discussion, so they come in with that information.

MS. ROGSTAD: Oh, that was done. The producers of the CER report did conduct focused searches looking specifically for MCIDs, and in those slides and also in the document that summarizes the CER in the tables, there's an asterisk next to the instruments for which an MCID has been identified.

DR. MAURI: Okay, great. Thank you.

MS. ROGSTAD: There's also in the

appendix of the full report, there's a table devoted to that information. Sorry I didn't make that clear.

DR. ROSS: That's okay. It looks like for people who want to pull it up, it's in Table C.1 in the appendix. Does that sound right?

MS. ROGSTAD: Yes, it does.

DR. ROSS: I'm just waiting for a file to open.

MS. ROGSTAD: And in your summary document, I guess I just incorporated it into, not the numerical information, but I incorporated it into the availability of an MCID. No, I think you just need to go to Appendix C.1 in the full CER.

DR. MAURI: Yeah, I see it now. I apologize, Teresa.

DR. ROSS: Provided there aren't any other clarifying questions, there's a list of six or so discussion questions for us just to go through. If people are okay, maybe we could keep going and not have a break, and then break for lunch maybe a little earlier if that works for people.

But the first discussion question, and we may not have much to say about any of these, but the point is to elicit any discussion if people want to talk about it, is did the clinical evidence review capture the appropriate literature. And so in our comments already around clarification we talked about the pharmaceutical intervention literature and the different sort of dates in terms of how far back it captures.

But is there any, do people feel like this was the appropriate literature to search for this question, and is there other literature that you would have wanted to have seen included?

DR. KHATRI: I found this to be quite comprehensive.

DR. DHRUVA: I would agree, and I think I felt reassured when looking through the two neurologists and the one neurosurgeon reviews as well, that they didn't seem to identify much more. I realize there were a few additions and Terry has thoughtfully included those, but there didn't seem to be any big misses.

DR. ROSS: Well, this is Joe. I guess I did want to follow up with Terry on that. I did think it was kind of interesting there were a lot of what I perceived as a number of additions, and I think that had to do with the approach in the evidence review to have a priority quantification, so essentially the original one just had the ones that were cited for reviews at the very most, whereas the experts then said well yeah, those are probably what was reviewed the most, but these other ones are also important, and have since been incorporated.

But I never got the sense that those endpoints that were put forward by the experts weren't in the reviews, it's just that they weren't, they didn't like rise to the top, and I just wanted to clarify that that's right.

MS. ROGSTAD: That is correct, and in some instances like with -- well, I guess I only see one example. The reviewers recommended that speech function and swallowing be assessed and that is, you know, that's actually one item within the non-motor symptom part of the PDRS, so it's a little bit

duplicative of something that's already been mentioned.

DR. ROSS: Okay.

MS. ROGSTAD: But yeah, everything that was recommended by the expert reviewers did show up in the systematic reviews, it may not have shown up as frequently in order to meet that prioritization threshold.

DR. ROSS: That's fine, thank you.

DR. MAURI: I agree that the combined prepared review with the comments from the reviewers was very comprehensive.

DR. ROSS: This is Joe. So the second question that follows from that is between the clinical evidence review and the external expert reviewers, do we all believe that the most important outcome domains have been identified and that the most important clinical endpoints have been identified? And some of us will have more expertise to speak to other endpoints that may not have been identified, but I'm curious if people, if there was anything that people thought was missing in terms of outcome domains or clinical endpoints.

DR. KHATRI: I'll just add as a

neurologist taking care of patients, I really did think it was quite appropriate and inclusive. I was glad to see the added comments about dysphasia for example, trouble swallowing and things like that. You know, caring for patients like that, I can't think of any measure that rises to the top that was missed.

DR. MAURI: This is Laura Mauri again. I made the comment and Teresa addressed it about the patient motor diary, that that could help complement, to call out the patient perception and reporting of their motor symptoms. And I recognize that it's already included and available for comment of the panel, and if it's raised up perhaps, it might be helpful.

DR. KHATRI: You know, if I could just add, Laura, Dr. Mauri, that I couldn't agree with you more. I'm glad you brought that up, I should have probably mentioned that in my first comment. I think that, you know, these patients go through so many changes, and then on top of that they're slow and they have cognitive delay in many cases, and so something

like a diary can really help get a grip on these patients and how they're will feeling, how they're really doing.

MS. GOLDSMITH: Hi, this is Amy Goldsmith, and I thought, I agree with everybody's comment. I think it was very comprehensive and I think, my one question, and I apologize if this was addressed somewhere and I missed it, but how was it identified what was sort of a priority one star and just a mentionable two star? Was that based on, you know, I guess I would like to see if that was really from the patient's perspective, that what they find most important versus what was identified in the study, I was just curious about that.

MS. ROGSTAD: I assume you're referring to the critical versus important but not critical designation. That was in one set of practice guidelines produced in Europe, and I believe that was simply our expert consensus, not empirically divided.

MS. GOLDSMITH: Right, okay. I think that's just really important to get that.

MS. ROGSTAD: Right, but to that point

as I mentioned, there was this one study cited in the CER where they polled prospective trial participants on what they think should be included in the upcoming trial of Parkinson's treatment, and their list was very similar to what the experts had recommended, you know, without differentiating between critical and important.

MS. GOLDSMITH: And I also echo the patient diary being so critical. I think that's a very good point, especially when tracking as the disease progresses. And lumping in speech and swallowing, as a speech pathologist I just think that's such a critical piece with patients' quality of life, and such a huge piece and such a driver for so many patients, that I'd like to see that rise to the top, and what Dr. Khatri was saying, I agree with.

DR. ROSS: This is Joe. I also though it was quite comprehensive. There were two questions about endpoints that I expected to see that I didn't. One I think is with sort of just the traditional like ADL, IADL measures. It seems though like there's just very motor

specific ADL measures instead, as opposed to sort of the broader ADLs, IADLs, and I wondered whether, you know, as disease progresses and symptoms are more severe, whether those sort of less specific but kind of broader measures might also have been used or reported on, if those were discussed.

And then the second is, I didn't see any measures around caregiver or caregiver burden, and we know that, you know, that sometimes these patients with more progressive disease and cognitive dysfunction is part of that, and I didn't know if those came up at all in any of the reviews, so I just wanted to raise that and ask about it.

MS. ROGSTAD: Yeah. I don't believe that the traditional ADL categories came up, I'll double check on that. And I considered not using that term, you know, replacing it in the CER in my summary of it, because that's where peoples' thoughts go to first, but motor-related ADL is the phrase that's used in that section of the UPDRS.

As for caregiver burden I think, and I'll check on this too, I think there are some

items related to that in the UPDRS. I'll check on that during the break.

DR. ROSS: Thank you.

DR. DHRUVA: I'll just jump in to mention, one of the challenges I think is safety, and I don't think that there is a good solution, but I was wondering if we could grapple with it for a couple of minutes, in that a noninvasive device, as was clear, a noninvasive device would have different risks than an invasive device. A permanently implanted device is going to have different risks than an ablation, the procedure itself is going to have different risks. And so it seems to me that the adverse events, and that came out in the expert reviewers, I'm forgetting, one of the three reviewers had mentioned this as well, but obviously it's intuitive to all of us.

So it seems to me that the safety endpoints, the direct adverse events associated with potentially a procedure or device are going to necessarily be different across the devices, and for those devices that may be developed that we don't know, you know,

whatever's in development that we're not aware of yet, I don't think there is a right answer, but it seems to me that this is one area that's going to require a lot of heterogeneity and, I don't know if flexible is the right term, but looking at what we think could actually be a device-related adverse event.

MS. ROGSTAD: Yeah. There was a little more detail on that provided by the reviewer than what I showed in the slide, so if you look at Table A.1 in the summary document, it is a little more detailed there about the adverse events that are attributable to different kinds of devices, but some of them are common across all of them.

DR. ROSS: The next question that was posed to us for discussion is, are there any key differences in the clinical endpoints that are appropriate for different patient subpopulations and different kinds of devices?

And I guess, Sanket, your point gets to this, which is that the safety-related outcomes may differ by device type, but they may also differ by subpopulation. And so I'm also curious of peoples' thoughts around the

sort of efficacy or effectiveness endpoints, if those differ and you know, if they should be considered differently for different subpopulations or different types of devices. Sanket?

DR. DHRUVA: I thought it was really helpful to hear from one of the reviewers about the importance of thinking about older adults and cognition, as well as mobility and the effect on gait and the effect on falls. I think to me, that is something that is critically important, especially when thinking about the Medicare population compared to younger adults. I think similarly with regards to safety, the risks and benefits may differ in an older adult of a given procedure than a younger person, and the effect of all time morbidity.

But definitely, I think that cognition and gait, falls, there can be so many different negative ramifications in terms of a spiraling lifecycle if an older adult has a bad fall or has worsening cognition of course.

DR. MAURI: Laura Mauri. I think it was really helpful content to make us think

about the preparation for the discussion that will happen with the panel. It could be helpful to segment by population, and I know some of the factors there were duration, by disease state, and then by device type, and to segment the endpoints in the discussion along those lines. That's why I think having that critical clinician discussion about expected benefits and risks and how they vary across these different factors could be really helpful in maybe preparing for that discussion with segmenting information, and that would be helpful for the review.

MS. ROGSTAD: There might be information in the handful of systematic reviews that said anything about adverse events. I can look at those and see if there's, you know, something that helps differentiate what to expect from different devices.

DR. ROSS: Other comments or reflections on this one? Well then, the next discussion question is, have the most important measurement instruments been identified? It's hard to think that beyond the review and then

the experts, that there weren't other instruments, but -- oh, Tim.

DR. BARREIRO: While there is palliative care issues, you know, and end of life issues included in some of these long questionnaires, some aren't just specific for that aspect, essentially going back to the comments about the older population, so I don't know if that was something that the group should consider.

And then the second part is that under the sleep quality, I notice that if that was the Epworth or the Berlin questionnaire were not included in some of the references, which are considered -- I mean, CMS demands it for sleep apnea, I'm not sure why they wouldn't demand it for X, Y and Z. So those are the two that stood out.

MS. ROGSTAD: Did you say Epworth and Berlin instruments?

DR. BARREIRO: Yes.

MS. ROGSTAD: Are those general or specific to sleep apnea?

DR. BARREIRO: They are specific to sleep disorder or sleepiness.

MS. ROGSTAD: Okay.

DR. BARREIRO: I do know that the Epworth is proprietary, or I'm not a hundred percent sure on that or who uses it.

And then you know, in the hospital a lot of people use the STOP-Bang questionnaire but that's, you know, I didn't want to get into that because I deal with people in the ICU that deal with these devices when they're going, and again, I think we should be looking at what can we do to improve people's life, and not what to do after the fact, and what to do if someone's in a crisis, so it's a little bit different, my thought process in trying to bring that into the counsel.

DR. ROSS: Tim, do you know, like the Epworth score or the Berlin score, how different they are from the PDSS, are they just broadly similar or --

DR. BARREIRO: The Berlin is very laborious and very detailed with a high sensitivity. The Epworth is just sleepiness, with a very poor correlation to sleep, but is demanded by CMS to get someone into a sleep study, which is very interesting to me. The

STOP-Bang is a very highly utilized tool to determine high risk for operative surgeries for people in the hospital, to determine whether or not they're missing a sleep disorder that may be a long-term quality issue or keep them in the hospital for a lengthy stay. So they are different across the board again, but looking at, again, to this whole question that we brought back, how do we judge these, who's doing them, all of these things in between there.

Simply most of them are, on, the Berlin the patient does, the other ones we ask them, but they can do them themselves.

DR. ROSS: Pooja?

DR. KHATRI: Yes, Pooja. It's interesting thinking about what you said in terms of the sleep measurements, Timothy, and I -- and so daytime sleepiness is of course a big part of Parkinson's, but then REM behavior disorder, we would not necessarily capture that with the Epworth for example. I mean, it could affect a little bit the quality of sleep, but it's more of a quality of life issue at night, and a safety issue. So I guess it's partly

captured by quality of life, but I just wanted to kind of share that thinking out loud, that and restless leg syndrome being a big component of Parkinson's disease.

Maybe I'll just add a related comment/question to our sleep specialists which is, this is something I don't know the answer to, but would we expect devices that target tremor to have any impact on things like REM-sleep behavior disorder, restless leg syndrome?

DR. BARREIRO: I do think that there's a possibility depending on the type of the device that it may mask it to some degree, or reduce it, but I think in general that because it's central in nature it would be easy to pick up on a full study. I'm just trying to follow in order, sorry.

The other thing that, as a pulmonologist, is that they deal with a lot of respiratory failure, so things that again, were a little bit interesting, spirometry, again depending on how the device motor functions before its expiratory forces are at vital capacity and declining function, and whether

people are acutely declining are important to a pulmonary plan and that may also be something to look at as part of that.

But again, I'm looking at that specifically as a subspecialist device, not for the general function, but we do know that the majority of them end up with pulmonary issues and mainly from aspiration or otherwise. So these are things that stood out to me. I see patients with advanced Parkinson's too late in their course to get them into the sleep lab and to get a functional assessment, and these are the things that stood out to me. Thanks.

DR. ROSS: Amy, do you have any comment on the swallow measures that were used or the instruments, or do they generally capture what you would have expected?

MS. GOLDSMITH: Yes, I didn't see anything that sticks out. You know, of course just from my own vantage point I just focus on that and how important this is, how important all of these pieces are, but yeah. And then you know, I'm the only that isn't a clinician here, so I will just appreciate the perspective and just, you know, it's just interesting to

look at it from, you know, what CMS will approve and use. And you know, when I see these patients, I just feel like they would try anything, so I feel like sometimes, you know, I hope everything gets to the docket so they can have that option.

DR. ROSS: So the next discussion question goes to the point that Laura was bringing up earlier around minimum clinically important differences, which we didn't review in much detail but they did, the question is, have available MCIDs from important clinical endpoints been identified?

Do you want to pull up appendix materials, Table C.1. For each of the instruments, it does appear that an MCID is listed. It's a little bit hard, it's like the one for the fog, it says it's three scale points but it doesn't say what the MCID is. The TUG, I assume it's 3.8 points, but it says MCD, not MCID, so that may be a typo. But for all of the UPDRS ones there seems to be a very clearly listed MCID along with several of the others. I don't have enough experience with these instruments to know whether I,

quote-unquote, buy the MCID, like if I agree with it or not, but if anyone has comments they want to make, or even additional material that they would want to see prepared for the full discussion as a larger group, if there's anything missing as you're looking at this table.

MS. ROGSTAD: This is Terry Rogstad. Just a word on this. MDC is minimal detectable change, which is more or less a statistical concept, not a good substitute for MCID, so I didn't highlight that in the summary. But I can say that no MCIDs were identified for any of the instruments that were used in essential tremor studies, just the MDC calculation.

MS. GOLDSMITH: This is Amy Goldsmith. I didn't see the get up and go listed. Was that something that is so common, is that not something they use?

MS. ROGSTAD: It was in there I thought, yeah. It might be an acronym that you don't recognize right away.

MS. GOLDSMITH: We refer to it all the time.

MS. ROGSTAD: Yeah. I think the full

name is time to get up and go, so I think it begins with a T.

MS. GOLDSMITH: Okay.

DR. ROSS: That might be the TUG that's listed as T-U-G.

MS. ROGSTAD: Let me look at the TUG, let me look at the T. Yes, TUG stands for timed up and go test.

MS. GOLDSMITH: Oh, you know what, it's right here, I see it. Thank you.

DR. ROSS: And Terry, just because I was getting to the end of the table just as you were saying that, I was noticing the same thing, that there aren't MCIDs listed for the essential tremor related endpoints. Do you think that's just because it's much less well studied so there's just not as many, there hasn't been as much research into the use of the endpoints as characteristics?

MS. ROGSTAD: No. The reason, it was also interesting that there were no practice guidelines identified for managing essential tremor, and I don't know enough to say why.

DR. KHATRI: You know, it's relatively treatable and not progressive, and so I'm sure

that plays into the level of research around it.

DR. ROSS: Sanket?

DR. DHRUVA: I also not being familiar with these instruments or using them in clinical practice, I also hung my hat on the three reviewers. And I think it's great that there was one from the neurosurgeon and the neurologists overall, and they didn't identify any, they didn't list anything additional except for the MoCA, which is actually one of the instruments that I am familiar with from clinical practice. And the instrument that was just in a publication last year was in people rehabilitating from a stroke and so it was not in the Parkinson's disease population. I just did a quick search and could not find anything in the Parkinson's population so I don't know. I think I found something in my patients with subarachnoid bleeds as well, so I don't, that I think is just a reported widely used instrument, the MoCA, and Pooja, you may ave way more expertise here, so I wanted your comments.

DR. KHATRI: Yeah. So the strip test

was listed and that's measuring more executive dysfunction, which is the most common cognitive component affected in Parkinson's disease. But I did like the suggestion of the MoCA because it would capture, you know, broader cognitive dysfunction as well, and like you said, it's widely clinically used.

DR. DHRUVA: That's helpful. And do you have any concerns about the validation, about the MCID being different in a different population than from Parkinson's, or should we kind of take what we have essentially, from that publication.

DR. KHATRI: That's a good question. I'm thinking about that. I think you could imagine, I think we take what we have. I can imagine justification for different MCIDs but I think it would be pretty tough for us to decide how to do that without a big formal study to like take a stand on it.

DR. DHRUVA: Thank you.

DR. MAURI: This is Laura. I'll just weigh in on your original question, Joe, about whether there's any additional information we need on the MCIDs. I think I've seen a table,

I think it's very helpful, and I think it points to the references that are relevant that could be used to guide the discussion for the panel. I think that panel discussion will be very interesting and important.

You know, one question that arises is, you know, in the areas where there is a newer endpoint or perhaps less validation, that may be of interest to see any difference, any statistical difference rather than an MCID when we don't have one available, but that's just a high level comment, I think, and the panel discussion will really be key.

DR. ROSS: The last discussion question that has been posed to us is what is the domain specific minimum durations of followup that should be observed in studies of devices to manage Parkinson's and essential tremor. By domain specific, I think what's being implied is the clinician assessed versus patient reported versus safety. And I'm curious, Steve, like this to me feels more like a question for the main meeting, but is it more, is it intended to just elicit like our initial thoughts on what durations of followup

we would have expected to see?

DR. FARMER: Yeah. I think in our first subcommittee what he had tried to do was be concrete so that we could have a panel vote on a specific duration of followup in different contexts. What was clear from the first subcommittee panel was that we would have a proliferation of voting questions that is not practical, and so what I have concluded is that it's better for us to have at least a conversation around some of the considerations that you might want to think through as you approach various different types of technology and circumstances that can be derived from the subcommittee or the full panel committee.

So your comments here can be supplemental to the full panel, so yes, whatever preliminary thoughts.

DR. MAURI: You know, my thought is that it really turns to that segmentation that I was talking about earlier, this is Laura Mauri. It relates to that segmentation that the durations of endpoints most relevant to the populations, situation, disease type and even the device type of the intervention. I think

it's immediately apparent, some safety things are obvious while others will take time to occur. So that same sort of, I don't know how that's going to look in terms of how I might present that for discussion, but I think that same segmentation could be helpful in framing the discussion for the panel.

DR. ROSS: Thanks, Laura. I mean, I think looking at what the expert reviewers said, my general sense is pretty similar, right? You know, when you're thinking about safety, particularly for intervention devices, you want to know that right away, like the first 14 days or one month. But the clinician assessed or patient reported outcome measures, you know, somewhere around three to six months, longer is better but you know, I'm less worried if they're shorter term in the sense that these are all, you know, actual outcome measures, so not surrogates, since I feel like if we were observing improvement within a six-month period, that's actually pretty great, and that's convincing to me. You know, whether it persists is a different question, but you know, there's at least good evidence. While you

always want longer term evidence, I think that six months for benefits is pretty good. Sanket?

DR. DHRUVA: Thanks, Joe. I certainly agree with you. I think that, and this is an out of what we're discussing, but I think it also depends on what the control is in the study, because some of these outcomes could be -- for example, if there's a sham control procedure, that I think then, a shorter duration of followup is more appropriate. If there is not a sham procedure with adequate blinding, then there is the potential for seeing some changes in some of the endpoints that may be less objective but generally -- and I think this is very tricky methodologically, but generally if there are these benefits that may be due to the procedure itself and not necessarily the device but just the fact that the patient received a procedure and we're not able to ascertain that because there was not a sham procedure, generally it's felt that those will, that will only be an initial bump, and I don't know if that's a few weeks, a few months, and then after you go out a while later, you

probably are not going to continue to see that bump in improvement. So I think study design is important in thinking about what the duration of followup is that I'd like to see.

DR. ROSS: Any other preliminary thoughts on duration, or is it just appropriate that we can have a full discussion in the larger group?

Okay. Steve, are there other points that you want us to address in more detail before getting to the voting questions, or have we covered what you had hoped we would cover?

DR. FARMER: I think we've largely covered what we hoped to cover. What I'm hearing is that there is not a dramatic amount of controversy across the panel here, and there's general agreement that we need to capture the appropriate endpoints, that the issues that we're considering are represented in the review.

So I don't have too much more to add, other than it is striking, the difference in the types of devices that you might have here, from a wearable to a permanent neurosurgical change. It's such a substantial difference in

context that it merits framing specifically for a wearable, what type of timeframe might be appropriate for a wearable and what type of timeframe might be appropriate for an intervention that is a permanent implant or a permanent ablation, a permanent change that's irreversible.

DR. ROSS: Yeah. I will say reflecting a bit on some of the prior meetings we've had, there was more controversy, you know, whether a surrogate marker should be considered and what that value had, and whether, you know, disease specific hospitalization was a good outcome versus a patient-reported outcome. And I think what is making this conversation feel like there's already a lot of consensus is all of the instruments are measuring essentially patient-reported outcomes on symptom burden and function, and it's kind of like right there and it's not really, there are no surrogates, we're not talking about hospitalizations, we are just focused on kind of like more intermediate disease function related processes, you know, for the eligible treatments.

You know, I think this is what we're putting on the table, because I guess Tim did raise a little bit on some of the respiratory related measures, like should we be thinking about later stage disease related endpoints and the instruments that would be used, or are we pretty comfortable in terms of the endpoints that are on the table here and the measures that are being used. I guess this is like a last chance to come up.

DR. BARREIRO: This is Tim speaking again. I do think it's reasonable that that be brought up, for the mere fact that most of the devices are in for a long period of time, they're called retentions, and because of that, what the long-term effects and issues that come have to be part of, have to be least thought of in my opinion in this disease.

MS. GOLDSMITH: This is Amy Goldsmith. So are we saying that if we're talking about these devices and a timeframe, and coupling that with insuring that there is some type of, you know, study or some type of, you know, something that kind of goes, you know, hand in hand with that as the disease progresses or as

we're looking at the device, you know, as sort of part of that approval piece from CMS to insure that those things are done in conjunction with each other. So I just want to say in a certain point of, you know, the device I guess is what I'm asking.

DR. MAURI: This is Laura Mauri. I guess I would think about it as two different parts to this. One is you have devices that vary, as we said, in terms of their mechanism, what the benefit might be. And what we know from the devices so far is they have different mechanisms and benefits and so they act in different ways.

To your earlier point, that's important to patients to have access to those. So if we -- and I think it doesn't diminish the fact that all of the outcome domains that we're talking about are relevant to the patients, but if we were to require that all of them be included for all devices at all times, then we would probably be limiting the ability to have interventions that were needed across these domains. So I just raise that as a counterbalance, not to say that addition --

because I completely agree that, you know, everything we talked about is relevant to patients, and for their care and continued development of devices to treat these symptoms, but we can't sort of expect every device to act on every domain. Or maybe it's not that apparent, I just wanted to state it.

MS. GOLDSMITH: That's a great point and I never want it to be limiting, if anything I want it to be something that would be accessible, so thank you, that's true.

DR. ROSS: So why don't we take ten minutes and come back at quarter to the hour depending on the time zone. Give people a chance to fill their water cups, we can think about this for a second and we can see if there's any other points we want to address as part of the further discussion and then we can probably get to the voting questions.

I expect, we'll see how long that goes, if we need another break for lunch or if we can get through that and then end early so people can have lunch. Does that sound okay to everyone?

MS. HALL: Yes, that's fine. See you

in ten minutes.

DR. ROSS: Okay.

(Recess.)

DR. ROSS: Everybody, welcome back. Tara, can you stop screen sharing? I assume that break slide's from you.

MS. HALL: We're working on getting that off. There we go.

DR. ROSS: Great. Okay. Well, does anyone want to open the floor back up again, and if people have any thoughts or considerations that they wanted to share, moments of epiphany that cam to them as they filled their water cup up? Great, okay.

So this has been a very good discussion and I think a great setup in terms of like having sort of a small group sort of thinking through some of these issues in advance of the larger meeting to help the team at CMS get organized and have the right materials prepared and to present with answers to the questions that they can anticipate.

Now we have to turn our attention to the voting questions. I always find the voting at these meetings is always a little funny.

I'll just sort of maybe lay out kind of the thinking of how it goes for people who haven't participated in MEDCAC meetings before. But generally, the broad idea is while we are asked to answer a specific question and vote, really by far the most important part of the voting part of the session is the comments we make and the discussion that we have that leads up to those comments. So you know, if the question is, is endpoint A very important, what's going to be valuable is you'll say yes, somewhere between not at all important to extremely important, but you'll give your reasoning for your vote, and that reasoning is then transcribed and used by the CMS staff as they come to a final decision when they list their final endpoints document.

In this case, the other thing to keep in mind is we can't vote on every measure, and so the value I think that we're going to provide is by providing some sense of the importance of different domains and different endpoints within each domain. But we're not going to go through and talk about, you know, is this instrument important, is this

instrument important. The idea would be that in the context of your vote, you will then talk about which of the instruments you think are most important in your practice or you know, best reflect the clinical symptoms and function that are, you know, that you think through.

Steve, is there anything you wanted to add before we turn our attention to the voting document, or did I provide the right kind of color commentary on that?

DR. FARMER: I think that's the right framing. We put together a mockup question, a question list just to get you started based upon the prior subcommittee meeting, but you're completely free to change it in any way you want.

DR. ROSS: So for us today, if people could pull up the possible voting questions document so you have it in front of you, I think that there's a couple different ways that we could think about approaching the first set of questions.

One being to vote on the domain, right, specifically, like do we want as a panel to go through and talk about surrogates, even

though there's no surrogates listed, and whether they're important or not, clinical assessment tools, patient-reported outcome measures and safety measures, and you know, we can all then sort of provide our vote.

Do we -- within each domain, do we want to talk about specific, like clinical endpoints, like this idea of a global change in motor symptom severity or gait function, and talk about whether those are more or less important, or do we want to do both, just be sort of recognizing the feasibility? I think actually, the domain-related questions will go more quickly because there's no surrogates. But in part the clinician-assessed ones, there's actually a lot of different endpoints within it, so it may be helpful for us to walk through them explicitly.

So I'm sort of opening up and want to get the group's feedback in terms of what they think will work the best. I will say just in the past again, for people that haven't participated in this, when we've voted on domains, what people would then talk about in their comments were which endpoints within that

domain they found to be most important. So it, I don't know that we need explicit questions on each of the domains. I'm sort of looking at how many there were in the PDF and there were potentially one, two, three, four, five, six, seven, eight, so it's a lot of voting questions, just to say it gets a little tedious, for those of you who haven't done this.

But if you hold up the slide that Terry had shared, slide 11, there's the global change in motor symptom, there's the gait function, there's motor complications, there's reduction of dyskinesia, there's cognitive function, there's motor-related ADL, there's non-motor symptoms, and then there's speech function and swallowing. So the question that I have for you guys as a group is do you think we should be discussing each of those eight separately, or when it comes time to voting on what's important, vote on the sort of broader all eight together, with people given the opportunity to highlight which of those are most important.

DR. DHRUVA: I think I favor the

latter approach because we'll still have the opportunity to mention specific ones in thinking about the Medicare beneficiary population. My rationale is that the different devices will target different endpoints, and so while I agree that we could go through, I think it's eight of them, and grade one is more important, or you now, sorry, vote on one is more important than another, I think it will also depend on the different device and what they are seeking to improve, how well they do that. So I think that it would be too complicated, and given the different types of devices, I think it would be too complicated and perhaps less useful to be so granular for this particular, for technologies for Parkinson's disease in this case.

DR. ROSS: Laura, I'm curious what you think, because I know you've participated in these before too. Do you feel like that will work?

DR. MAURI: Yeah, I agree with what Sanket proposed. I think as you said before in the discussion, that will be more granular than the voting questions. I think the level of,

you know, examples, I'm looking at Example 1(b) and how it's separated into global change in motor symptoms versus gait, function, postural instability, et cetera, that that sort of level but not going maybe the next level deeper of all the different types of skills that you could break each of those down. But I would hope to draw out in the conversation that same segmentation, you know, that we have been referring to about time courses of disease and how that reflects in what might be the more important symptoms for a given stage.

DR. ROSS: Can I just ask, because I want to make sure I understand. So do you prefer the 1.A or the 1.B approach, 1.A being that we talk through the domains of endpoints, or 1.B where we talk through the actual clinical endpoints within each of the domains?

DR. MAURI: No, I don't know if we're looking at the same document. But I was thinking that it would be not the very detailed of the PDRS versus all the different potential endpoints, but -- oh, I see.

DR. ROSS: Yeah, right. So like, would you want us to be talking about all, like

within one question, all the clinician-assessed endpoints, or like 1.B where we break them apart, not talking about the different instruments but talking about the different clinical endpoints that are measured. I don't know that there's a right answer.

DR. MAURI: I'm leaning towards 1.B and now I'm not sure if that's what you were suggesting.

DR. ROSS: I think I would go with 1.A, but I do worry though, because particularly for the clinician-assessed endpoints, there's a lot in there, and so I don't know.

Pooja, your hand went up. What were you going to say?

DR. KHATRI: I was just going to clarify what 1.A was again. But let me add a comment too, which is, my first inclination was to go with 1.B, although I've never attended a MEDCAC so I hesitated to do that, the reason being that like everyone said, there's a lot wrapped up in there, and I think there'd be a lot of value in understanding from our broad range of experts the relative value of each of

those endpoints in a way that I don't think would be as organized if we talked about 1.A, but I don't know if again, that's going too much into the weeds in terms of process, Joe and Laura and others who have done this before, so I defer to you.

DR. ROSS: I think we can try it. It will be just be a little bit more of a, sort of how to keep the conversation moving to make sure we get through them all, but that's okay. If we feel like more will come out of it in detail than by going through, I think it's worth it.

DR. MAURI: Could we find maybe a happy medium of having fewer domains?

DR. ROSS: Oh, that's a good idea. So maybe, Terry, could you put slide 11 back on in front of us? Because that's where there's the most clinical endpoints to discuss. For the PROs there's just two.

MS. ROGSTAD: Sure.

DR. ROSS: So can we just think about whether all eight need to be discussed, or perhaps some categories could be collapsed for purposes of the discussion questions. Oh,

Pooja, what were you going to say?

DR. KHATRI: Yeah, just for context here for me. The broader group, will it include several more neurologists to be able to have that discussion in terms of motor, non-motor symptoms, motor complications, this level of detail?

DR. ROSS: I haven't seen the agenda, so Steve, are you able to speak to that?

DR. FARMER: Terry, can you tell me who exactly is on the panel in terms of the neurology specialty? We can only empanel people on our MEDCAC roster and there were a limited number of neurologists and neurosurgeons available.

DR. KHATRI: Neurosurgeons too, thanks for saying that.

DR. FARMER: And as a consequence, that's why we engaged externally and got these three expert inputs in writing, so that could be entered in evidence in the MEDCAC panel, but the panelists will be across a breadth of representation from the whole healthcare field, not necessarily specialized in neurology or neurosurgery.

MS. ROGSTAD: Yeah, I'll add to that. We've had some trouble with people becoming unavailable for the panel meeting or having to drop off for other reasons, so I believe, and I'm passing the ball to Tara, who will have to confirm this, but I believe we will not have any additional neurologists on the full panel. But as Steve said, we did get the input from three outside specialists.

MS. HALL: Let me interject real quick, this is Tara. We are still working on that, so hopefully, I'm hoping in the next couple of weeks I can have a final roster, so I can let you all know that as soon as I find out for sure.

DR. FARMER: And I should also note that there was one neurologist involved in the original CER document itself as well.

DR. ROSS: That's helpful. Pooja, we're relying on you.

DR. KHATRI: I have to admit, that does make me lean a little more towards 1.A because I wonder if we can get that level of discussion that maybe I was gearing towards, but I'm open to what you think.

DR. ROSS: In part because you think there's not going to be enough disease-related expertise to talk about importance of dyskinesia versus motor complications and whatnot?

DR. KHATRI: Exactly.

DR. ROSS: Does anyone else have thoughts, knowing that Tara is working hard trying to identify more content experts to come in?

DR. MAURI: I think it would be -- I'm wishing Tara luck, because it would really enrich the conversation and it could be valuable to be able to have the conversation around these endpoints. My preference is that with the ones listed here, we would go for 1.B; however, because they are quite, maybe it will be a fast vote if there's not a lot of discussion, but I think it's useful input because they vary so widely in terms of how they're felt by patients and perceived by clinicians.

DR. ROSS: Laura, I'm coming to your side on this in the sense, I'm not sure that I had either side really, but I wonder whether we

just limit the voting on each of these individual clinical endpoints, the eight domains so to speak. Sorry, I shouldn't use the word domains, these eight endpoints just on importance, and let people reflect on that, as opposed to having people given the lack of content expertise, to talk about sort of clinical endpoint related MCID or followup and things like that. So we'd have like sort of an opportunity to talk about importance of these endpoints, but then when we talk about the MCID and follow-up related issues, we're sort of talking about it at the domain-related level. Is that sufficient?

And maybe it will give people the opportunity, because it'll now be on the table, you know, if they want to say within the clinician assessed health outcomes, you know, that cognitive function is really important at one year, whereas the motor symptom severity is really important at one month, they can say that. But we're not going to have people comment explicitly on each of the eight. Is that okay?

DR. MAURI: Yeah, I would agree with

that.

DR. ROSS: Okay. I think that helps us with question one.

DR. DHRUVA: Sorry, Joe, could you explain -- I don't think I quite understood your proposal at the end there. So we would take all eight of these clinical endpoints in the left column there and vote on a scale of one to five, from not important to extremely for global change of motor symptom, severity of gait function, et cetera?

DR. ROSS: That's right. We would also be voting for the other domains as well, just to be clear. So, there's also two endpoints within the PROs.

DR. DHRUVA: Oh, sorry, yeah, okay. So in total it would be somewhere around 12ish questions, or 12ish voting questions, okay.

I think that sounds, I think that makes sense. I'm just wondering if, depending on who Tara is ably to identify, I mean, I'll certainly do some more background reading, but I'm not caring for patients with Parkinson's disease in practice, and so you know, I'm just wondering if there's a way, I don't mean

assigning homework for the MEDCAC panelists once they're identified, but you know, right now I'm struggling with thinking about if today was the end of June and we were at the meeting, would I say well, you know, cognitive function is a four and non-motor is a three, or -- I'm struggling with how I would distinguish them given my lack of expertise. I'm happy to do some homework but I don't know, perhaps we should all do a little bit unless we have another neurologist or two on the panel, or neurosurgeon with us.

MS. HALL: Hi, this is Tara again. I'm going to interject. I just checked with roster, so we will have two neurosurgeons on the panel.

DR. ROSS: That's great, that's helpful.

So Steve, what I was going to suggest, particularly if we take this approach where we talk about each row of clinical endpoints as Terry has identified within each domain and are voting on their importance, rather than voting in subsequent questions on, which was in the example sheet on instruments and MCID and

followup, I wonder if we can adopt the approach we used for the diabetes one, which was to say that when people vote and comment on their rationale in discussion, to also address some of those points in their vote in terms of like the ideal duration of followup and which instrument they're -- because we're not really going into so much like instrument performance here, so I don't think people are going to say like this instrument versus that instrument, but the duration of followup is there, and there is an established MCID for an instrument, like having people comment like that, would that work?

DR. FARMER: I almost am thinking, so like if you have four domains and you say you may vote on the domain, but then have everybody prepared to say three or four sentences about that domain, and you know, and it may just be I think this domain is important but I'm unfamiliar with the individual instruments in their clinical application, or it could be I'm particularly, I feel like this one is particularly important and I want to emphasize that because of this reason. You know, that

might be the most efficient way, rather than individually voting on each one, because I think that would be too much.

But then you have, you know, just the four big domain ones and then a series of 12 statements within the domain, something like that approach, would that work?

DR. ROSS: So are you advocating for more of a 1.A approach than a 1.B?

DR. FARMER: I think so, yeah.

DR. ROSS: I think we can make 1.B work, so long as we don't have a whole set of additional questions on followup, duration and MCID. I think that if we had, you know, within the PROs, let's talk about sleep, how important is that one to five, and comment on when you would want to see that measured and like how important that is, I think we could go one by one. That would essentially give us 11 voting questions, eight clinical assessments, the two PROs and the one safety, and it would allow people to sort of articulate a bit around their rationale around device differences and whether there's particular concerns around an older age population, particularly for like sleep or

cognition. You know, it's like Sanket measured, or discussed before. I don't know, maybe I'm talking myself into it, and it's going to be a mess.

DR. FARMER: However you would like to, however the panel would like to do it is fine with me.

MS. ROGSTAD: Excuse me, Dr. Ross, this is Terry Rogstad at CMS. There would be two additional clinical endpoints from the essential tremor set of literature.

DR. ROSS: Oh, of course.

MS. ROGSTAD: So 14 total.

DR. ROSS: Okay. I still think we can do it, famous last words. How many people will be on the panel, how many people will have to vote for each question?

MS. ROGSTAD: 12 people on the panel.

DR. ROSS: Okay. If everyone keeps their comments to a minute or two, I think we can get through it. I think we'll have to leave more time for the voting than is typical, but I think there's going to be a lot of good points made and we should just encourage people not to be redundant, so we don't get 12 people

saying the same thing, they don't each have to say it. Pooja?

DR. KHATRI: How long is the meeting usually? I was just doing the math there and a minute times 12 times eight, right, 96 minutes, so I just wanted to know if we'd have enough time for discussion.

DR. ROSS: Usually it's about six hours if I'm remembering, Steve. So there will be probably, Terry will do the presentation, that will be blocked at 30 minutes or so, and then there will be probably 90 minutes of discussion after, kind of like what we had today.

DR. FARMER: So for these clinical endpoint review MEDCACs, we had been trying to get them shorter.

DR. ROSS: Okay, all right. Maybe we ought to do 1.A.

(Laughter.)

MS. ATKINSON: But we do have it allotted from ten to four.

DR. FARMER: If you really want to do something more exhaustive, we could do that if you think it's important.

DR. ROSS: Well, the reason, I just feel like in part because of the comments Pooja and Laura have made, I feel like when we talk about the clinical assessments, when people vote, I'm going to be asking them to call out which were the clinical endpoints that were most important to them. So it's like it's going to be there anyways, and I kind of prefer having the structure organized around where I know everyone is going to say they thought this was important, they thought this was a little bit less important and why. It will get everybody sort of on the record. That was my thinking. Sanket, what do you think?

DR. DHRUVA: Well, I am of both minds. I think, I have definitely been swayed more towards 1.A, but I think the voting generally takes a lot longer. I know, Joe, you're incredibly efficient, but Pooja, to your point, so not only do we all vote electronically and then Joe goes to each panelist and says okay, Dr. Khatri, how did you vote, Dr. Dhruva, Dr. Mauri, Ms. Goldsmith, Dr. Barreiro, et cetera, and everyone has to then say their vote at that point in time. And your back of

the envelope calculation makes me a little worried that it might be even longer. And if we want people to, because there's so much juice in the comments, I'd agree with Joe that that juice might then be translated instead to the voting, but you know, it will just leave a lot less time for comments and discussion.

DR. ROSS: I think we should go with 1.A and the onus is going to be on me to extract the key information about which endpoints were most important to each individual within the vote, and have them reflect on that in their comments.

And so Tara, I don't know if you're the one who drafts the voting questions, or maybe Michelle, but whoever is like --

MS. ROGSTAD: It's Terry and Steve.

DR. ROSS: So Steve, maybe when, you know, like in the diabetes one where you said like, you know, in your comments, please call out, you know, and I can look at that ahead of time to help with the editing, just so it's clear that we're going to call out, you know, like which were the clinical endpoints that were most compelling, which wee the clinical

endpoints that might have been least compelling, and then sort of their relative importance, but I think we'll do it and we'll be able to get there.

DR. FARMER: I think the most crucial thing here is to make sure that all the panelists know in advance that they have to be very tight in their comments. It will be a very long long meeting.

MS. HALL: When we have the pre-meeting, we can mention that to the panel members at that time.

DR. ROSS: Yeah. I'll stress it also. Like once we get to the point of voting, it's often a bit confusing for people who've never sat on this before to know how this actually works. So until it's even playing out, it's hard to guide people.

But you guys can hold me to task, so if you feel like we're not getting enough out, say something, just to make sure we're getting the comments we need. Okay.

So I think we're voting, Steve, for 1.A.

DR. FARMER: Okay.

DR. ROSS: For endpoint domains, and with like essentially asking people, so we will just have those four for votes, with the prompt sort of at the bottom sort of around which were the clinical endpoints of greater relevance or lesser relevance, and the sort of timeframe within which you'd like to see them assessed and those types of thing, okay?

DR. FARMER: Okay.

DR. ROSS: As opposed to separate voting questions.

DR. FARMER: Sounds good.

MS. ROGSTAD: And, question. This is Terry again. In the instructions that are sent to the panelists, do they need to be prepared to share their thoughts on the MCID information that's been collected, or follow-up duration?

DR. ROSS: I think people will probably have more to say, particularly if they're not content experts on the follow-up duration based on their intuitive, sort of like their clinical background. Without being experts on the instruments, and because we're not talking about each of the instruments in a lot of detail, people probably won't have a lot

to say about the MCID except that it's important that there is a validated MCID as part of the instruments that are being used.

DR. FARMER: If we were going to have a discussion, a detailed discussion of MCIDs, we really should limit that discussion to those where there isn't a published value, that it has been well established, and really it's where there is ambiguity and their isn't a clear way to interpret that information, that at least some degree of conversation of how we might think about this would be helpful, so that it's not leaving it to the CMS review team to make a judgment without any kind of context.

DR. ROSS: That's a really good point, and so this is reminding me that actually in the essential tremor voting, asking people to talk about whether they had a sense of a clinically important difference since there aren't established MCIDs. That's really where it will come out.

DR. FARMER: Yeah.

MS. ROGSTAD: Just one comment on it. That would require familiarity with the scales that are used and you know, their magnitude.

DR. ROSS: Yeah. We will probably not have expert comment on that specifically. Other comments or questions?

DR. KHATRI: I just want to say that this has been incredibly helpful in preparing for the next meeting too, and knowing how it works, in what context and what's valuable to CMS, so thank you for working through that.

DR. ROSS: Terry, one thing I was going to suggest, and I don't know whether it makes sense potentially to circulate the UPDRS, the full instrument for people to see as part of the materials, just because sub-domains of it that are included in many of the endpoints, and I think it might just help for people to be familiar with it. I don't know that we have to do it for all of the instruments, but that one in particular.

MS. ROGSTAD: I agree, I think that would be a good idea.

DR. KHATRI: And I'll just mention that I believe that the MDS UPDRS is the current one that's used, so that would be the specific one to circulate.

MS. ROGSTAD: Right.

DR. ROSS: But Terry, seriously, we are all incredibly impressed with this clinical evidence review and all the work that you've done to put this all together and getting the response from the experts, and now in response to the comments we're making, so thank you.

MS. ROGSTAD: Thank you.

DR. ROSS: Steve or Tara, any other questions?

MS. HALL: I was just about to ask, are we done, did we do this in two-and-a-half hours?

DR. ROSS: That's my rep.

DR. FARMER: Well, on behalf of CMS, I want to thank everybody for your thoughtful contributions to this conversation. We're really looking forward to the MEDCAC meeting and I know it will go very well and we will learn a lot from it. So thank you so much.

DR. ROSS: Thank you, everybody.

MS. HALL: All right, good bye.

(Whereupon, the meeting concluded at 12:21 p.m. EDT.)

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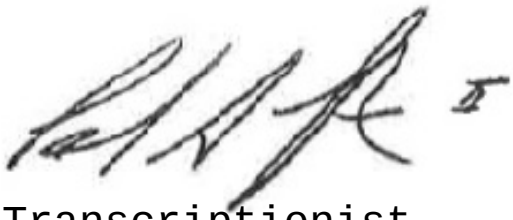

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