NATIONAL QUALITY FORUM

Moderator: Person and Family-Centered Care
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Sarah Sampsel: OK. Hi. This is Sarah Sampsel. And first of all, thank you all for joining the call, and thank you for being patient while we get started. I'll ask if Chris or Lee or both have some opening …

Christopher Stille: Right.

Sarah Sampsel: … welcoming comments. And then, NQF staff will do a roll call. We need to establish quorum or establish how many folks we have on the call. We'll have the discussion no matter what but we do want to see if we have quorum before we proceed. So, Chris and Lee, any additional comments?

Christopher Stille: Right. Well, welcome to those of you who are on the call. It was great to see you all in Washington last week. We've got a lot of great work done and still have quite a bit of work to do. But I think we're in very good shape. I hope any of you who are affected by some snow are digging out OK. It seems like it was – for most people it wasn't too big a deal, so that's good.

And so, welcome. And as you can see from the agenda, most of the discussion today will be on reviewing one of the measures that we reviewed last week.

Lee Partridge: And this is Lee and I echo the welcome from Chris from New York City where we didn't have the blizzard that everybody thought we were going to get. And then, we're going to turn it over first to Nadine for roll call and then to Sarah. And then Chris is going to take over for at least our first hour.

Christopher Stille: Yes.

Nadine Allen: Hi, everyone. Katherine Bevans?

Katherine Bevans: I'm here.

Nadine Allen: Samuel Bierner? Rebecca Bradley?

Rebecca Bradley: Here.

Nadine Allen: David Cella?

David Cella: Here.

Nadine Allen: Sharon Cross?

Sharon Cross: Here.

Nadine Allen: Dawn Dowding? Sherrie Kaplan?

Sherrie Kaplan: I'm here.

Nadine Allen: Carol Levine?

Carol Levine: Here.

Nadine Allen: Brian Lindberg?

Brian Lindberg: Here.

Nadine Allen: Sherri Loeb? James Merlino? Ann Monroe?

Ann Monroe: Here.

Nadine Allen: Lisa Morrise?

Lisa Morrise: Hi. I'm here. I will be (phone-only) only in a few minutes because I have to drive.

Nadine Allen: OK. Thanks, Lisa. Liz Mort? Esther Neuwirth?

Esther Neuwirth: Here

Nadine Allen: Thanks, Esther.

Esther Neuwirth: Esther Neuwirth here.

Nadine Allen: Great, thank you. Len Parisi?

Lenard Parisi: I'm here.

Nadine Allen: Thanks. Lee Partridge is here. Debra Saliba?

Debra Saliba: Here.

Nadine Allen: Thank you. Chris is here. Peter Thomas? And Carin van Zyl? OK, that's it. Thank you.

Sarah Sampsel: OK, great. Thanks, Nadine. And again, this is Sarah. And what I'll do is I'm just going to make a couple of opening remarks and then we'll turn the call over to the folks from CMS, Tara and (Anne) from RTI.

But first of all, we appreciate everyone's time and, you know, we really have a great group represented here. And we are – we certainly can try to be expedient with this time since we (do just the one) measure. But we also want to be sure we follow process and allow the developer, CMS, to present their information.

You know, there has been some e-mail traffic and we wanted to acknowledge that. But, you know, we do want to let the committee know that this request for committee reconsideration is allowable in the NQF process. We typically see it at the post-comment conference call. But since we have this time on the calendar and while these measures were fresh in everyone's mind, you know, we wanted to give CMS and RTI this opportunity to present their information and see what the committee would like to do with the information.

So, as you might recall, this measure, 2631, (presented) long-term care hospital patient with admission and discharge functional assessment in the

care plan that addresses function developed by CMS and RTI. (We failed) during the committee vote importance, and that was at 1B, which is the gap to measure. And …

Ann Monroe: Can you tell us what we voted? What our vote was, please?

Sarah Sampsel: Nadine or Mitra, can you pull that up while I finish?

Nadine Allen: Yes, we can pull up that vote.

Sarah Sampsel: Great. I mean pull it up. You don't have to put it on there. I don't think you have to put it on the screen. But if you could have the vote available, that would be great. So, you know, can a (process-wise) we'll pull up the vote so we (inaudible) where that vote was. There were only two votes on 1A and 1B. And then Ann and Tara will be providing some opening remarks and has been asked to concisely explain why and how they feel their measure meets the NQF criteria for your consideration.

We'll then turn the discussion over to the co-chairs. So Lee and Chris will lead committee discussants. And I believe Chris is going to lead for as long as he's able to stay on the line, and if we're still on, Lee will take over.

And then I just want to orient you that the committee then has two options. One option is to stand with your current vote and determine that the additional information brought forward does not want a revote from your perspective. And that will really be a verbal count of folks saying yes and no. And we will ask all members who are on the phone to – we'll go to the roll call and ask you to say yes or no.

And then, your other option would be to say that you do think the additional information wanted to vote. And in that case, the vote will take place via SurveyMonkey and you would receive an e-mail after the call. So, the actual vote through all the criteria will not happen on this call. The one vote that could happen is if you decide you want to revote on this call.

So with that, Nadine or Mitra, were you able to pull up the vote and can you read those off?

Female: Yes.

Suzanne Theberge: Sarah, this is Suzanne. I have them up. I can read it off if you like.

Sarah Sampsel: OK, that would be great.

Suzanne Theberge: For 1A, we had 6 percent vote high, 28 percent vote moderate, zero percent vote low, 9 percent vote insufficient – I'm sorry, 50 percent vote insufficient and 17 percent vote insufficient with exception. And then for 1B, we had 6 percent vote high, 11 percent vote moderate, 17 percent vote low and 67 percent vote insufficient.

Ann Monroe: Thank you.

Sarah Sampsel: OK. So with that, (Anne) and Tara, I'm not sure who is going to start.

Tara McMullen: Hi, good afternoon. It's Tara McMullen from CMS. And thank you so much, Sarah, and to the panel and to NQF for allowing us to meet with you today on this reconsideration call. I am joined by (Anne Deitrim), RTI, as well as my Deputy Director Stella Stacy, Stacy Stella, either way, Mandl, and our medical director here in the Division of Chronic and Post Acute Care, Alan Levitt, Dr. Alan Levitt.

And so, I'm going to turn it over to Stacy and Alan as they are going to open it up for us today.

Stacy Mandl: Great. Thanks, Tara. And thank you, everybody, for taking the time to get together. We really value your time and support in having this discussion. This particular measure is of significant importance because it really speaks to some of the foundation of care as a service in the health care industry. I've been a nurse for quite sometime, and I can tell you that assessing function especially at the detail level as it's presented within this measure and ensuring that the needs are marched through into a care plan and then carried out is remote.

I can tell you that from unit to unit, from hospital to hospital, I've been a nursing administrator as well as a nurse manager, as well as a bedside

clinician, the variance is tremendous. And to have – to sort of call under light the importance of evaluating function especially with our beneficiary population as well as the population as a whole, minute level changes in the frail elderly or for those who with multiple chronic conditions or even just those who have had a significant health event, the loss of function and the failure to protect function can have a life-altering, can be a life-altering experience in a downward turn for anyone. It's tied directly to, you know, rehospitalization and many other untoward events that are really sort of nosocomial, you know, events.

I also want to just point out that although care planning is standard of practice in nursing and it's required under the conditions of participation for our certified facilities, the requirements alone vary from setting, a specific setting to setting. And so, I just want to point out sort of the importance of bringing to light care planning where there are deficits so that our beneficiaries will have good and long-term outcomes.

And I'll just briefly touch on that this really does tie to care coordination under the IMPACT Act, which is an amazing (passed), you know, legislation. T is for Transformation. And in the transformation, the use of standardized data elements to have data that helps (inform) care coordination as an individual, you know, traverses the health care system cannot be understated. So, I just wanted to touch on the IMPACT Act for that facet in and of itself as being critically important.

So at this point, I want to turn it over to my colleague, Dr. Alan Levitt.

Alan Levitt: Thank you. Thank you very much, Stacy. Thank you for giving me the opportunity to talk and defend what I consider to be a very important measure in our post-acute care quality reporting programs.

I'm relatively new to CMS. I'm from the post-acute care world. And I spent my professional life, my academic career, at University of Maryland running or monitoring rehabilitation programs. These programs included IRFs at Kernan Hospital, which is now called University of Maryland Rehab and

Orthopedic Institute, the now closed LTAC's Montebello, and Deaton Hospital which is later be called University of Maryland Specialty Hospital.

What we, CMS, are asking for in this measure is what teams and facilities such as these should be doing on every admission that comes in everyday, assessing the functional status on patients in basic areas, establishing goals that are appropriate, and then reassessing those areas at (discharge).

This isn't rocket science. This is what you would want and expect to happen if you, or a loved one, are a patient. Any LTAC that's not currently doing this is really not doing their job.

That's why in this past year's rule based on the qualitative feedback, we received during the PAC-PRD that this was not being consistent, we followed in LTACs that we propose and finalize this measure, a measure of the fundamental process of assessment, establishment of goals and reassessment, along with the statutorily required bed mobility outcome measure that you reviewed last week.

Remember, Congress mandated in the Bipartisan Budget Act of 2013, that's for LTAC, CMS and I'll quote here, "Establish a functional status quality measure for change and mobility among inpatients requiring ventilator support." By us also including the process measure in this rule, we at CMS wanted to ensure that when collecting and submitting data for the mobility outcome measure mandated by Congress, that LTACs do not just study for the test. They look at all appropriate areas of function.

As I told you, I'm from the post-acute care world. In that world, we look for messages from the actions taken by CMS and also from those organizations that support CMS. Our message at CMS this past year in proposing and finalizing this particular measure was that LTACs need to assess and establish goals were appropriate in all areas of basic function. And not just in bed mobility because of a mandated outcome measure. We hope that by endorsing this measure that NQF will also convey the same message.

I'll now turn it over to (Anne).

(Anne Deitrim): Great, thank you. Can everybody hear me? Can everybody hear me?

Male: Yes.

(Anne Deitrim): Yes, great.

Male: Yes.

(Anne Deitrim): Great. So, I prepared a few slides. So, the first slide is the title, if you could maybe go to the second slide that would be great. So just to review, I know everybody heard a lot of measures last week so I just wanted to kind of review the measure. So as suggested by Alan, and Stacy, and Tara, we are, as part of this measure, asking for data to be collected on the areas of self-care mobility, cognition, and bladder management at the time of admission and discharge. And then the second component of the measure is reporting on admission a discharge goal.

And during the discussion, there were several questions about the, how tied the goals were or the care planning piece of that to the particular functional assessment item. So I have an example here that reinforces. So it may be that a patient requires quite a bit of assistance on admission for something like the activity to (roll) left to right in bed. And so, perhaps that scored substantial assistance which is a level two on the care rating scale.

And so what we would be asking as documentation of the care plan is that a discharge goal be reported on admission for that, for another item. So in this example, if the goal is related to roll left to right, it could be that the discharge would be that the patient achieved a level 3 partial or moderate assistance. So in this case, they would move up one level on the scale to be more independent.

So, on the next slide, I wanted to speak a little bit to the evidence and performance gap and priority. And we had submitted some supplemental materials prior to the meeting that I know at least one panel member had said during the meeting last week that she hadn't seen some of these materials. So I'm just going to go over some of that material at a high level and some additional information we pulled together. So, as I mentioned last week, the

patients in long-term care hospitals are quite complex, very ill. They opt to have functional limitations and were at risk for further decline.

So in terms of the number of patients affected, the report to Congress that MedPAC put together in 2014 showed that among the 420 or so LTACs, the cost was $5.5 billion to the Medicare program. And our analysis at RTI of the number of patients across all payer types is it was more than 216,000 stays in 2013.

Next slide. I wanted to give you a quote from one of the articles that we cited in our materials. So (Aaron) rushed to the study looking at functional outcomes for patients and then LTAC. And there's not many studies on this at this early point in time. This is really an emerging area. And so in particular, he said, the importance of utilizing standardized outcome measures and physical therapy practice has been well documented and accepted as best practice.

Despite increasing evidence supporting the role of physical therapist in the critical care environment, minimal data has been reported on how to measure functional improvement and outcomes of patients in LTAC in an LTAC setting. One challenge is identifying an outcome measure that is adequately sensitive to the wide variety of functional statuses of patients, that and LTAC including those with the low functional level. So I have the reference at the bottom of that slide.

Next slide, please. So we did cite three clinical practice guidelines as part of our evidence. And I think during the meeting, I also highlighted that we put our measures out for public comment. And we received 22 comments back from the public related to the outcome measure and the process measure. And many people highlighted the importance of the topic of functional assessment and thought these were appropriate measures and provided supportive feedbacks.

Next slide. So in terms of gap, I wanted to reiterate during the Post-Acute Care Payment Reform Demonstration, I was one of the people who did a lot of site visits. There was a total of 28 LTACs who participated in that project.

And we noted substantial variation in the collection of the type of functional assessment data that was collected for their patients at the time of admission and discharge. And there was a lot of variability in terms of the types of information that were being recorded as goals for the patient in terms of outcome.

So this quality measure, again, looks at self-care mobility cognition, bladder management at admission and discharge and goal-setting related to those areas. The opportunities for improvement include monitoring functional assessment, goal-setting overtime, functional assessment data and forming decisions regarding appropriate discharge placement. And then also, as Stacy referenced, making sure that if patients transfer from one setting to another that a common language is used so that there's best care coordination possible.

Next slide. So, Sarah, should I stop here or keep going?

Sarah Sampsel: No, why don't you go ahead and go all the way through.

(Anne Deitrim): OK. All right. So, in terms of reliability validity, I know we presented a lot of material at the meeting last week related to reliability validity so there's a lot of material that were submitted. I'm not going to go over it. But, you know, just, I guess, to review, we did a lot of studies in terms of inter-rater reliability, (video) reliability testing. We also presented some (rush analysis) looking basically at how items work together on these different concepts of health care mobility.

In terms of validity, we provided evidence in terms of three practice guidelines. We highlighted, I think, that we had three technical expert panels that were focused on this. So we've had a lot of input directly from experts from the long-term care hospital setting as well as experts in measurement and quality improvement. We also received public comments about the measures.

Next slide. In terms of feasibility, as Dr. Levitt mentioned, this quality measure was finalized as part of the LTAC quality reporting program in the most recent final rule published in 2014. And so, data collection will begin on April 1, 2016. LTACs do not collect and submit the data for this measure by the deadline. It may be subject to a 2 percent penalty percentage point

reduction in the annual payment updates for fiscal year 2018 and subsequent years.

And then last slide, Usability. So this quality measure is not currently reported or used in unaccountability application because the development has only recently been completed. And the measure is now being submitted for initial endorsement. We do believe that the consumers, purchasers, providers, and policy makers could use future performance results for this quality measure for both accountability and performance improvement to support achieving the goal of high quality health care for all the patients treated in the long-term care hospitals.

So that's the end. Tara, Stacy, Alan, did you want to add anything else?

Female: No, thank you so much.

(Anne Deitrim): All right, Sarah, back to you.

Sarah Sampsel: Great, thank you, (Anne), and Tara, Stacy, and Alan. I'll ask Lee and Chris to take it from here and move to committee discussion.

Christopher Stille: Yes, I'll lead it for the next 28 minutes until I'll have to step off. I would propose that we discuss the importance items first especially because gap was where we stopped last time. Just to remind people that importance items are evidence performance gap and priority. And I'll ask for comments and then I have one or two of my own.

David Cella: Chris, this is Dave Cella. Can you hear me?

Christopher Stille: I can hear you great.

David Cella: I'm going to go off the speaker. So, I mean, I'll start because I was one of the reviewers. And I think I was …

Christopher Stille: Great, perfect.

David Cella: … the primary reviewer. So, this – my memory got jogged after that e-mail correspondence and that was helpful, so I appreciate that, (Sarah). This was

the one where I was positive about importance in my review. And then when I heard that there indeed was a link even though the semantics of the measure didn't explicitly say they had to be linked, I learned that it was linked in discussion, which actually elevated my importance.

So I think what happened was the discussion closed after it was pointed out there really weren't any data to work, and then that drove an insufficient vote on importance. But I just wanted to reiterate that in my review, actually and still now, I was – in terms of the importance, I was a plus.

Christopher Stille: So, David, is there anything – I don't know if we had a chance to review over this over the last couple of days. Do any of the new things kind of changed your thinking or was it just kind of how you were thinking after you went home?

David Cella: No. Well, it didn't changed my thinking but, again, I was plus on importance …

Christopher Stille: OK.

David Cella: … even before hearing from people reviewing literature and, you know, and the public comments regarding how important the measure is.

Christopher Stille: OK. Other thoughts?

Rebecca Bradley: This is Becky Bradley. Can I just clarify because I totally agree to importance of measuring function across (inaudible) setting and, you know, I think this clearly documents a need that's lacking in LTACs (which is) there has not been this kind of effort. But just …

Christopher Stille: Becky, could you speak up a little bit? We can hear you but just barely.

Rebecca Bradley: OK. I'm going to – is that better?

Christopher Stille: That's better. Thanks.

Rebecca Bradley: OK. But just for clarity so I can understand because it was mentioned in the presentation, has CMS mandated this particular measure already for LTACs

or just the concept of measuring function, or is this particular measure already mandated for LTACs, (measurement)?

Female: Yes, this measure was finalized back here.

Rebecca Bradley: OK.

Female: It will be implemented into the LTAC program.

Rebecca Bradley: OK. So, in terms of data – collecting the data at admission and discharge?

Female: Yes, it starts …

Rebecca Bradley: OK.

Female: … the data collection …

Christopher Stille: April.

Female: … by April 1, 2016.

Rebecca Bradley: OK. That was my question. I believe that's clarified.

Christopher Stille: Are there any discussion from panel members.

Carol Levine: This is Carol and I apologize because I was not able to come last week. But could you clarify what initial endorsement means as opposed to something where you do have data to evaluate? This seems to me a different level of endorsement but I'm not sure about that.

(Anne Deitrim): So, this is (Anne). When I was presenting, I talked about the – this being a newly developed measure. So we don't have data yet to speak about how reliable the data is at the performance measure. And so, that's – I was just highlighting that. So, Sarah, I mean, I think there's expectations that when measures have been out that there's a lot more data at the facility level. Is that correct?

Sarah Sampsel: So, I see, let me – I'll just comment. At one point in NQF history, there was time limited endorsement. That kind of category of endorsement is no longer

in enforcement. So, (simply), this would be full endorsement of the measure for – you know, as it has been presented to you. And, you know, what would happen is then CMS would come back, you know, annually with measure maintenance in any updates and could present additional data as that data is collected in the future that you would also see.

(Anne Deitrim): So this is really endorsement of the concept then the content, then the importance. It's not saying anything about how it would actually work out in practice? That would happen later? Is my understanding right?

Christopher Stille: Well, really feasibility and usability are the criteria that we talked about, so.

(Anne Deitrim): OK.

Sherrie Kaplan: This is Sherrie Kaplan. There were a couple of these functional status measures that we considered and I want to clarify for myself. There was some confusion for one of them and I don't know. I want to make sure I understand this one that there – the two components are; a functional status assessment is done and then a goal for function is the second component. But the two are, they have to be linked or they are not because in one case, it was a documentation process issue so that if you documented a functional status assessment on admission and then you documented somewhere a goal for function, the two of them didn't need to be related. Is that not accurate for this measure? Or do they have to be related? r is it documentation only?

(Anne Deitrim): So, for – this is (Anne). So for this quality measure, the goal has to be tied to one of the self-care or mobility items. So if the person has a functional limitation in eating, rolling left or right, getting on and off the toilet, the clinicians can report goals for all of those items but they have to report a goal for at least one of those items. And when they report the goal, they have to use the functional scale so that they, say the person, they expect them to move, let say, from being dependent on eating to being, let's say, only requiring setup assistance. So they are directly linked in this particular measure.

David Cella: And what I was saying, Sherrie, was that learning that in the discussion, actually, increased my enthusiasm for the importance of the measure. But

then it got, I think, redirected, our discussion redirected to issues related to reliability and what they did not available and feasibility issues. And that's that – I believe that factored in to the importance vote. But my enthusiasm for importance was up on hearing that clarification during the meeting.

Sherrie Kaplan: Right. So this is being considered as an outcome measure, right?

David Cella: Yes.

Sherrie Kaplan: And this is …

(Crosstalk)

David Cella: Well no, it's…

(Crosstalk)

(Anne Deitrim): It is a process measure.

David Cella: It's a process.

Sherrie Kaplan: So – OK.

David Cella: It's a linked process, but it's all process.

(Crosstalk)

Sherrie Kaplan: So we're – OK. So, it's goal setting for improvement. It's …

(Crosstalk)

(Anne Deitrim): Right. Right, but we're not actually going to hold the facilities accountable for meeting those goals because there is a lot of variability in terms of the types of patients submitted to long-term care hospitals. And when we talk to our expert panel about having an outcome measure that worked across all LTAC patients, they felt that that was not something that was feasible at this point because we just didn't have enough data and it would be really, really hard to risk adjust.

Christopher Stille: Yes. This is Chris. Maybe I'll jump in with my points. In the importance category, I think there's a lot of evidence that was presented about the importance, and I think that's really good especially to substantiate this is a priority for something to look at. I thought of a couple of significant concerns about the data about performance gap. The only data that I could see were more or less qualitative data on the collection of functional assessment that there is variability based on site visits to 28 facilities. I didn't see any quantitative data for that. I didn't see any data for a care plan gap although I understand how the two would be linked.

And the other point that I wanted to make is that even in the initial measures category, other measures that we've looked at for initial endorsement do have substantial quantitative testing on these items. So, you know, I think it's part of what we look for. I'll stop there.

(Anne Deitrim): So this is (Anne). So maybe the – Sarah, you can make a comment. I mean my understanding is sometimes qualitative data is adequate for a measure when it's first being proposed especially process measures that are directly tied to expert opinion in terms of validity and clinical practice guidelines.

Sarah Sampsel: Sorry, I was having problems taking my phone off mute. Yes, I mean I would say, you know, this is where, you know, we want to make – and NQF wants to make sure that, you know, we're thinking about – you're thinking about this measure in relationship to where you want to see the data per se.

So, you know, I certainly think performance gap, if you go to the measure information form, you know, there are various ways that it can be exhibited. And I would say that there have been times maybe not through this committee but through others where the information on the – the gap might be more qualitative in nature or be more of a correlation. And I don't know if (Anne) or Lisa or anybody else from NQF want to comment on that.

(Crosstalk)

(Anne Deitrim): Chris?

Christopher Stille: Hello?

Sarah Sampsel: Yes, go ahead, Chris. I don't think there was a – I mean I don't know that there is anything else that NQF would want to add.

Christopher Stille: OK. OK, that's fine. And any other discussion of the importance category before we move on to validity and reliability?

Lee Partridge: Yes, Chris. This is Lee. Can you hear me now?

Christopher Stille: I can.

Lee Partridge: OK. Can we go back to your first slide? I think I, for one, was confused probably by the description of the numerator and the denominator of the measure. And I'm just trying to see what you're going to get, I mean what – from a long-term – when you start collecting the data, what are you going to get? And this is the way I understood it. That you're going to look for, first, that you use the standardized tool in making the assessment. And that tool, as I understand it, is the care rating system.

And then you're going to assess at admission and you're going to use the same tool to assess at discharge. At admission, you're also going to establish the goal. So I think, actually, your original submission said there were three components to the numerator. And that the long-term care facility has to say that they did all three, that they complied with all three, and that they used the standardized tool. Am I right?

Tara McMullen: Yes, that's correct.

Lee Partridge: OK, so then if you go on and talk about – and I think none of it, at least I didn't, zero in on the word standardized in there. When I went on and reread all your submissions again yesterday and the day before, you talked about the variations being, I believe and whether or not they used – oh sorry, that you're – you also had to address four specific areas in those assessments. You talked about the variation that – like they probably didn't all use the same tool and they may not have all ask questions in these four areas.

So there are lots of ways, as I see it, the long-term care facility could fail to make it into the numerator if they fell out on whether they use the standardized tool, whether they did at admission/discharge, whether they had covered the four areas and also whether they established a goal. And it's a tall order, am I right?

Tara McMullen: Yes, I mean basically …

Lee Partridge: OK. No, no, no, I'm just saying – I have been involved in the past with – the measures with 9 components of the numerator, and they tend sometimes to be hard measures to get a good grade on them. And I just wanted to be sure I was reading it accurately.

Tara McMullen: You know, may I make a comment about reporting of the data? This is Tara McMullen from CMS.

Lee Partridge: Yes.

Tara McMullen: The way that this measure has been proposed and it's proposed the use will be in the long-term care hospital, the data set, the assessment instrument, the LTAC care data set. And these items will be nested within the assessment instrument. And long-term care hospitals are required to collect on these items. So whereas someone may not have – well, we're requiring that they collect on at least one goal. So they have to collect at discharge mobility or self-care at least (inaudible).

If an individual passes away, if they transfer out the setting we will know that happened through other coding options that you'll see I believe if you have your specifications for the measure in front of you. So…

Lee Partridge: Yes, I do see that here.

Tara McMullen: OK.

(Crosstalk)

Lee Partridge: I understood why you're doing that. Somebody …

(Crosstalk)

Tara McMullen: I just wanted to clarify that the item of, well, the standardized tool. The tool (is) the assessment item. And the items themselves are standardized within each assessment instrument. So it will be collected upon. It's not that they have a separate tool other than what we're using and they could choose to use that tool. It's not – It doesn't work that way. I just wanted to clarify that.

Lee Partridge: Thank you.

Tara McMullen: Thank you.

Lee Partridge: That's all, Chris.

Tara McMullen: OK, thanks. I appreciate it.

Christopher Stille: OK. I think we should probably move on to the other criteria just in the interest of time unless anyone else has a burning issue on importance.

Ann Monroe: This is Ann Monroe. My question is just process. Are we supposed to vote again on importance before we move to the other things?

Christopher Stille: No, what we're – Sarah, actually probably said that best at the beginning.

Sarah Sampsel: Yes. So, no, we're going to go ahead and go through the entire discussion. And then we'll do a – you know, then we'll do kind of a vote online of who feels this information and this discussion more into revote of all of the criteria and we would do that offline.

Ann Monroe: All right, thank you.

Christopher Stille: OK. So, comments also on reliability and validity.

Rebecca Bradley: This is Becky Bradley again. Can you hear me?

Christopher Stille: Yes.

Rebecca Bradley: And I want to go back to the discussion about the goal because I guess that's where I'm kind of getting hung up. And if I'm family member looking for an

LTAC service for my family member and they're doing an assessment in setting a goal, I'm assuming that that goal is based on some kind of statistical information that it's being collected. And I think that's what's confusing me about this one is that we're talking about a standardized tool and a standardized assessment.

But the goal – the data to support the goal doesn't seem to be there. And I'm just curious and even CMS (inaudible) that you're not even holding the facility accountable for the goal. You're just really wanting them to collect the data at this point.

Christopher Stille: All right. This is something that, you know, has been done. This isn't new at all. I mean this is – whenever assessments are done in this type of facilities, goals are always established. The goals are established not by the individual doing the assessment but in collaboration, actually, with the patient and the family as well. It's an established goal that they all set together. And then, you know, at time of discharge, that sort of assessed – reassessment is done again.

Rebecca Bradley: (But the fact that goal is not based) …

Christopher Stille: The point of …

(Crosstalk)

Christopher Stille: … you know, is looking at that process. The idea that we will, you know, have the assessments being done, that if there is impairment that goals are established, they're not statistically based, there is no statistics on that end. We would use – probably if we ever did a measure comparing it, we'd statistically look and try to predict where things should be. But again, then, there is a final assessment that is done once the patient is discharged. It's the process of it.

Rebecca Bradley: And I guess to call it a quality measure that you're kind of (impressed) that you are, you haven't expected goals. And that the facility or the patient met or did meet that goal based on some kind of expected database and that's just – to me, that's clear.

Christopher Stille: No …

(Crosstalk)

Rebecca Bradley: I'm sorry?

Christopher Stille: This is just the process of establishing, you know, doing an assessment on admission and discharge and having a goal …

Tara McMullen: Yes.

Christopher Stille: … associated with it.

Tara McMullen: CMS is essentially attempting to collect data to look at, basically, a change in independence or these actions, these motor items on self-care mobility, and see if these items line up to a goal of care and then to standardize this idea out across settings. So that not only can we follow someone at a traverse, you know, the care continuum, but we could follow-up with them as their functional status changes, their independence changes. We know that what they have, the priorities, the processes what they want for their care is really being paid attention to on those who are taking care of the individual, the resident, the person based on what setting that they're in.

Alan Levitt: Right. We may comeback to you and see you in three to five years with a measure that you're thinking of.

Sherrie Kaplan: This is Sherrie Kaplan. I'm a little – I want to make sure that we understand. This is a process measure. It's about documentation only, right? Because the earlier individual, I think it was from – was it from RTI – who is speaking just before the last speaker?

Sarah Sampsel: That's (Anne).

Sherrie Caplan: Yes, (Anne). OK. So – the way I understand it, this is – it's documentation only, and it does have to be somehow linked. So there will be some determination of whether the goal that was targeted somehow related to the functional status assessment on admission and that it's only a documentation

issue, period. It's not about how much somebody's trajectory is changing or anything like that that was remotely related to an outcome measure, right?

(Anne Deitrim): That is correct. And I guess – this is (Anne) again. To add on to what Dr. Levitt said and Tara, I mean many rehab facilities have actually recorded goals on the IRF-PAI, and they actually do it for their own quality improvement. They'd look at whether patients meet goal. So, this is certainly something that a facility could do for quality improvement, but it is not what – CMS will not be looking at their goal. But it's certainly something a facility could do on their own for internal quality improvement.

Katherine Bevans: This is Katherine Bevans from CHOP. I just – I wanted to kind of follow up on (Sherrie's comment) because I want to emphasize that I agree with David Cella that this content of this measure is of great importance. And I don't know that many of us or I, for one, are not arguing against that.

My concern with this measure continues to be that which we, I think, brought up during the meeting, and that is that ultimately this measure is a percentage, right, based on a yes, no. Did you – for each case, where there are two assessments conducted and where the goals generated, yes, no, and then the percentages of yes for a particular long-term care hospital

My concern is simply that we just don't have the information at this point to gauge whether that measure, as it is defined, is reliable, valid, and if there's some indication from your experiences that it's feasible to collect. But the fact is you presented a lot of psychometric information that really supports the reliability and validity of the care measure. But it – this is also true that that's only half of what we're talking about here. We're also talking about the need to evaluate the goals.

And so, I guess, I, for one, feel a little bit stuck with this particular measure because, although, I see the real value of it and the potential of it and the need to move it forward, as it is defined, the measure we really don't have sufficient information to know whether it is reliable or valid as defined. And in the absence of approval criteria that is not full approval, I'm concerned because I feel like you don't want to work this effort and yet at the same time we just

don't have the information that we need in order to feel fully confident that it's met all the NQF criteria as they're stated.

Christopher Stille: Yes. And this is Chris. I agree 100 percent with what Katherine just said. I think there's, you know, awfully good evidence for reliability and validity of the care measure itself, the (CARE), the functional status measure. But I don't see any thing about the care plan for the measure. And I'm even a little concerned about the phase validity documentation that there's a goal, to me, doesn't really meet what most people would think of as a care plan. So, I guess I'm sort of concerned about both of those accounts.

(Anne Deitrim): So, this is (Anne). So, in terms of goal setting in a clinical practice – I mean, you know, I can speak for my experience working in inpatient rehab. I mean it's very variable how much the clinicians can set goals that are realistic. Patient goals can certainly change over time if patients get started with care. So, I guess I'm not sure to what extent that at this stage, you know, we could provide data about reliability of goals because, you know, I think that's a bit challenging to do. And as I said, they change over time. So …

Katherine Bevans: It's not – I'm sorry. It's not so much the reliability of the goal. It would be inter-rater reliability on the degree to which we're able to know what an appropriate goal set, yes or no. It's not so relevant that the goal for an individual changes over time that at admission, when that initial goal is presumed to be set, can we look at that record and say, yes, that goal has been set and it is, you know, an indicator from the care measure. Can we look at that and have some consistency let's say across raters, for example, to know …

(Crosstalk)

Christopher Stille: Yes.

Tara McMullen: This is Tara McMullen from CMS, and I just want to make a point that the appropriate in this argument, I guess, may not essentially fit within this measure. This measure is just collecting whether they had a goal …

(Crosstalk)

Christopher Stille: Yes.

Tara McMullen: … to one of these items. So I completely hear you. And, believe me, I'm a statistician, I agree with you. But that's not where this measure is at this point. The appropriate in this argument may not fit as the outcome is just looking at the items that you see for self-care, the items that you see for mobility and whether one of those items was documented on the goal of care at discharge.

Katherine Bevans: Sorry. Let me restate it. By appropriate, I meant whether it was reflective of a self-care item or a mobility item.

Tara McMullen: Whether it was linked, too, right?

Christopher Stille: Yes.

Katherine Bevans: Right.

(Anne Deitrim): Yes, so the way that the data would be reported if you'd have, you know, on the form it would say eating admission score. And then it would have what the patient's goal is right next to it. So it is directly linked, is that …

Christopher Stille: Yes, you know what? This is …

(Crosstalk)

Alan Levitt: We have, you know, electronic submission system that they submit the data to. And so we'd be able to actually see all the data elements and be able to link whatever would need be to be linked.

Female: Yes.

Alan Levitt: I mean, you know …

Christopher Stille: Yes.

Sarah Sampsel: So, if can then address real quick. This is Sarah. Chris, I know you have to step off so I just wanted to acknowledge that. And thank you …

Christopher Stille: Yes.

Sarah Sampsel: … (for being here) and we'll turn it over to Lee.

Christopher Stille: You know what? Can I just make one more comment, though, before I leave? Because I think, you know, as I'm turning this over in my head, my concern about the phase validity, it isn't – it's mostly around calling this a care plan. I think if it said, you know, documentation of functional status and a related goal, I would be OK with that as far as phase validity goes. But this is not a plan. So the plan is more than, you know, a plan is, you know, who's going to do what, for example. So I think that's really a better way to state my concern about that, and then that's really all I can say, so thanks. OK.

(Lisa Morisse): This is (Lisa Morisse) …

(Crosstalk)

Sarah Sampsel: Go ahead.

(Lisa Morisse): I just want to (inaudible) family members that had care plans and had goals. I would agree totally. A goal is not a care plan. Care plans tend to be much more in-depth. However, I really like the idea of a measure that links current functional status and the goal for improvement. So maybe what we're really looking at here is semantics. And can we tweak this semantic and then …

(Off-mike)

Christopher Stille: Yes. But semantics are important because people are going to say, "Do you have a care plan?" And if this a measure of having a care plan, you know, then it might not go, so.

Sherrie Kaplan: This is Sherrie Kaplan. I, you know, I remember repeating myself over and over again, but we don't have – in terms of attribution to the facility, we don't have any evidence of interclass correlation coefficients that would suggest that the signal to noise ratio, for example, that we could distinguish within facility variability from between facility variation to be useful in practice, is that

right? Or I mean is that because you don't have the data yet or is that because you have the data and it hasn't been analyzed that way?

(Anne Deitrim): We don't have data to analyze. So as part of the post-acute – this is (Anne) by the way. As part of the post-acute payment reform demonstration, we basically had volunteers, so we had 28 LTACs, and we gave them the standardized dataset to collect. And they entered it into an electronic system that made it very hard for them to not submit any data. So we just, you know, we – that's we're we got our reliability, validity analysis from. But we don't have data that looks at facilities over time.

Sherrie Kaplan: Yes, it wasn't facilities over time, but it was facility – between facility variation. You don't have a sense of whether this is useful for attribution to the facility as a quality measure. So there's more consistent pattern within facility and there's a lot of between facility variation. You just don't have those data yet, right?

(Anne Deitrim): Right. I mean, basically, we collected data. We said, you know, "Here's the data. You're a volunteer in this research project. You need to collect this data. You need to put it in to the electronic system," and it was really hard for them to bypass and not submit any data. So, basically, I mean we had a bit of missing data, but I think the highest that we reported on our forms was 6 percent, just over 6 percent for three of the items, mobility items overall across the entire sample.

Female: OK. Are there further questions on reliability and validity, or comments?

I hear deafening silence. Shall we move on to feasibility? OK. And the floor is open for questions or comments on this criteria. OK.

Sherrie Kaplan: Well, this is Sherrie, again. I don't want to be noisy on this call. But to the extent that …

Female: Go ahead, Sherrie.

Sherrie Kaplan: If we – if CMS pretty much set up a situation in which a reporting with like a lock, I mean, you know, you're going to get this reported back. Does CMS

and the developer feel confident that this is enough information to give you a sense of how this would work in practice?

Tara McMullen: CMS feels confident that this would give us enough information for how it would be used in practice. And to meet our five-year plan of quality measurement, development, and assessment.

Sherrie Kaplan: Did I understand that there was like no way the pilot facilities could not respond the way they're reporting on respond, there was no option not to respond is that how it's going to work in practice or no?

(Anne Deitrim): So under the quality reporting programs, the facilities have the option of leaving things with a dash, which means that they prefer not to share the information with CMS. And so, CMS doesn't allow blanks in the current quality reporting system for long-term care hospitals. But people can leave the blanks or they could choose not to submit an assessment. So then, you know, they are at risk for getting a penalty as part of the quality reporting program.

Stacy Mandl: This is Stacy Mandle from CMS. I just want to clarify the requirements of the reporting of this measure in the LTACs that was finalized for reporting the data in – for – in 2016. And for the calculation of this measure and all the data elements required for this measure, the data must be submitted. Failure to submit the data can result in a 2 percent reduction of the APL.

Female: OK. Any other questions for (usability)?

Female: Dawn has her hand raised. I wanted to know if she wanted to comment.

(Anne Deitrim): Dawn? Dawn, are you on mute? I don't think we – I don't think that Dawn is hearing us. I think – let's go on to usability. Any questions or comments here? OK. Sarah, I'm going to turn it back to you for the next step in our process. If there is no further discussion …

Sarah Sampsel: Sure.

(Anne Deitrim): … on the materials that have been provided.

Sarah Sampasel: So what we're going to do now is have Nadine go to the rule again and the question is yes or no. Do you feel this new information warrants a revote? And it's that simple. So, if we'll go to the roll call and yes or no, do you feel this additional discussion and information warrants a revote?

Female: And I'm sorry. Before you start the roll, I did have a question for CMS. And that goes back to our discussion a few minutes ago about the care plan. Would you be comfortable changing the title? I think particularly as it goes forward for public comment you may have some confusion if the words care plan are in there.

Alan Levitt: Yes, we would. I mean, again, this is – it's a measure really looking at assessment, you know, a goal establishment and reassessment. You know, a care plan maybe associated with how to meet that goal but that's separate from this measure. All this is in this data that's being collected on, by the assessments and a goal. Care plan is not being collected in this measure.

Female: OK. And can you give Sarah and company a rephrase title so that we can have 2631 appropriately leveled, labeled going forward?

Tara McMullen: Yes, when and if we have to do that we will work within NQF. Absolutely. This is Tara McMullen from CMS.

Female: OK. OK, sorry. Back to you, Sarah.

Sarah Sampsel: No, that's OK. So is everybody clear on the questions? Great. So, Nadine, go ahead and go to roll call, please. And, again, we're looking for yes, no.

Nadine Allen: Karen Bevans?

Katherine Bevans: Katherine Bevans.

Nadine Allen: Yes, sorry. Katherine.

Katherine Bevans: Yes. No.

Nadine Allen: No. OK, Samuel? Becky Bradley?

Rebecca Bradley: No.

Nadine Allen: David Cella?

David Cella: Yes.

Nadine Allen: Sharon Cross?

Sharon Cross: Yes.

Nadine Allen: Dawn Dowding? Dawn?

Sarah Sampsel: If I may interject there. It seems like Dawn is not able to – I'm not sure if she's listening or not. But Dawn, if you are listening and we can't hear you, you are welcome to extend your vote via the chat mechanism online. Go ahead, Nadine.

Nadine Allen: Sherrie Kaplan?

Sherrie Kaplan: No.

Nadine Allen: Carol?

Carol Levin: Yes.

Female: Dawn's vote just came.

Nadine Allen: Dawn's vote just came in. It's a no. Brian?

Brian Lindberg: Yes.

Nadine Allen: Sherri Loeb? Ann Monroe?

Ann Monroe: Yes.

Nadine Allen: Lisa?

Lisa Morrise: I would say yes with the big change and the clarification.

Nadine Allen: Liz? Esther?

Esther Neuwirth: No.

Nadine Allen: Len?

Lenard Parisi: Yes.

Nadine Allen: Lee?

Lee Partridge: Yes.

Nadine Allen: Debra?

Debra Saliba: Yes.

Nadine Allen: Chris?

Female: He's gone.

Nadine Allen: Sorry.

Sarah Sampsel: So we know we know via e-mail that Chris has voted no.

Nadine Allen: OK. Carin?

Carin van Zyl: No.

Nadine Allen: So all votes are in. We have seven no's and nine yes's.

Sarah Sampsel: OK, so, I mean that is the majority and we do have quorum. So, we will go ahead and proceed with a full vote, and that will be via SurveyMonkey. So the staff will put that together and it will be sent out to the committee, hopefully, today. And it's Wednesday, so we'll be asking for responses, I mean with log responses by Friday. But we'd asked if any that let us know if you would have a challenge meeting in that deadline. And it would be close of business on Friday.

So with that, you know, I think at least we have managed to get through that measure. And I believe the only other thing on the agenda was any other

discussion or questions that the committee may have in follow-up to last week's meeting.

Female: Do you have a date for the next call? Because I think we didn't get to the discussion of (continued) measures.

Sarah Sampsel: All right. I'm sorry. Mitra and Nadine, can you tell us when the post comment call is scheduled?

Nadine Allen: I want to say it's February 20th.

Mitra Ghazinour: Yes, so the post comment was scheduled for April 20th. That is correct.

Sarah Sampsel: Oh, April 20th. OK. So – and then the other, you know, kind of in response to related business competing, we still may not be able to have that conversation on that call. Basically, it's going to be dependent on, you know, if any additional measures are reconsidered and revoted after that public comment period because if you recall, a photo would be a good example of having seven measures that they have until the end of public (inaudible) to provide the data that was missing during their first submission and you would revote until any of those measures fall into related and competing. We have those conversations, but we can't do that until after a revote. So we may have two more calls. Actually, we can plan on two more calls.

(Anne Deitrim): And, Sarah, will we see a copy of the draft report before you put it out for public comment?

Sarah Sampsel: I guess I'm going to ask for process. Suzanne, does that – it does go – because it goes to the committee before it goes to public comment?

Suzanne Theberge: Yes, we do send out a draft with a little bit of time for you all to review and comment.

Female: And any expected time for that?

Suzanne Theberge: Probably mid to late February.

Female: OK.

Sarah Sampsel: Yes, I think we're looking at internally somewhere that week of February 16th. And I guess the other thing to mention here, I know folks who've asked about transcripts. And the transcripts, we don't have – we don't have it back yet but those will be posted on the SharePoint site and that should be tomorrow.

Female: OK. And if there are no further discussions, I think we should open it for public comment.

Operator: Thank you. At this time if you have a public comment, please press star then the number one on your telephone keypad.

You do have a comment from (DED Porter).

Female: Go ahead.

(Ded Porter): Hi, this is (Ded Porter) from HHS (SC). Just a process question. Will the updated information that was circulated between you all in the last week be included in updated specs for the measures so when the draft report comes out it will reflect its updated information?

Female: Sarah?

Sarah Sampsel: Yes. You know, and that was the other important thing about the timing of this call that will be able to reflect that at least the discussion. And the additional comments in the report.

(Ded Porter): Thank you.

Operator: And there are no further comments at this time.

Female: OK. Thank you, operator. And then let's – if there aren't any other questions or comments from our committee members, I think we are ready to adjourn 45 minutes early.

Female: Thank you.

Female: I'm good. Thanks.

Female: All right.

Male: Thanks.

Female: Have a good week.

Female: Thank you.

Sarah Sampsel: Thank you, everybody.

Operator: Ladies and gentlemen, this does conclude today's conference call. You may now disconnect.

END