THE NATIONAL QUALITY FORUM
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STEERING COMMITTEE ON NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR NURSING HOMES
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MEETING
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THURSDAY
APRIL 22, 2010
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The Steering Committee convened in Salon 2 at the Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, Maryland at 8:45 a.m., David Gifford and Christine Mueller, Co-Chairs, presiding.

PRESENT:

DAVID R. GIFFORD, MD, MPH, Co-Chair
CHRISTINE MUELLER, PhD, RN, FAAN, Co-Chair
ALICE BELL, PT, GCS
BRUCE A. BOISSONNAULT, MBA
HEIDI GIL, NHA, CCM
TOMAS GRIEBLING, MD, MPH
SISTER MARY ROSE HEERY, BSN, RN

MARY JANE KOREN, MD, MPH
BILL KUBAT, MS
BETTY MacLAUGHLIN FRANDSEN, RN, NHA, MHA, C-NE
ARVIND MODAWAL, MD, MPH, AGSF, FAAFP
NAOMI NAIERMAN, MPA
KATHLEEN C. NIEDERT, PhD, MBA, RD, NHA

DIANA ORDIN, MD, MPH
PATRICIA A. ROSENBAUM, RN, CIC

PRESENT, CONTINUED:

RONALD SCHUMACHER, MD, FACP, CMD

DARLENE ANNE THOMPSON, RN, CRRN, NE-BC

LISA TRIPP, JD

ROBERT A. ZOROWITZ, MD, MBA, CMD

NQF STAFF:

HELEN BURSTIN

DEL CONYERS

EMMA NOCHOMOVITZ

SUZANNE THEBERGE

T-A-B-L-E O-F C-O-N-T-E-N-T-S

P-R-O-C-E-E-D-I-N-G-S

8:52 a.m.

MS. THEBERGE: Good morning, everyone.

You should have received expense reimbursement forms by email earlier this week. If you didn't, please email me and let me know. And those should be submitted to Leslie Reeder-Thompson, our meetings person, who you received all the logistics emails from. If you have any questions about that process, send Emma or I an email and we'll help you sort through that.

And for the airport, we have a shuttle leaving the hotel at 2:30 from the front lobby that will take people to Reagan National Airport only. And if you are going to Dulles or BWI, you can get a taxi up front at the bell stand up front. And if you have any other questions about transportation, please let me or Emma know.

Any other questions regarding

transportation?

(No response.)

MS. THEBERGE: All right.

CO-CHAIR MUELLER: Well, we are seeing the home stretch. We're going to get there eventually.

I want to compliment all of you yesterday on the good job that you did in engaging in the process. I was wondering if there were any reflections that you've had over the night about any ways to improve the process.

Mary Jane?

DR. KOREN: One of the things that I really would want to get first of all is all the measures well in advance like ten days, two weeks in advance because it really lets you then put the ones that you're reviewing in context and also then be I think a more informed participant in the discussion and certainly in the voting.

MS. NAIERMAN: But not just the

measures. The voting -- the recommendations by the reviewer maybe not two weeks or ten days, but certainly a couple of days in advance so that we can review what the reviewers have said and chime in in a more informed way.

CO-CHAIR MUELLER: Okay. Anything about the process we went through yesterday -- how we could improve that? Go ahead.

DR. ZOROWITZ: I was a little curious as to how some of these evolved to get to the point where we were voting on them -- the first measure, the dementia measure. I think many of us were rather surprised that this was in no shape really to be in front of the committee. And I was curious as to how it got to that point without someone pointing out that the numerator/denominator had nothing to do with the title of the measure.

I think it was a little disturbing and I felt bad for Jackie presenting it, kind of walking into a buzz saw.

CO-CHAIR MUELLER: Yes, yes.

We'll just take that as a comment, or do we have any response? Because I don't --

CO-CHAIR GIFFORD: I want to get back at Jackie because she's gotten me a few other times. No.

(Laughter.)

DR. BURSTIN: In general, we do try to send all the materials out -- all the measures out in advance. For some reason that didn't happen. And we'll make sure that that does happen routinely.

Getting the information back from you quickly and having to turn it around is really a challenge, as you saw. So we've been trying to make it as early as possible. You guys get the information and can get the information back to us. But that, to be honest, continues to be a real struggle to get it back in advance so we can share it back with you. But if nothing else, we do try to

routinely get the entire set of measures out as quickly as possible.

We do screen the forms. And again, I think in screening it the staff mainly looks for completeness.

Is there anything missing we need to go back to? We obviously need to add a little quality check to say complete but actually logical. Is there something really just wrong here? We usually rely on committees to do that. But we'll just have to do some more internal processing to make sure that doesn't happen.

CO-CHAIR MUELLER: Thank you, Helen.

MR. BOISSONNAULT: Can I jump in with one?

I hate to be contrary, and I wanted to say something that you should do again, which is those little memory stick things. I mean, I would like to get it in the mail. But that is so much better than like

getting miscellaneous emails or going to websites and trying to sort of figure out where Measure 001 is, because I end up printing out 1600 pages. And it costs a lot to shred it.

The way that little memory stick was laid out, you don't need to print it out. I mean, it really is so easy to navigate. I think that was a huge plus.

The other thing that I would keep and maybe even go further on -- and this is a questionnaire issue -- sometimes we focus a lot on the numerators and denominators and are they the right ones. And we gloss over really important issues on who owns the data, how will the data come. The issue of MDS 3.0 was really central yesterday, and also the fact that they essentially passed a law saying we're going to gather certain data had, I think, relevance to our discussion.

And so those sorts of au courant things -- being au courant on the ownership of

the data, I think that NQF did a really much better job this time on that whole thing of who owns the data and how are we going to deal with it. And I would even say that almost should be one of the issues -- numerator/denominator data ownership and structure -- because that third point was completely in there but not as its own category like how are we going to get the data.

CO-CHAIR GIFFORD: On a minor piece, you reminded me. Dede brought it up yesterday.

I'd prefer to see the denominator definition first, then the numerator as many people actually try to put the denominator definition in with the numerator definition because you don't understand it until you see that. And just seeing that order helps understand that it's usually what's the eligible and then what are we dividing it into.

MS. BELL: Just one more thing, and this speaks a little bit to having the information more in advance.

Yesterday, the question was asked at the end were there other measures that we might consider. And I think although the information shared was very good, having a night to even reflect on it, I've thought of other things. And had I had all of the measures in advance and not one component of what I was thinking about is in the context of all the measures we're reviewing, what else might we consider. I think that would be helpful too.

CO-CHAIR MUELLER: All right. Thank you for that feedback. And we'll get started.

So we're going to start with function measures. And actually we're talking about urinary incontinence and nutrition and activity today.

So our presenters I believe are

from RTI. I'm sorry. NCQA. Right.

DR. BURSTIN: While Sue's getting up to the mic, this is actually a measure that's up for maintenance. It's already been endorsed for the last three years. We're bringing it to you to get an expert consensus of whether it should still remain in the portfolio.

CO-CHAIR MUELLER: It's 030, or 0030. So on this grid, it's the very last one.

And are you from NCQA?

MS. MILNER: Yes. I'm Sue Milner.

CO-CHAIR MUELLER: Okay. So if you'd just introduce yourself and then you can get started.

MS. MILNER: Sure. I'm a senior research scientist in the Performance Measurement Division at NCQA. And I do a lot of work with our geriatric measures. This is one of that particular measurement set.

The measure is called Management

of Urinary Incontinence in Older Adults. It is one of several measures that we have that is included in the Medicare Health Outcome Survey which is a survey instrument that you discussed about two days ago.

There are two items -- questions that are included in this survey. The first deals with the percentage of Medicare members 65 years of age and older who reported having a problem with urine leakage in the past six months and who discussed this problem with a practitioner. And the second measure involves the proportion who had a urine leakage problem in the past six months who actually received treatment for that problem.

This has been a measure that's been included in the Medicare Health Outcome Survey for several years now. It underwent cognitive testing several years ago when it was first included. Our Geriatric Measurement Advisory Panel has reviewed the measure I believe twice since the measure was created,

most recently last year. And we've given you several years' worth of results for this measure.

What we see is that there unfortunately hasn't been a lot of movement in terms of Medicare Advantage Plan members or SNF plan members on this measure in the past several years. For the first part, discussion of urinary incontinence, most plans report about 55 percent of people discussing this issue with their provider. The treatment unfortunately is not nearly so good. Really only a third of patients who have a problem with urinary leakage actually receive treatment.

So we feel that there's a strong need for this measure, and that plans and providers should be working more closely with patients to engage them in order to get more people into treatment and get more people aware of this problem.

So I'll stop there. You have a

very long measure work-up. And I'd be happy to answer any questions that any of you have.

MS. NAIERMAN: Could I ask a question, please?

How will this apply to people with dementia? We're talking about nursing home settings.

MS. MILNER: Those folks would be screened out by the Medicare Health Outcome Survey instrument. So you have to be cognitively able to fill out the instrument or respond on the telephone.

CO-CHAIR MUELLER: Mary Jane, I believe you're the first reviewer on this. So we look forward to hearing what you have to say.

DR. KOREN: Well, I will begin with a disclaimer which is I am not an expert in this area. But fortunately the second reviewer is an expert. So he will fill in for you where I have gaps.

Overall I think, as we discussed

yesterday, the importance is high. I mean, this is not only a clinical issue. This is a quality of life issue. And I think that the fact that it is a measure has been used. And so we know that it does meet a need.

What is interesting is that while there's not a huge spread between sort of the worst and the best providers in this area, even the best aren't that good. So there is I think really a lot of room for improvement in this area. Obviously, it is evidence-based. And there's sort of good relationships to outcomes.

The thing that I really liked about it was I think often when we talk about treatment we sort of automatically think about pharmacologic, but that there are some very even non-invasive -- I just learned last night -- some very non-invasive procedures that can be done that really can pretty much improve urine leakage. So I think that tied to this needs to be a big educational push to get

people aware of that.

This measure is harmonized with other similar measures. The other thing that's nice about this one as opposed to some of the others is this is for both genders -- male and female, not just female. The measure is very well defined and very precisely specified. So we don't have a problem there.

One of the things though that I was concerned about was that we now -- I mean, this is a measure that's being used and in existence -- but in many instances, it doesn't seem like any kind of an analysis has been done about how has it worked out, has there been any testing of the measure's properties since it was endorsed. And there are I think perhaps things to be learned if people had sort of analyzed some of the data of the experience with this particular measure.

I also was looking at the applicable care settings, and I had the same question that Naomi did. This is for a

nursing home population. And we do know that the presence of dementia is fairly high, which still doesn't mean that people can't answer a questionnaire appropriately worded and administered. So I think that we have to realize that dementia is really a long spectrum of disability. It's not an all-or-nothing phenomenon. And so we really have to be sure that people with dementia, even a fairly significant or moderate amount, are queried so that they can tell about it or talk about it -- bring it up. So that was an issue there.

Again, it hasn't been tested for any unintended consequences, any kind of background of how did this work. And so I would hope that that would have been done.

But I'm going to stop there because as I said, I think Tomas can probably tell you a lot more about this measure from the sort of the technical end of it.

DR. BURSTIN: And actually before

Tomas weighs in, I just want to emphasize this is a measure for maintenance. It's not specific to nursing homes. We just thought you guys knew a whole lot about incontinence and we'd take advantage of you being together.

DR. KOREN: Okay.

DR. BURSTIN: I think the primary use is in fact in the ambulatory care space, although it's applicable across a wide range of settings.

DR. KOREN: That's right.

DR. BURSTIN: Okay.

DR. KOREN: So it's Medicare Advantage Plans and also SNF plans, many of whom are institutional SNFs.

DR. KOREN: It's interesting I think that to the extent that you could get this used in assisted living would be really helpful because often continence is one of the discharge break points for assisted living. So the ability to control incontinence in this population is critical for where they're going

to live.

DR. ORDIN: I'm sorry. I'm reading it now for the first time. Maybe you were going to do this, Tomas.

So the denominator is people who say they have either a big problem or a small problem -- any problem?

MS. MILNER: I'm sorry. I don't have the survey questions.

DR. ORDIN: It says they answer yes. And then the next question, did you have a problem in the past six months. And then it says how much of a problem if any was the leakage for you. And the answer is either a big problem or small problem.

Are both those populations included in the denominator?

MS. MILNER: Yes. Those are summed to include --

DR. ORDIN: Okay. And in the numerator --

CO-CHAIR GIFFORD: It's answer

question 42 or 43. It's yes or yes to either one. You're in the denominator. It's not yes and yes. It's yes or yes.

DR. ORDIN: Well, I think if you answer yes to 42, I assume that you go to 43, right?

DR. GRIEBLING: That's how I interpreted it.

Basically --

CO-CHAIR GIFFORD: So it's yes and yes, not yes or yes.

DR. GRIEBLING: Right. I think the denominator is everyone with incontinence. And then 43 tries to do a sub-analysis and stratify them by whether they have a small problem or a large problem.

DR. ORDIN: Okay. But the measure has both.

MS. MILNER: I can get back to you on that. I unfortunately didn't bring the correct file with me which lists precisely what the questions are and so forth.

DR. ORDIN: And my other question is to receive urinary incontinence treatment, is there a specific question on that? Because -- I'm sorry. Is this two measures? Is this one measure? Maybe you can --

MS. MILNER: Yes. I believe that that is clarified for the respondent. So in other words, they're given some suggestions as to precisely what treatment means.

DR. ORDIN: Okay. So they have to have talked to their provider about it. And then underneath that is like I chose not to -- no treatment recommended, I chose not to have treatment, I had one or more of the following treatments -- something like that?

MS. MILNER: No. It's not a matter of whether they selected treatment or not. It's whether they received it.

DR. ORDIN: Okay.

DR. GRIEBLING: So I would echo Mary Jane's comment about this incredibly important problem. I think the science behind

this is very strong.

The data that you have from the ambulatory setting is very good. And I think that certainly this would be applicable to both assisted living and to skilled care.

The other benefits, it is looking at both genders which is very good. The PARI measure, which is an ambulatory care, is focused specifically on women right now. And actually as a urologist, I'm participating in that. So we report on that. So that measure is all women over the age of 65 -- have you asked them about incontinence, which is basically what this does.

The numerator has two components. So it's have you discussed it, and then have you had treatment for it.

I think there's some feasibility issues. And Mary Jane and I discussed this just a little bit. I think part of it is collecting the data because this won't be captured necessarily in MDS. This is going to

have to be collected separately. So there may be some feasibility issues. You'll have to get that either from the records, from the care provider or through survey from the residents -- whether they've actually discussed it with a provider and then whether they've had treatment for it.

Treatment is also very broadly defined with this. So it could be behavioral therapy, it could be pharmacotherapy, it could be surgical therapy. And so I guess that would be my question, if there's going to be more of a definition about treatment or if it's going to be very broadly examined.

MS. MILNER: Well, our goal in part because of the length of the medical outcome survey and the fact that it's a survey that deals with a number of issues is to be broad. So the focus of the survey is not just incontinence.

DR. GRIEBLING: I think the other thing is it certainly harmonizes with other

measures in other settings, which is something that we talked about being a goal for NQF. So it harmonizes with the PQRI measurements in ambulatory care yet harmonizes with the A cove measurements incontinence and the guideline's recommendations.

MS. NAIERMAN: Can I ask a question?

How do you see this applying to people who cannot report as it were if their dementia is such? So if this is self-reported or if the inquiry is with the residents, do you see that population being left out of this kind of survey?

DR. GRIEBLING: Potentially. And I think that's one of the potential disadvantages here. And again, I would seek advice from our sponsor about that.

Certainly the people that have cognitive impairment or mobility impairment will be people who are at higher risk. And so I worry that we're going to be losing that

higher-risk population in this because those are people who may benefit most from discussing it, and even if they can't discuss it, having it brought to the awareness of their care provider -- the clinician -- so that there could be some kind of treatment offered. Because even patients with cognitive impairment or mobility impairment may benefit from some types of therapy -- assisted toileting, those types of things.

MS. NAIERMAN: So just a follow-up question, does that mean then in a sense that if a nursing home is being judged as it were or rated by a consumer about the quality of care, will the data then be skewed in a sense because there's perhaps more frequency of this problem in a population that is high risk, the consumer may not be able to get the information on the full extent of the problem?

DR. GRIEBLING: I think that is a significant concern for this. And I think that's part of having taken a measurement that

was developed initially for ambulatory care and extrapolating and moving it into a different care setting. So I think that caveat has to be taken into account when you're looking at this patient population.

DR. ZOROWITZ: Just as a point of clarification, are we voting on this specifically for use as a nursing home measure, or are we voting on it for other purposes -- as an ambulatory measure? Because as a nursing home measure, I think we're kind of understating the usability and feasibility problems. And considering the fact that 50, 60, 70 percent of nursing home residents have dementia and that incontinence is a team issue, it's not a matter of discussing it with your provider. It's kind of putting a square peg into a round hole. So I'd just like a little clarification.

DR. GRIEBLING: And I think that's actually a very good point. I mean, when I was going out into nursing homes, one of the

questions we'd often get asked by the director of nursing is are you going to see everyone of our patients -- everyone of our residents or everyone of our incontinent residents. And my answer was no, I don't think that's appropriate. You already have things in place that allow you to screen for this and to potentially treat it.

So I agree that that's a question of whether talking to a physician specifically is the specific issue.

MR. BOISSONNAULT: I was -- go ahead, Helen.

DR. BURSTIN: Again, this is a little bit of a different measure. It was not submitted specifically for the nursing home project. It was not specific to nursing homes. We put it here because the level of measurement and analysis that NCQA proposed or that the settings for which it's applicable includes nursing homes. So you wanted to take advantage of your know-how.

But I do think it would be reasonable feedback. Think about this in the broadest sense of the word -- ambulatory, home health, assisted living, whatever the case may be. If there are specific issues with the nursing home, it'd be a very logical question back to NCQA for them to respond back about how this has worked as part of the work you've done with the nursing home community and how well this has been tested specifically for nursing homes.

But I think the intent here was to get your expertise particularly on the evidence, and is this a logical way to approach the issue for the broadest possible population. And if there are specific concerns about nursing homes, that would be really helpful to hear.

MR. BOISSONNAULT: If I can just jump in.

So this is the illustration that makes the point I was saying before about the

data because I think feasibility when they ask the measure developer, this is a required field or set of fields from what CMS -- if it's ambulatory patient in Medicare Advantage, this is an already existing form that needs to be filled out. It's not new work for the providers if it's a Medicare Advantage patient, correct?

MS. MILNER: Well, let's take a step back.

So CMS for Medicare Advantage and special needs plans requires that those plans complete the Medicare Health Outcomes Survey.

MR. BOISSONNAULT: On every patient who falls in that category?

MS. MILNER: No, not on every patient.

The way the survey works is we pick a rather large cohort. And we follow them for two years. And they're asked the same series of questions during each year. So it's a sample from each Medicare Advantage

plan and each SNF plan.

Now it just so happens -- again, most of the population that is reporting this measure on the Medicare Health Outcomes Survey is a non-institutionalized population. There happen to be some special needs plans that are institutional SNFs. So those individuals, if they're mentally capable of filling out the survey on a piece of paper or they have a telephone and we can follow up with them that way will be in the sample frame and will complete the survey.

But I mean, CMS is really assessing largely ambulatory people in the Medicare Advantage and SNF population with this particular measure. That's the cohort that it's aimed at.

MR. BOISSONNAULT: I like it more after asking you the question and I'll just say why. This is not a measure of provider performance. This is a measure of plan performance which is why you are representing

who you do.

And so, the applicability to nursing homes because of the database definition that we're drawing from is actually not an issue because we're not asking for a measure that would work potentially with the sampling methodology that you're describing in the nursing home setting. There may be parts of this definition. But the data -- the questions when you dig into them say that this is a measure of planned performance, and therefore -- with all due respect -- I actually think this is not. And I still think we can vote on it.

But my caveat would be with respect to Robert's comments. Feasibility may be N on this one in the nursing home environment because we don't gather the data, right?

DR. ZOROWITZ: There are MDS 3.0 questions about incontinence. And I don't remember what they are off hand.

But it's collected in a very different way a) because of the high degree of incontinence and the high degree of dementia. Much of the information about urinary incontinence is gathered observationally by staff rather than by asking the patient. And it is in the MDS 3.0.

So there is a mechanism for gathering the data in the nursing home. But this is not a feasible way of doing it in the nursing home. And I think this is an excellent measure for the ambulatory environment.

But I mean, I would ask Ron with Evercare, for instance, a high percentage of Evercare patients -- Evercare is essentially a SNF.

MR. BOISSONNAULT: I just want to unplug myself from the conversation and say I'm very comfortable with this as an NCQA measure. Unless something comes up, I'm not comfortable if we're voting on it as a

provider measure -- period -- for nursing homes.

DR. BURSTIN: Let me try it one more time. I'm sorry. I don't think I was clear.

We're using you really as more of an expert panel here about a measure for which we think you're going to know a whole lot of stuff.

It really is an issue. This is a health plan level measure that NCQA does. They do specifically indicate in their form to us in that measure submission that applicable care settings would include nursing homes.

But again, it's a level of health plan performance. You're not voting on it in terms of its entry into the nursing home set. So it's more of a broader conversation about the measure. We'll then move it on to our consensus, then approval committee who will do the final maintenance decision.

We're using you as an expert

panel. So take it from that perspective.

I do think it's important information back to NCQA since they've checked that applicable care settings would include patients in nursing homes that it probably needs more study in terms of how you could use -- that's what it says on the form. It does say --

MS. MILNER: Right. But Helen, that's because they're institutional SNFs. And there are some people in the sample frame, and in the sample each year who are in nursing homes.

DR. SCHUMACHER: Right. So if --

MS. MILNER: We're not saying there are a lot.

DR. SCHUMACHER: If I could just comment then.

So it doesn't seem like it would be a very useful measure for institutional special needs plans who exclusively enroll people who live in nursing homes. It doesn't

seem like it would be a very good way to get information about those residents. It might be a good measure for people who live in the community, but not for institutionalized residents because of the way the data is obtained.

And I think part of that is cognitive status of the residents. The other part is just a practical matter of how do you survey nursing residents. Most of them you can't get a hold of. You can't call them. And many of them aren't going to be able to fill out a survey.

MS. GIL: I would like just to add that while I agree that probably a majority of residents cannot be interviewed, we're really pushing the individualization of care. And I think we need to remember that as we think about this very, very important proactive issue with dealing with the quality of life issue.

I think the assisted living on

what Mary Jane said is just an amazing place to start this, test it, and really see. I think the push for education that she also mentioned we found in assisted living that are proactively working on these issues. The biggest barrier is the resident who doesn't want to self-communicate or expose the problem. So I think the education coming with it is real important.

MS. MILNER: Well, I very much appreciate the feedback. One of the things that our Geriatric Measurement Advisory Panel will be looking into this summer is the development of measures around dementia. And I can clearly see that incontinence is definitely something that we want to explore further in that particular population. So I very much appreciate this discussion.

CO-CHAIR MUELLER: Just one point of clarity for me. Currently do any nursing home residents get a survey in the mail to complete this if they're in a Medicare

Advantage Plan?

MS. MILNER: If they have an address and the Medicare Advantage Plan has it, then they're certainly eligible to participate in the sample frame. And if they respond either by mail or by telephone and meet the criteria for the survey, then yes, they can participate.

CO-CHAIR MUELLER: So the point that I'm trying to get at is this could potentially or has been potentially used with nursing home residents already.

MS. MILNER: Yes, it has.

CO-CHAIR MUELLER: Have you ever been able to pull out the data and see how it looks compared to others or what kind of response rate was received?

MS. MILNER: We haven't analyzed the data at that level. Typically what we do is we analyze the data at the aggregate plan level.

CO-CHAIR MUELLER: Yes. But I was

just thinking --

MS. MILNER: But we do have individual patient-level data. So yes, the kind of analysis that you're talking about is possible. And with funding, that's something that we certainly would consider doing.

CO-CHAIR MUELLER: Okay.

CO-CHAIR GIFFORD: Any final comments on this because we don't need to vote on it? It's a feedback to a CSAC and --

DR. BURSTIN: We'll take it to expert -- and we'll proceed. And I think the feedback about use of it in nursing homes is really helpful. So, thank you.

MR. BOISSONNAULT: I think it's a great measure for comparing plans. I think it is unfeasible at the nursing home level.

DR. SCHUMACHER: But again, it may be a great measure for comparing plans except for institutional-based plans that enroll only people who live in nursing homes.

DR. MODAWAL: I just had a comment

about the treatment part of the new measure in terms of how you worded it. And sometimes a person may consider a tablet or some prescription in a medication. And as you know, a part of the treatment for incontinence is also advice in terms of exercises and Kegels and all.

And I wonder if treatment is the right word. It could be advice or/and treatment may be a better way to phrase the second part because many persons may not like to take tablets or have side effects, and they may be doing some exercises and using other forms of scheduled voiding and things like that.

MS. MILNER: This is a good point. And when the measure was originally developed, we did a fair amount of cognitive testing with patients in order to really try and understand when we say the word treatment, what do they perceive that to mean.

And the measure is phrased this

way because as a result of the cognitive testing, that was the best way it was felt to capture all of those treatment options. And certainly Kegel exercises and advice and that kind of thing have been a treatment modality for a very long time.

So it's not --

DR. MODAWAL: So there was no confusion on the part of the persons taking the survey that a physician or a provider mentioned you can empty your bladder every two hours or just do some exercises, the same as a taking a tablet or a medication for that?

MS. MILNER: Yes. When we did the cognitive testing, we explored the degree to which people understand exercises and kind of physical and behavioral changes that they make themselves to the treatment. And patients perceived it that way.

DR. MODAWAL: Okay.

CO-CHAIR MUELLER: So not vote, right? Okay.

Well, thank you so much. We hope this was helpful.

MS. TRIPP: Actually, can I chime in just quickly?

Since you came here seeking feedback and not a vote, I was just wondering if you had any questions for the panel because I don't know if you asked any questions. But before you left, I thought I'd just make sure that there wasn't anything else you wanted from the panel.

MS. MILNER: I think that you've all provided very helpful feedback. I'm going to do some more thinking and certainly talk with some of my colleagues about precisely how this is used and so forth in institutional SNFs. But you've certainly given me some ideas as to how we might be able to use the survey information that plans already spend a lot of money to collect in order to generate some more information which would be helpful for quality improvement purposes around this

topic.

So thank you all very much.

CO-CHAIR MUELLER: Okay. We're going to be moving to 002. And our sponsor for this is the RAND Corporation. We're wondering if they are on the phone.

MR. WENGER: You have Neil Wenger, and I think Carol Roth is also on the line.

CO-CHAIR MUELLER: Well, Neil, if you'd like to get started presenting the measure.

MR. WENGER: So this is an MDS-based measure that is predicated upon the large amount of literature indicating that for patients with incontinence who have the ability to toilet, that behavioral intervention should be entertained first. These data are available in MDS indicating whether patients have incontinence, whether their incontinence is deteriorating and whether they have a functional capability to toilet.

Those are the denominator indicators. And in order to pass the measure, one must have received toileting assistance during the time period which also is collected both in 2 and MDS 3.0.

We have been able to implement this in a large sample of nursing home patients who are dual eligible in about half the counties here in California. It demonstrates actually only a small proportion of the patients do enter into the denominator. But it also demonstrates that the scores are low and that there is need for improvement.

This measure, just like the one that we presented yesterday, is part of a battery evaluating care for vulnerable older patients. And this measure from a validity perspective has been related to the quality of life incontinence scale in community-based patients though not in nursing home patients in a trial that we conducted.

But the statistically significant

relationship occurs only when one takes the composite of quality that includes both diagnosis and treatment and not just this measure alone.

I'm glad to respond to questions.

CO-CHAIR MUELLER: Tomas, if you want to present.

DR. GRIEBLING: So from an important standpoint, an incredibly important problem, high prevalence. There's a lot of data from a scientific standpoint supporting behavioral intervention, both in nursing home settings and in other settings.

When you look at the majority of those studies however, they have a very targeted focus in terms of how that behavioral intervention is delivered to those residents. So from a scientific standpoint, although there's very good data to support this, my concern is that it's lumping this together based only on the MDS definition which is scheduled toileting, prompted voiding and

bladder re-training. So the data itself also includes things like pelvic floor exercise.

It's unclear the standard to which the behavioral intervention will be delivered from facility to facility. And I think that's a concern. So I think facilities could say that they do bladder re-training but the level and the quality of how they're actually administering that I think could vary quite widely. And I'm going to actually ask Alice to come in on that in a minute.

In terms of usability and feasibility, I mark partial for both of these. I think again it depends on staffing in large part. And then the question of whether that's the appropriate therapy, whether scheduled toileting is going to work for some patients. And we really probably need to be a little more individualized in patient care for this measure. That's my concern.

MS. BELL: And I would add I think a couple of things.

We do know that prompted voiding alone when it's done correctly, when it's done on a 24/7 basis, when there is consistency in the intervention is a very effective intervention. I agree with Tomas. The problem here is the definition of the intervention and how specific we are and what the standard is for implementation and performance of that measure.

As well, the issue that we're looking at only patients who can self-toilet, which is a concern to me because I think conceptually and in reality, prompted voiding is an effective measure regardless of whether the patient can self-toilet or not or an effective intervention. And so I'm not sure why we're carving out the population to only look at patients who can self-toilet.

Those would be my primary concerns.

CO-CHAIR MUELLER: We'll open it up to the committee.

CO-CHAIR GIFFORD: Bill is the secondary reviewer.

CO-CHAIR MUELLER: Oh, I'm sorry.

MR. KUBAT: No, that's fine. The secondary review would be what I would just echo what Tomas and Alice have said with maybe one additional comment.

I think as we've said with virtually everything that's been presented, the importance of this issue is stance. I mean, that's not the question. But in terms of the readiness of this measure, particularly where it talks about under the validity that the outcomes haven't been tested, that's a significant issue or question for me.

CO-CHAIR MUELLER: Neil, would you like to comment on some of the issues that were raised?

MR. WENGER: I think that the first issue raised is a valid one. We are limited by what MDS collects and whether such data in any way reflect the trials that have

demonstrated effectiveness is not clear.

However, I have to comment that this measure in the community-based sample is part of the collection of measures that goes through both diagnosis and treatment that is directly related to improvement in incontinence quality of life based on serial measures from patients and the outpatient setting.

So that suggests to us that we are getting at important components though they be derived from in that case the medical record, and in this case MDS. So it suggests the same kinds of things that you see in clinical trials. In fact, the effect of high-quality care or higher-quality care is not much different than the effect of a drug, at least at low dose in these intervention trials. So it gives us some belief that these data that are collected to identify numerator cases are important.

The issues concerning not

excluding people who don't have toileting function based on the MDS is an interesting one, and was debated by our expert panel during the exclusion process. And it's very much similar to the conversation that we had yesterday that they felt that there are many cases where patients with advanced dementia could very much benefit from such treatment, and you would want it to be provided to them. But to say that a treatment was inadequate because someone with advanced dementia didn't receive a behavioral intervention may not fit well with the capabilities of many of the patients. And therefore, they shouldn't be included in the denominator.

MR. BOISSONNAULT: I have just a quick question which is if I understand the measure as designed, you would expect that nursing homes that have favorable results on your measure would also have lower use of pharmacy for this purpose. And if that is true, if that is a measure of success, then

have you done any validity testing to see if the process that is being recommended by this measure actually delivers the results that might indicate that it's working?

In other words, when you looked at the sample populations, are the nursing homes that do this showing lower use of pharmacy to treat incontinence?

MR. WENGER: That's a great idea. Now one would just like for all of these other outcome measures that you're debating, one would need to be able to adjust appropriately. But that would be a really, really nice way to validate this measure.

But one must also recognize that the measure applies only to a small proportion of patients. So it may be difficult to see it at the nursing home level because again, it's only a small proportion of the incontinent patients who will qualify for this measure.

DR. GRIEBLING: This is Tomas Griebling again.

A couple of questions related to when you talked about the community care data that you have, I'm assuming those are people that are residing in the community, not in a facility. Is that correct?

MR. WENGER: Correct.

DR. GRIEBLING: And what type of interventions were included in that? Because the way the measure is designed, your limited because of what MDS collects which is scheduled toileting and prompted voiding, and "bladder re-training." So my concern is does that really match the type of intervention that was probably provided to those community dwellers which was probably much more interaction in terms of pelvic floor exercise, pelvic floor training, diet modification -- those types of things? And so I'm concerned that there may be sort of a leap here in looking at that data from communities and then applying it to a nursing home.

MR. WENGER: I would agree with

you. And maybe I'll let Carol comment on this.

But in that analysis, we are beholding to what the primary care providers document in their medical record. And I might posit that MDS collects much more standardized valuable information than what a clinician happens to document about what they did for urinary incontinence, though it is likely that they're doing more pelvic floor exercises, or at least documenting that sometimes.

Carol, can you comment?

(No response.)

MR. WENGER: Maybe we lost her.

But I --

MS. ROTH: I'm sorry. I had my mute on.

Probably the most common measure that we found was the pelvic exercise. But overall, we felt that we generally found a very low incidence of that anyway overall in terms of behavioral intervention.

CO-CHAIR MUELLER: This is Chris Mueller.

When you look at the MDS 3.0 items, the best we're going to get for a numerator is that they've had a trial of a toileting program. We're not going to know what type of behavioral intervention.

And the other item that's missing from the numerator is how to determine that they are self-toileted -- who are able to self-toilet. So that was not in the numerator.

MR. WENGER: That's part of the denominator.

DR. GRIEBLING: It's in the denominator. It's G.1.A.i), ability to self-toilet.

And this goes back to the exclusion criteria which are going to be advanced dementia and poor prognosis which is essentially people toward the end of life. Unfortunately this isn't going to capture

people who are cognitively intact but may have mobility impairment that prevents them from self-toileting. So we're going to lose that population with the way the exclusions are defined.

MS. TRIPP: Also, I think they need to go back and re-write them with the MDS 3.0 because these are 2.0 measures. And one of the items in their denominator, that question is no longer in existence on the MDS 3.0. So we'll need to remove that.

MR. WENGER: I think we responded to that in the question period. Carol, can you --

MS. ROTH: Well, actually the whole point of the transition to 3.0 did come up although the clarification questions that we were asked to answer were limited. And we were asked to only respond to the questions that were specified. So even though some of the questions asked about that transition, we didn't report all of it although we have done

that crosswalk.

CO-CHAIR MUELLER: Bob, you were going to say something.

DR. ZOROWITZ: Yes. Just as another question of clarification, are we voting on this as a time limited measure as well?

CO-CHAIR MUELLER: According to this no. That box is not checked.

CO-CHAIR GIFFORD: As a committee as we did yesterday, someone who asked for time limited it up, and we can take anyone and move it down. We're not going to vote on what they --

DR. ZOROWITZ: I mean, as I look at this it says to me it fits many of the criteria. It's a very important measure. I think it measures something that we need to know about. It's an important quality indicator because the data collection is both feasible and usable assuming that it can be crosswalked to the MDS 3.0.

I guess the question is because this is going to be looking at a fairly limited population. As a publicly recorded measure, is this going to reflect overall the quality of incontinence care in the nursing home? Or is this going to be too narrow to really reflect for public recording purposes -- management of incontinence is an extremely important issue in nursing homes. It is under-recognized, under-treated.

So I can't overstate the importance of an incontinence measure. The question is whether for public reporting purposes, is this just too narrow. So I'm just wondering what's the purpose of it, particularly if it's not going to be a time limited measure. I mean, I would recommend that it be time limited to see how it's going to fall out after a period of time.

MR. BOISSONNAULT: I would also on the quality improvement side echo some of Robert's remarks, which is I think sometimes

in health care we focus too much on effort instead of results. And if the result we're trying to get here is lower interventions with pharmacy when other less costly and troublesome interventions are possible, I guess I would rather see us get the data on the results because we know how much we're spending on pharmacy. We know who these patients are. And I would rather have a results measure than a proxy process measure frankly where there's no science saying that when you do this you get the desired result.

DR. GRIEBLING: And I would echo that. I think it is narrow in focus. We'll look at a very limited population of residents. And it's focused specifically on process. So I think facilities could end up having very high quality marks for this because they've implemented a program but there's no look at whether the program is actually applicable to a given resident and ultimately whether it's effective.

CO-CHAIR GIFFORD: I think an interesting kind of side comment that we don't need to spend too much time on is if we think the MDO item is too vague and inclusive, why is it an MDS item? I mean, even if the MDS is supposed to be used for care planning purposes and for documentation and for triggering everything else, it sounds like the way it's worded and structured it's a worthless item. And we've had that criticism for a lot here.

So there's a lot of money, time and effort spent in collecting the MDS, and I'm a big believer of the MDS.

One of the interesting things we talked about this is how much we want perfect clinical specificity at each individual patient encounter versus sometimes we want to exclude people because it's a justifiable exclusion but there may be only 100 cases in the entire country. And so figuring out how you exclude is not going to change anyone's measure overall.

And so I don't know where exactly you go with that. It sounds like what Neil is saying is that at least in the outpatient setting, the same sort of vagueness of a question, they're seeing a validity in some relationship because there's always some trend. It's not perfect. It's clearly not what we'd want an individual case area. But when you're sort of getting a higher-level sense about a facility overall if it gets too vague, you end up not seeing any validity because then it really is a wash. But they seem to be capturing enough.

But it's also I think feedback to CMS that as they hear the comments about MDS items that are too vague to be used in a measurement set. I'd ask if they're so vague here, how could you use them on patient care because that's really what the MDS is supposed to be done is for patient care. If they're that vague, it's a worthless question on the MDS. Get rid of it.

MR. BOISSONNAULT: Could I just respond to that?

Sometimes when you raise a useful bit of internal information that mid-level clinical staffs can use at a hospital or a nursing home to the level of a nationally reported grade for which pay for performance might even be involved, these simplistic process measures have perverse consequences exactly like the doctor described where you create a check box. And we saw it with some of the CMS measures on process where a beta blocker and an aspirin are absolutely essential internal measures for hospitals. But as soon as they became publicly reported, they sort of lost of their correlation to mortality which is what we were trying to improve.

And so, I don't know -- I'm not a clinical expert in this area -- but because it may not be one of the 50 measures that makes it to be looked at for nursing homes, that may

not be reason not to ask it for internal use.

DR. ORDIN: I have a question of the proposers of how did you anticipate this being used? Because I think you're right. You're dealing only with over age 65. I think it was similar to the measure we discussed yesterday which was it had to be dual eligible Medicare/Medicaid, and you have to have the administrative data available. How are you using them in California? How do you foresee them being used in other settings? I mean, do you see this being helpful for public reporting for people to use in rating nursing homes?

MR. WENGER: Well, the feedback that we have received from nursing home administrators is that they felt that this measure comparing themselves to other nursing homes could stimulate them to do better nonpharmacologic incontinence treatment for capable patients who could be toileted.

We didn't have a conversation with

them concerning public reporting necessarily. But if they felt that it would push them from a quality perspective, then it's likely the public reporting will do the same thing.

CO-CHAIR GIFFORD: Any final comments or questions for RAND?

(No response.)

CO-CHAIR GIFFORD: I would suggest then giving the comments a vote on time-limited approval with update on the crosswalk with the 3.0 and at least an exploration whether RAND could look at a conversion validity test of how this measure looks with treatment I think, Ron, as you brought up -- if that's possible or not.

MS. TRIPP: Actually, David, if I could ask a question before.

CO-CHAIR GIFFORD: Yes.

MS. TRIPP: I think there are some really important points being brought up about the possible effect of public reporting for this particular measure. And so I guess my

question is can you assess the likelihood that this measure would create a false impression that incontinence is being appropriately identified and treated? That really worries me for taking a tiny picture of a big problem, and it creates a rosy impression. I think that could have very adverse consequences for nursing home residents. I think it's bad policy.

DR. GRIEBLING: I would concur with that assessment.

CO-CHAIR GIFFORD: So I would add then for RAND to give us some feedback on the impact of this measure on either gaming by the industry or misleading information that effective management is actually being done when it may not be effective management. Is that a way to put it?

MS. TRIPP: Yes. I don't think I was so much thinking of it as gaming or being misleading. I was just worried about the construction of the measure itself might paint

the wrong picture so that it takes a very serious big problem and makes it look like it's going just fine.

CO-CHAIR GIFFORD: Well, I think Neil did allude to it early on that in this outpatient this has to be done as part of a panel in conjunction at least with diagnosis and other issues. So I think some more information on that would be helpful from RAND as well.

MS. BELL: And if I could just add -- and not to beat a dead horse -- I think what I'm struggling with here is a couple of things is that we've had in place this concept of bladder re-training, prompted voiding, behavioral interventions for incontinence for a long time, and we're not seeing improvement. So the issue is at this point for me first of all how do we define those methods because people say they're doing it. But what it is is not well defined. And second, what is the outcome?

So what is critical to me is are we seeing a) less of an incidence of incontinence developing because we know the numbers in terms of the risks of patients who come in continent and within a year are incontinent while we're supposedly doing the right thing. And secondly, what is the result of these interventions once we define the intervention actually on managing the incontinence and associating it with the type of incontinence which there's distinct differences based on the type of urinary incontinence as to what treatment is going to be effective?

So I know that's a lot more than is on the table. But that's what I'm struggling with because I don't think this gets us anywhere near there.

DR. ORDIN: I want to follow-up on what Lisa said again because I thought that one of the criteria for usability -- I mean, one of the whole purposes of going to NQF is

that it is a publicly reported measure. And I can see where this measure would be very useful to a facility.

But in terms of usability and usefulness to the public, which is I understand an important criterion here, I don't feel that it has been demonstrated that it's been met. And I'm not sure that public reporting on this has even been trialed. Am I right?

MR. WENGER: Right. It has not been publicly reported.

DR. BURSTIN: NQF-endorsed measures are intended, meaning the idea is they're appropriate for public reporting. There's not a requirement at initial endorsement that the measure's actually been out there or used for that purpose. It just lets you believe it passes the criteria for endorsement, and as such could then be used for that.

We would examine at the

maintenance period of three years whether the measure's actually been out there for public reporting yet. But it would be an early test of a measure that hasn't yet gotten out in that way to see if it's in fact been publicly reported yet.

DR. ORDIN: Not that it's been publicly reported, but the information you get from public reporting is useful. I considered that during --

DR. BURSTIN: One aspect of those on usability that you would have to consider strongly. Yes.

CO-CHAIR GIFFORD: So yes, I'll maybe add what Dede said and Alice and Lisa said. And they've said it better than I. But I think that's probably precisely what I was trying to get at in terms of the outcomes issue.

And the other issue for me has always been as I looked at all of these measures, and considering our discussions

yesterday in terms of what other domains and types of measures need to be considered and so forth, it was hard for me to look at this with this particular measure with all of those kind of questions that have been named to think that it provides that much more compelling value, that this needs to be added in lieu of other things that need to be explored and added in terms of measures.

So I think in terms of harmonization, how does it harmonize for the consumer that's looking at Nursing Home Compare? Because they're not looking at Nursing Home Compare vis a vis Hospital Compare vis a vis other ones. They're looking at the measures that are on Nursing Home Compare and how does that help me discern, and does this one provide that much more compelling value in the midst of all of that. I don't think it does.

DR. GRIEBLING: And I think the problem is because it's looking at process.

Did we deliver this rather than looking at outcome? Did it have an effect?

CO-CHAIR GIFFORD: I think this is going to be a fun vote to watch happen.

I will put out -- and don't be swayed by saying -- I think it should be a consensus. I'm going to put it out and it may well go down.

Time limited with a crosswalk to 3.0 looking at potential conversion validity with the medication if possible, this issue of both gaming, misleading, but also the usability from a reporting standpoint.

I guess I'll start with abstaining. Anyone need to abstain from the vote?

(Dr. Ordin abstained.)

CO-CHAIR GIFFORD: You're going to abstain from the vote? Okay.

Anyone not in favor of that vote?

(Thirteen not in favor.)

CO-CHAIR GIFFORD: All in favor of

that?

(Four in favor.)

CO-CHAIR GIFFORD: So 13 to 4 with one abstaining. So it does not pass.

Anyone want to make any other recommendation?

(No response.)

CO-CHAIR GIFFORD: They're comfortable with that? Okay.

Next measure.

Neil and Carol, thank you very much for getting up so early in California time.

MR. WENGER: Thank you.

CO-CHAIR GIFFORD: Hopefully the conversation was good feedback to you all.

MR. WENGER: Good. Thank you.

CO-CHAIR GIFFORD: Okay. On to measure 19 -- RTI.

MS. CONSTANTINE: Good morning, everyone.

I would just like to start by just

asking a question given these three measures are incontinence, catheterization use and UTI. If I should talk about the group of them as a whole or if you'd like me to focus -- just give you a short overview with the first one or one at time? The group? Okay.

Okay. The purpose of the first measure dealing with incontinence is the proposed measure reports the percentage of low-risk, long-stay residents who lose control of their bowel or bladder in nursing facilities.

I'm sorry. Nineteen? Okay.

And specifically by low risk, we mean that those residents who are not severely cognitively impaired or totally dependent in mobility, are not comatose or have an in-dwelling cath or an ostomy. In regards to what we mean by losing control of their bowel and bladder, on the items on the MDS 3.0, it's specifically those residents who are frequently or almost always incontinent of

bowel or bladder.

In regards to importance, the impact of incontinence profoundly effects nursing home residents in regards to embarrassment, generally in health and quality of life factors such as social functioning is affected by incontinence, and physically managing incontinence can help prevent infections, pressure ulcers, other complications, and mentally as well the treatment can promote well being of the resident by restoring their dignity and social interaction.

We also know that scheduling toileting and bladder programs can successfully be implemented among nursing home residents to address incontinence and the risk factors. And this includes residents who are cognitively impaired.

In using the MDS 2.0 data looking at the data from April to June of 2009, CMS reports that the national prevalence of this

quality measure was 49.4 percent, and it ranged from a low average of 37 to a high of about 69 percent. So we know that this is a major concern.

In regards to the background, there are no changes in the measure specification per se, but there have been changes in the MDS 3.0 focused on making the measure more accurate. Specifically in the MDS 2.0, there is a little bit of a different set of response options. And those are continent, usually continent, occasionally incontinent, frequently incontinent, and incontinent, and it's in the last 14 days.

For the MDS 3.0, the usually continent was eliminated. And the look-back period is now seven days. And one of the issues with the previous measure was that asking staff to think about two weeks back was somewhat daunting, whereas a seven-day look-back is something that's much more usable and I think feasible for the nursing home staff.

Also, in regards to looking at the issues of those cognitively impaired residents that are in the high-risk group, again we have the brief interview of mental status which is a performance-based measure and will better help us to identify those residents, although staff assessment -- there's some items that are also utilized to identify those residents.

In regards to the proposed cath measure, it reports on the percent of long-stay residents who have had a cath inserted in their bladder over the last seven days in a nursing facility. And again, this has been an issue that has been definitely recognized because overuse of catheters to manage incontinence other than for short periods is a potential sign of sub-optimal care and an indication that further assessment in alternative treatment could be offered. And then were not properly monitored or maintained, caths can cause chronic pain or infections leading to greater functional

decline and obviously decreased quality of life for the resident.

And the in-dwelling cath quality measures can serve as a potential reminder to facilities about the importance of assessing and limiting cath use whenever possible. And at any given time, more than 100,000 residents in American nursing facilities have catheters in place. And using the MDS 2.0 data from April to June of 2009, the national prevalence average was 7.7 percent with the low of 5.2 to a high of 11 percent. So essentially, the data items for the MDS 3.0 are the same as 2.0. But again that look-back period has decreased from 14 days to seven days.

And additionally, during our technical expert panel and also clinical input from some research by the University of Colorado, there was concern regarding neurogenic bladder and obstructive neuropathy. And those have been added as specific exclusions as part of the measure.

Let's see. And for the UTI, the purpose of the proposed measure is to report the percent of long-stay residents with a diagnosis of UTI in nursing facilities. And again, nursing facility residents often develop infections. And among these, UTIs are very common.

The symptoms of urinary tract infection include fever, painful or difficult urination, frequency and urgency, blood in the urine, flank pain, and even deterioration in mental status such as increased confusion. Some patients who develop urinary tract infections go on to develop blood infections.

And so again using the MDS 2.0 data, but to give you an idea of the prevalence, the average for April to June of 2009 was 9.7 percent with the low from 5 percent to a high of 14 percent. Another in terms of importance of the measure, it's significant in that it's the only quality measure that really targets infection. And

this is obviously an important indicator of how facilities manage and prevent infections.

So essentially the underlying items of the MDS 2.0 and 3.0 are the same. But there was some question in regards to having some false positives and negatives. There was one study that had been performed in 2004. And the MDS 3.0 although the items haven't changed, it's much more focused in terms of having a more precise definition of UTI. And also it still does look at the treatment of UTI in the last 30 days.

And finally, a small change, unpublished data analysis of the MDS 2.0 by a Dr. Mor of Brown University found some seasonal variation in this particular measure. And to address this, the proposed measure uses a six-month average for the facility rather than the data from just one quarter.

And that's it.

MS. GIL: Can you just give us an overview of the change in definition on the

3.0?

MS. CONSTANTINE: Sure. For the urinary tract infection, it requires a physician, a nurse practitioner or a physician assistant or a clinical nurse specialist to have the diagnosis of UTI in the last 30 days -- oh, I'm sorry -- a physician, nurse practitioner, physician assistant or a clinical nurse specialist must be the one that diagnoses the UTI in the last 30 days. Or you could have the symptoms attributable to a UTI which may include fever, urinary symptoms, pain or tenderness in the flank, confusion or a change in mental status, change in the character of urine or current medication or treatment for a UTI in the last 30 days.

DR. GRIEBLING: So I think Roberta's done a very nice job of summarizing the improvements that have been made in the continence measures in MDS 3.0 compared to 2.0.

In terms of importance, clearly

established, huge problem. Incontinence and cognitive problems are often cited as the two most common diagnoses leading to nursing home placement. I gave that complete -- in terms of scientific data, I also thought the information was not quite complete.

The one caveat that I would have is in the way the numerator statement is worded, I'd want to make sure that when we analyze data in the future we're able to sub-stratify whether residents were incontinent of bladder, whether they were fecally incontinent or whether they had dual incontinence because we know clearly from data that people who are dually incontinent of both bladder and bowel are much more vulnerable and have significantly worse outcomes. So we don't want to cluster them all into one group. We want to be able to sub-stratify that.

The other thing that's really nice about this measure is it's looking longitudinally at this. So if I'm

interpreting this correctly, it's going to capture people who come in continent and then identifying people who may become incontinent. And Alice pointed this out that that's a huge concern. And you cite data about that in the references that the risk of developing new on-set either urinary or fecal incontinence is fairly high in nursing homes and how to try to prevent that. So I think this measure is getting at that. So I think the usability and feasibility are both very high.

CO-CHAIR MUELLER: As the second reviewer, I absolutely concur with what Tomas said. And also this part about stratifying urinary incontinence from bowel incontinence I think is a real important issue particularly because the care interventions are so different. So you don't really know what you're moving -- urinary incontinence, bowel incontinence. And I would be curious about the discussion that might have occurred in regards to proposing this measure and

continuing to keep those two together.

Otherwise, I did rate everything as complete.

MS. CONSTANTINE: In regards to given that the measure is or -- bowel or urinary incontinence, there's a lot of attention given to urinary incontinence but not so much at times bowel incontinence which is equally important. And so I think that the thought was initially that with this quality measure to be sure that you include both.

But I certainly appreciate the fact that stratifying would be important especially also having a category of bowel and bladder because they're at most risk. And we would certainly take that back.

CO-CHAIR MUELLER: Just to clarify then, there would be two measures that would be publicly reported?

MS. CONSTANTINE: I think it's like we could stratify to take a look at bladder, bowel and bladder and bowel.

CO-CHAIR MUELLER: Yes, dual.

DR. GRIEBLING: I think it can be one measure. But I think the way the data are ultimately presented needs to allow people to interpret the percentages whether it is urinary only, fecal only or both.

MS. CONSTANTINE: Okay. Thank you.

DR. GRIEBLING: And that's going to be really important because that will lead them to interventions and potential changes in interventions which could lead to changes in outcome.

MS. CONSTANTINE: Okay. Thank you.

CO-CHAIR MUELLER: Thank you for clarifying.

DR. ZOROWITZ: The measure has been in use. And I found this a very useful measure. I think as a public reporting measure, it's a very good measure of nursing home quality. Internally for quality

improvement purposes, we've also found it useful.

When somebody flags on this measure, it's very easy to dig down into the MDS and found out whether it's bowel or bladder and take action on it. So as far as publicly reporting, I'm not sure that the distinction is going to be that important.

And many of the behavioral interventions that apply apply to the other, although pharmacologic interventions are very, very different. But behaviorally, there's a lot of cross over. So my experience has been that the measure as written -- previously written with MDS 2.0 -- works pretty well. It's a good outcome measure. And I understand the rationale behind keeping them combined.

So far as public reporting, I'm not sure that separating them out would be all that useful.

MR. BOISSONNAULT: I just want to -- because you're familiar with the MDS. So

in other words, if you have eight in the numerator, you can go back to your own internal data. And is this typical of the nursing home setting where they could go back to their internal data and say here are the eight that were incontinent and you actually are looking at the charts and can say this is this kind of incontinence?

DR. ZOROWITZ: Yes.

MR. BOISSONNAULT: Does that meet your concern?

DR. ZOROWITZ: No. And I agree with you that in terms of public reporting, it may not be as big an issue. But certainly if people are going to be using this for any kind of research or developing subsequent interventions, if you lump all of it together, there's no way you're going to be able to separate that out.

And I agree that you can find that in the MDS. But it would be nice to have it within the measure as well. And I think it's

a relatively simple thing to do.

In terms of the type of incontinence, the measures in MDS don't address that in any way shape or form. Is it urge, stress, overflow? Never addressed in any of these measures.

MR. BOISSONNAULT: If I can address it, that's a difficult question because as you know there's a lot of mixed incontinence in nursing homes. I think it's way beyond the scope of MDS to gather that kind of information.

But just for anybody that is not familiar with how MDS is actually used in nursing homes, there's really two ways of getting at the information. One is on an individual basis. When an MDS is filled out, it immediately will generate wraps and care plans for individual items. But also, I don't know if most nursing homes, but at least many nursing homes are collecting data electronically, and therefore have easy access

to electronically analyzing the data. So for instance we can go to an item and if it says that 30 percent of our low-risk patients have lost control of their bowel and bladder, it's very easy to identify those patients that flag and then to drill down and look at the actual MDS items that led to that flag and see which of them are bowel and which of them are bladder.

So internally as a QI measure, it doesn't matter that they're combined because we can separate them out. And I would imagine most nursing homes, if not all nursing homes, can do that. For public reporting purposes, I see less utility to dividing them out. For research purposes, nationally I think the MDS data can be separated out.

So I'm kind of looking at this as voting on it as a quality measure for public reporting purposes. My own feeling would be that it's adequate the way it is.

CO-CHAIR MUELLER: Bill?

MR. KUBAT: Just a couple of comments.

One of the things that was striking to me as I was looking at the documents is that surely it is a continuation measure and 2.0 to 3.0. But those refinements seemingly will have a significant impact because the averages move from 10.-something to 7.-something. And the extent to which that's all a function of the look-back period or more refinement in terms of things like the culture pending issue that I've heard folks reference -- the culture issues and treatment issues -- that piece is not clear to me. But the numbers moved. And they dropped 3 points approximately. And that's a significant piece to note in light of the importance of the measure.

The other thing that is striking to me -- and I don't want to belabor this point so I'll just say it -- but when we've had the earlier discussions about the issue of

wording in the negative or wording in the positive, well, this is one that lends itself that way, or at least to overt consideration. And that whole process is a conundrum to me because I hear CMS say that's maybe our intent that we want to do more of that in light of harmonization. I hear us say and NQF say that we consider it as they're written. And if we invert it, it's not an NQF-endorsed measure. But this is then being introduced by CMS.

So I'm not sure what the message is in that light. So I just let it go at that. It's an important measure.

DR. ORDIN: I think this is going to be true for all the CMS measures. It was yesterday.

Again, the exclusion of people with missing data and ensuring that really was a long-stay population. So maybe we could just say it once.

And I do want to say another thing about the positive versus the negative. I see

these a lot and I find it very confusing.

But somehow if someone is seeing a 93 percent versus a 97 percent, it isn't as striking as if you see a three percent versus a seven percent. So I think for some of these lone numbers, maybe there is a public reporting advantage of having lower being better when you're reviewing these small numbers just so there in the face more.

MR. KUBAT: Well, and again, I don't want to belabor that point. But what I say maybe in response to that is look at Hospital Compare.

DR. ORDIN: Right. That's my point too.

CO-CHAIR GIFFORD: Okay. So we're going to vote on summarizing and to approve the measure as is with two minor modifications which is close the 100-day loophole, address the missing data-issue, and provide -- I'll summarize that dialogue between -- ask the vendors to provide back data looking at the

measure with bowel alone, incontinence alone, the two combined or bowel overall and get a sense what would it look like and then give us a recommendation as to why the experts or given the data and the frequency how best it maybe should be presented and differently look at it. Because I think until we actually see the data, it may be the bowel and urine incontinence is so highly correlated, it doesn't even matter that you have bowel alone in there. But at least until we see that data, it's hard to have that. So that would be the vote before us.

DR. ORDIN: And I would add one other thing that if we're going to ask them to do that, I think we have to ask them -- as with the influenza -- to show how they're going to publicly report it in a way that is understandable to the public.

CO-CHAIR GIFFORD: Okay. So the caveat is not only look at it, but the recommendation is how it would be best to

communicate that to address the usability portion as well. It's a good comment.

You want to add more?

MR. BOISSONNAULT: No. Some are conditional which I don't think we actually do. These are just recommendations.

The question is --

CO-CHAIR GIFFORD: The two conditions would be to close the 100-day loophole and the missing data. The bowel thing would be a recommendation.

MR. BOISSONNAULT: Okay.

CO-CHAIR GIFFORD: Okay?

MS. CONSTANTINE: Okay. Thank you very much.

CO-CHAIR GIFFORD: Anybody else want to comment on that I put forward and clarify it? No?

Approve two conditions, close loophole, missing data, give us data on bowel and how to present. How's that?

(Unanimous agreement.)

CO-CHAIR GIFFORD: Oh, you already voted. Good. All right. Great. Okay.

I want to make sure everyone's clear on the recommendations. Okay.

Next one. I guess, we had also 3 but we have some reviewers. The reviewers want to comment on the catheter piece.

Is there anything to add that's not been mentioned? I will say that the loophole, the missing data one is already there. But catheter, anything unique about the catheter we want to talk about?

CO-CHAIR MUELLER: Naomi? I think you're the primary reviewer on this one.

DR. SCHUMACHER: No, I am.

CO-CHAIR MUELLER: I'm sorry.

DR. SCHUMACHER: I am.

CO-CHAIR MUELLER: You are?

DR. SCHUMACHER: Yes.

CO-CHAIR MUELLER: N-A-I looked like Naomi to me. That's why I went there.

DR. SCHUMACHER: Okay. So just a

couple of things.

So this measure is residents who have or had a catheter inserted and left in their bladder.

Just one thing before I launch into this. I just wanted a clarification. This was a five-day look-back period because I thought you said a seven-day. And I saw five-day look-back.

MS. CONSTANTINE: Okay. Let me doublecheck it. I think it's a seven day.

DR. SCHUMACHER: I think it was written as a five-day look-back. And so just a clarification on that.

Catheter in the bladder at any time during the five-day look-back period or daily during the five-day look-back?

MS. CONSTANTINE: Any time.

DR. SCHUMACHER: Okay. That's what I thought.

So this one captures the percentage of long-stay residents, and again

the 100 day we talked about already, who've had an indwelling catheters in the last five days noted on MDS 3.0. It's a process measure. Was previously endorsed.

The importance I don't need to talk about.

The five-day look-back period, there was comment in here that it was felt to minimize the assessment burden, reduce the opportunity for error, and that it performed well during national testing.

The exclusion that was mentioned was residents with neurogenic bladder or obstructive uropathy. These conditions were felt to justify catheter use to reduce the risk of other complications.

And we already talked about the missing data piece. I noted that as well.

Reliability scored very high on this one on the University of Colorado and the RAND studies. There was comment that the measure stability was unstable over time with

18.9 percent of the facilities having a significant change from one quarter to the next.

Validity. There was the comment that you made about seasonal variation which was similar to variations that are seen in hospital and skilled nursing facility utilization.

Usability and feasibility I thought were good.

I just had a couple of questions and concerns that I want to raise for the group.

One was about the effect on this measure when you do exclude neurogenic bladder and obstructive uropathy. On the data that we saw, the mean percentage on this measure from MDS 2.0 was only 5.6 percent. And there was very limited variability across facilities. The inter-quartile range was noted to be less than five percentage points. So wondering about that.

Also, the fact that those diagnoses I think relatively frequently -- and I'll let Tomas comment on this as well as the secondary reviewer -- but I just wonder if those diagnoses are on record. And I've seen those diagnoses get put on the record when somebody just has like one episode where they're not able to void in the hospital and they get that diagnosis. So how is that diagnosis going to be taken into consideration here? And does that create an excuse to leave a catheter in for a longer period of time because they carry that diagnosis from the hospital?

I doubt this would happen, but is there an opportunity to gain the system by having a physician put that diagnosis down so the catheter can be left in place? I don't think that would happen. I think it would be easier to just remove the catheter. But I'm just raising it as a possibility.

And then I think Tomas had also

some thoughts about the F-TAG for incontinence and some other comments.

DR. GRIEBLING: I would concur with Ron's comments. I think in general this has been very well structured, clearly strong importance in scientific background.

In regard to the diagnoses of neurogenic bladder and obstructive uropathy, I think that is a concern to put them in an exclusion in the denominator, with the concern being that those people could then simply have indwelling catheter placed as an easy out.

The other option for treatment for those patients is intermittent catheterization. And there's clear data to show that intermittent catheterization has significantly lower morbidity associated with it in terms of infection and problems. The problem is it's a significantly more labor-intensive treatment on staff. And so my concern is that we may sort of gain the system in that people will then just put a catheter

in these people and not even try to do intermittent catheterization which would be preferable if it's possible. So I think that would be the one thing.

I think this does harmonize fairly well especially with the F-TAG. I think it's 316 is about urinary incontinence and catheter use in nursing homes. So I think that's a good thing with this measure.

DR. KOREN: The other problem that you could get into is that often people come from hospitals and they've had a catheter in for a long time, and particularly with old men when you first took it out. They do have obstruction and they can't pee. And so a trial of intermittent catheterization in fact can relieve what's an obstructive uropathy. And so we really have to look at that.

DR. GRIEBLING: Well, and similarly looking at them is the patient potentially a candidate for medical therapy? So if they have obstructive uropathy, could

they potentially benefit from alpha blocker medications or 5-alpha reductase inhibitors or things? I think that's beyond the scope of this. But ultimately trying to pair it to pharmacology and polypharmacy, are they on medications that are putting them into urinary retention -- those types of things?

But I think that's again beyond the scope of what's being proposed here.

CO-CHAIR GIFFORD: So what I'd put before the group then is approve as a measure with two conditions: close the loophole and missing data, the numerator and a recommendation to provide data on the number of times exclusions happen -- percentage of that -- both by neurogenic and obstruction -- look at it both together, and potentially recommendation to the CMS as well, some look at the accuracy -- this is from a sort of a reliability/validity testing -- but some accuracy of the diagnosis of obstructive and neurogenic bladder.

The CMS, you may want to give this guidance since it's probably an F-TAG through this -- Jean's still here -- through this survey shop, these were all out there. And we can actually doublecheck on this from a data check standpoint. It would be helpful.

So before us approve with two conditions, one recommendation.

DR. BURSTIN: Just a quick comment. I guess there was a question about the fact that two of these measures were paired in the last round, and do you want to address that issue again this round?

CO-CHAIR GIFFORD: What do you mean paired?

DR. BURSTIN: Two measures that would always be reported together is how they were in the last round. I just think it's worth at least having that discussion.

CO-CHAIR GIFFORD: Well, let's do them all and then we'll come back to that.

DR. BURSTIN: That would be fine.

Yes.

CO-CHAIR GIFFORD: Okay. Ignore the woman to my left.

(Laughter.)

CO-CHAIR GIFFORD: Okay. Any abstaining?

(No response.)

CO-CHAIR GIFFORD: Anyone opposed?

(No response.)

CO-CHAIR GIFFORD: All in favor? Okay. It passes.

(Unanimous agreement.)

All right. The next measure and we'll come back to Helen's point in a second.

Eighteen -- UTI?

MS. GIL: Okay. Obviously an update to the 3.0.

This indicator is going back to what to -- was saying about the drilldown. I think it really impacts in terms of looking at all kinds of issues relevant to care, and importantly so individualizing bladder

programs as well as obviously infections. So I think this obviously has significant importance.

The seasonal variation I think is an important aspect as well that I think it's really important with this change. And we should also note that this is limited to long stay based on the ETI from hospital rate. So I think that makes a lot of sense as well.

In terms of testing it to make sure that over time it's valid is obviously a piece in our timely limited testing. Its usability and feasibility is high. This is pretty straight forward and complete from my perspective.

Bill?

MR. KUBAT: Nothing to add to that other than the notation again that the UTI numbers dropped. And the extent to which what element of the refinements in the 3.0 are contributory to that, but three percentage points -- I mean, dropping from 10.-something

to 7.-something is significant. And in terms of how that's reported, communicated, explained in terms of the drop I think is an important piece. And this probably relates to any or all of the issues that we've reviewed -- all of them that relate to 3.0.

At the time that I was looking at this last week, the train-the-trainer session was going on, and there was discussion there that some things are being changed as we spoke or as the meeting was taking place. And so the overarching question was are there any changes that had been done prior to all of this work being done or are anticipated that impact how any or all of this is considered. I assume the answer to that is no. But I don't know that with certainty.

But the other thing also to acknowledge that because there are significant changes in the refinement of the RAI manual and the fact that that's not going to be out until end of May, early June at best, it just

compresses the time frame for implementation and just exacerbates all that training and education pieces.

DR. GRIEBLING: I would agree with both of the reviewers. I think this is a very important measure and something that's very usable and very feasible.

On a little bit more of a subtle note, which I'm not sure we're going to be able to capture at a measure level, is the definition of urinary tract infection. And my fear in this and what I see clinically are a lot of people that are sent to me for evaluation of "recurrent urinary tract infections" who in actuality have asymptomatic bacteriuria. And there's clear evidence that shows that the overall prevalence of asymptomatic bacteriuria both in community-dwelling elderly woman particularly and long-term care residents is about 20 percent, and that longitudinally over time those numbers stay similar but it often changes individuals.

So if you look at a population of people now, about 20 percent will have bacteria in their urine that's completely asymptomatic, and generally the recommendation is those people don't need antibiotic treatment. If you look six months from now at the same population, you'll have about 20 percent, but it may be different women.

And so that's my fear in this of people getting misdiagnosed as having a urinary tract infection. So I think the real clarity is just making sure that we're defining it correctly as symptomatic urinary tract infections.

MS. ROSENBAUM: And just to ask about that, I was wondering about that when that was going on because is that defined as symptomatic?

MS. CONSTANTINE: Yes.

MS. ROSENBAUM: So that's how somebody would judge that and mark that down as an infection.

DR. GRIEBLING: Right. The way that I read this measure, it is defined as symptomatic. And we need to remember that in the elderly population, symptomatic is different than in young people. So fever, chills, dysuria, pain with urination, common in young people, not as common in older people. So the criteria about confusion, anorexia -- those types of things -- are important in this measure because those are symptomatic in older adults.

MS. GIL: Tomas, thank you so much for mentioning it. I have it in my notes simply again going back to that drilldown where you're really looking at the data. A lot of times, you are looking at that reoccurring issue at the end of the day. So being able to really cipher that out I think is important and why I asked for the definition. So thank you for that, Tomas.

DR. ZOROWITZ: As an interesting side note to this, I concur with everything

you've said. Urinary tract infections are probably over diagnosed in nursing homes. And one I think attractive perhaps side effect of this measure would be to give an incentive to nursing homes to more accurately define who has a urinary tract infection and who doesn't.

It would be nice to reduce your measure simply by accurately diagnosing urinary tract infections and not -- what happens practically is a patient becomes a little bit more confused. A urine sample is obtained. It shows bacteria, and they're diagnosed with a urinary tract infection when in fact it was asymptomatic bacteriuria. And the confusion may be because of medications, because of fluctuations and delirium because of fluctuations of dementia. And I think this will help keep facilities honest in addition to looking at the other quality implications of it.

MS. ROSENBAUM: Actually there is a published definition for that from my

organization. Because if you're surveilling infections in a long-term care facility, you have a written definition. And it excludes the bacteriuria -- the asymptomatic.

So as long as that's used, and it sounds like from what you stated about the criteria for an infection, it's pretty much along that line.

DR. GRIEBLING: And part of that issue is that often -- and I concur with all of those comments -- is that often that diagnosis is then made solely on the basis of a dipstick urinalysis, and there are significant issues with the overall sensitivity of specificity of a dipstick urinalysis. The sensitivity is -- but the specificity is not great.

Clinicians then need to move to the next step which is to do a urine culture to make sure that the treatment is then truly treating an organism that's going to be responsive to whatever that therapy is.

Again, that's beyond the scope of the way this measure is designed. But ultimately that's what we need to try to get to.

MS. GIL: I just want to mimic what Robert said real quickly again in terms of making the data usable for organizations because this is why we're all here. We want this data to be looked at and used to drive care and outcomes. So something that can help streamline this would be very important.

CO-CHAIR GIFFORD: CMS?

DR. LING: Just one additional comment and a response.

We appreciate the concurrence with the toil that we put in to try to focus this on symptomatic and to take the emphasis away from asymptomatic bacteriuria. And this was one of the areas that we focused so intently on that caused a little bit of a delay for the manual. So it was well intended.

DR. GRIEBLING: And I think it's

really important that you did that. I think that's very, very important.

DR. BURSTIN: One issue on the horizon in terms of harmonization is we're about to embark on our large HAI project this year, actually in the next couple of months. And CDC is submitting an updated case definition and measure to NQF around UTIs, especially catheter-associated UTIs. So I think we just need to make sure we harmonize that going forward.

That won't be endorsed for at least nine months. But I think it's an important future thing to make sure the same rates of UTIs that go into hospitals we should really be defining the same way.

CO-CHAIR GIFFORD: It's really important as we do that because I work with CDC everyday, but also bridging the geriatric world.

CDC defines UTIs in the young people. And what you're hearing here is it's

very different in the elderly. And this issue came up on -- and the geriatric -- whatever this -- the geriatric measures panel that I was on, we talked a lot about the same thing with that.

So what I hear before us is approve the measure, close the loophole, missing data. And then for the vendor and the development, I don't hear anything else. I'm going to summarize this in a recommendation back to CMS though. But approve the measure with the closing of the loophole and missing data.

You have a pained look on your face, Rob?

DR. ZOROWITZ: No, I'm fine.

CO-CHAIR GIFFORD: Okay. It's a happy time. We're getting through the measures. We did the pain yesterday. We got that done.

Any abstaining?

(No response.)

CO-CHAIR GIFFORD: Any opposed?

(No response.)

CO-CHAIR GIFFORD: All in favor?

(Unanimous agreement.)

CO-CHAIR GIFFORD: Okay. The recommendation to CMS again to Jean Scott and everyone else is the RAPs and the F-TAGs need to really be improved probably on this very issue of overdiagnosis of UTI. And it needs to be done in a way that empowers the medical director and the nursing staff to take on my colleagues who are the ones who really are ordering the urinary cultures when as soon as they see the bacteria they feel compelled to treat.

DR. GRIEBLING: And it also needs to harmonize to the never event in acute care. So the fact that patients who are admitted to us in acute care settings, if they develop an iatrogenic urinary tract infection that will not be covered under payment by CMS, that all has to be harmonized in this.

CO-CHAIR GIFFORD: The big problem is you need to empower the nurses to take on the doctors because there's a synergy between the nurses and the doctors here. The nurses feel compelled to do something. The doctor says we'll just order a urine. And it starts a cascading event. The urine comes back abnormal. The doctor says then give him an antibiotic. The calls stop. Everyone's happy. Except the patient's the one that's harmed during the whole process.

So until you're in a position to help break it and work with the state survey agencies, the reporting and payment and linking it all together, I think it would just be very powerful.

MS. ROSENBAUM: And that plays into overuse of antibiotics too in the elderly population.

CO-CHAIR GIFFORD: Exactly.

All right. We finished incontinence. Please know the incontinent use

the bathrooms.

(Laughter.)

CO-CHAIR GIFFORD: And we're back here in 15 minutes.

Okay. I move we approve all three measures as is. Everyone in favor? Okay. You guys can go. We're done.

(Whereupon, the above-entitled matter went off the record at 10:45 a.m. and resumed at 11:00 a.m.)

CO-CHAIR GIFFORD: Okay. So what we need to do now is reflect back over the measures we've gotten. So reflect back over the measures that we've done so far, and what we've passed and haven't passed.

Okay. So a couple of quick announcements. I was just talking to fill the time in. You sit down when I talk.

So show of hands of people who need to take the shuttle to National Airport for the 2:30. In the back too. Yes. So we've got to count one, two, three, four,

five, six -- six people. Okay. I counted you. Did I miscount? Was it seven?

Show of hands again. I clearly can't count. One, two, three, four, five, six. Yes, six. Okay.

Why do you want to know about BWI?

How many people are going to BWI?

Is there a chance we're going to end early?

We could always hope.

Okay. On the issue that Helen brought up last time, the two measures that we approved -- the two incontinence measures. In the past, there was a recommendation from NQF that those measures always be used together because of the potential for gaming. Kind of like what we said before. If you can put a lot of catheters in a lot of people to get out of the exclusion for the other. So when the exclusions in one measure are used to get you out, there is also a quality measure elsewhere. There's usually been a

recommendation to pair those two.

So what it would be is that the low-risk bowel and bladder and then the use of the catheter. Those two would be paired together.

I would ask do you think that the UTIs should be paired as all three or they can be done that -- the other two we didn't approve. So it would just be those two.

Comments on whether they should be continued to paired or not? They currently are paired.

No comments or questions about it?

MR. BOISSONNAULT: What do you think?

CO-CHAIR GIFFORD: I just do what I'm told.

So I would put forth to the committee that they be paired. That's what I think, Bruce. They should be paired.

MR. BOISSONNAULT: Could we ask the developer? Should they be paired?

MS. CONSTANTINE: Yes, we agreed that they should be paired.

MR. BOISSONNAULT: I move that we vote to pair them

MR. KUBAT: Just a question in relation to that.

Not to be overly simplistic, but does the paired mean just reported in proximity or does it mean some explanatory commentary?

CO-CHAIR GIFFORD: I think the explanatory commentary and other stuff is up to the people who would use it. But essentially we're endorsing them almost as a single measure that they have to be done together. If someone's going to use them they shouldn't just use one of them.

So whether it be CMS or the Rhode Island Department of Health wants the report, I'd have to use both of them together.

DR. BURSTIN: All right. So essentially, you would always report them

together. They would not be a composite. You wouldn't get a single score out of it but you'd always make sure those two measures flow together to be able to look at the issues between them.

MR. BOISSONNAULT: More specifically would the implication be that the baseline dates -- if one of the issues is squeezing the tube of toothpaste, you wouldn't want someone to be able to use timing issues.

So is that what you mean by reporting together that they would be drawn from the same data set timing?

DR. ZOROWITZ: I think currently if you look at the QMs, both of those items are always on the QMs. I don't think that this means that they're going to be linked and there's going to be something that says you have to look at both of these measures.

I think the point is that if one of them is going to be reported, both of them must be reported. Regardless of where on the

list of QMs they're reported, they both have to appear.

MR. BOISSONNAULT: But we would be looking at the same data set and same data timing for the two different measures. Isn't that part of the point is to keep someone from squeezing the tube of toothpaste by playing with timing or something?

MR. KUBAT: Do we do the same thing with restraints and falls?

CO-CHAIR GIFFORD: I'm going to the other measures as well. In fact, that's why I tabled it there. I wanted to see if there was other stuff. So, yes.

So on this one, always ask the patient. So we're asking the vendor if they want to do it. The recommendation before us to pair it as before.

All abstaining?

(No response.)

CO-CHAIR GIFFORD: Favor?

(Unanimous agreement.)

CO-CHAIR GIFFORD: Against?

(No response.)

CO-CHAIR GIFFORD: Okay. It passes.

To Bill's point, were there any other measures that we did yesterday -- now you've got to remember what we did yesterday -- that should equally be paired?

Restraints or falls? Yes, Alice?

MS. BELL: I was just going to say that that would be my recommendation is that falls and restraints be paired. I don't know what we did -- to be honest with you -- that would fall into that.

We did the injurious falls. I don't know if we talked -- I apologize. I'm blanking on the restraint measure.

But yes, I would say restraints and falls should definitely be paired. And if we had talked about both physical and chemical restraints, so psychotropics as well as physical restraints that there be a pairing.

CO-CHAIR MUELLER: Could someone remind us? I know we did not approve the two A&A fall indicators. Did we approve any fall indicator?

MS. BELL: I believe we approved the injurious fall.

DR. MODAWAL: Major.

MS. BELL: Major injury. So major injury fall with restraints.

MR. BOISSONNAULT: Could we have numbers?

MS. THEBERGE: 008 and --

CO-CHAIR GIFFORD: 21.

MS. THEBERGE: -- and 21's the restraints.

So it's percent of residents experiencing one or more falls with major injury long stay, and percent of residents who are physically restrained long stay.

MR. BOISSONNAULT: And are they both from the same data set?

MS. THEBERGE: Yes.

MR. BOISSONNAULT: Okay. Because pairing if they're not from the same data set makes no sense. You can still game it.

DR. ZOROWITZ: Just to throw a little point of dissent, we know that neither chemical nor physical restraints reduce falls. And in fact, they probably increase them. So I don't know what the necessary importance of pairing them would be because if someone thought that they could use restraints to reduce falls, their fall rate is probably going to go up or remain the same.

So I think it's a different issue than the other one. I don't really think it's necessary to pair them.

MS. BELL: And I agree with you that statistically it does show that we -- and actually the risk of injury is greater with the fall when a restraint is used. I think there was just some concern -- I think the interests might be -- and maybe this is a time-limited thing -- is that people may

attempt to use restraints even though the result would be more injury and more fall. And so the pairing might just be to see how often are people attempting to solve one issue with the other even though the outcome is going to be more negative, I guess, if that makes any sense.

CO-CHAIR GIFFORD: Along those lines, I didn't like the fact that we even put the fall measure -- I mean the restraint measure in the fall section because it denotes that restraints are somehow tied to falls. Restraints really are quality of life issues. They should be grouped as a quality of life issue outside of that.

But that doesn't mean that pairing aren't maybe important issues around quality of life and other aspects. And since they are -- they go together, it doesn't have to be that they're squeezing a toothpaste going different ways. It could be that we still think that they're so important you'd want to

pair them together.

So that doesn't mean that voting to pair them isn't wrong here. It doesn't have to be the rationale for it.

MR. BOISSONNAULT: To the vendor, I think -- and this may have been a more limited conversation among some of us -- but I think there's some evidence that restraints actually lead to more harm falls. And so the point I think Alice was making in pairing was in fact exactly consistent with what Robert was saying is to sort of highlight the linkage that if you think the simple solution is to just bind people in order to reduce harm to them that you may see -- the literature suggests the inverse. And so that would be the point of pairing.

But do you have an opinion on pairing those two?

MS. CONSTANTINE: I would suggest pairing them because I think until we see the data and falls is a new measure. So I think

it would be very good and also to remind us to take a look at them together and see which direction that they go and to be very cognizant of that for us as the developers as well as facilities and to monitor that. So it makes sense to me to pair them.

MS. CONSTANTINE: And again, part of the definition of pairing is that we're not playing with time frames, that to the extent that we can we're drawing from the same time frame even though they're different measures. Or do the measures not allow for that in this one like they did with the last one?

DR. ZOROWITZ: I was just going to say there is a difference here. Because with the incontinence measure and the catheter measure, if you put in a catheter you eliminate one person from your incontinence measure. So there really is an effect of one on the other.

This is the opposite. You cannot reduce your fall rate by putting restraints on

somebody. So you're not going to have the adverse effect on measurement by putting a restraint on somebody as you would by putting a catheter in someone and eliminating them from being measured as an incontinent person.

So I think the reasoning in pairing the two is very different.

MR. BOISSONNAULT: I agree with that. I'm not sure it goes away. But I agree.

DR. ZOROWITZ: And the only caveat that I would have is that the falls measures is relatively new. And while I think it's interesting to look at a restraint measure with a falls measure or several falls measures, I wouldn't want to say specifically it should be paired necessarily with this falls measure because we don't yet know how this falls measure is going to work since it's new and it's going to be tested.

So I'm convinced. So could we recommend seeing if in fact there is a sort of

perversity of serious harm when there's an excess of binding people or whatever -- yes, restraints as opposed to making it a requirement of passing the measure. I think you're right making it.

DR. MODAWAL: There is some relationship of course of falls and restraints. But I think the type of restraints and where you use it actually in terms of all the restraints are not bad. I mean, they're considered bad but in terms of falls or injuries, perhaps there's less chance to use in bed to make it more harmful than those which are used in a chair.

So I think some qualification is needed in terms of what kind of physical restraints we want to look at. And we're not talking about falls actually. The main issue was in the outcome and the indicator was the injury -- the major injury, and I think the relationship with the major injury and the physical restraints.

CO-CHAIR MUELLER: So it means that there's this recommendation not to pair those two?

MR. BOISSONNAULT: Not to require it.

CO-CHAIR MUELLER: Not to require. Right.

DR. MODAWAL: Just to look at but not --

DR. ZOROWITZ: You may find that higher restraints is associated with the higher falls measure. Or higher harm. Right.

CO-CHAIR MUELLER: I don't believe that requires a vote though. It's just a nice friendly recommendation. Okay.

All right. We're going to start on measures related to nutrition and other functions. So item 24, residents who lose too much weight.

DR. NIEDERT: I was the primary review on this one.

CO-CHAIR MUELLER: But we need our

developer to talk about it first.

MS. BERNARD: I'll ask the same question that Roberta asked earlier. And that is there are three measures in this set. Do you want me to go over all three of them or one at a time?

CO-CHAIR MUELLER: The first one seems so different than the second two.

MS. BERNARD: Okay. So --

CO-CHAIR MUELLER: So let's just do the weight one.

MS. BERNARD: Okay. I'll do that initially.

But the three measures -- what they have in common in this set is that they're longitudinal measures. And the weight loss measures looks at -- well, it updates the current MDS 2.0, weight loss measure, by adding physician-prescribed weight loss as an additional category in the underlying item, and using a two quarter average for the facility rather than a single quarter to

address concerns about seasonal variation.

Nursing facility residents often have chronic diseases and functional impairments that present a challenge for proper nutrition and hydration. Residents with weight loss are at higher risk for functional decline, hip fracture and mortality. And consequences of weight loss may include muscle-wasting infections and increased risk of pressure sores.

The prevalence estimates of poor nutrition and unintentional weight loss among people in institutions vary from two percent to 41 percent. Using the MDS 2.0 data for April to June of 2009, the national prevalence of too much weight loss in nursing homes was 9.2 percent with a range of low from an average of seven percent to a high of an average of 11.4 percent.

So to summarize the changes in the underlying items, there's a slight different between MDS 2.0 and 3.0. And the MDS 3.0

weight loss now has a three response category with the two new ones referring to physician-prescribed weight loss.

So the response categories are no or unknown, yes on physician-prescribed weight loss regimen, or yes, not on physician-prescribed weight loss regimen. And it's only that second one that's used for this measure.

The improvement in measurement in this is that as a result of some work that was done by Vince Mor who found seasonal variation in the measure, the proposed measure uses a two quarter average for the facility rather than a single quarter.

And that summarizes the changes in the measure from the current one.

CO-CHAIR GIFFORD: Seasonal variations that go up at Thanksgiving or Christmas or --

DR. NIEDERT: I looked at this measure, and obviously having my first career for 35 years being a dietician and being a

dietician in long-term care, it is one of those very close to my heart.

We know that the importance because of all of the ramifications of poor nutrition which she alluded to -- the increased falls, the increased fractures, certainly impaired skin. So we know that unintended weight loss, it's always been a quality measure, has been for some years. The interest to me is that there is tons and tons of research and we know about it. Yet when you look at the statistics, they haven't gone down any since we started keeping this measure.

I would agree that the measure is important. But I think a caveat of that because I think in the verbiage it talked about only one area of concern. And I would like to see the consequences of not only poor quality but certainly of increased mortality, morbidity and high use of resources also listed.

Some of the evidence that they reviewed was over ten years old. But as all of us know, the evidence is there.

There was mention of no formally related evidence. But the American Dietetic Association has done some extensive review of unintended weight loss with ratings. It has been measurable information where they looked at different studies.

And I think one of the omissions of this information probably was because there was no registered dietician on the TEP which I felt was certainly lacking when the dieticians do deal with the nutrition issues much more than most physicians or nurses.

There was also no mention of the guidelines done by AMDA. I know that they have those. And I would have liked to have seen those included in some of the references.

One of the things that bothered me in the review material was that one of the quotes that was used was from Dr. Morely that

contends that there are minimal intervention studies demonstrating any salutary effect on weight loss. That was the quote they used. But this is kind of beside the point, and I'm not sure of its relevance if we're trying to prevent weight loss -- when he says there's nothing to do anyway. So that quote I would have liked not to have been there.

I think from a scientific point of view and the usefulness of the information, I think there's some concern for facilities that specialize in end-of-life or dementia because their numbers are going to be statistically higher because of their population. So I'm wondering if that couldn't be stratified -- the information couldn't be stratified or adjusted to be more beneficial for that segment.

I didn't see any other problems with usability. Most of us are using it as a tool to help prevent weight loss or decrease our unintended weight loss in our facilities.

And certainly the CMS surveyors and state surveyors are using it to inspect our homes.

I didn't see any problems with feasibility at this point either, but I will let -- Bob was my cohort in crime on this one, so I'll let him discuss anything else that I left out.

DR. ZOROWITZ: I concur.

The only other point, end-of-life was not an exclusion criterion. And I have mixed feelings about that because while we often see weight loss in our terminally ill residents, it's not universal. So I wonder just as a question whether that might have been why it was not an exclusion factor.

DR. NIEDERT: The other issue we'd have to look at -- this was long-term stay, so it goes back to our 100 days that we talked about. And there's something else I just thought of and I just lost it. I think maybe I have dementia. It had to do with dementia too unfortunately.

Oh. Not marking the box because you're not weighing those residents that are at end of life and you have orders many times. That shouldn't count against you, I don't think, especially if they're in palliative care and many times they might have bone cancer and metastases. And so by moving them you disturb them and cause them increased pain, so why would you weigh them to begin with? You know what the outcome is. They're losing weight.

So I'm not one of these dieticians that demands weekly weights or whatever on residents in end of life.

DR. MODAWAL: I have the same question. I don't know whether in nursing homes do they classify a patient in the hospice care separately?

DR. ZOROWITZ: There is an item on the MDS 3.0 which is end of life. And I don't have the -- I think it's J1400. I'm not --

DR. MODAWAL: And if it is

possible, they can be. If it possible, then they can be excluded from the --

DR. ZOROWITZ: It's J1400.

But the problem I have is that not all end-of-life patients need to lose weight. Many of them do. And this is getting back to Kathleen's point. If you know they're going to lose weight and there are not effective interventions, then there's no point to weighing them. And therefore there would be no data entered. And I think that should not be held against the facility.

But there are many end-of-life patients that given enough attention and time in helping them eat, they are able to maintain their weight. So that's why I'm asking whether that was the reasoning behind not having J1400 as an exclusion factor.

MS. BERNARD: That was the sense of the technical expert panel -- the sort of conundrum that you brought up, that because someone is on hospice does not mean that they

necessarily have to lose weight.

DR. ZOROWITZ: I've seen just in my own experience many Alzheimer's disease victims who are nearing the end. They start losing weight. We pay more attention to them. And all of a sudden, they stop losing weight.

I would hate to see an indicator exclude them and therefore the facility feels they don't have to make the same effort because I think it is possible -- and I think this is a quality of life and comfort issue as well. So I would agree with not having it an exclusion factor.

MR. BOISSONNAULT: Robert, are there significant groups of other patients for whom -- here's why. Let me frame the question.

So Diana and I both have said in the absence of indications to the contrary, leaving it blank should be assumed that you did not comply. And what you're saying is for patients at end of life who are designated in

MDS 3 as end of life that leaving it blank should not be viewed as a negative. You should drop the patient. But are there not -- and this is really my question -- are there not other patients besides hospice as defined by the MDS 3 who also you might not want to move to weigh? And so my question is should the issue that Diana and I have been bringing up just not to apply to this measure generally as opposed to only for end of life?

DR. ZOROWITZ: Is lack of data an exclusion in this? I didn't remember. It is.

I would probably leave it as such and give the benefit of the doubt to the facilities because the flip side of this is that some facilities are not very good at regularly weighing patients. And on my hat is sometimes doing expert review for law firms. Sometimes you'll see that weights, somebody just forgot to do it for six months.

But in this case, I think we should give it the benefit of the doubt and

leave it as is.

DR. ORDIN: Well, I have to tell you I'm a little uncomfortable with that because you can make the same argument for all the other things that we said. There are conceivable reasons why people shouldn't. But it leaves you so open to gaming. Someone could say for those five months oh, you know that patient was too much in pain to be weighed or something.

So I don't know. I mean, I'm really conflicted on this one.

DR. MODAWAL: Weight as a measure is as was pointed out hard to do. And many times it also variable. There's inaccurate measurement of weight as well. You see the nursing home chart and the weight's going all over the place many times.

I wonder if weight loss trend would be a better measure than spot readings at six months or 30 days.

And certainly in terms of the end

of life patients and hospice patients, it depends on the case mix. I think some of the nursing homes if they have a higher case mix of these end-of-life patients or patients who cannot be weighed or have patients who are declining despite best efforts, my concern is that they may look badly.

MR. BOISSONNAULT: Diana, the difference with this is that this field could potentially cause discomfort to the patient whereas the other fields if you leave them blank, it's just an administrative thing.

So I hear you. But I think this is slightly different because it has clinical implications to fill it in or not fill it in.

DR. ORDIN: My argument would be either it is perhaps to exclude it, that if we think there's so much leeway in whether you should fill it in or not, perhaps those people likely to have it not filled in should be excluded from the measure.

DR. ZOROWITZ: Well, keep in mind

that this measure has been a quality measure already. And to the best of my knowledge, it hasn't been a huge issue of facilities leaving out the information deliberately.

MS. BERNARD: I would also like to remind you about the definition of the measure -- a loss of five percent of the resident's body weight during -- or more -- during the month prior to the assessment, or a loss of ten percent or more in the six months prior to the assessment, so that there is a window.

In other words, the resident could miss a couple of weights and still be included in this measure. You'd have to have a lot of missing data in order to exclude them.

DR. NIEDERT: And I can say in all my practice and the facility I work at right now is an over 800-bed continuing care retirement community, we maybe have one percent -- two at the very most -- where we would not be weighing that person. It's not a large number of residents who are not

weighed.

It's just those people that probably we do weigh weekly in the nursing home where I work because that's the demands that the DON and I have. So we weigh all the 100 people that are under SNF and nursing facility care weekly.

The only ones that we exclude are those that we know are within probably four weeks of expiring, and that we know that it would be very, very uncomfortable for them to be weighed and moved -- the person that's got 4-plus edema and CHF and can barely breathe let alone get them to move.

DR. ZOROWITZ: And your denominator is large. There's not that many exclusions. So in order to have a significant number of data exclusions meaning that you couldn't have weighed them for over six months, that would not reflect well on the home. And I suspect that after submitting that material, probably the state would ask

some questions.

CO-CHAIR MUELLER: Are we ready to vote?

I think the only condition would be the 100-day issue, but it seems like we are agreeing that we would want to keep the exclusions. Okay?

All those in favor, raise your hand.

No? Abstain?

(Unanimous agreement.)

CO-CHAIR MUELLER: Okay. We'll move on to 22, percent of residents who need help with activities of daily living has increased. This is a long-stay measure.

And would this one make sense to do the second one also? That would be 23?

MS. BERNARD: Yes, it would because any changes to the MDS are consistent.

So the two measures, they're both long-stay measures. They're both longitudinal measures.

The percent of residents whose need for help with activities of daily living has increased updates the current quality measure by using the slightly revised ADL items in the MDS 3.0.

The underlying data items in the MDS 2.0 and 3.0 are the same with minor clarifications. The minor clarifications are the inclusion of two categories -- activity occurred only once or twice, or activity did not occur. But they get re-coded into total dependence. So essentially it makes no difference in terms of the measurement.

These two measures address an important area in the care for older adults in nursing homes -- I mean, for the residents of nursing facilities. These residents are at risk for functional decline which is associated with a decreased quality of life. Greater dependency in activities of daily living is a risk factor for negative outcomes including pressure ulcers and hospitalizations

and their associated costs.

Using the MDS 2.0 data for April to June of 2008, the national prevalence of increasing need for help with ADLs in nursing facilities was 16.1 with a range from a low of an average of 10.6 to a high of an average of 24.2. So there's indeed variation.

As far as the percent of residents whose ability to move in and around their rooms and adjacent corridors got worse. There are the same changes to the MDS 2.0 as with the ADLs with the inclusion of those two categories. And the importance is similar in that immobility increases the risk for unwanted sequelae and an impact on quality of life.

And the prevalence for this measure in terms of mobility decline, the national prevalence was 15.7 with a range of 10.2 in one state and a high of 25.7 in another state.

So these are the changes to the

measure from the one that's in current use. And I'll be glad to address any other questions.

CO-CHAIR MUELLER: For 22 -- there we go. Bill, you're the primary.

MR. KUBAT: Yes. Thank you. And Sister Mary Rose was the secondary.

And I think we're broadly in agreement on this. This is obviously a continuation measure, just moving it into the 3.0 platform.

I think as we reviewed the materials on each of the points on importance, scientific, usability, feasibility, in all of those areas if not complete, partial or somewhere in between, what was significant I think or just of note is that what's consistently noted throughout any or all of those areas is that there broad consensus about the importance of the measure and the issue. But there are consistently limitations that aren't compelling enough to not advance

it.

One relates to the sensitivity of it in terms of Medicaid payment policies or practices within states. So it's not just measurement that drives behavior, but it's reimbursement that drives behavior. So naming and acknowledging that limitation in terms of the quality improvement side or the use of the measure as a CQI tool by facilities because of what's consistently acknowledged or named, the inability just on the basis of the measure to be able to differentiate decline due to inadequate care as opposed to just unavoidable decline.

And then the third, the issue of cognitive impairment and the relationship of that and the challenge or the difficulty of being able to risk adjust in relation to that.

So those things are all named. They're not necessarily mitigated. But the overarching consideration is that the measure still stands even in the context or in the

midst of those limitations.

So I'll turn it over to Sister for any other additional comments she might have.

SISTER HEERY: Yes. Bill and I both agreed on that.

The only issue that I had was that hospice residents are excluded. And my concern with that was that we have a large population of cognitively-impaired residents in our home, and we do see the trend of hospice now starting to come in and be involved with those residents. And just because someone's on hospice doesn't mean they're quality of life should shift and we should lose late-loss ADLs.

I respect hospice. I think they have a big part to play in nursing homes. But when we're looking at this, I think we need to be careful that we don't start excluding that large population. That could be a problem. So that was my one concern.

And I think we discussed hospice

with weight loss and things. It's not necessarily the end so we need to promote and be proactive even with our hospice residents.

But I concur with Bill.

CO-CHAIR MUELLER: Any questions or comments?

MR. BOISSONNAULT: I have more angst about this than Bill or Sister Mary Rose as it relates to pay-for-performance. And the problem for me is we cannot endorse and say but don't use it for pay-for-performance. That's outside of the scope of what the NQF can do.

Not having delved into the sort of details -- just looking at what's written in blue on the memory stick that we have -- I don't see anything that makes me comfortable that the ability to stratify for nursing homes that have patients who are going to be immobile and might have a higher percentage of them -- maybe you don't need to talk anybody else down, but if you want to, could you try

and talk me down that some overzealous administrator isn't going to say we've got to find eight percent in the budget, let's use -- if you know there's a patient who's legitimately going to be immobile, or if you know that a nursing home has a high percentage of patients that are going to be immobile, is it fair to compare absolute results on this measure from nursing home to nursing home and to pay different using that? That is my question.

MS. BERNARD: Okay. I was going to ask you to clarify your question because I was having trouble understanding.

So you're asking whether the measure is reliable enough to be able to compare the performance of one facility versus another facility?

MR. BOISSONNAULT: If you take this sample from the MDS 3 or 2 -- and I sort of look over to my CMS colleagues -- I'm not inclined to say let's keep this secret. But

I really think this one brings out the issue of risk stratification or some way to make sure because we have some on the hospital side that we're going to be dealing with that we loved having them out there but I think we're going to hate initially having them on pay-for-performance.

And so let me add one other thing because it's a larger issue. I would love to know how the World Health Organization countries who also are measuring this stuff deal with this and some of the other measures. I really wish we would not be quite so myopic in our perspective when we look at how others measures. We should try and harmonize with the World Health Organization. But that's a separate issue.

On this one -- and maybe Robert can comment on it -- but if this was a pay-for-performance measure, do you start to get cold sweats at night?

DR. ZOROWITZ: Well, I'm looking

at some of the information here. And you would expert there to be variability among institutions.

According to the University of Colorado study, it says that there was variability -- a reasonable degree of variability. But I would think that -- I mean, we're not looking for zero here. There's going to be variability among institutions. And you won't flag until you're significantly higher than other institutions. I think that will be somewhat of a bell curve.

But according to this, they looked at that and felt that there was some variability. But I don't think that's going to affect the value of the measure. I mean, you may get one or two facilities here and there that take a particularly vulnerable population susceptible to functional decline. But they don't seem to have found that that -- that was more the exception rather than the rule.

MR. BOISSONNAULT: So you don't think there's going to be a ton of outliers who cannot control the fact that they're outliers based on the way the measure is done?

DR. ZOROWITZ: No, I think there will be some variability. You're always going to have patients -- residents who have functional decline. That's to be expected to some extent. But I don't think you're going to have an enormous number of outliers unless you have a facility really specializing in very clinically complex residents.

DR. KOREN: I think that the point that Robert is making is that the ideal number is not zero, and that there will be a baseline, that all facilities will probably have a certain number of these people because they do have end-stage dementia. They will have hospice patients.

So it's not like you're saying if you're not zero, you're not good. What you're saying is you don't want to be outlier on the

top. And there aren't a lot of places that sort of specialize in just these people.

MS. BERNARD: I think if I could just add one more comment to that that when you have a rate-based measure, you're looking at the variation in rates by facilities. And you know I think as Dr. Koren said that they're not going to be zero. It's not as if you're not going to have people whose mobility changes.

And in this particular measure -- these two measures -- we've not found a risk adjustment model that has been useful.

MR. BOISSONNAULT: Yes, I'm pretty deep in the weeds on the statistics. I'm not looking for zero. I'm looking to avoid what Demming called the red beads experiment where you are doing all these things but there are factors that are either random -- which is the red beads -- or completely out of your control as it relates to your population.

But as long as the folks who run

these centers say no, we don't think there's going to be a lot of outliers who for some reason have 30 percent patients right off the top, then that's you guys.

MR. KUBAT: One other factor with that -- and just hearing the conversation prompts me to think about it -- there's more than one element or aspect to Medicaid payment policies that potentially have an impact on this, and will continue to have an impact on this.

It's not just reimbursement to the SNF that people document in relation to you. But where you have those variations in payment practices within states or across states, you also have variation in the development of alternative services. So the extent to which there's more of a focus on assisted living on home- and community-based services -- which is a function of Medicaid dollars and so forth -- that's going to impact the population that is then served generally in the skilled

facilities in that state. I think that's also a function of the variation. And that's going to be reflected in ADL decline.

MR. BOISSONNAULT: What you're saying is there's going to be a systematic impact on that.

My experience in this -- and I waver a little bit on whether I should name names, so I won't -- when evaluating one of the world famous heart center open-heart surgery rates, by most risk adjustment methodologies, this one center looks wonderful. But when you sort of dig under the hood, you discover that more than close to two thirds of their open-heart surgery patients are traveling from all over the country to get there. So the patients -- the one third of MI patients whose first symptom is death or trauma -- are out of the sample in risk adjustment -- at least early risk adjustment wasn't fully capturing that.

I just think at a minimum we

should on this measure say there's some real cautionary issues about including it in a bundle that goes toward reimbursement. But I know we can't do that. That's enough for now.

DR. GRIEBLING: One of the points that I think is important in terms of especially looking at outliers and expected functional loss is that the way you've structured this it focuses on four specific ADLs. It's not all ADLs. So it doesn't include mobility. And it's looking specifically at the ones that tend to be lost last -- so the ones that are preserved.

And so I think that that focus helps to narrow that gap somewhat, and I think that will help with this measure. I think it's strengthens it.

And I'd also strongly support Sister Mary Rose's point. I think hospice needs to be included.

SISTER HEERY: And I'm sorry. The other thing is that most people that are in a

proactive program are preventing these late loss. So there's payment on the other end that you're getting. So it's a wash across the board. So a good facility should be not here. Yes, it should not be here.

CO-CHAIR GIFFORD: Let's see if I can summarize that.

I think it's approve measure as is except for the 100 day and remove the hospice exclusion.

Is that a condition or a recommendation? Recommendation. To look at what it would mean to that and the pros and cons of that. Okay.

So condition, close the 100-day loophole and recommendation to look at the hospice removing.

All in favor?

Abstaining?

Opposed?

(Unanimous agreement.)

CO-CHAIR GIFFORD: Okay. On to

number 23.

MS. THOMPSON: Yes. Under the measure specifications, first of all I have a lot of issues with this particular measure. The measure reads "percent of residents whose ability to move in and around their room and adjacent corridors got worse." However, the numerator that they're looking at is locomotion on unit, which reads "how resident moves between locations in his or her room and adjacent corridor on the same floor, if in a wheelchair, self-sufficiency once in the chair."

So the part of the title of the measure that talks about the ability to move in and around the room isn't even addressed because that's a different question on the MDS 3.0 altogether.

Secondly, with regard to this, the issue that I have with regard -- and I was kind of hoping it would be fixed in the 3.0 but apparently it was not something that was

meant to be. If it looks at equally if the resident can do this ambulatory or in a wheelchair, it's for self-sufficiency. So if you have a resident who is extensive assistance in locomotion on the unit ambulating with extensive assistance, and the next assessment they are now extensive assistance but they are in a wheelchair, theirs is no change to this code. So that decline is never captured on this issue of the MDS.

And of course the reverse is true as well. If the resident required extensive assistance in a wheelchair and improved to the point of being extensive assistance ambulating, and as far as -- what I learned in nursing school is walking is always better than riding except when you're going to town -- that incline itself is also not recognized in this so that you have a lot of -- I just found that to be a big issue that this particular numerator gets very, very messy.

Also as was stated by CMS, it did add the number 8 on number 7 as it happened one or two times. The 7 and the 8 get rolled into the 4 which is extensive assistance for the intent of this measure. However, in the eyes of PPS, the 7 and the 8 equals an independent. So there will be disparities between any public reporting of the quality measure as it relates to this and that information as it relates to when they post any PPS statistics.

The other issue I have is that it talks about just a one-level decline. So if a resident is independent and three times in over a 24-hour period times seven days they required cuing, that is a decline.

In the late loss one that was talked about earlier, the nice thing they did is they talked about a two-level decline and one late loss ADL, or one-level decline and multiple ADLs. It would have been nice if they would have looked at the independent and

supervision like maybe a decline from a zero to a 1 to a 2 or a decline from a 2 to a 3, or something like that, to take into respect. Because I tell you what, if you did an MDS on me today, I would have declined on my locomotion on unit-based and cuing over the last seven days on where my room was.

(Laughter.)

MS. THOMPSON: I have been in so many hotels and tried to get in so many wrong rooms. It's just unreal.

The other thing that is -- and we do talk about -- they do exclude residents who are already at a level of total dependence because they can't really decline any further than that, adding the 7 and the 8. They also do exclude residents who are comatose, life expectancy of less than six months or receiving hospice.

Again, I think that because it's a one-level decline that constitutes decline, I think we have a problem with -- I don't know

what the current term is. We used to call them the old old -- the residents that are in their 90s, and that you're going to see that slight decline just as part of aging -- mine happens to have it in the 50s, but most other people it's in the 90s -- that there's exclusion for that. So I felt that this was minimally met at best with regard to the scientific area.

As it relates to usability, because there is so much noise in that particular number of not knowing residents who improved or declined based on the appliance they're using as part of their self-sufficiency, and also in the measure itself they just basically in this area talked about the fact that well, we already have one. So there wasn't any proof as to how this by itself -- this measure by itself -- is very usable. I don't see it's usable because you have to dig through it too much to find the noise -- get rid of the noise to find the meat

of what you want. Although I do believe that the idea of being able to somehow identify a resident's change in their mobility is very important. I don't believe that this measure in the way that it is written what with data we can get out of there is meeting that point.

With regards to feasibility, the fact it is feasible. It's in the 3.0. We have a way of sending the data. It's just that it's not very usable and the fact that they did identify that there would be so many inconsistencies and errors based on that.

So as far as me personally, I don't propose this measure be continued. I do remember you talked yesterday -- someone talked about the fact there's going to be some functional -- there's going to be some kind of a group that's going to be looking at functional. And I think that this needs to go there. We need a group that looks at how to handle those kinds of things. I don't recommend this measure.

Diana was my co-reviewer, so I'll turn it over to her.

DR. ORDIN: It was just really painful to see their validity and reliability testing of this measure. I mean, not that they did it, they did it very well. But the results because this is a very highly risk-adjusted measure. And basically the people who did it did it pretty well.

And I will quote what they said. This is their R-squared, which is sort of a portion of the variance that -- yes, that's attributable to what they're taking into account. And their risk adjustment was like .11. So basically --

MR. BOISSONNAULT: .11 percent or 11 percent?

DR. ORDIN: .011.

MR. BOISSONNAULT: So 1.1 percent R-squared?

DR. ORDIN: Right.

MR. BOISSONNAULT: Is that

accurate?

MS. BERNARD: It did not explain the variance.

MR. BOISSONNAULT: What?

MS. BERNARD: The risk model did not adequately explain the variance.

DR. ORDIN: Right. And the C statistic showed that it was -- if it was .5, it would say little better than chance. And I think the C statistic here -- I can't remember -- it was very low. It was certainly below chance. So just the risk adjustment methodology alone I think makes this a totally, unfortunately unacceptable measure.

And I also look forward to having some standardized cross setting ways of looking at functional status.

Yes, the C statistic was --

CO-CHAIR GIFFORD: So the two reviewers have recommended that the vote be to not pass the measure. Anyone want to ask questions as to how to elevate it to a higher

level?

So we have before us --

MR. BOISSONNAULT: No. Is R squared of the risk adjustment the effectiveness of the measure or of the risk adjustment portion of the measure? I mean, looking at CMS, do you guys -- do you guys do this now? You don't report this. Do you report this measure now in 2.0?

MS. BERNARD: It is part of the current measure. I don't know if it's publicly --

DR. ORDIN: It looks like the testing hadn't been done.

MS. BERNARD: The testing had not been done on the MDS 3.0 with the exception of what Saliba & Buchanan did in developing the 3.0.

There was a desire in the 3.0 to change some of the function measures. But that presented an issue for the states that depend on these data for their payment.

So the measures are essentially the same -- I mean, the items are essentially the same between 2.0 and 3.0. So even there's not been testing on the 3.0, we don't anticipate that there would be much difference because the items are essentially the same.

MR. BOISSONNAULT: So there are two issues that came up, both of which are unclear to me at least.

One was a sort of a potential definitional mismatch between the numerator and denominator. Did I get that right? The wording is slightly different even though it's implied that it's the same.

And the other that I actually think may be less of an issue is that risk adjustment doesn't help.

MS. BERNARD: Risk adjustment does not help.

MR. BOISSONNAULT: But that doesn't mean the measure doesn't work. It just means risk adjustment proved superfluous

or ineffective at increasing the precision of the measure.

MS. BERNARD: Yes.

MR. BOISSONNAULT: But what I don't understand from this -- and I think we have to look to you because we're not technical experts on the measure -- is what is it in the underlying measure without risk adjustment that is compelling?

MS. BERNARD: You mean in terms of --

MR. BOISSONNAULT: You don't like the way I ask questions. I can tell.

(Laughter.)

CO-CHAIR GIFFORD: Is there anything salvageable out of this measure? If you drop risk adjustment, does the measure still work?

MS. BERNARD: If you drop risk adjustment, it works or it doesn't work just as well as it works or it doesn't work currently.

This is a difficult --

MR. BOISSONNAULT: What the Colorado study said is risk adjustment did not make the measure better.

MS. BERNARD: That's right.

MR. BOISSONNAULT: But that doesn't I think talk to the underlying measure --

MS. BELL: If I could -- just the underlying measure -- you asked about elevating this measure. I think the issue is that the percentage of residents for whom the primary mode of mobility was ambulation who lose that ability. So that the problem is we're comparing mobility, ambulation and wheelchair mobility again on an equal leveling.

And in point of fact, Darlene, if you go back to what you said, it's even worse because if they go from walking with assist to being in a wheelchair independent, that's an improvement in this measure. So to me, the

means by which you look at this is those individuals for whom primary mode of mobility was ambulation who see a change in that, either more assist or to an assistive device in the form of a wheelchair.

MR. BOISSONNAULT: I'm not concerned about risk adjustment. I'm concerned about a mismatch which is essentially what you just described -- a mismatch between the definitions and -- the sort of finding things that are happening in he numerators and denominators.

MS. BERNARD: You mean the inclusion of both wheelchair and self-ambulation?

MR. BOISSONNAULT: -- percent would move from walking to wheelchair being a good thing.

MS. TRIPP: Could I ask a painfully simple question? I think.

Is there any evidence that this measure works?

MS. BERNARD: Well, it works in what way? Works to --

MR. BOISSONNAULT: Any way.

CO-CHAIR GIFFORD: Is there a way to salvage this measure? It's going down in flames.

MS. BERNARD: I will make one last --

CO-CHAIR GIFFORD: We are pulling the plug. The family meeting is in ICU right now. Do we pull the plug or not?

MS. BERNARD: Here's the struggle. And in some ways it somewhat analogous, but perhaps not as good as the ADL, that mobility is an important issue. Loss of mobility, loss of any kind of autonomy and independence in long-term facilities is an issue.

These are the items we have. And so we are trying to propose a way of measuring mobility given the items that we currently have.

Is it ideal? No. Is there

another way that we would like to measure mobility? Yes.

These are the data. There is an area that's of importance. And we laid out very frankly this is why it's important, this is the data we're using. And these are the issues that have emerged when this measure has been looked at. We have uncovered as much as we can.

Are we concerned about this measure? Definitely. Do we appreciate this discussion? Absolutely.

And that's as far as I can try to salvage your pulling the plug as I go down in flames.

(Laughter.)

MR. BOISSONNAULT: I hope you do two things. I hope you fix the MDS 4 so that --

MS. BERNARD: Well, you've got the right people in the room to do that.

MR. BOISSONNAULT: -- so if there

is -- if we're understanding what I think the experts have conveyed, there may be a sort of a mismatch in the numerator and denominator that could lead to unintended consequences of rewarding people from walking to wheelchair and some other mismatch issues that have more to do with the validity.

So I hope you don't like stop reporting it. On the other hand, I don't know what the vote will be.

MS. BELL: And I'll just say in the interest of CPR that I don't like it, but if we go to just the issue of from a quality of life standpoint does an individual have the means by which to get themselves from point A to point B independently, whatever that means is, there is some merit in the fact that the individual continues to remain at whatever level of independence. Because sometimes being in a chair independent is better than walking dependently. Those situations definitely arise.

So if we look at it just from that quality measure, does the individual possess the autonomy to move in the most independent way, then I can see some utility. But at the same time, I feel very strongly that this comparison of level of mobility is wrong and distorted.

DR. ZOROWITZ: And I agree with that. But also keep in mind that this is looking at a population. It's unlikely that a lot of residents that we're looking at and the number will have changed from walking with assistance to independence in a wheelchair. So I think there's some wiggle room within that percentage not to get too all wrapped up with -- you think it's going to happen frequently?

MS. BELL: I think the potential is for it to happen frequently. And particularly when that change demonstrates improvement. So yes, I think the potential is there.

I believe today that there are too many people in wheelchairs in nursing homes. And so I think the potential definitely is there to overutilize wheelchairs as we see it today.

MS. GIL: I guess my points were going to be the same that regardless of functional status, residents are given a wheelchair upon the time that they're moving in. And so how do we really look at this indicator in a way that we prevent that from happening, as well as in a way that we can reward and recognize and look at ways that organizations are trying to get residents out of wheelchairs today?

DR. ZOROWITZ: I mean, personally I don't think -- I mean, this measure has been with us for some time now. I don't think that it has been a cause of putting residents into wheelchairs. And I don't think its absence will cause residents to come out of wheelchairs.

MS. BELL: I agree with you.

DR. ZOROWITZ: I understand the flaws to the measure. But at this point I think it's been fairly workable up to this point, and the changes are not all that significant with MDS 3. I think it's still a flawed but usable measure.

MS. BELL: And I don't disagree with that. I think what might change getting residents out of wheelchairs is a different measure that says if their primary mode of mobility was ambulation that their primary mode of mobility continues to be ambulation or that we move them toward that.

So I'm just saying I think a different measure could influence it. I agree that this measure one way or the other probably won't.

DR. ORDIN: I just want to point out something.

We talked about the risk adjustment. But there are really reliability

problems with this measure too. I mean, after their tests they said a ten percent discrepancy rate would be good. And they had an over 30 percent discrepancy rate.

So I totally agree. I think we absolutely need a measure that addresses this. But I think it's probably worth working very vigorously toward a better measure.

MR. BOISSONNAULT: I'm going to go further.

If you say look, if you don't approve it, we're going to stop putting it out there, then I'm going to vote for it. So I would rather you continue until you have a better measure.

But do you guys think this meets the gold standard of what we want to do for ambulation? Because if we approve this one, the chances that we'll look at another ambulation measure -- you know what I mean? There's an either/or effect at the National Quality Forum that I don't how it plays in.

CO-CHAIR GIFFORD: Before CMS answers that, just so you realize, you can criticize Bill and I for being asleep at the switch at the last nursing home steering committee meeting. I think we can only chew on the previous panel, right?

As was pointed out, we didn't have all the depth reliability and validity testing at that time. So a lot of the votes were based on the merit of the topic. We now have the luxury of knowing more about the validity and reliability.

I think this sounds very similar to the staffing. We all desperately want to see a staffing measure, but we just didn't feel comfortable with what we saw in the staffing measure. I think Dede is pointing out that now that we've seen some reliability just because it's out there, whether you're going to drop it or not, the reliability testing that was done is very similar on the items that exist out there now.

Am I wrong, Dede, on this?

So what you're saying is if you're going to vote to keep the existing measure, you might as well vote to pass this measure because the existing measure is just as flawed as this measure.

MR. BOISSONNAULT: Yes. I personally think we're better with this measure than the absence of any measure based on what Robert I believe said that they actually look at the measure, they dig in, and they say well, was this our fault or not our fault.

I think the question for me is -- so I hope CMS continues to put it out there -- but the question for me is is this the gold standard that we want to set potentially because the tail is going to wag -- I think nursing homes are the tail that are going to wag the dog on this measure for the rest of health care. Is this the measure that we want to hang our hat on?

CO-CHAIR GIFFORD: I believe CMS will answer this question. But I believe when MDS switches over to 3.0, the 2.0 measures will be sunset unless those that immediately crosswalk over with minor changes that don't have to come back for review as new measures. So this has come back as a new measure for review and approval here. So that probably would mean that the existing measure would sunset and go away.

MR. BOISSONNAULT: They publish things that aren't -- CMS.

CO-CHAIR GIFFORD: Oh, they can still use --

MR. BOISSONNAULT: It just won't have the endorsement or the gold standard.

CO-CHAIR GIFFORD: Yes.

PARTICIPANT: They won't have any data though. Isn't that the issue?

CO-CHAIR GIFFORD: No. There are hundreds -- not hundreds -- lots of measures that are used in the survey process. There's

lots of measures used elsewhere. There's all sorts of stuff.

But if they want to put something in this to compare, they essentially -- there's loopholes as always -- they essentially needs consensus endorsement. NQF is the most convenient, broadest consensus endorsement process.

DR. MODAWAL: I just want to make a comment.

The main issue of independence and dependence and I think it was point out actually, if the denominator can be refined in terms taking people who can walk on their own or who have the ability to self-propel the wheelchair, that could be one kind of denominator. And then the rest would be obviously dependence in terms of whether it's assist or propelled.

I mean, I think if the denominator can be refined, I guess a very important question to address that would be a good

quality indicator straight away knowing that how many functional people or mobile persons are there in a nursing home.

CO-CHAIR GIFFORD: CMS, the parents of the child on life support, would you like to make a comment?

DR. LING: So where do I start with this response?

I think let me start by saying even given the caveat that one of the criteria that NQF sets before us is that the measure be publicly reportable.

We recognize the limitations of the measure that's before you. So I don't know what wiggle room you have to consider this measure on its merit as it stands before you because we recognize this is not the measure -- this is not the measure that we would like to hang our hats on to report change that is meaningful for the nursing home residents. But we will need the opportunity to go ahead and test the MDS data -- the 3.0

data -- and given your feedback, construct a measure that actually may achieve what we're hoping to convey.

And take that for what it's worth. But that's my response.

DR. ORDIN: So do you need the limited NQF endorsement to do that testing?

DR. LING: I suppose we can proceed even without -- I mean, we would bring it forward -- bring a new measure forward in the next go around. Helen, would we be able to bring a new measure forward in the next go around? Not the next go around, but when the MDS data are available.

DR. BURSTIN: It sounds like there's going to be a need to do that. We'll actually be doing a lot of testing on the MDS 3.0 anyway. I just think that in general you guys are welcome to iterate on this measure as long as you'd like and get it right and bring it back in. I mean, it sounds like you're not ready to publicly report this measure anyway.

So why seek endorsement if it's not ready for prime time I guess would be my take.

MR. BOISSONNAULT: Was it your intention to put it on Compare?

DR. LING: The intent for the gold standard measure that we will create would be to publicly report it.

Now would we? I believe this measure is being publicly reported as part of Nursing Home --

MR. BOISSONNAULT: Yes. In 2.0, it is is my understanding.

DR. LING: Right. So then I would say that we would not need the time-limited endorsement to proceed with the testing.

CO-CHAIR GIFFORD: I don't know how to salvage this. It's going to be an interesting vote.

Given the discussion in sort of following the NQF sort of standards for how and what we've talked about for the measures, I would say that -- at least I will put out

for vote that this measure not pass. And if we decide that that doesn't pass the vote -- people want to see it pass -- then we'll have to frame another dialogue on how to make it pass.

MS. TRIPP: Can I just ask a quick process-type question?

Assume it goes down. CMS re-works it. When could they get something NQF-approved that looks -- when is the earliest that can happen?

DR. BURSTIN: It's not exactly clear. But I think part of it depends how long it's going to take to re-work this measure. It's not clear to me.

And the other possibility is is this something you could give conditional approval and over next month or so, they bring it back. Because I just don't know how much life support this is on -- to continue your analogy -- and how much it could be tweaked to make it work for the cycle while they work

towards a better -- it sounds like the better measure isn't even this one necessarily. So the question is can they tweak this one enough to make it acceptable in the short term while they develop the better measure in a year or two.

MR. BOISSONNAULT: Two choices. One would be to vote a yes/no on the proposal, and then a yes/no on a 12-month limited which I'm still -- I really don't want to see the measure completely go away personally -- while they work it out because I think they will. That's a needless gap.

There's another option if CMS wants it which is when we do our conference call, as opposed to waiting -- would anything change enough between now and when we do our conference calls in the next three months that would allow you to bring the measure back because you may want to go for the full three-year endorsement as opposed to some 12-month thing we could get out of here now.

DR. NIEDERT: My concern is if we do this, why didn't we do something like this in staffing yesterday because we nixed staffing because of the same issues. And we did not say staffing was any less important. We knew it was.

And to me, this is saying this is not apples and apples. And I think it is. I don't think it's apples and oranges. I think we've got apples and we've got apples. Today we've got Delicious and we've got Jonathan but we've still got apples.

Otherwise, we're saying that this issue is so much different than staffing. And truly in my heart, I don't think so.

MR. BOISSONNAULT: Well, to my earlier comments about the importance of the data source, there was a law passed that I think changed the staffing question fundamentally for me. I'm not going to speak for everyone on the panel.

But when the federal government

said CMS, you will collect and report data on staffing, that made the issue very different for me than this one.

MS. TRIPP: There is no federal law. I mean, with the staffing there is a federal law that's going to mandate the most comprehensive staffing data we've ever had. And CMS has been working on that since the '90s.

So there is no parallel here. There is no federal law that mandates data of this sort be reported, which is why I think you're seeing a different reaction.

But I do think there's a real urgency that NQF have a staffing measure for sure. That's the reason I think the two are getting different treatment, not because they're different issues, just because there's that federal law out there.

CO-CHAIR GIFFORD: So our vote is not on the importance. Yesterday, we conceded that everything is really important. It's

clear that this is a really important topic like staffing and many other topics.

We could equally vote on nursing home caps. I think all of us would vote that nursing home caps is an important thing. We could vote to pass it right now without even looking at it.

So I guess NQF does have a process. We have criteria here. We sort of wiggled away from a lot of the criteria here, and we haven't gone through each of the things. We've got four conditions -- the scientific aspect, the importance of it, the usability and the feasibility.

And I think we need to sort of somewhat adhere to that process and try to figure out how to vote on this as a measure up and down because it's not just about how NQF is going to use this measure. Remember, in Rhode Island we publicly report measures independent of CMS. And we rely on NQF measures.

So NQF is not an endorsement for CMS and what it is. And also once the measure's endorsed by NQF, we lose control of it. We can do whatever we want with it. And we do. We don't play with the specifications or anything, but we play with how we compare. We can play with how we frame it and discuss it in Rhode Island different from CMS because I disagree how CMS does it. So we do that. But that's not part of the approval process here.

DR. BURSTIN: I just think one suggestion, given the amount of discussion going on in that back row, it sounds like it's not clear what the next step is. And one option would be to just defer this. Don't vote on this today. They've heard all the comments about this measure. Let them see what is doable to bring back to you on conference calling, just not vote on it today.

And I would actually make the same --

MR. BOISSONNAULT: That's my recommendation.

CO-CHAIR GIFFORD: Would you like to withdraw this measure for our review?

MR. BOISSONNAULT: No, no. They just have to --

CO-CHAIR GIFFORD: I know. Are you willing to defer it?

DR. BURSTIN: That's not necessary. It's purely that the committee can vote to defer it until clearly CMS has heard and RTI has heard the issues. Can they try to build a better mouse trap to address some of these issues and bring it back to you? And frankly, if you wanted to do the same thing on staffing, that's an option as well.

CO-CHAIR GIFFORD: All in favor of deferring the measure until some future date -- kick the can down the road? Okay.

Anyone abstaining? Anyone opposed?

(Unanimous agreement.)

CO-CHAIR GIFFORD: Okay. Thank you.

MS. NAIERMAN: May I ask a question then?

CO-CHAIR GIFFORD: Yes.

MS. NAIERMAN: I'm thinking of the pain measures and the opportunity to review those completely different --

CO-CHAIR GIFFORD: I think the pain measures fall very close in this category. They got a little bit higher. But if you read our recommendations, the tone and effort was very similar with the pain measures.

And I think there's other sets of measures. I think it's clear that we would like to see other measures -- other stuff and continued effort -- a vote of not passing or even the limitation is set. This should not stop. We strongly encourage pursuing. We strongly encourage CMS to continue to support measure development and expansion of the

measures that are out there.

MR. BOISSONNAULT: Yes. The CMS pain or the other?

CO-CHAIR GIFFORD: The pain's passed. They were time limited with about five conditions. No public reporting and five conditions listed on there.

MR. BOISSONNAULT: Yes, but we can't actually --

CO-CHAIR GIFFORD: Yes. We'll follow up. It's be an interesting CSAC. It's not over yet. We still have some more time on this.

So that concludes going through all the measures. I want to thank you all for a robust discussion on the last one. A lot of energy for a day and a half.

I wanted to take -- what time is it? We still have a little time -- just a quick moment to go around the table again and hear from you now that you've had a chance to reflect overnight any additional measures to

the comments that you wanted to added in before from yesterday.

You don't have to reiterate everything you said yesterday. We already got that. If you have something new, it is fully appropriate to say pass, I don't have anything and it doesn't make you look bad. You don't have to feel compelled that you have to speak at the mic.

You're saying to add something if you want, or some different. If it's something to add, I'm just going to go around. You'll get your chance.

MS. TRIPP: I think I have to leave in a moment.

CO-CHAIR GIFFORD: Okay.

MS. TRIPP: And I was just going to announce that I'm passing around something.

Yesterday I talked about anti-psychotics and I sent around a White Paper, but emailed everyone. These are the talking points that I wrote. These will give you a

quick summary of the White Paper.

Any improperly stated items are attributable to me only. And the White Paper is by Stephen Crystal and Judy Lucas. They're both at Rutgers.

And so just very briefly, the high points of this are there's evidence that indicates that more than half of the anti-psychotic use in nursing homes is contrary to CMS guidelines. There is apparently a strong correlation between especially long-term anti-psychotic use and mortality.

There's a UK study that showed that residents taking APs for 24 months had a survival rate of 46 percent as compared to a survival rate of 71 percent for residents who were taking a placebo. So this is a very, very significant issue.

There have been two black box warnings, one in 2005 and one in 2008. They have not significantly decreased the use of anti-psychotics in this population.

So this is just sort of an awareness raising. And I do believe that Stephen and Judy are going to try to work on developing a measure for NQF approval at some date.

So I appreciate the time, and I appreciate you letting me go out of turn.

CO-CHAIR GIFFORD: Tom, I'll start with you going this way.

DR. GRIEBLING: The only other thing that I'm thinking about and again in terms of global quality of life that we really never look at in this population is sexual health.

CO-CHAIR GIFFORD: What was that? Sexual health?

DR. GRIEBLING: Sexual health.

CO-CHAIR GIFFORD: I just wanted to make sure I heard it right.

DR. GRIEBLING: It's a topic -- as a urologist, we deal with that a lot. It's a topic that we just really always kind of

ignore in nursing home residents.

CO-CHAIR GIFFORD: Bruce?

MR. BOISSONNAULT: A global comment to NQF not specifically related to this panel which is I don't think we need to harmonize with the rest of the world. But it would be nice if we could pick a half a dozen key things that we want to measure in collaboration with the World Health Organization because I think part of the pain of the debate we just went through was the sort of unwillingness to acknowledge where we are weak compared to the rest of the world and the inability to get access to data that everyone agrees is measured the same way vis a vis the rest of the world.

Plus I think they know a lot of stuff we don't know because they have better data bases in some instances.

MS. ROSENBAUM: I think I'd like to see -- this just occurred to me as we've been discussing things -- some emphasis on the

use of pharmaceuticals in many areas, for instance, controlling incontinence or stimulating appetite or antibiotic use, the anti-psychotic use. It's not mentioned in a lot of the measures.

MS. GIL: Just in terms of efforts to harmonize, in looking at some of the proposals that came forward, the process in terms of really engaging the dialogue in a way that really fits the environment. I think it was a little frustrating I think for all of us because I think they were really important measures as we all agreed.

So I don't know if there's anything that we can do to strengthen that process in collaboration with those organizations. But I think that the issue of harmonization is just so important.

DR. KOREN: I have nothing new to add.

Helen, do you want me to mention that that you have on the screen there?

DR. BURSTIN: I'll just preface it by saying that yesterday there was a specific mention of this measure that's already NQF endorsed called the care transitions measure developed by Eric Coleman with support from the Commonwealth Fund.

And it turns out the measure's already endorsed at the facility level. It doesn't say specifically hospital. It specifically says facility. So it would be something that could be very appropriate for nursing homes. And we talked about how we could talk with Eric to maybe obviously modify the wording slightly on some of those questions so when I left the nursing home particularly for the short stays. I just wanted to get people's input.

Mary Jane, if there's anything else you want to add?

DR. KOREN: I would just add one thing which is as nursing homes become more and more post-acute care settings in which the

ability to prepare patients to go back into their homes in the community and not then bounced back into the hospital is really critically important. And Eric's work sort of has boiled down the predictors of re-hospitalization to three items. And what's interesting about them is they're items that are answered by the patient, not by a care provider.

So I would urge us to sort of start to think about those as a way to look at the quality of the preparation that the post-acute care nursing home does to prepare people to be in the community and not bounced back at some point.

CO-CHAIR GIFFORD: Helen, can we ask Eric to fill out one of these things so we can talk about it at a future call meeting and get some feedback on it relative to nursing home?

DR. BURSTIN: Yes, we can actually --

CO-CHAIR GIFFORD: The questions up there do say hospital.

DR. BURSTIN: Sure. Yes. It just went back through our care coordination committee and was just re-endorsed. So we'll just take that form and have him just do an addendum of if there are any specific thoughts about nursing homes, we'll bring that to you in your follow-up call because I think it's a really good opportunity for CMS and others to view something in the public space that's got such a good track record.

CO-CHAIR GIFFORD: Thank you, Lisa, for everything. Very helpful. Good comments.

DR. MODAWAL: I just had questions about communication. And I think CTM is a good way for hospital communication, but actually the communication within the interdisciplinary team in the nursing homes and communication of physicians with the different levels across the --

DR. ZOROWITZ: I've enjoyed the meeting a lot.

I would like to see a more formal structure in the voting so that if we see items that are --

CO-CHAIR GIFFORD: I'm going to come back and talk in a second and get your feedback on the process.

DR. ZOROWITZ: Oh, am I out of line here?

CO-CHAIR GIFFORD: Yes, you're out of line.

(Laughter.)

DR. ZOROWITZ: You know you're all great people, and I'm really having a great time.

(Laughter.)

CO-CHAIR GIFFORD: I'm looking for a new measures reviewer and stuff. You're going to get -- we're going to go around and give a chance to give comments on the process here and some feedback on the measure --

DR. ZOROWITZ: I'm sorry.

CO-CHAIR GIFFORD: That's okay. I didn't tell you that's what was coming. So you didn't want to miss the opportunity.

MS. BELL: I apologize. I'm going to be running too.

But I don't have anything to add other than what I've already contributed today.

MS. NAIERMAN: I'd like to add one more measure for consideration which is timely and appropriate referrals to hospice.

CO-CHAIR GIFFORD: Bill?

MR. KUBAT: I think what I would add is not a particular measure, but thinking about the things that were described and mentioned last year -- or I mean last night. Yesterday was such a much more robust addition to where we left off four years ago. And that's tremendously, tremendously helpful.

But one of the things that occurs to me is that -- and I continue to like the

use of the word harmonization and that concept -- but harmonization is in the eye of the beholder. And so what harmonizes for NQF, what harmonizes for CMS, what harmonizes for public policy and regulators, what harmonizes for the consumer are different things.

And so there really needs to be I think almost a preferential bias in skilled nursing and long-term care to advance those issues and measures that relate to quality of life, culture change and so forth.

DR. ORDIN: I don't think I have any new measure to add. But once again, I think just in this process, I've been struck by how little information or how poor the information has been on usability by the public. And since public reporting is one of the mainstays of our evaluation criteria, I think we may want to figure out how to beef up the evaluation criteria and how that submitter -- beef that up.

CO-CHAIR GIFFORD: You did not

listen tow hat I just said to Bob.

(Laughter.)

DR. ORDIN: But you didn't stop me soon enough.

SISTER HEERY: I have nothing to add. Thank you.

CO-CHAIR GIFFORD: Christine?

CO-CHAIR MUELLER: We had a measure today about toileting -- behavioral interventions for people who were able to get themselves to the toilet. I'd like to see for a future measure looking at toileting programs for incontinent residents in general or any resident in nursing homes who have incontinence, and also to take advantage of some of the new items on the MDS that might help with that.

CO-CHAIR GIFFORD: So now the same thing. I'll start in the middle with Bob. Go around. But some of you gave it at the beginning -- some feedback on just the NQF has continued to revise and improve I believe the

review process. And I think it's my fourth panel I've been through. And each one has been slightly different but gotten better. And so any opportunity to give some feedback on that broader process would be helpful and appreciated.

And so I'll just quickly go around and get that feedback. So Bob, go ahead.

I think all of us getting the measures earlier and all the measures taken off the table, we got that. I heard that. Sorry, Bob.

DR. ZOROWITZ: I would like to see some formalization of other options to just voting up or down with and without recommendations. That is tabling an item that needs improvement, directing a work group to come up with a better measure -- something that would keep the measure in the process.

The staffing issue, I think, is a perfect example. I think we all felt that was important. We don't want it to go away. But

I'm not sure whether right now there's going to be an effort to bring back a better staffing measure. But I think that really should be -- we should be able to vote on important, not ready for prime time, but go back, come back in three months with a better measure as a formal part of voting.

MS. NAIERMAN: I would assume that most of us are more content-oriented and less scientifically-oriented. And it would be helpful for me in another round to have a scientist statistician in the room who would actually explain to us and also be an advocate on our behalf rather than on the measure developers or anybody else -- kind of a consultant that we can talk with about the scientific merit of these measures.

DR. BURSTIN: I just want to follow up to that.

We actually for the outcomes project for the first time had a consultant statistician who did reviews on every measure.

We didn't do it for this because they seemed like ones we sort of knew a fair amount about. But it may be something we'll do for all projects in the future.

CO-CHAIR GIFFORD: Alternate back and forth.

Arvind? Process?

DR. MODAWAL: I thought this went very well. This is my first time. And it was an experience and some of the things can be improved.

I thought should be a one-pager like rules in terms of -- not more than one page -- in terms of our evaluation and voting just to explain the process because we are learning as we were doing these. That would be helpful.

CO-CHAIR GIFFORD: Bill?

MR. KUBAT: I think the other thing that I'd add is that it wasn't -- at least for me -- it wasn't always clear in terms of all the 25 things that we looked at

what was the concise feedback from the TEP. And to have that more clear would have been helpful in my own discernment.

DR. KOREN: This may have been said. I'm not sure. But I would have found the conference call that we had with the slideshow preparing us for this meeting to have been much more helpful after I had received the materials than before we got the materials because it was very hard to track. And it didn't really mean anything. Once we got the materials, it would have meant a lot.

DR. ORDIN: Well, I only had one idea anyway.

I think being able to write -- to sort of follow up on what Mary Jane said -- to be able to make comments on the form instead of going back.

MS. ROSENBAUM: I've really enjoyed this. This has been my first time here. But I kind of felt I had to learn as I went on some of this. And I think a little

more preparation with some of the forms -- maybe getting them ahead of time would help because I think it's really very stimulating and I've learned a lot. Very good.

SISTER HEERY: I have to agree. It was my first time and learned as I went along. The information would have been a little more helpful.

And I agreed on the voting that if we knew that, we could have done maybe some other things and kept proposals there.

DR. SCHUMACHER: Just a couple of comments.

One is that it might have been helpful if instead of up on the screen trying to scroll through everything, and it was really small and we could barely read it anyway. If there's some way to sort of summarize what the reviewer said and put that up there. And even maybe to think about summarizing some of the data from the technical expert panel -- something like that.

There's just too much to try to put up on the screen. So if there's any way to shorten that and put something up that's more meaningful.

As far as other components of the process, I agree with what Dr. Koren said about the conference call that it would have been more useful if we had received some of the information first because we really didn't know what you were talking about for those of us who were new to this. And just some suggestions for that call would be maybe to sort of number one, give us a better idea for the big picture. What is it we're trying to do here? Who are we going to be sitting in front of? Who are we going to be hearing from in terms of the presenters? I didn't understand any of that until I got here and saw it for myself. And also maybe even to just on that call kind of walk us through an example of how a primary reviewer should present the information, what that should look like, what points should be made, and give us

more by example rather than just presenting a bunch of data to us.

DR. GRIEBLING: I just echo that comment. I think a model review presented during the conference call would have been helpful.

MR. BOISSONNAULT: And I go back to Ken Kaizer days in my involvement on and off with NQF.

I think the results suggest that things went pretty well. I actually am leaving Washington feeling very, very good about even where there was not sort of unanimity and even with some of the things with which I did not agree, I think the issues were actually explored quite well.

And so I would not want the process to become constricting or a barrier to the flexibility we sometimes need to for example table things or whatever. So I was actually more comfortable with the ambiguity than some of what I heard today.

If I were going to sort of offer a suggestion, you can work us harder. I think the indication that I perceived in the past was expect to spend between one and three hours on each review that you're not a primary for, and that you're going to spend maybe more than that if you're going to check the references for the ones that you are primary on. Because it is our job to check the references.

Now we know there were some barriers to that that I'm not going to get into although I think for the ones we were primary on, it was a nonissue. And so I wasn't even particularly disturbed by that.

But I think when you've set out the expectations -- we're setting national policy. This is extraordinary work. And I'm honored to be here. And I think we should go home feeling pretty good. And when I get my next letter, I would not be upset if somebody said it looks like it's going to be about 40

hours work to prepare for this. Are you willing? Because that's what I enjoy doing.

MS. THOMPSON: The only thing I would like to add is I think that especially it would have been nice if we would have had copies of the MDS 3.0 form and at least a reference manual to -- I mean, I actually had a copy. I gave it to him. I don't want to take it home with me. But I think for those that are not as intimately involved with that form to be able to look at it to see where is this data coming from. And when we are looking at measures that are not related to the MDS 3.0, if some of that reference material could be available for those that don't know where that source document is and what it means.

DR. KOREN: David, I know that we're off of the measures. But I just thought of one. And I don't know quite how you would use it -- but to think about, which is use of safe lift practices in nursing homes. I think

it has huge impact not only for the quality of care for the residents, but I think it also has impact on staff. We know it's a pretty dangerous job. Back injuries and workers' comp are really big issues. And there are starting to be some really well-defined criteria for what safe lift practices are. And I think we should start to look at that.

CO-CHAIR MUELLER: Well, I echo a number of these things. And I'm very grateful to a co-chair who had four times practice at this. And this is my first time also. So the prepping for this was a challenge with limited time. But anyway, very grateful to have the opportunity to work with you.

I have to only imagine that NQF has worked tirelessly on coming up with this form for people to fill in. And boy, I don't have any suggestions for how to make it better. But I still found it hard to read that tiny little print. I wanted to get rid of the balloons so I could expand it but you

had locked it, I think. So I couldn't get rid of the balloons. You know how to accept the changes? Yes. I couldn't accept the changes. But maybe it is an age difference, but we just really need things a little bigger these days.

So anyway, just a suggestion about any continuing to improve the forms.

MS. NAIERMAN: I just wanted to take the opportunity to take you both, David and Christine. I thought it was very, very well done. Smooth coordination and a wonderful sense of humor. Thank you very much.

CO-CHAIR GIFFORD: Well, I too want to thank you all. But actually, we're still not done.

Sandy, you probably have a public comment? If I don't know you, I don't --

MS. FITZLER: I do. You don't know me.

CO-CHAIR GIFFORD: Were you going to give a public comment?

MS. FITZLER: I have a few, and this is from this morning's discussion.

I am concerned that we're not looking at UTI for the short-stay population, only the long-stay. And I'll tell you why. The inappropriate or misdiagnosis of UTI is a problem, not just for long-term care but for other settings of care. And this is a transition of care issue because we see a lot of patients coming in who have been put on an antibiotic in the hospital for a UTI, but we're seeing a lot of folks who are having hips and knees.

And the post-op protocols for the administration of an anti-coagulant. And we know that we have problems between a drug-to-drug interaction between the antibiotic and the anti-coagulant. And we should be picking this up earlier. So I would like to see some kind of measure that forces our attention on this in the short-stay population.

My second issue is with a measure

just discussed not too long ago. And that's the percent of residents whose need for help with daily activities has increased. I think this is important but I really don't think that this means anything to the consumer because this is why they're putting patients into a long-term care facility in the first place. They know. They are watching a decline in their family member. They know that decline is there. So to me, this is confusing to them.

Now, if we flipped this measure so now we're looking at the residents whose need for help with daily activities has maintained or improved, that would mean something to the public. And this is what we are talking about when we're talking about measures that are stated in the positive.

So I do have a request that we ask CMS when they're testing these measures to see how many of these measures can be flipped, to see if they're still valid and reliable when

they're flipped, and I'm doing so only because I have been assured by numerous sources that they would try to do this.

Thank you.

CO-CHAIR GIFFORD: Anyone on the phone for comments or questions?

(No response.)

CO-CHAIR GIFFORD: Other public members?

MR. GRUHN: Thank you. I'm Peter Gruhn with the American Health Care Association.

There was discussion earlier about outliers and risk adjustment with respect to the ADLs. And one thing that troubled me a little bit was -- at least my take -- was that facilities that may be specializing up to your type of your patient or so forth, we can overlook that in terms of the measure because there's not that many of them, and it may not be all that critical in terms of the measure and how we evaluate that facility.

But I just submit to you that if this is an -- and then what's a sufficient number? Is it maybe 50? One in each state that might be the premier center for treating traumatic brain injury folks or rehabbing them? Whether when one looks at the QM for that but they get skewered on it, how is the public to distinguish that facility from a facility that is not doing so well or not of a high quality and so forth?

So I'd urge the panel and researchers to keep that mind. Look for appropriate risk adjustment for particular measures.

And then a second piece on there was some discussion on a number of the measures on seasonal adjustment and going from one quarters worth of information to two quarters of information, doing a moving average as I understood it. In looking at the QM information on a quarterly basis that CMS publishes where the nursing home compare, for

many of the measures one can clearly see seasonality. Measures will go up. Measures go down. Performance will look worse, let's say, in the first and second quarter depending on a particular measure, and then decline dramatically through the year and them bump up again the following year in the first and second quarter. A two quarter average might help mitigate some of that variability. But it's not going to get down to the underlying issue, I don't feel, of smoothing out and adequately adjusting for the seasonality.

Really, you might want to consider looking at a four-quarter average or some other methodology for making that type of adjustment.

Thank you.

CO-CHAIR GIFFORD: Any other comments from the public?

(No response.)

CO-CHAIR GIFFORD: CMS?

(No response.)

CO-CHAIR GIFFORD: Okay. Well, I too want to thank the NQF staff who put a lot of effort into this in assembling all the material, and particularly Suzanne, Del, Emma and Helen. Really it was very helpful. So thank you.

(Applause.)

CO-CHAIR GIFFORD: The Court Reporter in the corner is taking everything down for us.

And the sound, I have to say I have been in many, many meetings, and the sound and the power strips and everything else really have been wonderful. It's one of the better ones I've ever been to. So I want to thank you for that.

(Applause.)

CO-CHAIR GIFFORD: And then lastly, I'd like to thank you all because you do have day jobs. And despite Bruce wanting to spend even more time doing it, I think you all did really spend a lot of time and were

very thoughtful and took your role very seriously. And so I want to thank you and the feedback you gave.

I enjoyed it a great deal. So thank you a great deal. I want to thank all of you for your effort.

And our work is not done. We will continue to meet by email and calls. So we still have some other work to do. And I think we set a really good tone. And it is exciting to set some national policy and everything.

Christine, do you want to say anything?

CO-CHAIR MUELLER: I think I said earlier thank you and I look forward to continuing to work with you.

CO-CHAIR GIFFORD: And I believe lunch is out there. We're not going to have a working lunch. We're not going to come back after this because I knew if I released you for lunch, none of you would come back.

So we did finish early. So thank

you guys very much.

MS. THEBERGE: Just a couple of quick things. I just wanted to let you all know that next steps we will be setting up a conference call early in May to discuss some of the conditional recommendations. We're going to take all that back to the developers, talk to them, come up with a report. So we'll be in touch with you early next week about getting that call scheduled. And we'll also be sending around the report for your review.

MR. BOISSONNAULT: Are we still in terms of the evaluation materials that we received and so forth still not at liberty to share those?

DR. BURSTIN: Once the information is posted on the NQF website for comment, it's public information. At this point, it's not yet. It's still deliberations with the measure developer. So I would use those appropriately.

CO-CHAIR GIFFORD: And I will

recommend to NQF that you all get double bonus payments for your work. So thank you. And you can double it.

(Laughter.)

MS. THEBERGE: Thank you very much, everyone.

(Whereupon, the above-entitled matter went off the record at 12:53 p.m.)