THE NATIONAL QUALITY FORUM

STEERING COMMITTEE ON NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR NURSING HOMES

MEETING

WEDNESDAY
APRIL 21, 2010

The Steering Committee convened in Salon 2 at the Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, Maryland at 9:00 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
DIANE E. MEIER, MD, FACP
ARVIND MODAWAL, MD, MPH, AGSF, FAAFP
NAOMI NAIERMAN, MPA
KATHLEEN C. NIEDERT, PhD, MBA, RD, NHA
DIANA ORDIN, MD, MPH
PRESENT, CONTINUED:

PATRICIA A. ROSENBAUM, RN, CIC
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
KAREN PACE
SUZANNE THEBERGE
C-O-N-T-E-N-T-S (CONTINUED)

Measure NH-001-10 (AMDA) (Continued)

Discussion 61, 70
Mary Jane Koren 70
The Commonwealth Fund

Discussion 73

Vote 84
NH-025-10 (CMS) 85
Percent of residents who have symptoms of major depression
Barbara Gage 86
RTI
Sister Mary Rose Heery 90
Mother Angeline McCrory Manor

Betty MacLaughlin Frandsen 92
AANAC

Discussion 92, 117, 125

Vote 116, 124, 131

Staffing Measures 132

NH-006-10 (ANA) 133

Skill mix - registered nurses (RNs), licensed vocational/practical nurse (LPN/LVN), unlicensed assistive personnel (UAP), and contract
Rita Munley Gallagher 133
American Nurses Association
C-O-N-T-E-N-T-S (CONTINUED)

Staffing Measures (Continued)

Dr. Nancy Dunton 135
American Nurses Association
Christine Mueller 137
Co-Chair

Betty MacLaughlin Frandsen 141
AANAC

Discussion 142

Vote 174

NH-007-10 (ANA) 182
Nursing care hours per patient day

Betty MacLaughlin Frandsen 182, 188
AANAC
Bruce Boissonnault 183, 189
Niagara Health Quality Coalition

Discussion 184

Vote 190, 191, 202

Pain and Pressure Ulcer Measures 202
Roberta Constantine 203
RTI International

Diane Meier 207, 215, 217
Center to Advance Palliative Care
Naomi Naierman 214, 215
American Hospice Foundation

Discussion 217
C-O-N-T-E-N-T-S (CONTINUED)

NH-009-10 (CMS) 263
Effective pain management (short stay)

Vote 263

NH-010-10 (CMS) 264
Percent of residents with moderate to severe pain (short stay)

Vote 272

NH-011-10 (CMS) 264
Percent of residents with moderate to severe pain (long stay)

Vote 272

NH-012-10 (CMS) 273
Percent of residents with pressure ulcers that are new or have not improved (short stay)

NH-013-10 (CMS) 273
Percent of high-risk residents with pressure ulcers

Roberta Constantine 273, 284
RTI International
Mary Jane Koren 277, 285
The Commonwealth Fund

Lisa Tripp 283
John Marshall Law School
Discussion 286
Vote 293
C-O-N-T-E-N-T-S (CONTINUED)

Shula Zorowitz 293, 300
Village Care of New York/Village Center for Care, Inc.

Kathleen Niedert 299
Western Home Communities Discussion 300

Vote 309

Vaccination Measures 309

NH-014-10 (CMS) 309
Percent of residents who were assessed and given the seasonal influenza vaccine (short stay)

NH-015-10 (CMS) 309
Percent of residents who were assessed and given the seasonal influenza vaccine (long stay)

Shula Bernard 310
RTI International Discussion 314, 323, 339
Bruce Boissonnault 321
Niagara Health Quality Coalition

Diana Ordin 338
Veterans Health Administration Vote 345
C-O-N-T-E-N-T-S (CONTINUED)

NH-016-10 (CMS) 346
Percent of residents who were assessed and given the pneumococcal vaccine (short stay)

NH-017-10 (CMS) 346
Percent of residents who were assessed and given the pneumococcal vaccine (long stay)

Shula Bernard 346
RTI International
Patricia Rosenbaum 347
Association for Professionals in Infection Control and Epidemiology
Ronald Schumacher 352
UnitedHealth Group

Discussion 353, 359

David Gifford 357
Rhode Island Department of Health Co-Chair
Vote 361

Fall Measures 362

NH-008-10 (CMS) 363
Percent of residents experiencing one or more falls with major injury (long stay)

Roberta Constantine 363
RTI International
C-O-N-T-E-N-T-S (CONTINUED)

Arvind Modawal 366
University of Cincinnati

Darlene Thompson 369
Kindred Healthcare
Discussion 373
Vote 396

NH-005-10 (ANA) 396
Falls with injury
Isis Montalvo 396
National Center for Nursing Quality

Nancy Dunton 401
American Nurses Association
Arvind Modawal 404
University of Cincinnati

Robert Zorowitz 405

Village Care of New York/Village Center for Care, Inc.
Discussion 406
Vote 422

NH-004-10 (ANA 424
Patient fall rate
Isis Montalvo 424
National Center for Nursing Quality

Nancy Dunton 424
American Nurses Association
C-O-N-T-E-N-T-S (CONTINUED)

Alice Bell 424
  American Physical Therapy Assn.

Heidi Gil 425
  Planetree

Vote 426

NH-003-10 (RAND) 427
  Physical therapy/assistive device for new balance problem
  Neil Wenger 427
  RAND Corporation

Alice Bell 430
  American Physical Therapy Assn.

Arvind Modawal 432
  University of Cincinnati
  Discussion 433
  Vote 453

NH-021-10 (CMS) 454
  Percent of residents who were physically restrained (long stay)
  Roberta Constantine 454, 460
  RTI International

Lisa Tripp 458, 461
  John Marshall Law School
  Ronald Schumacher 463
  UnitedHealth Group

Discussion 463
  Vote 472
C-O-N-T-E-N-T-S (CONTINUED)

NQF Member/Public Comment  473

Sandy Fitzler  473
American Health Care Association

Toby Edelman  474
Center for Medicare Advocacy

Isis Montalvo  478
National Center for Nursing Quality

Administrative Topic - Dinner  480

Comments by Committee about  480
what measures they would like

to see developed
9:12 a.m.

MS. THEBERGE: We are so glad to see you all in person finally.

My name is Suzanne Theberge. I am the Project Manager for this project. I would like to ask my colleagues here to introduce themselves.

MR. CONYERS: Thank you.

Good morning. My name is Del Conyers. I am the Assistant Managing Director of Performance Measures at NQF.

DR. BURSTIN: I am Helen Burstin. I am the Senior Vice President for Performance Measures at NQF.

I also want to add my welcome.

MS. PACE: Good morning.

I am Karen Pace. I am the Senior Program Director at NQF and work with measure evaluation and methodology and also some other projects.

MS. NOCHOMOVITZ: Hi. I am Emma
Nochomovitz, NQF Research Analyst.

Nice to meet you all.

MS. THEBERGE: And I would also like to ask our Co-Chairs to introduce themselves real quickly.

CO-CHAIR MUELLER: Hi. I am Christine Mueller, and I am at the University of Minnesota School of Nursing.

CO-CHAIR GIFFORD: I am David Gifford. I am the Director of the State Department of Health in Rhode Island.

MS. THEBERGE: We went over some of these slides earlier in the orientation call. So, I am just going to skip through them all real quickly, at least what is NQF.

Okay. So, let's go around and introduce everyone else.

CO-CHAIR GIFFORD: Mary, we will start with you.

SISTER HEERY: Hi. I'm Sister Mary Rose. I am from Columbus, Ohio.

DR. ORDIN: And I'm Dede Ordin,
Office of Quality and Performance, VA.

MR. KUBAT: Hi. Good morning.

I am Bill Kubat from the Good Samaritan Society in Sioux Falls, South Dakota.

MEMBER NAIERMAN: I am Naomi Naierman, American Hospice Foundation.

MS. BELL: Alice Bell, American Physical Therapy Association.

MS. FRANDSEN: Betty MacLaughlin Frandsen from AANAC.

DR. NIEDERT: Kathleen Niedert from the Western Home Communities in Cedar Falls, Iowa.

DR. ZOROWITZ: Bob Zorowitz from Village Nursing Home in New York.

DR. MODAWAL: Arvind Modawal from the University of Cincinnati Medical Center in Cincinnati.

MS. TRIPP: Hi. I'm Lisa Tripp.

I am with the John Marshall Law School in Atlanta, Georgia.
DR. KOREN: I am Mary Jane Koren. I am with the Commonwealth Fund.

MS. GIL: Good morning. Heidi Gil from Planetree from Connecticut.

MS. ROSENBAUM: Pat Rosenbaum, infection control and epidemiology consultant.

DR. SCHUMACHER: Hi. I am Ron Schumacher. I am from the United HealthCare and Evercare.

MR. BOISSONNAULT: Bruce Boissonnault, Niagara Health Quality Coalition.

MS. THOMPSON: Darlene Thompson, Kindred Healthcare.

DR. GRIEBLING: Good morning. I am Tomas Griebling. I am at the University of Kansas in the Department of Urology, the Center on Aging, and also with the American Urological Association.

CO-CHAIR GIFFORD: Okay. Can we hear from the peanut gallery?
MS. DOWELL: Robin Dowell from CMS.

MS. MANDI: Stacy Mandi from CMS.

DR. LING: Shari Ling, CMS.

MS. GALLAGHER: Rita Munley Gallagher, not CMS, the American Nurses Association.

(Laughter.)

MS. TOBIN: Judy Tobin, CMS.

MS. FITZLER: I'm Sandy Fitzler from the American Health Care Association.

MS. CONSTANTINE: Roberta Constantine, RTI.

MS. GAGE: Barbara Gage, RTI.

MS. SCOTT: Jean Scott from CMS.

MS. BERNARD: Shula Bernard from RTI.

MS. VANCE: Jackie Vance, American Medical Directors Association.

MS. EDELMAN: I am Toby Edelman,

Center for Medicare Advocacy.

CO-CHAIR GIFFORD: Do we have
anyone in the black box at all today? Anyone calling in? Do we have some people in the black box? I always want to know what's in the black box?

(Laughter.)

Anyone out there want to speak?

MS. BERRY: Ellen Berry, CMS.

CO-CHAIR GIFFORD: Ellen, you're just like coming in as a voice. There's not even a black box.

(Laughter.)

So, very ethereal today. Oh, there's the black box, yes. It's more a rectangle.

Anyone else?

(No response.)

Okay. We are going to skip over the disclosure of interest. We are not going to disclose any interest out there. So, we're going to keep it secret as we go forward for the rest of the day.

(Laughter.)
I think everyone has filled the forms out and done it all and everything, yes.

No, Helen is rolling over. See, you shouldn't have picked me as a Co-Chair.

But we are going to go through a quick overview, Suzanne. So, I will hand it over to Suzanne.

MS. THEBERGE: All right. So, as we talked about on the phone, NQF is a private, nonprofit, voluntary, consensus standard-setting organization with over 400 member organizations.

We are here today to do our consensus-development process. We are going to gain consensus about which measures and practices should be national voluntary consensus standards for nursing homes. We have public and private sector representation on our governing board and our focus is on the entire continuum of healthcare.

I wanted to go a little bit over the consensus-development process as it
relates to you folks on the Steering Committee. This is a schematic of part of the CDP, and you folks are in the yellow box.

After we go through today and discuss the measures, the next step is that NQF staff will draft a report on the recommendations. Then, we post that for review and member and public comment.

After we receive comments on the measures that you have voted to endorse, then we will submit the comments back to you for consideration and have a conference call later this summer to discuss these comments. The Steering Committee may respond to comments by revising the report or submitting comments on the comments.

Once the Steering Committee has reviewed the comments and revised the report as necessary, the NQF member body will vote on the final version of the Steering Committee recommendations. The voting period lasts 30 days and will happen in late August through
September.

Candidate consensus standards that are approved by the NQF membership will proceed to the next step, which is the decision by the CSAC. The CSAC reviews the recommendations of the Steering Committee and the voting results and then either grants full endorsement, time-limited endorsement, or denies endorsement. Our CSAC vote will happen in mid-October.

Finally, the NQF Board of Directors will affirm or deny the CSAC's decision, and the Board meeting will happen in December. After the Board ratifies the consensus standards, they are, then, posted to the NQF website.

Appeals can be filed on endorsed standards only within 30 days of the Board's endorsements, and appeals are reviewed and evaluated by the CSAC, and they make a recommendation for action to the Board, which needs to happen within seven calendar days.
The Nursing Homes Project is funded by the U.S. Department of Health and Human Services. We are going to be focusing on measures and patient experience-of-care surveys that specifically address nursing home quality measures for public reporting and quality improvement. This is a followup to the Nursing Home Project that was completed in 2004.

The goals are to identify and endorse measures for public reporting and quality improvement in the nursing home environment. Here's the project timeline with some more specific dates for some of the processes that I mentioned earlier. As you can see, we are on the third step now, the Steering Committee in-person meeting.

The role of the Steering Committee is to come together as a group of experts to evaluate the measures in-depth and to make recommendations to the NQF membership for endorsement, and then give us your expertise.
Then, again, as I mentioned earlier, you will respond to the comments submitted during the review period.

The Co-Chairs, upfront here with me, will represent the Steering Committee when the CSAC meets. The other role of the Steering Committee is to respond to any direction from the CSAC.

Your in-person obligation is limited to this meeting, but if we are unable to finish going through all the measures in the next two days, we will hold a conference call to follow up and finish that. Then, we will also have a call in the summer to discuss anything that comes up in the commenting period.

As you all know, you were assigned a few measures to review. We worked hard to assign them to you based on your areas of expertise or because we thought you would bring a valuable perspective to this particular measure.
You will be leading the discussion that you were the primary reviewer for. So, once we call your measure, we will ask whoever the primary reviewer was to speak to that. You should share your rating of each subcriteria, and the secondary reviewer should chime in as necessary, especially if you disagreed about something. We definitely want to hear about that.

Your review should be concise and provide the expert view for the Steering Committee. Listed below are some talking points that should help you frame your discussion.

You should introduce the measure by referencing the measure ID and a brief description. Then, you should talk about whether the specifications are complete. Were they clearly stated? Is all the necessary information there to reproduce the measure? What are the strengths? What are the weaknesses?
One of our criteria, is this important? Is this measure important to measure and report? Is it scientifically-acceptable? What are the results about the quality of care? Is this measure usable? Would the results of the measure be understandable to the intended audience and likely to be useful for decisionmaking? And is this measure feasible?

And finally, you should mention any revisions or clarifications that you see necessary and your recommendation with any caveats, if you think the measure is not ready yet, if you think it needs further specifications, et cetera.

Now I am going to turn this over to Helen to talk about our endorsement criteria.

DR. BURSTIN: Great. I spend enough time with these Steering Committees, you would think I would have mastered the microphones.
In fact, we have one next door, in case you saw lots of other people with little NQF name tags. This is day two of our Outcomes Steering Committee. So, I will be popping in and out between the rooms, but Karen Pace, who introduced herself at the other side here, is our lead methodologist and the one probably most grounded in understanding our criteria.

I just wanted to really emphasize a few things that Suzanne mentioned, really making the case that we really are trying to stay very grounded in those criteria. This is intended to be a really thoughtful review process of those measures. The more we can stay grounded in those criteria and subcriteria, the more objective we can be.

So, we tried to as much as possible objectify the process, make it as clear as could be. We have updated our NQF evaluation criteria almost a year and a half, almost two years ago, Karen. It seems like
just yesterday.

The intent of that was several reasons. First of all, we really wanted to strengthen the criteria to make sure we were really bringing in the right set of measures that could help both for public reporting as well as improving quality.

The other thing was there was a sense that we wanted to raise the bar. We wanted the measures to be getting better and better, so that we are really assessing true quality.

So, when you are going to be seeing a mix today of process measures and outcome measures, process measures certainly still have a place, even in light of the Committee meeting next door for the next two days, but we really do want to make sure that those process measures clearly have a link to outcomes. They should be strong enough, they should be fairly proximal to the outcome, as opposed to very distal and far away from the
actual outcome. So, that if you actually
tried to work on that process measure, you
could actually move the needle on our ultimate
goal, which is really improving care and
outcomes for patients.

We also wanted as much as possible
harmonized measures within sites of care,
across sites of care. Now this is probably
one of our last Steering Committees that is
setting-specific. We are really going to try
to move towards, for example, probably in
2011, a Committee that is focused on function,
that allows us to, in fact, harmonize a lot of
the measures that look at function or some of
these issues across hospitals, nursing homes,
home care.

The divisions are not that
helpful. You really want to be able to take
a broader, more episode-based view of care.
These very narrow, setting-specific measures
aren't necessarily, I think, where we want to
be in the long-term.
For where we are right now, there is a specific purpose and a need for these. These measures, the nursing home measures, have been around for a while and clearly in need of updating. We were really pleased when we got the updated measures from CMS.

But you should think about harmonization issues. For example, if you know there is a similar measure in home health, and it is just kind of off, it would be very helpful to raise those issues and say, does this really need to be different? Or, actually, there will be an issue coming up later, for example, of a falls measure that was just looked at in the Mental Health Outcomes Project where they said, you know, we don't really need a separate falls measure for psych facilities. Can't we just have a falls measure?

So, again, I think those are the kind of issues we will be bringing to you on harmonization, again, as much as possible, a
stronger emphasis on outcomes, and I mentioned
the outcome link thing.

For those of you who have been
engaged in our process to date, here's a
couple of the highlights of what's different.
The first thing is the importance to measure
and report is now a must-pass criterion.
Basically, if you are not going to get useful
information out of it to really drive
improvement, you could stop right there.
There are three subcriteria embedded within
importance to measure and report.

First of all, is it one of the
national priorities and goals, the National
Priorities Partnership that NQF has convened,
has put forward? Is it clearly an area of
high impact in terms of mortality, morbidity,
impact on the population, whatever the case
may be? And the third piece that we are doing
a fair amount of work on, that Karen is
leading as well, is, is there strong evidence
to support the measure focus?
If those three areas aren't satisfied, there's no need to proceed with the rest of the evaluation of the measure. We will stop right there. So, that is a must-pass criterion. That is a new change for us compared to the prior years.

The next three are just a few highlights. Scientific acceptability is really about the measurement properties. The evidence is under importance to measure and report.

Here we are really looking at issues particularly of reliability and validity. You do have some untested measures in your midst today. The only way those could go forward is as time-limited measures. Carol will be for you a resource to help you understand some of those nuances.

Usability, really especially important, I think in some ways, for nursing homes because these data are publicly reported. We really do want patients and
families to be able to have measures they can use to understand and make better decisions about their care, to say nothing of providers and others who also help make those decisions. Usability also includes the subcriterion harmonization. So, that is where we would really want you to emphasize that point.

And lastly, not surprisingly, given where we are going and a whole lot of money on the table for HIT at the moment, we also want to see how feasible it is to collect these data using electronic data. I realize nursing homes has got a dataset attached to it, but over time, as the transition happens to broad-based electronic systems that are interoperable, how much of these data could be collected through routine care, through the natural process of care?

Next, and just lastly, there are four conditions for our consideration. Even if a measure is not in the public domain,
we've got to have a measure steward agreement
signed to allow others to use the measure.
With this measure steward, there is always a
requirement that the measure steward has to
agree that they are going to maintain and
update the measures.

We have a regular maintenance
process to ensure that measures stay current.
Evidence changes so quickly that, literally,
yesterday we were looking at diabetes measures
and saying, "But the ACCORD trial came out
March 15th." Okay, guys, it's April; it's
April 20th.

(Laughter.)

But there is clearly a need to
make sure we are staying current. So, we have
a process that allows us to look at that. But
part of that means the steward has to agree,
yes, I'm going to maintain this measure; I'm
going to keep up on the evidence base, and
make sure this measure, in fact, maintains the
currency of the evidence.
The third one is especially important and, again, not as much an issue for nursing homes because there's a natural path for public reporting of nursing home measures. The intent is these measures should be usable for both public reporting and quality improvement. So, there may be measures that would be very useful internally within nursing homes, for example, but wouldn't necessarily rise to the level of saying you would be able to understand differences between nursing homes by publicly reporting that measure. We really want to look at the measures that would allow you to do both.

Then, finally, the staff have gone through and at least ensured that what we have submitted to you for your consideration at least is complete. So, we didn't get into the nuances of reading things; we leave that to you, but at least we have gone through it and worked with the developers to make sure you've got a complete submission.
Time-limited endorsement is something you are going to spend a fair amount of time on today, depending on how many of those measures come up. We are, again, working through some of these issues. There's still a little bit of uncertainty, I think, from measure developers about our intent of time-limited endorsement.

The original idea was that there were measures out there that were so important to the field really wanted them, but they hadn't yet gone through testing. So, we put forward this ability to bring through untested measures under a categorization called time-limited.

We have recently passed a change in our time-limited process with the Board of Directors. There's really a sense that we want to narrow the funnel of untested measures that come to NQF.

There is some criteria that we have set up for what time-limited measures
could come forward. The idea would be that there's no currently NQF-endorsed measure that can accomplish this, and therefore, bringing in this in an important area makes sense.

The second thing is there's a critical timeline. There's a legislative need. There's a regulatory need to have these measures in place.

The third, I think, is really important as well, is that the measure is not complex. I think there's a general comfort level that a fairly simple process measure is going to get tested over time. You are not going to see perhaps a huge amount of change based on testing, but a complex measure with risk adjustment or a composite, we don't feel comfortable putting forward as time-limited. So, I think we have already gone through the process of pulling out anything we think didn't work in that case.

The last thing is we used to allow up to 24 months for measure developers to test
their measures. We are finding it difficult to get the testing in a timely manner. I think it is also difficult for end-users to feel comfortable using some of these measures if they are still untested.

So, the Board has recommended, and we are in this interim transition period at the moment, that we would like to try to get the testing results back within 12 months, rather than we were seeing almost all the developers, of course, waiting until month 24 to bring that in. I think the sooner we can bring in those testing results, the more comfort we have in the fidelity of those measures for people to use them for public reporting.

Karen is also leading a testing task force we are doing right now that is helping us think through exactly what we mean by different levels of reliability and validity, what's going to be required at submission versus what will be required at
that testing point.

I think I turn it back to you now, yes? And I give this back to Suzanne.

Any general questions for Karen or me?

MR. KUBAT: Yes. Bill Kubat. Maybe sort of a question or a comment.

DR. BURSTIN: Yes.

MR. KUBAT: But I had the privilege of serving on that first Steering Committee. One of the things that I have noticed, and some of it is the pace, and so forth, by which the work here has been done, but I just have to acknowledge I have felt a little bit of frustration in the work here.

Because one of the things that we did in that first Steering Committee, and I realize it was the first one, but we spent a considerable amount of time at the beginning identifying what measures should be on there. What are the domains and the kinds of measures that should be reported, and so forth?
Here what we have done has just been responding to what's been submitted and responding very quickly and responding to a very narrow band.

DR. BURSTIN: Yes.

MR. KUBAT: And it feels very fractured. When I have thought about harmonization -- and I like that word; I have been intrigued with that. I like the word. I like the thought. I like the concept.

But I think in terms of harmonization not just in terms of NQF-endorsed measures, but I think in terms of what is publicly reported. NQF-endorsed and publicly reported are not synonymous.

I think in terms of not only what is on Nursing Home Compare, but Nursing Home Compare vis-a-vis Home Health Compare vis-a-vis Hospital Compare vis-a-vis Dialysis Compare, and they are consistently, I mean they are dramatically different tones in terms of the measures, in terms of the wording, in
terms of the domains. And there is no
platform to be able to address that.

So, I just need to say that.

DR. BURSTIN: Yes, and actually

you do have one platform, although I think the
issue is it will operate in the future, which
is that one of the things we would really like
this Committee to say is, what didn't you get
that we should make sure comes in in the
future?

I think the issue is these sets of
measures were getting old. They needed to be
updated. CMS has been working with their
developer to update those measures. They
clearly needed to get cleared up, and that is
the intent of this.

But we very much would like you to
identify what those measure gaps are. As we
think towards, for example, this Committee
maybe in 2011 or 2012, where we are going to
do functional status, for example, across the
settings of care, or, also, I know there was
some concern, and certainly David and
Christine expressed it strongly, a strong
desire to have nursing home CAHPS come to the
table, for example, as a patient experience-
of-care survey.

We did speak with CMS. We also
invited AHRQ to potentially submit it on their
own. That hasn't happened yet. We are still
sort of seeing if that is a possibility.

But, again, if there are
measurement gaps that we can put out to the
field to say, if you are working on things
over the next two years, please do these, that
is a really important role for the Steering
Committee. Even if you couldn't do it in
advance, let's help set the field going
forward.

Does that help? Good.

MS. THEBERGE: Okay. So, we had
25 measures submitted to the Steering
Committee for review. We have broken those
measures out into some categories for a little
easier review.

Mental health, we have two measures. Staffing, we have two measures. Pain and pressure ulcers, we have five. Vaccination, we have four. Falls, we have five, and function, we have eight measures.

The way this is going to work is we are going to ask the measure developers to speak very briefly, about three minutes for each measure developer to talk about the measures in that section, what their intent was. Then, you will go through each measure, and the measure developer for the measure you are discussing will be sitting up here and able to answer any questions that come up.

Before we begin, CMS is going to spend a few minutes speaking about the transition from MDS 2.0 to 3.0.

Then, also, we have two similar measures in the falls category. So, we will be discussing that later. Then, we have one measure that is up for maintenance.
So, now we are going to start looking at our measures, unless there's any further questions.

MR. KUBAT: Maybe related to 2.0 and 3.0, a naive question, but I did understand from the train-the-trainer sessions of last week that there are changes being made even as we go to 3.0. So, does any of that impact what we are doing here?

DR. BURSTIN: Sounds like a question, hopefully, CMS will be able to address for us. But just as one more thing to add, if the measures change in the interim, so if there is a significant change made on one of these measures, even before the next window, and we will do maintenance on these measures, NQF does have an ad hoc maintenance process.

If the evidence base changes, if there is a material change to the measure, we can go with an off-cycle review and exam it for maintenance whenever, as necessary. So,
if there are changes that happen, it doesn't
have to be a static thing. We can actually
move this forward as well.

CO-CHAIR GIFFORD: Does everyone
around the table know, feel comfortable with
what the MDS 2.0 is or 3.0 is? Does anyone
not and you would just like two seconds of
what MDS is?

(No response.)

Okay, good.

I'm getting whispers from both
ears, and I can't do it. I can't even hear
whispers from one ear.

(Laughter.)

Are we doing it now or later?

DR. LING: Hi. Good morning.

My name is Sheri Ling. I am a
medical officer with CMS in the Division of
Chronic and Post-Acute Care.

Any ophthalmologists in the house?

I may need one. Okay. Then, I am in trouble.

All right.
So, I am a medical officer with
the Division of Chronic and Post-Acute Care in
the Quality Measurement and Health Assessment
Group at CMS.

I just want to take a couple of
moments to tee-off the 3.0-based measures that
you will be hearing about, and RTI will be
speaking on behalf of CMS about providing you
with the details of the candidate measures
submitted for your consideration.

But just as a prelude, to speak a
little bit about 3.0, MDS. 3.0, and to take us
back to 1995, so why 1995? The MDS 2.0 has
been and served a primary data collection
vehicle through which we have obtained
comprehensive information on our nursing home
residents.

1995, if you think about where you
were and what you were doing in 1995, and what
we have witnessed since 1995, in that brief
time interval, we have witnessed the
introduction of effective therapies to abort
myocardial infarctions, translated more recently to preservation of neurologic function, averting stroke. We have witnessed AIDS converting from a terminal illness to one that can be survived. We have also witnessed treatment of peptic ulcer disease and blood ulcer disease with antibiotics. These are things that were just unfathomable in 1995.

With these changes in medical technology and with the medical practice, we have also observed a shift in the way that our system functions in how we deliver care to our residents, to our patients, and with that shift also has been a shift in the sample that resides in the nursing home. We no longer have a homogenous sample of residents. We have residents who are either under our care because they are recovering from an acute illness or because they do have more chronic care needs.

So, these are two different subpopulations that we have, for all intents
and purposes, lumped into the category of nursing homes. Now it was necessary for the MDS to change to accommodate some of those shifts in our population.

Importantly, it has also changed to integrate state-of-the-art assessment techniques. It has also changed to importantly represent the residents' voice. And it has, importantly, changed with the burden of care in mind to be an efficient and comprehensive and standardized data collection vehicle. So, these are changes that are implicit in the measures that you will be presented today.

So, my concluding statements about the measures that are submitted for your consideration are that they are grounded on the concept of importance. They are important because they represent clinically-important conditions that we are charged with the care and keeping of our residents and our patients. They were considered important by consensus
through our technical experts panels.

They incorporate the enhancements of the 3.0 instrument. Along that line, importantly, the measures are framed, we have taken a stab at redefining subacute from longer or more chronic care. You will see that, that the measures are distinguished, subacute or post-acute versus chronic.

It is also important to know that there is evidence in the form of literature supporting the concept and, also, evidence that the instruments from which these measures arise have been tested and it has been validated.

The final concept being that it is our intent at CMS to publicly report the quality measures that are put forward. It is important this public reporting meets the original intent of OBRA, the origin of the resident assessment instrument and of the MDS.

So, that is actually all I have to say. Thank you for your attention.
DR. ORDIN: Sheri, can I ask a question?

DR. LING: Yes.

DR. ORDIN: I mean I think it came up in my review and, also, in my co-reviewers. How are you defining long stay versus short stay? Because at the beginning of the measure it said 100 days.

DR. LING: Yes.

DR. ORDIN: And maybe you could elucidate that?

DR. LING: Yes. And we toiled over this definition. The reason that we took a crack at redefining, based on the 100-day cutpoint, is because when we actually analyzed using the old criteria, just making that distinction, we found that there are people who met the criteria in both buckets.

So, we are trying to be clearer about who is in which bucket and, in that sense, taking into account or at least acknowledging that the two subpopulations may
be meaningfully different, different issues. 
So, we drew the line in the sand at 100 days 
as a starting point. 

I think RTI can further elaborate on that. 

MS. CONSTANTINE: Good morning. 
I am Roberta Constantine from RTI. 

One of the improvements in the MDS 2.0 to 3.0 has been the addition of the comprehensive discharge assessment. That has really enabled us, also, to make improvements in looking at the quality measures from the short-stay population to the long-stay population. 

Based on analyses that were performed by CMS, it was found that approximately 38 percent of residents were discharged within 14 days. So, prior, with the current measures, often a patient would be discharged before -- you couldn't look at them at another point in time. 

So, this is a great improvement
because it now allows us to really take a look
at patients before they are discharged. So,
I just wanted to add that.

DR. LING: Thanks, Roberta.

MS. THOMPSON: This is Darlene Thompson.

I don't know if this is the time
to ask this or not. But in the two measures
I have, which are considered long stay, there
is no definition as to how you are calculating
that 100 days. Are you taking it from the
date the stay began, A1600, versus the
reference date, the assessment reference date,
or the discharge date? Or what are you using
to calculate that 100 days?

Thank you.

DR. LING: For those who are
listening and for the record, it was based on
the admission date.

CO-CHAIR MUELLER: Are there any
other questions from the group for CMS?

(No response.)
DR. LING: Thank you all.

MS. THEBERGE: All right. We would like to ask the measure developers for the mental health measures to come up. That would be AMDA and RTI.

We are going to start with Measure 001, assessment of dementia, and then 025, percent of residents who have symptoms of major depression.

MS. VANCE: Good morning.

I am just adjusting my chair, so the light doesn't blind me. Thank you. Should I begin? Thank you.

Good morning.

I am Jackie Vance and with AMDA, the association that is dedicated to long-term care medicine. We are very pleased to present this dementia measure to you.

We firmly believe that this measure is of national importance, especially in relation to quality improvement. This measure addresses a process that is
strategically important in maximizing the health of large populations of persons within the long-term care continuum. It addresses the important medical condition, as defined by high-prevalence incidence, morbidity, mortality, and disability.

Up to 70 percent of nursing home patients do carry a diagnosis of dementia. Yet, it is believed that this disease is underdiagnosed. Dementia carries a range of behavioral, cognitive, functional, and mood impairments that can significantly affect patient-centered outcomes and quality of life.

The measure also addresses a clinical condition that requires high expenditures in both in-patient and acute care. Due to the current variability in practice, many patients may either have unrecognized dementia upon admission to the nursing home or patients have a diagnosis of dementia that was never screened with a validated instrument, leading to an
appropriate diagnosis or not having the
dementia staged, leaving that practitioner to
basically guess where the person is
functionally and cognitively within that level
of dementia, causing poorly-coordinated care
across many settings and the potential for
inappropriate and non-compassionate care for
these patients with end-stage dementia, and
overuse of aggressive, inappropriate care.

This measure also ties in all six
dimensions of healthcare performance
improvement within the IOM's report "Crossing
the Quality Chasm". That is safety,
effectiveness, patient-centeredness,
timeliness, efficiency, and equity.

Because once the physical
functional/cognitive psychosocial domains have
been assessed from this measure, the results
assist the practitioner, the care team, the
patient, and their family in creating a
patient-centered plan of care that is not only
appropriate for this stage of dementia that
they are in, but the functionality within that
level of dementia.

So, in other words, this measure
was taken from the American Medical Directors'
Guideline on Dementia from that second step.
And the second step within that guideline is
how you create that entire care process, how
you move forward from there. So, it is
extremely useful in decisionmaking for that
person.

We do know that the IOM, CMS, and
others stress that healthcare should be
patient-centered. The individual patient's
culture, their social context, their specific
needs deserve respect, and the patient and
their families should play an active role in
making decisions about their care. We believe
a measure such as the one we are proposing is
necessary to ensure patient-centered care with
a person with dementia.

In the handout that I passed out
to you, I have given you sections of the MDS
3.0 that are relevant to the areas that we stress that should be assessed. With the MDS 3.0, we are very excited because the data that we are asking to be assessed can be captured electronically. The brief interview for mental status, renewed interview which is the PHQ-9, the behavior section and the functional status sections are all rated very high on kappa statistics and highly validated. Now this will allow for both electronic data capture while using a validated tool, which are goals for our measure.

So, I guess, in closing, we ask that you would consider our measure as suitable. We are certainly open for discussion.

Thank you for your consideration.

CO-CHAIR GIFFORD: Thank you, Jackie.

A couple of points. I am the primary reviewer on this, but before going there, I just have a couple of things to
comment on for some groundrules as we go forward.

One, we are going to have the measure developers give a very short, two-minute-type overview. Then, the primary reviewer gives an overview, and we will let the secondary reviewer elaborate on the primary reviewer, if they have any other additional comments.

Then, really have an open discussion. I would like to try to get as much input from people as possible. Try to keep it on the topic because I would like to get quickly to an up-or-down vote. We may want to do it in a staggered way, which is we have different criteria. We can vote as is, vote with some modifications, vote time-limited, or turn down altogether.

I certainly will give a priority of anyone at any point who wants to sort of call the question, call the vote, if we are beating a dead horse. There is no need to sit
here and beat the dead horse and say the same stuff over and over again. So, if someone wants to call the question, I will let people call the question, so we can get forward on it.

We have a lot of measures to go through today and tomorrow. Some of these measures I think will be relatively quick. So, while it is an interesting topic, like on this topic I might feel really a lot about, but we can move quickly or we can take a long time on this one, or vice versa, going forward.

So, I think all the topics are incredibly important to the population of nursing home residents. We will take that off the table right now. I don't think there is any measure that wasn't equally important to the nursing home population. So, I think it is going to be more into the other aspects.

The last comment is that, as we talk about particularly usability and
feasibility of the measure, remember that
while many of these are being sponsored by
CMS, no insult to CMS, but they pay for a
majority of the nursing home care. They are
a driver in many areas.

But many of the NQF measures are
used by many other people. There are some of
the organizations around here. There's a lot
of the nursing home chains that are starting
to use these measures. States are starting to
use these measures. Advocacy groups are using
these measures. Researchers are using these
measures, and other payers besides CMS are
starting to use these measures, too.

So, as we think about this, this
is not just about measures for CMS and for
Nursing Home Compare. These are measures that
could be used for other purposes. So, I want
to make sure that is part of the dialog as we
go forward. Because certainly, as measures
are developed, they are developed for
different purposes.
Any sort of comments or suggestions or additions on the groundrules?

Yes, Kathleen?

DR. NIEDERT: I have a question, and this is my first experience in this group. Could I have just a brief explanation of how the verbiage came about to explain the different areas that we have, who wrote it, how it was developed? Because some of it I feel needs some wordsmithing if it is to go out to the public.

CO-CHAIR GIFFORD: Suzanne, do you want to answer that or do you want me, not involved, to answer it?

MS. THEBERGE: Are you speaking to the text of the measure? The text of the measure was entirely written by the measure developers.

I'm sorry.

DR. NIEDERT: In the measure I reviewed, there were some questions. There were actually some questions within the
verbiage, as if they had a thought, but they
didn't complete the thought. So, I just was
curious as to how that came about and whether
it just was an oversight when it was being
developed and sent out.

CO-CHAIR GIFFORD: Yes, the forms
that we have were completed by the measure
developers. We did not go back and edit it
for clarity. If something didn't make sense,
we might sometimes ask people to put
information in, but the language is all from
the measure developers.

I don't believe this language, I
mean NQF is sort of public; everything is
public, but this is not necessarily what's the
type of information that might go into a
technical report that goes out there for use
on something as we go forward. I am not sure
we need to spend time editing the language of
the reviewers out there.

CO-CHAIR MUELLER: I would add
that, if that resulted in any concern about
the measure as you were evaluating it, we have
our measure developers here. So, there could
be some dialog.

DR. NIEDERT: Thank you.

CO-CHAIR GIFFORD: Yes, we are not
working for the measure developers. If they
want to hire us outside this room, they could
hire you outside the room to help with the
language, but we are not working for the
measure developers.

MS. PACE: Just one other thing.
In those forms, it is clearly identified if
there were any questions from the staff that
they wanted you to consider. So, that is a
whole separate section. We have done that
purposely, so that you know everything is
coming from the measure developer, except if
there was a specific item that said it was
supplied by staff or a question by staff.

MEMBER NAIERMAN: May I ask a
general question about dementia?

CO-CHAIR GIFFORD: Yes.
MEMBER NAIERMAN: The two notions that we have just talked about, dementia and then short- and long-term stays, what is the cross between the two?

The reason I ask is because I was asked to review the pain measures. It is pertinent to know if, indeed, the short-term stay folks are less likely to be with dementia or not. Is there some kind of an intersection between the two that can be predefined or assumed in advance?

MS. VANCE: Dementia, it really doesn't matter whether short- or long-term stay.

MEMBER NAIERMAN: So, the post-acute or subacute folks can also be with dementia?

MS. VANCE: Absolutely. For example, let's say that someone has a certain level of dementia, and they were in an assisted living setting and they fell there and fractured a hip, and they came to your
nursing home for rehab, but their plans are to
go back to the dementia assisted living.
These are the people which really, for us, we
feel that would benefit from this measure.
The measure would cause people to
truly look at the person with dementia and
assess them, and find out where they, within
that dementia, what is their functionality to
develop a strong plan of care for them.
Because these are people that are moving back
and forth across the continuum of care, and
let's not guess where they are in the
dementia. Let's validate where they are
within the dementia.

DR. MODAWAL: I'm sorry, I have a
question related to that about dementia and
short stay and long stay.

MS. TOBIN: May I make a request?
Could each speaker introduce themselves, so
that we know who is speaking and, also, for
people on the phone to know who is speaking?

DR. MODAWAL: Thank you. Yes, I'm
Arvind Modawal. I'm a geriatrician and professor of family and community medicine at University of Cincinnati Medical Center.

My question is similar to what was mentioned earlier on. There are differences in the population and our evaluation is short term and long term. Because as a nursing home physician, basically, acute stay or short stay, which we are calling as part of the MDS, is really kind of a rehab crisis situation. You know, these patients are coming from hospitals, and after the CMS-mandated three-day stay, and they are delirious and confused and all. At that time, actually, we can suspect that they may have underlying dementia because of the rehab and the recuperation that is taking place after UTIs and pneumonias and other medical problems.

The emphasis at that point is really to give them rehab, get them functioning, let them provide the baseline, and then pass it on to the primary care
Physician and the community when they go home.

So, I think, as part of the nursing home staff and the management, including clinicians, it will be a big task to start evaluating dementia when we have a bigger problem with delirium, which has a mortality which is as high as having MI or sepsis.

So, we really need to tease that out. We can actually suspect underlying dementia, but we cannot -- and I say "cannot" -- objectively diagnosis dementia in the presence of confusion and delirium. So, that is the difficulty the staff and the physicians will face. That is the importance of diagnosing.

CO-CHAIR GIFFORD: This is a wonderful discussion we could spent all day on. It turns out it is probably not germane to the measure. So, I am going, as the primary reviewer on this measure, and since we don't have other dementia measures before us,
actually, this distinction between long-term and everything else, I will give you my review, and you will discover it probably doesn't really matter what you are saying.

Clinically, I agree with everything you just said. I am a geriatrician in a nursing home, too.

Let me give you my quick view as the primary reviewer. This measure, as was previously described, was to assess the percentage of patients over 75 that had current signs and symptoms of dementia, were assessed in the physical, functional, and psychosocial domains with a valid instrument, and documented in the medical record. That is the way it is described there.

From an importance standpoint, I think we all heard that dementia is a very prevalent illness in the nursing home population. It has profound impacts on the quality of life and the clinical outcomes. So, in that sense, it is an important domain
to be measured.

In the description of the measure, though, it is unclear how the measure is actually defined. I could not really figure out how it was defined in there. There's no description on how to define signs and symptoms of dementia for the denominator. It is not described. The numerator and denominator appear to be described as presented to us by CPT codes, which don't build into the validated instruments, nor does it list the validated instruments that are to be included out there.

On reliability and validity testing, there was no reliability/validity testing presented.

From a usability standpoint, it is unclear, given the previous issues, how usable the measure is because it needs to be worked on, but it potentially could be usable.

From a feasibility standpoint, it doesn't appear very feasible because it is
lacking too much definition out there.

Based on that sort of quick summary and overview, let me ask, Mary Jane, if you have anything to add before my recommendation.

DR. KOREN: I basically concur with what Giff has outlined.

I would also add that the new MDS 3 actually does have some cognitive screening items on it that seem to be fairly well correlated with other validated instruments. So, I think that in the development of MDS 3 there was really an effort made to screen. And as I said, it is a minimum dataset and it is not a thorough full-blown assessment.

But there is a way now to screen people on admission for dementia. So, I would concur with Giff's assessment.

CO-CHAIR GIFFORD: So, therefore, based on my review and Mary Jane's comments, I would recommend to the group that we vote not to approve this measure as is. I would
say that the amount of work that needs to go into it is so great that we are not measure developers; we are not here to develop measures as our duty today. It would take us all day to figure out how to develop the measure, though it is an incredibly important topic.

That would be my recommendation to the group.

CO-CHAIR MUELLER: Any comments from the members?

(No response.)

CO-CHAIR GIFFORD: All in favor of the recommendation?

MS. PACE: Before, one of the things just that we need to be able to document is how your recommendation relates to our criteria.

CO-CHAIR GIFFORD: Do you want us to do it by each one?

MS. PACE: Well, what we generally do is ask the Committee to evaluate
importance, scientific acceptability, usability, and feasibility. Now, if you could state on which of those criteria it fails and the group agrees, we could just say that that was unanimous. But, in general, we need to have that documentation of how the recommendation fits the criteria.

CO-CHAIR GIFFORD: Okay. Then, I will break down my recommendation.

MS. PACE: Okay.

CO-CHAIR GIFFORD: I would say, for importance, I would recommend that it passes for importance.

From reliability/validity, it fails.

From usability, it is hard to determine. I just can't determine because of the way it has been presented.

And from a feasibility with what is presented, it fails.

And I would just, for speed on this measure, I would just bundle those
together then for a pass, but I think some of the subsequent ones we may want to get more into the detail of everything, I would agree.

And, Jackie, as an AMDA member, it pains me to give that feedback to AMDA.

DR. NIEDERT: So, what I am hearing from you is that we are not saying the measure is not important. We are saying it is truly important; it is just that this measure needs more work?

CO-CHAIR GIFFORD: That is a kind way of putting it.

DR. ZOROWITZ: Bob Zorowitz, Medical Director at Village Nursing Home, also a member of AMDA. So, I sympathize with Jackie.

When I read the numerator and the denominator, the problem is not the importance of the measure, as you have said. It is how it is described here.

And actually, if the MDS 3 is done, you are going to have 100 percent of
your residents at least having a basic screen
for dementia, and a brief interview of mental
status has pretty good correlation with other
standard screens for dementia, such as the
Folstein mini mental state exam and other
instruments.

    So, I think the MDS 3.0 itself is
going to solve a lot of this problem. I am
not sure, if you were to go and say what
percentage of patients have been screened for
signs and symptoms of dementia, if everybody
has had the MDS done, you are going to have
100 percent, at least basic. What they do
with it is a different issue.

    But I would agree with the way
this measure is described is not very helpful.

DR. MODAWAL: Yes, Arvind Modawal.

    I would just like to say, I mean
this is an incredibly important area
clinically. I think those measures, I don't
know whether we are going to hear this in the
long stay as well, but it would be very
relevant for the nursing home population as opposed to short stay.

MS. TRIPP: This is Lisa Tripp with the John Marshall Law School.

I think I want to echo what Bill said earlier. I think, as a process matter, at least for me, it is very difficult to sort of get two minutes of a discussion and then be asked to sort of vote on whether something meets these criteria with just minutes to think about it really. I think we got a list, I think we got all of the measures with the feedback maybe yesterday by email at about four o'clock in the afternoon.

So, I don't know what other processes are available, but at least for me, it is difficult to think about these things and respond in seconds. So, I just want to throw that out there.

CO-CHAIR GIFFORD: It is a good point, and probably this is not the best measure to start with. I mean I think you are
going to see much more lengthier presentations by primary reviewers and secondary reviewers. I mean I was a secondary reviewer on another one; I would do it very different.

This measure fails. Mary Jane, do you want to elaborate? I mean both Mary Jane and I are big believers in the topic and everything else.

Mary Jane, do you just want to give some confidence to the group that I am not glossing over it and saying just fail it?

DR. KOREN: No, I --

CO-CHAIR GIFFORD: I think we will have a much lengthier discussion on a lot of the measures. I am trying to move us, and I am cognizant of time. We've got four measures to try to get done by 11:30, and it doesn't mean we have to spend 20 minutes or 30 minutes on each measure. There's going to be some measures that we are just going to go through like that.

That is why we have to have some
reliance and confidence in our colleagues around the table, that they have done a good job with their primary and secondary reviews.

But we do have the other measures to get into greater detail. I know on some of the other measures we are going to spend a lot of time and debate on them.

DR. KOREN: Right. No, I have nothing to add to Giff, except to also say I am an AMDA member. So, I am sorry that we can't recommend it, but it just isn't there.

CO-CHAIR MUELLER: I would just remind the members that we actually have four voting options. One is that it satisfies the evaluation criteria.

The other is that the measure satisfies some of the evaluation criteria, requires further information, clarification, and refinement. That is No. 2.

No. 3 is do not recommend because it does not satisfy the evaluation criteria.

And then, the fourth is a time-
limited endorsement.

MR. BOISSONNAULT: Bruce Boissonnault.

So, importance and usability are not the issue, as you saw it? Is it the actual math?

CO-CHAIR GIFFORD: Yes. I mean, in the name, it doesn't specify any of the aspects in the name of the title. I mean the name and the description is that it is the percentage of patients who present with signs and symptoms of dementia. That is not defined anywhere in the material they submit. Now I know how I would do it with the MDS 3.0, in MDS 3.0, but it is not defined anywhere.

Then, the numerator is that they were assessed with a reliable instrument. None of the reliable instruments are defined, how you would actually collect that.

And actually, the numerator is defined by the CPT codes that physicians would use in billing patients there. So, if they
billed at a moderate or high level, it seems to be assumed there was. The denominator, though, seems to be defined by CPT codes as well. So, it looks like I can't even figure out how to calculate the measure.

But even if that was all there, there's no reliability, zero reliability in validity testing at all. So, once you have failed that, I can't even figure out how to get into usability or even feasibility.

But even if the feasibility, the definition in the description everywhere is that this should be documented in the medical record. We can spend a lot of time debating whether the MDS is part of the medical record or not, but it doesn't even rely on the MDS for its measure specification.

MR. BOISSONNAULT: Would guidance to the developers, then, be the title of the measure is somewhat inconsistent with the mechanics of the measure?

CO-CHAIR GIFFORD: Jackie, I hate
to be --

MS. VANCE: If I may say something --

CO-CHAIR GIFFORD: It's not inconsistent. It just isn't there.

MS. VANCE: But if I may say one small thing in our defense, and if it is an option, and then it may fail, to allow a refinement and let the Committee reconsider it. Because I have to be honest, the way the question was written about the CPT coding, it did not look like it was a numerator. So, we misunderstood that question, and I have to be honest. That was not our intent to make CPT coding a numerator. So, I will be honest.

And this was our first attempt at ever submitting a measure. We are not methodologists. We are just passionate about clinical care.

So, we did not understand that, and also understand that it was in the middle of a blizzard, that everything was shut down
when we were creating this measure.

(Laughter.)

So, no, I'm not making -- I'm just
letting you know that it was a really weird
situation.

Then, the MDS 3.0 all came out.

In the midst of this, we were allowed to make
refinements as far as data capture, but we
weren't allowed to change the original how we
put the first measure out. And if we would be
allowed to submit a refinement for
consideration, and then if you still wish to
fail it, at least we would be given a chance
to do that.

CO-CHAIR GIFFORD: I mean I think
this comes down to we are dealing with the
information presented before us.

MR. BOISSONNAULT: I got that.

CO-CHAIR GIFFORD: I go back to my
original thing. We are not measure
developers. We are not working for the
measure developers here. Our task is to up-
and-down vote these with what we have presented before us.

Now if we think there is enough to give guidance back, I mean I think Jackie heard a lot of feedback on it to help revise it. I would concur with part of her excuse. I know how I would give advice for it back, but I would just say, given this measure, it probably was not a good measure to start with because of it; I would still stick with the recommendation that it fail.

MS. PACE: I would just like to make a clarification, too. The recommendation with conditions is for a very narrow aspect of the measure, if there are codes that are missing. It is not to totally define a measure.

So, it really is for narrow aspects of a measure that need to be adjusted, relooked at. So, that is not a general -- you know, we really aren't advocating that.

The other thing that hasn't come
up, but just so you know, I think Helen mentioned it a little bit. But we are moving to a new cycle of looking at measures, both measures that are endorsed, plus bringing in new measures on fairly regular cycles. So, that gives measure developers time, if a measure doesn't pass, then from the feedback of the Steering Committee, they can look at really spending some time on developing the measure and bring it back to NQF at that time.

CO-CHAIR MUELLER: This measure was not submitted for testing, is that correct? I haven't checked to see.

CO-CHAIR GIFFORD: Yes, they expressly say that it has not been tested for reliability/validity.

CO-CHAIR MUELLER: But it wasn't submitted? Because there is that criteria where you can submit for testing.

MS. PACE: No, there is time-limited endorsement --

CO-CHAIR GIFFORD: No, you have
time-limited, yes.

MS. PACE: -- for untested measures, but if you have a measure that is not even specified well --

CO-CHAIR MUELLER: Okay, got it.

MS. PACE: -- again, you get into measure development versus you've got a measure that is well-specified and ready to go to testing.

CO-CHAIR MUELLER: So, maybe this was a good one to start with, so that we can kind of just learn all the things we have to think about.

Are we ready for a vote?

Okay. So, what has been proposed by the measure reviewers is to not recommend the measure for endorsement.

Do we do hands? How do we do this? Yes, okay.

So, all in favor of that recommendation, please indicate by raising your hand.
(Show of hands.)

Those not in favor, please indicate.

(No response.)

Do we abstain? Is that an option, to abstain?

Any abstentions?

(No response.)

Okay. So, it appears that it is unanimous that this measure not be recommended.

CO-CHAIR GIFFORD: I think, Jackie, the message you hear is dementia is very important. We would love to see something revised and worked on, and we appreciate the complexity of the application process.

The next measure is, I guess we get two minutes from RTI, the measure developer, and then we will hear from the reviewers.

MS. GAGE: There we go. Is that
better?

Barbara Gage from RTI. Thank you for having us here today. We are really excited.

As Dr. Ling mentioned, there is a whole series of CMS measures that are designed to better reflect the patient voice in terms of measuring quality of care. This first one that we will be looking at is a perfect example of that.

The work that we are presenting has been based on several technical expert panels before this. Many of you know the members, people like Dr. Deb Saliba, who has been working closely with us on all of these measures, as well as Eric Tungalos and members of AMDA and members of the associations, members of the different research communities. So, we thank and recognize all of them for their input. Members of the clinical community as well, Dr. Levenson from Genesis, as well as members from other healthcare
providers, including the Kindreds and a few others who are at the table here today.

So, thank you for having us.

This measure that I am presenting is on the percent of residents who have symptoms of major depression. This is for the long-stay population. It is based on the numerator is the PHQ-9 item, which has been heavily tested in the research communities. I can say more about that, if you would like, but it is a summative score identifying about nine different areas that might be a reflection of depression in the patient. That is the numerator. The denominator is any admission in the nursing facility.

So, it is an improvement on what was in the MDS 2.0 measure because it now looks at any patient, any resident in the nursing facility, rather than just looking at worsening of depression within the nursing facility.

Its importance, this is probably
not a group I need to speak to the importance of identifying depression in the long-stay nursing facility community, but it is expensive, complicated, and, most importantly, it is treatable. So, identifying it and dealing with it is considered to be very important. There is a series of studies we have put in the materials documenting the importance.

The usability, or I'm sorry, the reliability and the validity, the scientific acceptability, these items have all been tested. In some of the work that Dr. Saliba did earlier, the reliability was excellent on the individual items. The average kappa between the gold standard nurses for the PHQ-9 resident interview was .935, and between the gold standard and facility nurses it was .96.

So, this is an item where the patient voice is encouraged, but the staff voice can be used if the patient voice can't be captured.
The validity was also quite good. The kappa was .685, which is a fairly high kappa on a measure like this. So, the proposed quality measure is a ratio constructed from those two tested items. So, we feel good about the scientific acceptability.

The usability, whether this item, is it really a practical item that would be used in the nursing facilities? Yes, it is important to identify depression, and this is a scientifically-acceptable way to identify and decrease the prevalence in the nursing facility population.

The feasibility, the good thing about the measures that our team is presenting today is that they are tied to the MDS 3.0. So, when it comes to implementation, all of these items will be collected on all of the nursing facility residents in the U.S. as of October. So, feasibility seems pretty feasible.
(Laughter.)

That's inarticulate there.

CO-CHAIR GIFFORD: Thank you, Barbara.

Sister Mary Rose, you're the primary reviewer.

SISTER HEERY: Yes, I was. My name is Sister Mary Rose.

I found this a very good proposal. I thought it was well-thought-out. I thought it was well-presented. I thought the literature supported it. From a nursing home perspective, I am looking forward to using this tool because I think it will be very good when we report quality that we will all be reporting the same thing, no longer apples and oranges.

We will be moving away from the 2.0, where we had ability to look at what assessment we would use. That sometimes didn't give the public a good comparison because we were able to, I don't want to say
present the wrong thing at times. The way we collected our data was not consistent.

So, I think the PHQ will give us good data to collect. It will also help us to bring information back to the families and the physicians, and we can, then, have the treatments working and be more proactive.

So, I felt, reading through it, it did -- I would ditto what she said -- it passed the criterias needed. I think it would be a very usable tool for both the facility and the public and help us to compare.

The only thing I didn't understand, one question was the exclusion. People didn't rate three of them. That was my only concern. But other than that, I thought it was really well done.

CO-CHAIR MUELLER: Betty, you are the second reviewer. Would you like to comment?

MS. PACE: We need to turn off some of the microphones.
MS. FRANDSEN: There we go. Okay.

I'm Betty Frandsen, and I was the secondary reviewer. Sister Mary Rose and I did confer on this in advance, and I agree with her assessment. I had independently come to the same conclusion.

I felt that it passed on all the criteria. It was actually a pleasure to read, and it came across as very usable, very well done, clear, and with great benefit to residents.

MS. THOMPSON: This is Darlene Thompson. May I ask a question? Because I agree with Lisa; I didn't have an opportunity to read all the other ones.

Can you tell me what the summary score has to be for the resident to count in the numerator?

MS. GAGE: Yes. The PHQ-9 is an existing item. So, the calculation of the --

MS. THOMPSON: I understand how you calculated. You calculated off the
frequency. But it is a 0-to-27 score for the resident. What is the cutpoint that counts the resident on the numerator as falling into this measure? Any number? So, if you are not a zero, you are possibly --

MS. GAGE: Yes, it is a summative score.

MS. THOMPSON: I know, so any --

MS. GAGE: So, yes.

MS. THOMPSON: If I have a 1, I'm as depressed as a sum of 27, according to this measure?

MS. GAGE: You are not as depressed. In terms of the quality, in terms of measuring -- I don't want to misspeak. So, let me pull this out.

MS. THOMPSON: Okay, I am trying to read it on the board there. So, it is not going from the total?

CO-CHAIR GIFFORD: No, it looks like --

MS. THOMPSON: It is going from
particular questions?

CO-CHAIR GIFFORD: It looks like they have a PHQ score of 9 or 10, and it may give it a sensitivity of 88 percent and a specificity of 88 percent.

MS. THOMPSON: Okay. So, if the total score is less than 9, they don't count it on the numerator in this particular measure? Is that what you are saying?

CO-CHAIR GIFFORD: At least that is under the testing of the current use.

MS. THOMPSON: Greater or equal to 10, okay.

SISTER HEERY: They were broken down as a category.

CO-CHAIR GIFFORD: Let me ask. Everyone has laptops. Does everyone have the thumbnail drive with all the measures on it. Does anyone have the thumbnail with all the measures on it?

Because people that don't have their laptops, if you want to just come up and
look over my shoulder and read through it, I am fine with that. But if we want to just share some of the laptops, so people can look at and read certain sections of the measure, if you want to look at it, it would be helpful. It is also up here, if you want to look at it.

SISTER HEERY: Darlene, it was levels of depression that they looked at, and they had different scoring systems. So, I believe it was under 9 that wasn't considered depressed.

MS. THOMPSON: Okay, because the only reason I am asking is I understand that, if the resident can't complete it, you do the staff one, and the staff one has one additional question. So, there's three additional points on the staff one. So, there is a little bit of discrepancy in the numbering. So, I was just trying to figure out where is that cutpoint, because on the staff one they could be, but, I mean, if the...
resident finishes it, they may not. So, for validity.

MS. PACE: I don't think it is clear that, at least in the numerator statement that it is clear what counts as depression.

CO-CHAIR MUELLER: Right. That is what is missing from the definition.

MS. THOMPSON: And I didn't even read this one, and I couldn't figure it out.

MS. GAGE: The logic is under the 2(a)(3) with the numerator details, yes.

CO-CHAIR GIFFORD: But it doesn't tell you a total score.

MS. THOMPSON: So, then it is not total; it is a combination of these items?

CO-CHAIR GIFFORD: It is not the actual PHQ; it is a subset of the PHQ?

MS. GAGE: Yes, and it is a ratio measure. So, if you go to the -- five or more, okay, that was the definition. I hate to speak from memory.
But if you go back up, you have to have five or more of the items on the bottom and at least one of the items on the top as true in order to trigger the numerator, in order to be counted in the numerator. So, at least one of the following is true.

The PHQ-9 is a series of nine statements asking about whether the patient -- in the past two weeks, has the patient had little interest in this, little interest in pleasure? There is a whole series of issues for concentration, self-value, responsiveness, patience, decreased aptitude, decreased mood, energy, et cetera.

So, you go through the interview item with the patient. Then, if the patient responded as true to at least one of the following, where their score was at least five times a week or higher, five times in the last two weeks or higher, that they have had either at least, one, little interest or pleasure of doing things, feeling down, depressed, or
hopeless half or more of the days over the
last two weeks. So, they have at least one of
those and five of the others. Then, that
score goes into the numerator.

Then, the denominator is the sum
of the residents in the facility, and the
level of the score, the thresholds -- did we
think about the thresholds?

MS. PACE: So, it is not really a
summative thing? It is just --

MS. GAGE: The numerators are
summative. The numerator, the PHQ-9 is the
numerator.

MS. PACE: Right, but you said you
would get into the numerator if one of the
group of --

MS. GAGE: The two on the top or
the five --

MS. PACE: If one of those is
present and five of the following, but it is
not saying you add up the scores?

MS. GAGE: Oh, correct.
CO-CHAIR MUELLER: It appears the numerator is not the score of the PHQ. Rather, it is the items are --

MS. GAGE: Yes. Thank you.

So, it is a facility measure that identifies the proportion of the patients, the percent of the residents who have been found to have depression based on --

CO-CHAIR GIFFORD: I think the question, it is not clear in the document as to how you are defining who is having depression. At some point, you have to make a cutpoint.

MS. GAGE: Yes.

CO-CHAIR GIFFORD: And it is not clear how you define -- I mean I think what we are asking is, what is the score? It is a complicated score. It is two of these, four of these, three of these, and two of those. But, at some point, you add those all up, and what's that number? I think that is what the group is looking for, to understand this
better.

Is that a fair summary? Darlene, is that what you are looking for?

MS. THOMPSON: Yes, and, also,
because on the staff one there's three additional points. And depending on what that cut is, there is a discrepancy between the validity of whether that numerator is going to be the same.

CO-CHAIR MUELLER: The way I read it, it does not look like it is a cutpoint issue. It looks like the items on the PHQ are, if any one of these nine items are a positive, then you count in the numerator.

MS. GAGE: Right.

CO-CHAIR MUELLER: It is not about the total score or a cutpoint score. Is that how --

MS. GAGE: That's correct. It is a prevalence estimate. My apologies for the additive score. I was thinking more of the PHQ-9 and how it is used, but in the quality
measure it is an identification of the presence of the depression.

MS. PACE: So, the description of the numerator statement said that it is based on the total sum severity score, which I think is leading people to think you are adding up numbers and coming up with a score.

MS. GAGE: We should clean that up.

MS. PACE: It is maybe a little discrepancy between how it is described and how it is actually done.

CO-CHAIR GIFFORD: Dede?

DR. ORDIN: I have a question. Obviously, this tool is used a great deal, and it is being incorporated into measures.

Is this the same definition of positivity that is used in other measures?

MS. GAGE: Yes, it is. It is. This measure comes out of Dr. Saliba's work, which is the same work that is feeding into the VA work and the other settings. So, yes.
Our goal in having such a diverse team is to create greater harmony across the different efforts that are underway in related measures.

DR. ORDIN: I also have a denominator question, and it came up, I think it is going to come up a lot because it came up in my two other measures.

It looks like in the denominator it is possible to get people who were there for less than 100 days. So, that is why I asked the 100-day question before. I mean because you are looking at a quarterly MDS or you are looking at an MDS that could happen less than 100 days after admission. This is true of a lot of the measures, not just your measure.

MS. GAGE: Yes. For the long-stay population, there are exclusion criterias built in.

I am going to turn to my colleague Roberta, who can recite all of the short-
stay/long-stay differentiators.

Roberta?

MS. CONSTANTINE: Well, some of them are more --

MS. GAGE: Roberta, you have to go to a microphone.

MS. CONSTANTINE: Hi.

In some cases, really it depends somewhat on the measure as well as what particular assessments that you are referring to. For example, in a lot of the long-stay measures, you are excluding the admission over assessment, but then, on the other hand, you are including a quarterly or an annual or a significant change or a significant correction assessment. But it is somewhat measure-specific at times.

MS. THOMPSON: This is Darlene Thompson.

I think the discussion we had earlier about the resident being in the facility 100 days and using that as a guide,
that should be the guide for all the long stays. Because even with what you indicated, that you don't count the admission, you don't count PPS, but you count a significant change, a managed healthcare patient could have a significant change assessment done in day 20 or day 6, or whatever, of their stay. Then, they are going to be thrown into that long-stay measure.

So, I think one of the things to look at is that, if we are talking long stay and everybody thinks a resident has to be in the building or be a resident for 100 days, and we are going to go by that date the stay began, then that should be added to the denominator of all the long stays. Then, I think we won't have this confusion across the board, because both of mine are the same as well.

DR. ORDIN: Okay. So, it would be an exclusion if someone is less than 100 days?

MS. CONSTANTINE: That is a good
point. We tried, in sort of writing the
measures, to say it is the long-stay
population and, therefore, the long-stay
population would have a stay of 100 days or
more, and then refer to the assessments,
whether they are the quarterly, the annual,
the significant changes, significant
correction assessment.

But thank you for bringing up that
point. We will try to be sure that we make
that clearer in the measure itself.

CO-CHAIR GIFFORD: I have a
question. On the validity testing, it appears
that it is related to the sensitivity and
specificity of this for detecting depression.
I have a different validity question.

This is really a quality measure
or a measure used for quality improvement.
What I didn't see was, and understanding there
is no perfect measure, so we can fail all the
measures because none of them are perfect, but
I didn't see validity testing as a quality
measure, that a facility that scores high on
this is doing worse quality than a facility
that is scoring low on it, nor did I see
validity testing that showed that, if I did
better management, my score would change.

SISTER HEERY: I believe it was in
the literature review that they did talk about
that validity and how the score would change
if you were more proactive in your approach to
treating depression, is where they had a lot
of information.

MS. GAGE: The use of the
quarterly assessments identifies that change
at the facility level, and the use of the
quality measure, these items were tested for
their validity, and in terms of the depression
being identified, the literature suggests that
reducing prevalence was a good indicator of
quality, of improved quality, as this is a
treatable condition.

I think a lot of this comes down
to the fact that depression is treatable, and
a good nursing home shouldn't have growing problems with depression. They should be treating the conditions, and it should be going down over time.

CO-CHAIR GIFFORD: But isn't this measure just a cross-sectional measure? I mean, if it is measuring quality and change, and that is the focus, shouldn't it be a change measure, instead of a cross-sectional measure?

MS. GAGE: It is at the facility level. If you think about how the MDS items are used and how they are collected every year, every facility will have an item collected at that point in time.

The former item on the MDS 2.0 was actually a measure of the percent of patients whose depression worsened or the percent of patients in the facility, the change in the percent of patients in the facility with depression.

The construction of it was not
really a good, valid measure. It excluded populations who could have entered that group over time.

So, by measuring the percent of all nursing facility residents with the depression, based on the measures, at a point in time, you can see at a facility level whether that percent has changed over time. And this is the long-stay population. So, there is a bit of a presumption that it is not due to case mix changes.

DR. MODAWAL: I have a question related to that. In terms of the validity, I think it is a very important question because, is this tool a screening tool or is it as good for management and followup as well? I don't know how these things -- I mean I have used it in an office setting, but I don't how applicable will it be as far as the protocols for MDS goes and the follow up of our patients, and using it as a quality measure. They are not interchangeable sometimes.
MS. GAGE: No, they are not.

Where the quality measures usually target the overall effectiveness of a provider, this gets at that issue of, is there a quality issue? The care-planning aspect, which I think you are referring to in terms of how to treat, is not captured here. This is not intended to go that far. It is only intended to identify the prevalence of the problem.

DR. MODAWAL: So, if the prevalence of the problem is a question that needs a screening in a facility, you know, then should we put some time limits, okay, once a year or every six months, rather than a routine MDS feature?

MS. GAGE: Yes.

DR. MODAWAL: Just like we are talking about falls, you know, that we should ask about it once a year.

MS. GAGE: Yes.

DR. MODAWAL: Can that be put in to make it more usable and feasible?
MS. GAGE: Yes, and this will be used; the assessments that are used in the identification are the annual, the quarterly, and the significant change. So, there is an annual measure at the facility level. A good question.

MS. PACE: I think I just want to clarify something. The question about validity that came up is an important question for you all to think about. Frankly, it is something that the Measure Testing Task Force that Helen mentions is working on. For both reliability and validity, it is kind of at two levels, at the data level and, then, at the computed performance measures score level.

So, what David is asking about is what evidence, if any, does the computed measure score? Obviously, depression and the evidence regarding depression and treatment is good, but that is not about the measure score as it has been presented.

So, one of the questions -- and I
I think it relates to many of the measures, that you might want to talk about the philosophy of this idea of cross-section prevalence being a quality measure versus what the evidence is talking about is actually identifying individuals and treating individuals and seeing that.

I think that goes across several of these measures, if you could maybe talk a little bit about the general philosophy there?

MS. GAGE: Sure. Thank you, Karen.

The measures that we are bringing forth for CMS are a set of measures to monitor quality of care in the nursing facilities for the beneficiaries, the residents that are being treated in the nursing facilities. While they rest, while the measures rest on the individual items which are what can be tested in terms of reliability and validity, the MDS 3.0 items, we have not yet had the chance to test the new measures because the
data collection just begins in October.

So, we are using the reliability and the validity that have been tested in past research, which is how you approach scientific acceptability: have these items been used well? Does this make sense? Are they carrying through statistically?

So, the application of the items into a standardized measure for the annual assessment in monitoring the program and the quality of care in the individual facilities is built on the work that has been done at the item level.

MS. PACE: So, I guess one question that gets at some of these issues is, so only patients that have been at the facility longer than 100 days will be in the denominator. So, it is really the presumption that the nursing facility has had time to identify and treat depression. So, the prevalence of depression in your patients post-100 days indicates that the nursing home
or nursing facility has not really been identifying and attending to.

So, is that kind of the basic assumption of why you can use this as a quality measure?

MS. GAGE: Yes, that is correct.

This is a treatable issue.

CO-CHAIR GIFFORD: Bill?

MR. KUBAT: Yes, a question. The discussion has been helpful. But particularly in light of the measure and the validity discussions, and so forth, is there any additional significance?

Two of them that I always gravitate to, one of them is 4(d), susceptibility to inaccuracies, errors, and unintended consequences, and there's nothing there. No research could be identified.

Can you comment on that in light of the discussion we have had thus far?

MS. GAGE: My understanding of the item is whether an item could be
misinterpreted when being applied, when being used in the facility by the clinicians. With the PHQ-9, this has been so heavily tested in so many communities, the language is quite clear. So, it is not applicable. Or "no" I guess would be a better answer.

MR. KUBAT: I think, actually, ultimately, this measure is a measure of the facility, not the individual, but it is an aggregate of individuals.

MS. GAGE: Correct.

MR. KUBAT: What is presented here is high kappa, high reliability testing, high sensitivity and specificity at the individual level.

MS. GAGE: Yes.

MR. KUBAT: Nothing is presented at the facility level because it hasn't been calculated just based off MDS 3.0.

MS. GAGE: Correct. Yes.

MR. KUBAT: Is that a fair summary of that?
MS. GAGE: That is.

MR. KUBAT: So, that is why your answer that we don't know.

DR. ORDIN: I think part of the thing that would be helpful in looking at potential adverse impact of this measure is to look at it over time with the use of psychotropic drugs, because one of the things that could happen is overuse in response to that.

So, that is one of the reasons for testing it as a measure rather than as -- you know, it has been totally validated as a screen for an individual patient.

CO-CHAIR GIFFORD: All right. So, I am going to call the question on the different components. So, the importance of this measure, people feel it completely meets everything -- I am going to say, just summarize the recommendation before the group that you are voting on, that we vote, the completeness, it passes. We are happy with
the completeness of this.

   Everyone in favor of that? Show
of hands. We just need to see it.

   (Show of hands.)

Anyone abstaining?

   (No response.)

Anyone against?

   (No response.)

   Okay. On reliability and validity
of the scientific evidence of this measure,
what I would put forth to the group would be
that it recommends passing with the caveat
that Darlene has brought forward, that the
definition of 100 days be modified to really
be 100 days. There's no loophole in there.
So, there is actual calculation back to the
admission date. I think that that is probably
what is before the group.

   Yes, Ron?

DR. SCHUMACHER: Ron Schumacher.

   Just a question on that. Is there
a potential loophole there if there are
hospital admissions during the time the person is in the nursing facility? Does the clock start again on a new admission?

CO-CHAIR GIFFORD: The way the MDS is filled out -- of course, I haven't filled one out in a while, about five years. So, I apologize. But it depends on how the admission occurs.

If they are officially discharged from the hospital and going back over it, if they come back, then they need a new MDS filled out. So, it should change it, I believe.

But I think the reviewer, Darlene, or anyone close to the MDS, RTI, is that right?

MS. CONSTANTINE: Depending on the definition and what occurred, it could be a significant change assessment.

CO-CHAIR GIFFORD: You need a microphone. Sorry.

MS. CONSTANTINE: My best friend.
Hi.

Depending on the definition, like the patient going back into the hospital, it could be a significant change assessment by definition or it actually could start the clock ticking again, if they cycle back into the hospital.

And there's also, I think, a time limit of three days as well in regards to a hospitalization and then the patient coming back.

So, that is why we tried as best, with the discharge assessment, the addition, that we could really sort of try to segment out the short-stay versus the long-stay population. But it is true, you know, it is not 100 percent a perfect formula to be able to identify them completely, fully, in sort of either bucket.

DR. SCHUMACHER: So, I was just worried about unintended consequences resulting in increased hospitalization for
depression, so that the clock could start
ticking again.

MS. THOMPSON: This is Darlene
Thompson.

With the definition for doing the
MDS, if the resident is discharged even for an
observational stay that is over 24 hours, then
they have to be discharged. When they come
back, you would enter the new data into A1600.

So, what you are discussing about
a long-stay patient that took a short stay in
the hospital now becoming a brand-new clock is
correct. However, you could put a caveat in
there by looking at, if the prior assessment
was a discharge with return anticipated, and
the resident comes back, because you do have
to answer a question if it was a re-entry.

So, I think that if the
individuals would go back and look at the
exclusion for the denominator to cover those
instances, I think that is going to take care
of your issue.
MS. GAGE: Thank you.

CO-CHAIR GIFFORD: Any other comments on reliability and validity?

(No response.)

So, what we have before us would be voting that it does meet reliability/validity except for the small modification. So, we are in that modification range of defining the 100 days more clearly.

Any others? Yes, Dede?

DR. ORDIN: I would just like to bring up for consideration that perhaps we would like to do a time-limited one on this and ask for a study of the validity of the measure.

MS. GAGE: We will be, as we go live in the October 2010 data collection, we will be testing all of the measures.

CO-CHAIR GIFFORD: Barbara, I don't know if you realized what you just said yes to. That means we were voting this is a time-limited measure.
MS. GAGE: Oh, no.

CO-CHAIR GIFFORD: So, the measure, this is a time-limited measure, and change their submission to a time-limited measure, is that right, Barbara?

MS. GAGE: No. No, no, no. This is an improvement on the previously-endorsed measure.

DR. ORDIN: I agree that it is an improvement on the previously-endorsed measure, which was very problematic, but I am concerned about potential adverse impacts. And is this really measuring quality and there's a way that you could look at the medication that is going on? At the individual level, what is the change in the measure? I mean use it as the clinical tool to validate that, yes, this is, indeed, reflecting quality of care in a facility. I know you guys know how to validate this.

(Laughter.)
CO-CHAIR GIFFORD: Are you suggesting a modification of the vote before the Committee or a vote --

DR. ORDIN: Yes.

CO-CHAIR GIFFORD: Okay.

DR. ORDIN: I am suggesting that we consider --

CO-CHAIR GIFFORD: Use time-limited with the 100-day change?

MS. THEBERGE: I believe the staff had marked this as time-limited endorsement only.


DR. ORDIN: Here I thought I was being so radical.

MS. PACE: Let me just make a clarification.

Again, this is where NQF has not been real clear about accepting data reliability and validity versus measure score.

So, we could go either way with this. So, I
think it is an issue of what the Committee thinks are the dangers or potential dangers or need for more information as the implementation of MDS 3.0.

So, it certainly can fit in either category. We need your guidance on that.

I think there was also a need to put a clarification in the numerator, so that it was clear how that was actually computed.

The other thing I will just mention about measures that are endorsed, whether it is time-limited or full endorsement, that as it is implemented, if the community identified issues with it, that is something that could be brought back to NQF for ad hoc review.

So, there are other options, but certainly the time-limited is, under these circumstances, something for your consideration.

CO-CHAIR GIFFORD: Comments from the Committee counter to the proposal on the
table or in the pit? That is the way we are organized here.

(Laughter.)

Arguments not to time-limit it?

Anyone?

(No response.)

Okay. So, what is before us is time-limited approval with the caveat to modify the 100-day definition more clearly.

Any other comments before we vote?

(No response.)

Everyone in favor of that?

(Show of hands.)

Anyone abstaining?

(No response.)

Anyone opposed?

(No response.)

For the record, I vote for it, yes.

MS. GAGE: Thank you.

CO-CHAIR GIFFORD: Yes?

MR. KUBAT: Bill Kubat here.
Maybe this is just a general question, and I don't mean this as a distraction. So, if it is, you just tell me. And I don't know if this is a question for the developer, for NQF, or if it is a question for CMS.

But there are a number of measures where you could ask this question. How is it considered whether or not the measure is appropriately-worded as is or worded in the positive? I mean you could take this measure and say it is a percent of persons "free of". And the reason I ask that question, and to me it is a harmonization question, is that you see that kind of language throughout much of Hospital Compare, and so forth.

So, how does that relate to what we are about here? This measure and, again, you could relate it to any number of others.

MS. GAGE: Shari, would you like to answer?
The CMS measures in general have
the approach -- that is why you are seeing it
in all of the Compare. CMS is moving towards
a positive interpretation of whatever is being
examined. So, these are all consistent with
that approach also.

MR. KUBAT: So, that means that
CMS would, then, as they are using these
endorsed measures for purposes of Nursing Home
Compare, what have you, they have the latitude
or the sense that they will invert them and do
them in the positive? I mean, what does that
mean?

CO-CHAIR GIFFORD: No, the measure
we have before us is the percentage with the
diagnosis. If the diagnosis is viewed as a
negative, then it is worded in the negative;
it is a, quote, "negative" measure. If having
the diagnosis is a positive thing, then it is
worded in a positive thing. But it is worded
in the percent with this activity.

You know, NQF has endorsed
different types of measures. I mean a lot of
the medical error measures are all in the sort
of the negative, if you use that term, versus
the "free from". So, we flip back and forth.

Many of the original measures were
measures in the process measures, which tended
to be processes that were supposed to be done.
So, they were viewed as in the positive. As
we move more to outcome measures, the outcome
measures are more of the disease of interest.
So, one could argue that they may be viewed in
the negative.

But, next door, they are doing a
lot of outcome stuff, and the outcomes are not
free from disease. They are the outcome often
of interest. So, it is an interesting issue.

As far as what you do with
reporting it, I mean the validity in reporting
and the structure of this is as is, which is
percent with the disease or with the measure
of interest. Here, the goal would be to have
very few people depressed, and therefore, you
would argue that it is framed in the negative.

To flip it around and to the reciprocal, you know, I guess anyone can do anything with any measure. It is not just CMS. Anyone could do that. So, it is really tested and structured in the way it is presented to us, and we are voting on it the way it is presented to us.

MR. KUBAT: Well, and I don't want to belabor the point, but I do think it is an important one. So, as I understand it, then, if CMS does invert it or use the reciprocal, then that is not an NQF-endorsed measure?

CO-CHAIR GIFFORD: Correct.

MS. TOBIN: Judy Tobin from CMS.

The Compare site is a public-facing site meant to word the measures in such a way that the general public can understand and interpret them. So, some of the wording is changed for that general public digestion of the measure.

DR. ORDIN: I have a question.
This is Dede Ordin. I have a question for NQF.

I know you said it, but what does time-limited mean, because there is no way that this can be tested until 3.0 has been used for probably a year?

MS. PACE: And when is 3.0 being implemented?

DR. ORDIN: October.

MS. GAGE: It is being implemented in October. We have plans to begin testing in the January period, after a quarter of data have come in and people have experienced --

DR. ORDIN: Right. I mean our current policy is testing within 12 months.

MS. GAGE: And that is not possible here.

MS. THEBERGE: The final endorsement won't be until December though. So, that would be 12 months from December when the Board endorses.
just at the beginning.

(Laughter.)

These measures haven't graduated yet.

Okay, the next one would be on usability. What I heard from the group was that the usability was probably --

MS. PACE: voted already, didn't we?

CO-CHAIR GIFFORD: We voted on importance of reliability and validity. I'm just following the rules. I just do what people tell me to do. The time-limited and that was all related to the reliability and scientific aspects of it, right?

CO-CHAIR MUELLER: I think everybody thought we were voting on --

CO-CHAIR GIFFORD: All right. I'm very good at misleading people. It's what I do for a living these days.

I will lump usability and feasibility together because I am assuming
everyone felt that that was reasonable to move forward on. Any caveats to that?

(No response.)

All in favor?

(Show of hands.)

Any abstaining?

(No response.)

Any opposed?

(No response.)

Then, I would take the whole measure as a whole set. Now the whole set, which is to approve it time-limited with 100 days out there.

Any abstaining?

(No response.)

Any opposed?

(No response.)

All in favor?

(Show of hands.)

To make sure you guys are listening, I changed the order.

(Laughter.)
Okay, Christine?

CO-CHAIR MUELLER: All right, our next set of measures is staffing measures in the nursing home, and our steward is the American Nurses Association.

I am the primary reviewer on one, and Betty is the secondary on that same one. Then, she is the primary reviewer on the first.

Rita, I don't know if you're --

CO-CHAIR GIFFORD: 11:45 is the break, Dede, 11:45, right there on paper. We are doing what everyone says. We are not varying. We are going right through on this.

CO-CHAIR MUELLER: Yes, although I wish otherwise.

I'm sorry, I have too many papers.

So, what do you mean by No. 6?

MS. GALLAGHER: This is Nursing Home 006.

CO-CHAIR MUELLER: 006, and both of these measures are quite related, and the
documentation was the same for both measures. So, I don't know how you are planning to approach that.

MS. GALLAGHER: Well, I think that, at the pleasure of the group, it might be best to entertain them together.

Karen, is that --

MS. PACE: Yes, I would have them hear comments about both of them, and then they can discuss them individually. But I think it would be easier for you to just talk about both of them.

MS. GALLAGHER: Okay. I am Rita Munley Gallagher. I'm a Senior Policy Fellow with the National Center for Nursing Quality at the American Nurses Association.

I am here to follow on to the comments earlier made by Helen Burstin regarding ANA's willingness to work to expand the 0204 and 0205, which are currently endorsed NQF measures, to reflect appropriately the nursing home setting.
As you heard earlier, the Mental Health Steering Committee in its deliberations in the recent past two weeks, I guess it was, requested that that activity take place. And how that will be operationalized is that a work group will be empaneled, and members of the Steering Committee will be invited to participate in the definitions that need to be included in the expanded measure. That would be the same suggestion for this group.

NDNQI's principal investigator, Dr. Nancy Dunton, is on the telephone, and she would be pleased to speak to you about any of the technical aspects of the measures. I am here merely to express the measure developer's willingness to expand the measures and move forward with them for additional settings.

So, Nancy, are you there?

DR. DUNTON: Yes. Thank you, Rita.

Good morning, everyone.

I think it is appropriate to
review these measures together, total nursing hours per resident day and skill mix. They are structural measures that have been shown in the research literature to be significantly related to improved functionality of short-stay residents and decreased probability of death, improved resident functionality, and fewer medical errors and survey deficiencies, and reduced adverse outcomes and cost.

So, the specifications of the measures are as they were for the hospital setting in that the total nursing hours for patient day or per resident day in this instance is defined to include hours provided by all categories of nursing licensure status, and resident days in this instance would be the patient census.

The reliability and validity of these measures have not been studied by us in the nursing home setting, although we have conducted criterion validity studies of both measures on the hospital setting and found
them to have very high ICCs, in the range of .95.

The measures, there is sort of limited evidence of usability in that these concepts are represented on Nursing Home Compare, although the measures that are proposed here differ in source from the measures reported there, which come from the annual or the 9 months or 15 months annual surveys of nursing homes, as opposed to from payroll records and patient censuses.

The data collection is feasible because, of course, there are payroll data and patient census data in nursing homes, generally in electronic format, although certainly not from a medical record or from the MDS.

So, we are asking for time-limited endorsement of these measures because we know that their reliability and validity testing need to be conducted in long-term care settings, and the NQI has the ability to do
that because there are skilled nursing facilities, rehab units, and nursing homes affiliated with member hospitals who will be willing to serve as testbeds for the demonstration of feasibility of data collection and the reliability and validity testing.

CO-CHAIR MUELLER: Okay. I am the primary reviewer on this one. We are going to be, first of all, talking about the skill mix by RN, LPN, and nursing assistant.

The way that measure works is it is the proportion of the direct-care nursing staff that are providing 50 percent or more direct care that are RNs and the proportion that are LPNs and the proportion that are nursing assistants. Then, there is also a measure, a complementary measure, about those that are contract or agency-type staff.

So, my assessment is that this is really important, an important measure. We can go back to 1970-something when there were
hearings on the Hill about staffing and quality in nursing homes. So, when we think about the fact that this was in 1970 and we are in 2010, and what we are still wondering about is staffing and quality in nursing-homes-related, it does puzzle me a bit.

But, regardless, there has been a great body of literature on nursing staffing and quality in nursing homes, and that was not probably as well-represented in the presentation of this measure as I know of the body of literature that is out there. So, it was a little struggle for me to check, yes, this is important because the evidence to support the importance wasn't as strong in the measure that was presented.

So, I would just hope, I expect a number of you are quite familiar with that literature and know that we have a good, growing body of evidence; particularly RN staffing and nursing homes is probably the strongest.
We tend to see in many of the studies that there is this inverse relationship between staffing and quality; when it comes to practical nurses and CNAs, the evidence is somewhat uneven. So, I would support it as being important.

In terms of the rest of the criteria that we need to look at, as was mentioned by the developer, there has been no reliability and validity testing about the measure in nursing homes. There is very limited reliability and validity testing.

There was a study, and I hope that our CMS colleagues might end up commenting on this, with a contract with the Colorado Medical Foundation, where they were testing different measures of nurse staffing and nursing homes and have a report out that came out in 2008. That was not referred to in the measure that was presented. There are some recommendations from that body of research about what might be reliable and valid.
The usability and feasibility, what is being proposed is that it is payroll data. In this study that CMS contracted the Colorado Medical Foundation, they found that it was very uneven about whether nursing homes could, indeed, systematically and consistently have valid payroll data. So, the feasibility is questionable.

I don't know, being a time-limited measure, how we are going to go about ensuring that we get good payroll data from nursing home staff. Having said that, I also know that in the newly-passed Health Reform Act there is some legislation language in there, or language in there, about testing these measures and getting nursing homes to submit reliable data for staffing.

So, it is about the timing of all of this and when, indeed, it would be we would have data that could be actually collected and then tested for reliability and validity. So,
it just kills me, having done most of my research in nurse staffing and quality in nursing homes, to say at the end I don't know if, even in a time-limited way, this measure is ready for testing, but I would be anxious to hear the responses from the rest of the Committee. Some comments from CMS and ANA, of course, would be very helpful.

But before we do that, I would like to defer to the second reviewer, Betty.

MS. FRANDSEN: Likewise, I felt that it was a very important measure. However, the other three criteria, I felt the information that was provided were lacking. I couldn't understand how to translate what was presented as having been usable in a hospital setting, how it was going to translate to long-term care as it currently is functioning in capturing this information that is provided in the OSCAR reports.

Therefore, it is hard for me to say, when I think it is so important, that I
think that the idea is probably ahead of the
usability and feasibility that was presented.

CO-CHAIR MUELLER:  Bill?

MR. KUBAT:  Yes, Bill Kubat.

I echo both of those comments.

I'm going to remember from the first Steering
Committee meeting thinking about the
importance of domains. Staffing was one. But
the issue then is the same issue now: how do
you consistently and reliably gather the data?
It doesn't exist.

Now some other things I think that
were named then, but are even more significant
I think now, is the issue of how you -- I
don't know if it is necessarily a risk
adjustment, but how do you account for acuity
and differences in acuity in relation to
staffing?

Then, secondly, in terms of some
of the definitions, now with more of an advent
with culture change, and so forth,
appropriately accounting for versatile
workers, and so forth. So, it is a more complex environment now than it was then, but it is still a very important issue.

CO-CHAIR MUELLER: Okay. I see Mary Jane, and then I see someone from CMS, and Lisa. Did you have your hand up first, Lisa?

MS. TRIPP: Oh, I will cede it to Mary Jane.

DR. KOREN: This is very quick. I think that Bill raises a very interesting and important point, which is that with some of the innovation that is going on in nursing homes, we want to be careful that we don't choose a measure that straitjackets us or prevents really some innovations and trying new models, and doing things like that.

So, while I echo the importance of licensed and other staff in nursing homes, I just want to be careful it is not an unintended consequence.

MS. TRIPP: If I might also add, I
think there's an issue of harmonization as well. There is going to be a new CMS quality measure with regard to staffing. It is required by the new law. So, there is going to be data collected electronically from payroll and, also, from cost reports and other auditable sources. So, that data is going to be a lot of data.

Actually, Janet Wells is here with NCCNHR, who has been heavily involved in this. If you wanted to explain a little bit about what exactly is going to be the information that is going to be gathered, I think it would be helpful.

CO-CHAIR MUELLER: So, it looks like CMS is deferring to NCCNHR right now, huh?

(Laughter.)

MR. WELLS: Yes, maybe I don't need to say anything since Jean is here, but in 2001 the CMS issued phase 2 of a monumental report on appropriateness of nurse staffing
ratios in nursing homes. As a continuation of that contract, since 2001, CMS has been developing quality measures and a data collection system for nurse staffing.

It hasn't been implemented because CMS has not moved forward with regulations to collect the data electronically from payroll. That will happen now under the healthcare reform law.

I just want to say, from a consumer perspective, we think it is extraordinarily important to have quality measures for nurse staffing. The healthcare reform law requires measures based on hours per resident day, turnover and retention rates, which we think are very important. It also authorizes collection of other types of staffing data as well.

So, we hope that there will be quality measures. In 2004, NQF recommended that there be a staffing measure when data was available. We hope we are not waiting another
six years before there are recognized quality
measures for nurse staffing, but we do think
it is very important to recognize the work
that has already been done at the University
of Colorado.

CO-CHAIR MUELLER: Go ahead. I
can't see your name.

MR. BOISSONNAULT: I'm Bruce
Boissonnault.

I am the secondary reviewer with
Betty on the next measure, but I would echo
what the Committee seems to be opining. There
is another harmonization issue for me, which
is this measure implies that more is always
better, that there is not diminishing marginal
returns when you reach a certain point.

With what I hope CMS is eventually
going to do, we can use the same data that
gathers the hours to tie back to the
productivity piece because just measuring
hours without also looking at productivity in
the same database I think is a tragic mistake.
And the other point that I wanted to make is the way the denominator -- it is a sort of detailed thing -- but the way the denominator is defined, to me, straitjackets us from the perspective -- I think basketball, sort of man-on-man coverage versus zone coverage. We don't know which one is going to work, but a lot of the zone coverage players are excluded in counting hours. I think that is potentially problematic. Nonetheless, I think the importance of knowing staffing can't be overstated.

CO-CHAIR MUELLER: Jean?

MS. SCOTT: Yes, I'm Jean Scott from CMS.

I guess I would like to make several comments, first of all, having to do with the healthcare reform and what we are actually required to do, and what we are actually doing at CMS vis-a-vis the collection of staffing data.

The health reform bill actually
requires us to collect not only nursing care, nurse staffing data, but, also, therapist data and other medical personnel data. So, that is what we will be collecting.

The work has begun with this. We have had an IT contractor for about a year building the requirements for the system to collect these data. Now, obviously, when you put a new data collection in under the CMS data collection system, the amount of bureaucracy is incredible with it because you have to make sure you don't crash everything else, because it will be under the big computer system.

So, it is taking some time, but we will have this up and going as required within two years of enactment of the health reform law. So, we do expect that to happen, and it is moving forward.

I wanted to say a word, too, about what has been done and what hasn't been done with the validity testing and a word about the
feasibility testing of collecting the data.

I also was the government task leader for the study that is being talked about with the Colorado Foundation for Medical Care. That study did, in fact, develop a database of more than 1400 nursing homes for which we had a year's worth of payroll data, but we had purely a payroll data dump. So, it was a different thing than asking the facilities to give us the data themselves and to do an extract of the data.

With the data from the data dump, so to speak, there actually was a measures development effort, and those were tested against some of the quality measures and also against things like for the short-stay population for discharge back to community, for rehospitalization for the long-stay population. So, there has been some measure development. It is not this measure that was tested, though. It was measures that were developed under that contract which get to
some of the same things.

We have not done any testing of measures that include physical therapists or other medical personnel. We have, however, done some work beyond that study to look very carefully at what could and couldn't be done with an invoice-based system to bring in contract staff, which also is an important piece to this, particularly with the therapy staff. We are looking at that.

We have also had some conversations with Dr. Katz from AMDA, who is helping us think through other medical personnel, because that does include physicians. We are going to be looking at physician extenders. We want to look at advanced practice nurses as a separate group.

And one word about the feasibility study that was done, because we think that that sort of misrepresents how feasible this really is to do. The feasibility study that was done was a targeted feasibility study. We
only included nine facilities in that, and it was a targeted study, in that we were trying to identify what the problems would be.

I mean, if you look very carefully at that study, and it is on the CMS website still, if you look very carefully, we went to facilities on things like Indian reservations to really try to pick up the mom and pops who would be difficult. We know this is quite feasible with payroll vendors, and it is feasible for facilities that have a good IT department. It is going to be more difficult, and we are taking that into account in designing the new system.

MS. PACE: I just want to make one comment to the Committee. In terms of your decisions, it should be about the measure as presented, not about what may happen in the next three years. You have the option of approving this measure based on the criteria or not. In the future, if a new and better measure is available, they have the
So, I just want to lay that out in terms of you should make your decision on this measure based on how well it meets the criteria. And in the future, if better measures are available and are brought to NQF, certainly, we welcome that.

MR. BOISSONNAULT: The best we could do, though, is a 12-month limited endorsement based on the application itself, correct?

MS. PACE: Exactly.

MR. BOISSONNAULT: So, we are already --

MS. PACE: Right, right.

MR. BOISSONNAULT: -- at a certain threshold.

MS. PACE: Right.

MS. THOMPSON: This is Darlene Thompson.

I was just going to indicate that
the fact that, even though payroll data is
electronic, most payroll data does not break
out productive from non-productive. They are
either by job title, which could be held by a
licensed personnel and non-licensed personnel,
or they will be by the criteria or their
credentials, which, then, wouldn't indicate
whether in the productive or non-productive
state.

So, the feasibility of being able
to gather this data, even though we have
electronic payroll data, there's no way that
would be able to occur.

MR. BOISSONNAULT: I was just
going to say, if CMS writes rules that says
submit the data this way, then I think the
payroll systems will very quickly respond.

MS. THOMPSON: I agree, but it
will take work on the payroll systems because
not everybody uses the same one. So, there
will be that outlay to the centers, plus some
time to wiggle out the issues that are going
to come up with that. So, might as well allow that to happen before we even look at being able to pull productive time.

CO-CHAIR GIFFORD: Can you help me? I'm confused by the measure. I want to go back and look at the numerator.

It excludes all non-clinical people, and the numerator says it has to have greater than 50 percent of their shift in productive time to be included in the numerator. Then, it reports the number of hours. And the denominator is all RNs, LPNs, and UAPs.

So, I'm not sure; what is this measure? Is it percentage of total hours of individuals who spend more than 50 percent of their productive time providing direct patient care? Is that --

MR. BOISSONNAULT: And certain matrixed functions I think are excluded that might actually in some settings be care. So, if you move to a matrixed organization, you
could be penalized by this measure, the way I read it.

CO-CHAIR GIFFORD: Well, before we get there, I am just trying to understand the measure itself. Why isn't it close to 100 percent? When you start excluding everything out -- or is the key here productive hours, and they don't define productive hours?

MR. BOISSONNAULT: The key is the denominator, which is patient days. So, in other words, are you flying the airplane with only one pilot or do you have three?

CO-CHAIR GIFFORD: The denominator is hours.

MS. PACE: Multiple numerators.

CO-CHAIR GIFFORD: Oh, the denominator is not days; it's hours.

MS. PACE: Right.

MR. BOISSONNAULT: But it's patients. So, it is how many --

CO-CHAIR GIFFORD: No, it's LPNs.

That is why I am confused.
MR. BOISSONNAULT: Okay, sorry.

I'm on 7.

CO-CHAIR GIFFORD: I'm looking at this measure here. The denominator is LPN, RN, UAP hours, and the numerator is hours. So, the denominator is all hours of this group that does something divided into the productive hours there. I can't figure out where they come --

CO-CHAIR MUELLER: Okay, I'm going to give it a try.

So, first of all, you get in the numerator if you are 50 percent or more providing direct care.

CO-CHAIR GIFFORD: Just is it zero/one or is it hours?

MR. BOISSONNAULT: Zero/one, right?

CO-CHAIR MUELLER: Yes.

MR. BOISSONNAULT: You either are more than 50 percent --

CO-CHAIR MUELLER: Or you're not,
right.

DR. ORDIN: Could I ask a favor? Could you start with the denominator?

CO-CHAIR GIFFORD: Yes, yes.

CO-CHAIR MUELLER: Yes. The denominator would be anybody who is 50 percent or more and all the hours of those people.

CO-CHAIR GIFFORD: But that's not what they say in there. Can you put up 2(a)(8)?

CO-CHAIR MUELLER: 006.


CO-CHAIR MUELLER: Yes.

CO-CHAIR GIFFORD: The denominator says, data elements, LPN and LVN hours, hours, hours, hours. It seems to be hours.

CO-CHAIR MUELLER: 006 is hours.

So, let's say you have 10 people in the nursing home that are 50 percent or more providing direct care. It would be, the
combination of all their hours would be the denominator.

Then, the numerator would be, there's a variety of formulas you will get. You will get one formula of the percent of RNs or the number of RN hours divided by the denominator, and that will give you the proportion of RN hours that this facility provides.

CO-CHAIR GIFFORD: Yes, but I am still confused. So, if you take all RNs who are doing direct patient care, do they have to be more than 50 -- this denominator doesn't say the 50 percent cutoff.

CO-CHAIR MUELLER: Right. No.

CO-CHAIR GIFFORD: This is just all RNs everywhere, right?

CO-CHAIR MUELLER: Okay.

DR. DUNTON: This is Nancy Dunton. Can I --

CO-CHAIR MUELLER: Yes, could we have the ANA person say something?
DR. DUNTON: This measure, it is currently endorsed for hospital settings. It includes in the numerator all hours provided by, let's say, RNs who spend at least 50 percent of their time in direct patient care. In the denominator are the same kind of hours for staff who spend at least 50 percent of their time in direct patient care of RNs, LPNs, or LVNs, or nursing assistants. So, it is a proportion.

CO-CHAIR GIFFORD: But that is not what is before us. At least what I am verbally hearing isn't, right? Am I reading it wrong?

DR. DUNTON: Yes, I think you might be reading it wrong because --

CO-CHAIR GIFFORD: Well, can you look at 2(a)(8)?

MS. PACE: So, what they are saying is, in 2(a)(4), it is the total number of productive hours, and 2(a)(8) is the same, which --
CO-CHAIR GIFFORD: All right,
2(a)(4). Yes.

MS. PACE: Total number of
productive hours worked by all of those staff.

CO-CHAIR GIFFORD: Yes.

MS. PACE: And then, the numerator
is not adding those up, because you're right,
they will add up to 100 percent. The
numerator is looking at the skill mix. So,
what percent of those total hours are RN
hours? What percent of those total hours are
LPN hours, et cetera?

So, it is designed to be, the
numerator categories are designed to be
computed separately. But if you would add
them up, you would get 100 percent, yes.

CO-CHAIR MUELLER: So, you would
get three QIs, RNs, percent of RNs, percent of
LPNs.

CO-CHAIR GIFFORD: Oh, I've got
you. Okay.

MR. BOISSONNAULT: Let me ask --
CO-CHAIR GIFFORD: So, it is a distribution?

MR. BOISSONNAULT: Right, it is the weighting of RNs versus LPNs versus --

CO-CHAIR GIFFORD: So, it will add up to 100 percent?

MS. PACE: Right.

CO-CHAIR GIFFORD: I've got you. Okay.

MR. BOISSONNAULT: Which is why we were both getting to 100 percent.

MS. PACE: Right.

CO-CHAIR GIFFORD: I've got you.

MS. PACE: Right. So, the idea is to look at the mix of the personnel providing care. But it is still the question of what's good and --

MR. BOISSONNAULT: The commas don't mean pluses; they mean one each.

CO-CHAIR MUELLER: Yes.

MS. PACE: Right.

CO-CHAIR MUELLER: Okay.
MS. GIL: This is Heidi Gil.

I just wanted to mention that, obviously, with this formula, the concern, given the current state of short-term rehab and nursing homes, the fluctuation in staffing based on census, and making certain that, obviously, the public reporting piece of this would be for any consumer to understand, as well as I know that the nursing homes are all really getting good at reporting better on the annual survey the staffing because of the five-star rating. But that is just coming about as five stars come about. So, to see the accuracy come with this kind of system really scares me.

DR. MODAWAL: Yes, Arvind Modawal.

I just still have a comment related to that. Why this 50 percent came up? Because, as you are saying, a lot of staffing, they are working less than 50 percent. So, there should be a simplistic way that we would look at all hours for individual categories.
and then hours worked in the clinical setting,
you know.

CO-CHAIR MUELLER: I think, if I am hearing you correctly, what the 50 percent means is you have somebody who works full-time, but they spend 50 percent or more of their time in direct care.

DR. MODAWAL: Yes.

CO-CHAIR MUELLER: Okay.

DR. MODAWAL: What I am saying is that a lot of part-time employees are working less than 50 percent, yet contributing to the mission of care in the nursing home. So, they are maybe there, you know, one day a week or a half-day a week, or something like that. So, that is also an RN level or LPN level, and it should also be accounted for because they may not find RNs or LPNs who are able to give that degree of time because they are agency nurses; they are nurses coming in just interested in part-time work.

CO-CHAIR MUELLER: Well, I think
it would account for those. It is, if you are there for that day and you are spending 50 percent or more of your time in direct care, it counts.

DR. MODAWAL: Okay.

CO-CHAIR MUELLER: It is not an FTE.

DR. MODAWAL: Oh, I see.

MS. GALLAGHER: Perhaps if we were to conceptualize the 50 percent as meaning you were actually providing care as opposed to you were the Director of Nursing?

DR. MODAWAL: Yes, I think it needs some clarification.

MS. GALLAGHER: Sort of a categorization of the person, not how much time they spend all together in the activity, but, rather, that they are providing care as opposed to supervising others. That is the aegis of the issue.

MR. BOISSONNAULT: So, if you are looking at the ratio, essentially, it is the
ratio of RN, LPN, and UAP of the total direct-care hours. They don't risk-adjust it. Why wouldn't you want to risk-adjust this? Or stratify by patient acuity? Because we know that there are nursing homes, I mean we have seen by the long-term stay, the short-term stay, and the number that gets kicked out, and everything else, you would probably want to risk-adjust this, I would think.

DR. DUNTON: This is Nancy Dunton again.

The intention in the documentation is that it would be risk-stratified by type of care, unit type.

CO-CHAIR GIFFORD: I just need a 2(e), which says risk adjustment. For outcomes, it says not available, not available, not available.

MR. KUBAT: And it says, under 2(a)(12)-(13), no risk adjustment necessary.

CO-CHAIR MUELLER: What about stratification?
CO-CHAIR GIFFORD: Stratification is risk adjustment.

CO-CHAIR MUELLER: Right.

MS. GALLAGHER: The intention is stratification by unit type, which is how it is currently operationalized in the hospital. As I indicated earlier, what we will be doing as we add the behavioral health aspects, we will be working with an expert panel to define what exactly their units would be, and we would expect that the nursing home community would provide input into what their units would be also.

CO-CHAIR MUELLER: Okay. I would like to see where we are right now, a straw vote.

All of those that would be ready to vote on this measure, could you raise your hand?

MR. BOISSONNAULT: Ready to vote

or ready to vote yes or no?

CO-CHAIR MUELLER: Ready to vote.
(Show of hands.)

All right, it looks like we have the majority that are ready to vote.

So, the recommendation is that this measure, the first one, not be accepted. I have to go back to my notes here. That is the recommendation on 006.

Sorry. We will go through the criteria.

So, the idea, the first is that it is important, and the assessment is that this is a very important measure. The testing of the measure is that there is no evidence of that, and we do have to keep in mind this was intended to be a time-limited measure.

The third is usability and feasibility. That was also assessed not to be adequate.

So, the conclusion is that, therefore, this cannot be an endorsed measure.

Any comments before we would go to a vote in regards to what I just said?
MS. PACE: So, you are not even recommending for time-limited? You're saying to vote it down? That's fine. That's fine. I just want to clarify.

CO-CHAIR MUELLER: Well, she just whispered in my ear this is time-limited. So, I forgot that.

MS. PACE: So, the vote could be time-limited endorsement, yes or no? So, it really would only be eligible for time-limited endorsement. So, if you vote yes, it would be yes for time-limited status. If you vote no, it is just not going to be recommended at all. Does that make sense?

CO-CHAIR MUELLER: Yes, and time-limited, this is on the memo that all of you got and I didn't, so I am catching up today. There's three strategies we can use. One is time-limited for measures that satisfy most of the evaluation criteria or the other is recommended for time-limited endorsement with conditions or do not
recommend for time-limited.

My concern with time-limited is I don't know if they can be pulled off in a year. So, that is where my hesitancy is.

Any comments on that?

MR. BOISSONNAULT: Madam Chairman, I think time-limited implies that we are all very comfortable with the measure and are just waiting for the evidence to support what is common sense. So, when we call the vote, that would be my read of the situation, if we vote yes for time-limited.

CO-CHAIR MUELLER: Okay. So, we need not worry about that 12-month thing?

MS. GALLAGHER: Well, first of all, the change from 24 months to 12 months is rolling in. That is what is going on now. The consensus-development process has moved to 12 months in consideration of time-limited.

I think that, first of all, it is not likely that this measure would even be endorsed until the end of the year. Is that
correct, Karen?

MS. PACE: That's the --

MS. GALLAGHER: Yes, probably

December. So, it is really a longer

timeframe. Obviously, we would begin work

earlier rather than later. So, I guess we are

talking closer to 18-19 months, if we were to

begin in the near future.

CO-CHAIR GIFFORD: But I think, to

Bruce's point, you're right, time-limited is

that we think it is a good measure; we think

it just needs a few little things sort of

worked out. It is not at the level, on the

previous one, where we could say, okay,

Darlene said just change the 100-day thing and

we think it's fine to go forward. I mean we

ended up modifying it for another reason, but

I think we felt much more comfortable as a

group.

Time-limited is more of that

category. So, if there needs to be

substantial work in it, you know, if we
really, really like it and think it is important, and there's promise that it can be done in a short timeframe, yes, we should move forward on it. But if it is not, then it should get voted down.

It doesn't mean that they shouldn't continue to work, it's not important, or it should go forward on it. I go back to the point that we are not measure developers around the table, as much as we would like to.

MS. TRIPP: If I could just make the point on harmonization, this is certainly a very important issue; there's no doubt. Federal law is going to mandate that this data be collected, in light of federal mandates it. CMS is doing it right now. I worry, and this is not to take away from the effort that was put into this, I just worry that it would generate more confusion with the public to have dueling measures. I think that is a significant concern.
CO-CHAIR MUELLER: So, we are calling the vote on recommendation for a time-limited measure, a time-limited endorsement.

MS. TRIPP: I'm sorry, Madam Chairman, did you give your recommendation as the reviewer, referencing the time-limited? Because I don't know that I heard it, if you did.

CO-CHAIR MUELLER: Yes, my recommendation was based on needing to know a little bit more from CMS because I needed to hear what they had to say to know what box to check, actually. And the conversation here, I think, was somewhat helpful, too.

MS. PACE: So, that is just what you are voting on. She is not saying that is what she is recommending. You're recommending yes or no on --

MS. TRIPP: That is what I was just trying to figure out, exactly what your recommendation was.

CO-CHAIR MUELLER: Yes. So, well,
I guess I would say that it would perhaps be worth our while to recommend it for time-limited endorsement. So, that's where I'll stand.

DR. ORDIN: Can I hear from the secondary reviewer?

CO-CHAIR GIFFORD: I'm not the secondary.

Yes, Betty?

MS. FRANDSEN: My recommendation would be not to move it forward as it was presented. It's not that it's not important, but there's too many gaps in what was presented.

CO-CHAIR GIFFORD: So, the vote before us is to endorse it with time-limited without any conditions, but to hear back more data in the future.

So, I guess any abstaining?

(No response.)

All in favor of it?

MR. BOISSONNAULT: All in favor
CO-CHAIR GIFFORD: Of time-limited endorsement? That is what is before us.

(Show of hands.)

All opposed?

(No response.)

CO-CHAIR MUELLER: I will abstain.

CO-CHAIR GIFFORD: Christine abstains.

CO-CHAIR MUELLER: Yes.

CO-CHAIR GIFFORD: I'm looking at the time. We are behind a little bit. We would like to take a comment from any of the members of the audience who are on the phone. Then, we will take a quick break to grab lunch, come back in, and we will resume. So, we are behind a little in the schedule, but I think as we get the gist of how to move through this, we will pick up speed as we go forward and feel more comfortable with the process.

MS. TRIPP: I just have a quick...
clarification question. I don't mean to slow everybody down.

Was that vote on 06 and 07 because they --

CO-CHAIR GIFFORD: Just 06.

MS. TRIPP: Just 06?

CO-CHAIR GIFFORD: We are going to come back to 07 and talk about 07.

MS. TRIPP: Okay.

CO-CHAIR GIFFORD: Sandy?

While Sandy walks up to the microphone, anyone on the phone who would like to make comments?

(No response.)

Okay.

MS. FITZLER: I have a few comments.

First of all, I would like to thank Bill Kubat. AHCA has been greatly involved in trying to get as many issues stated in the positive. Since we had the first measures in 2004, we have been working
on this, and CMS did assure me that we were
going to get as many as possible stated in the
positive. So, I would like you all to keep
that in mind because I'm not seeing a lot of
that.

My second issue, with the
specificity of some of the measures like the
percent of residents who have symptoms of
major depression, long stay, the denominator
size in many facilities can be quite small.
We have some facilities who are currently at
80 percent short stay, some of them close to
100 percent short stay. I mean you look at
the trending of care in long-term care
facilities; we are seeing more and more of
this.

Given this, currently in MDS 2
measures, if the denominator is too small, we
just don't see the measure. Is that still
going to be the same for the MDS 3-generated
measures?

MS. CONSTANTINE: Hi. Roberta
Constantine again from RTI.

Yes, for public reporting purposes, the short-stay measures, if a facility has less than 20 residents, it is not publicly reported and 30 for long-stay residents, given the issues with HIPAA and also looking in regards to the validity of the measure statistically with small numbers.

MS. FITZLER: I would just like to respond. My concern is -- and, Dr. Gifford, you said this early on when you started -- that we have to look at the measures and where the measures are being used or all the potential areas where they are going to be used. It is very difficult, then, when you are looking at five-star and assessing quality or in a value-based purchasing program, how can you assess, then, quality, if not all the measures can be reported by the facilities being evaluated? So, it makes it difficult.

MS. GAGE: It can still be monitored. You just don't want to publicly
MS. FITZLER: Barbara says it can still be monitored. You just don't want to publicly report. But the reason why we don't publicly report is because there's an issue with validity. Am I correct?

MS. TOBIN: Privacy.

MS. FITZLER: Just privacy?

MS. TOBIN: As you get down to a small sample, when you have so many characteristics identified on a patient, it becomes more and more possible to identify who you are reporting on. So, it becomes, in part, a privacy issue as well.

MS. FITZLER: Okay. So, the sample size, then, is not the issue here?

CO-CHAIR GIFFORD: Any other comments from the audience before we break for lunch? If you want to stand between the Committee voting on the measures and lunch, make a comment.

(Laughter.)
If not -- yes?

MEMBER NAIERMAN: I just have one quick question. Approximately what percentage of nursing homes are that small?

MS. FITZLER: What do you mean small?

MEMBER NAIERMAN: Well, 20 and 30, respectively, number of patients. How many, when you say ones will be excluded?

MS. FITZLER: Somebody here from CMS may know the numbers, but currently, under MDS 2, there's quite a few homes that don't produce all the measures right now. I am just looking at some of the measures that we have as we see the transition to more and more post-acute care, and seeing that become more problematic.

I don't have the number. Does anybody?

CO-CHAIR GIFFORD: A lot of the sample sizes are by all the exclusions that get you down in that problem. Actually, in
Rhode Island we have 92 licensed nursing homes, and I think there is less than 10 that are under 40 by total bed size. Because, actually, financially, you can't make it when you are under 40 beds. It is almost mathematically impossible at the current reimbursement rates for Medicaid and Medicare.

MS. THOMPSON: And the number 30 for a long stay, I've got a 150-bed facility that 90 percent of their residents are short stay. So, therefore, they never get enough measures to hit the long stay because they don't have 30 residents consistently that are in the facility for more than 100 days. So, it is not necessarily the size of the building. It is the length of stay of the residents in the building.

CO-CHAIR GIFFORD: What I would like to do is lunch is ready outside, right? Lunch is ready outside. We are going to do a working lunch. Collect lunch, go to the bathroom, check your BlackBerry, check your
emails, come back. We will do 10 minutes of sort of eating at 12:15, and we will start back up with a working lunch in here. Okay?

(Whereupon, the foregoing matter went off the record at 11:52 p.m. for lunch and went back on the record at 12:18 p.m.)
1 A-F-T-E-R-N-O-O-N   S-E-S-S-I-O-N
2 12:18 p.m.
3 CO-CHAIR GIFFORD: Okay. Working
4 lunch means working lunch.
5 We still have one of the staffing
6 measures before us. It is No. 10, the nursing
7 home hours per patient day, No. 7.
8 Betty, you're the primary
9 reviewer?
10 MS. FRANDSEN: Yes. This one is a
11 companion piece to the one we looked at on
12 skills level. The title is nursing care hours
13 per patient day.
14 The difference that is presented
15 in this one, rather than in the skill set, was
16 the numerator and the denominator are
17 different. The numerator for this measure,
18 total number of productive hours worked by
19 nursing staff with direct-care
20 responsibilities, and the denominator is
21 patient days during the calendar month.
22 Other than those two differences,
the measure has the same items presented. In my review of it, I felt that it contained the same issues that we dealt with in reviewing No. 6. Although it is a very important measure, I did not feel, as it was presented, that it met the other criteria.

CO-CHAIR MUELLER: I would just add this is time-limited also.

MS. FRANDSEN: Yes, it is.

And my secondary is Bruce.

MR. BOISSONNAULT: Very briefly, it meets the importance criterion, hands down. Scientific acceptability was sort of a maybe with caveats. It excludes certain teams, the issue we already discussed about man-to-man coverage versus zone coverage, the implication of a linear relationship between staffing.

And as far as usability, I had yes, with some "but's". The measure does in the end, though, it would measure what it says it will measure.

My other concern was the sort of
lack of evidence that it would move the bar on
all of the things that it said it would move
the bar on. In other words, there was an
explicit statement in the application that it
would improve quality, undefined.

Coordination of care and safety,
and I did see what I thought was enough
evidence on the safety indicator, but the
others weren't in the app.

So, my recommendation was, because
it is a time-limited application, it was no,
notwithstanding that I think the importance of
the measure is unquestioned.

CO-CHAIR MUELLER: Further
comments from the Committee?

DR. KOREN: I didn't read these
particular reviews, but there's one thing I
was thinking that I heard in the discussion
before, which is the idea of parsing out what
nurses in nursing homes do as productive
versus unproductive time. I think maybe that
comes from a hospital model.
But, you know, I think that we really have to examine what the role of an RN, for example, is in a nursing home, and to argue that maybe some of the most productive time they have is when they are supervising and serving as team leaders to the care team.

So, I think we should be really careful utilizing terms like productive and unproductive. Their job is to do assessments. Their job is to lead a team. Their job is to be a resource, being leaders.

So, I think we need to really be careful about the terminology and not just sort of bring it wholesale out of an acute system.

CO-CHAIR MUELLER: That is a good point, or even to have a definition of what productive means.

Any other comments?

(No response.)

Okay.

CO-CHAIR GIFFORD: So, we actually
were admonished at lunch for not following the rules. We actually need to go back and make sure we do this, not only vote on each of the four categories, the importance of scientific usability and feasibility, but we make sure we are voting on whether we think it is complete, partial, minimal, or needs lots of work.

And for the measure developers in the room, having been a previous measure developer, I understand the amount of time and energy and resources it take to develop a measure and validate a measure and to fill out these forms. That said, I know there's no perfect measure.

So, there is going to be a lot of criticisms and comments, but I think the responsibility of the group here is to go through a process, I think a well-thought-out process by NQF, to endorse a measure that has some meaning behind the NQF measure. That doesn't mean that I think the work that you all have done has not been recognized and
everything else, but to move along, I am going
to push, and if you can't tell, have some very
frank and quick discussions about it.

Part of the reason, I am not in
Rhode Island, so I don't have to worry about
being politic anymore. Just to say it is what
it is on some of the measures, so we can go
through and get everything, but it doesn't
mean that the measures that we haven't done
aren't incredibly important.

I think all of us, as I said,
think almost all the measures before us, we
can almost all vote right now -- what's the
term we use? We can sort of bundle them all
together and just all vote that they are all
important, and most of them meet the
importance metric. You wouldn't have invested
the time, you wouldn't have had the funding to
get to that time, they wouldn't even be before
us if they didn't even pass that measure.

It really is getting into the
scientific usability and feasibility. That is
going to be really hard as we go forward on that.

So, just understanding that, just because a measure gets voted down, it doesn't mean that it is not important and that it shouldn't be worked on and shouldn't come back to the group for our future stuff, because I think we want to see those types of things.

All right, that said -- yes?

CO-CHAIR MUELLER: So, we do a vote for each, we ask for a show of hands for complete? Is that how we would do that, Suzanne? Okay.

So, for the importance to measure and report for 007, we have a show of hands for -- all right, we are redoing our thing here.

So, we would like the reviewers, the two reviewers, to go through each and give your rating for each of the four criteria.

MS. FRANDSEN: This is Betty Frandsen again.
For importance, I scored it partial.

For scientific acceptability, the reliability and validity, I put minimal.

For usability, partial.

And for feasibility, as it is written, minimal.

MR. BOISSONNAULT: All right.

There's a couple of submeasures that actually have that.

I'm confused because on the form it says, "Was the threshold importance met?"

That's a yes/no.

MS. PACE: Importance is yes/no.

MR. BOISSONNAULT: Okay. So, yes.

Then, forgive me, my copious notes here. To be or not to be.

CO-CHAIR GIFFORD: Can I put a motion on the table that, for all the measures, we vote that they all were important for a yes? Is there anyone from any of the primary reviews who would like to argue that
their measures were not addressing an important topic and had enough material presented to meet the importance criteria?

(No response.)

So, if we bundle that, that will move us along. Then, we only have to vote on the three things each time. Okay.

All in favor of all the measures being important?

(Chorus of ayes.)

All right. Okay. Good.

I always wanted to do that. I see it before committees every night, the legislature, and they always bundle everything together. I have always wanted to do that. So, thank you.

(Laughter.)

MR. BOISSONNAULT: The scientific acceptability, I said partial.

The usability, I actually thought it would be usable. So, a "C".

And feasibility, I think it is
certainly feasible.

CO-CHAIR GIFFORD: So, that would be a complete, partial, or minimal --

MR. BOISSONNAULT: No, a "C".

CO-CHAIR GIFFORD: Complete, okay.

MR. BOISSONNAULT: Yes, a "C".

CO-CHAIR MUELLER: Okay. So, we will vote on scientific acceptability. All those that would be in favor of being complete, raise your hand.

(Show of hands.)

Partial, raise your hand.

DR. NIEDERT: I'm not comfortable with that, when I haven't had a chance to actually review the measure, to go ahead and vote on each one. I've not looked at the citations. I've not looked at any of the information except what five minutes that we have had here.

MS. PACE: We generally like to get the Committee's assessment of each of those criteria because your vote to recommend
or not recommend needs to be grounded in the criteria. So, if you want to, by consensus, say the reason under those criteria that it is not going to pass that particular criterion, we can talk about that.

But, basically, where things go from here is out to public comment and eventually to voting. Your recommendations need to be justified in the evaluation criteria. So, what we have been doing as a general approach is having the Committees vote on whether the measure meets the criteria, and then, ultimately, that should lead you to your decision about the recommendation.

So, if someone has another approach, so that we can make sure that these recommendations are grounded in the criteria, we can certainly entertain that.

DR. SCHUMACHER: I think it would really help us if, as it is stated in some of the materials that we got prior to coming in here today, if the primary reviewer and the
secondary reviewer could just tell us if they reached consensus on it, and if they can tell us what their ratings were. I mean that is about all we have to go on because we didn't review all these topics.

So, if they reached consensus, that's great. I am more likely to agree with that. If they didn't, let's talk about the areas where they disagreed.

MS. PACE: And I would say that what is more important in terms of understanding the decision is the reason, not necessarily the rating. So, if the primary reviewers will go through the criteria and say, "This is why I think it was not important" or "This is why I think it did not meet scientific acceptability," if the group agrees with that, we can work with that in terms of being able to present something to the public of the reasons for your eventual not recommending.

David, do you think that can work
to at least make sure we understand under each criteria the reason, what the concern is?

CO-CHAIR MUELLER: Yes, I think so, too. Then, we would not have to do this one by one?

MR. BOISSONNAULT: Well, on this one, to Kathleen's point, the issues in 6 were very similar. I actually think they were sort of out there. We could argue about whether the research exists or not, but there were some fundamental sort of harmonization/usability issues and some scientific issues that came up, I think, that apply here.

So, for acceptability and usability, that was where I think we had issues.

MS. PACE: So, this is the other option. Because, as, hopefully, you understood all along, these decisions are Committee decisions, not individual reviewer decisions. If, on a particular measure, you
don't feel capable of voting, then don't vote on that measure.

But we really do need to have these decisions grounded in the criteria. That is what the criteria are there for, and we want to get a sense that the Committee has addressed those and, also, that the final recommendation makes sense. So, if the votes on the criteria are different than --

CO-CHAIR GIFFORD: But we don't need to know how many think it is complete, partial, minimal, or non-responsive?

MS. PACE: Well, generally, we have been doing that. If you want to put forward a particular rating, based on the primary reviewers, and see if people agree with that, we can work with that as well, but we still need to have these decisions grounded in the criteria.

MS. TRIPP: I actually had a suggestion that might speed it up. Certainly, where there's unanimity among both reviewers,
we could simply make a motion that we adopt their rationale, you know, we adopt their rating. We could do that. Then, if people disagree, they could opt out, maybe disagree. But it does seem very time-consuming to go through each one of these and give four options for each one.

CO-CHAIR GIFFORD: Diane?

DR. MEIER: Oh, sorry. Diane Meier.

We were intended to be pretty intimately familiar with all the measures in order to be able to vote at this level of detail. So, you know, had I known that perhaps, and we had enough time to do that, then this might have been a reasonable request. But I don't want to vote in any direction on something I haven't read other than, you know, on this level of detail. We have to trust each other and the work. Otherwise, we should all be reviewing everything.
DR. NIEDERT: This is Kathleen.

That is exactly, that was my point to begin with. I think that all of us in this room are either researchers or have done research. Most of us in this room are PhD's and MD's, at least at the MS level. So, I think we should have had more, if you wanted us to vote on every one of these issues, usability, feasibility, scientific, then we should have had adequate time to have reviewed it.

I agree that we can go along with the two reviewers.

CO-CHAIR GIFFORD: Well, let me suggest a modification to what Lisa, I think, presented. Hear the recommendation from the two reviewers, but I think we should, and if you want to put it in the record, you can put down what they voted there, but I think the vote, ultimately, we are really voting collectively as a group on this.

I think we should have the
discussion, so we know where it is. So, clearly, it is going to be the up-or-down vote or the vote on whether this should go forward as is, should go forward with modifications, time-limited, with or without modifications, or it is not ready for primetime.

Then, use the two reviewers' comments to reflect the Committee's work of what is out there, but then not go through each of the votes. It is not a good use of our time, and it is not productive. We are going to spend less time actually talking about meaningful reasons why we have concerns. I think that would be a more meaningful way.

So, I mean, what I would say, then, on this, for this measure, is that we had a lot of similar discussions before, I think as Bruce said, and there is some disagreement about usability and feasibility, which we may want to hear a little bit more about. But let's sort of take their two comments. They can go in, but let's really
I have a broader up-or-down vote on the measure itself because, in essence, that is where, when I tried to break it out before, you all thought we had voted on the whole thing anyway. So, I think it makes more sense to move in that way. That would be more productive use of our time.

I see a lot of head-nodding.
Okay.

Janet can call me and say ban me from NQF after this.

MS. PACE: I think as long as we get specific comments about the criteria, as you have been doing, as you have been going through, that we can put that together.

CO-CHAIR MUELLER: So, it may be useful -- between Betty and Bruce, you just had some discrepancy in usability and feasibility that I think we should sort out a bit.

MR. BOISSONNAULT: With the exception of the fact that I am a definitive
no overall, what I submitted, I don't know if
that is acceptable, but what I submitted on
the measure in writing stands.

I'm looking at Karen because I
think there's a process here. We are all
learning.

MS. PACE: Right, and we are, too.
With every project, we learn something new.

MR. BOISSONNAULT: I mean, do you
want me to list them off again because I
have comments on all four?

MS. PACE: No, I don't think that.
I think the question is that you thought it
was --

MR. BOISSONNAULT: I thought it
was 2 and 3.

MS. PACE: -- completely usable
and --

MR. BOISSONNAULT: Excuse me.
Completely feasible, completely important, but
scientific acceptability and usability
especially, period, those two were much more
problematic.

CO-CHAIR MUELLER: Okay. I'm sorry, I misunderstood. I thought you had said complete for usability.

MR. BOISSONNAULT: Well --

CO-CHAIR MUELLER: So, the discrepancy is just feasibility.

MR. BOISSONNAULT: Scientific acceptability and usability, I am going to say I had concerns about that were very specific.

CO-CHAIR GIFFORD: Bruce, I'm going to hold you to the same standard I do with my son. I reserve the right to change my opinion at any time. So, you feel free to change your opinion on that.

MR. BOISSONNAULT: By the way, I know what you are referencing, and you are correct, but as far as my remarks that I have made through this, scientific acceptability and usability are the issues for me.

CO-CHAIR GIFFORD: So, the measure overall would be --
MR. BOISSONNAULT: I recommend no.

CO-CHAIR GIFFORD: You recommend no.

Betty?

MS. FRANDSEN: I recommend no.

CO-CHAIR GIFFORD: So, overall recommendation is no.

Any discussion on that?

(No response.)

In favor? In favor of no?

(Show of hands.)

In favor of the vote before us, double negative.

Any abstaining?

Any against?

Okay. The next measure then, pain measures. RTI is going to give an overall of the pain measures.

Well, amongst the primary and secondary reviewers, are there any of these measures, short- or long-term -- some of you came up to me during the break that we should
bundle together and talk about and maybe
discuss together. I know that there's been a
lot of talk about the immunization measures,
to do long- and short-term together, each one,
because of the similarity and the nature of
it.

You would actually recommend all
of these be done together? Concerns are going
to be identical, okay.

Any other primary reviewers on the
pain measures agree with that, bundle them all
together? Okay. Are you guys the only two
primary and secondary reviewers on all the
pain measures? No one else doing any? You
didn't share the pain? Okay.

Go ahead. RTI, are you going to
give a quick overview of them? Okay.

MS. CONSTANTINE: I will be giving
an overview on the group of the measures, so
both pain and pressure ulcers. Also, I will
try to limit my discussion of importance and
cut to the chase, in the interest of time and
what Dr. Gifford had to say.

In regards to these measures, the purpose of the pain measures specifically is to monitor and report on the percentage of both the long-stay and short-stay residents who have moderate to severe pain, and the new measure we are introducing to report the percent of short-stay residents with effective pain management.

In regards to importance, you know, the evidence definitely suggests that pain is consistently undertreated in nursing facilities, especially with residents with cognitive impairment. At least 40 to as many as 85 percent of nursing facility residents have persistent pain, and pain is often not fully documented.

In regards to the Omnibus Budget Reconciliation Act of 1987, the mandate was to promote maximum practicable functioning among residents and, hence, pain and pain management is very important.
Also, the Advancing Excellence in America's Nursing Homes has made management of residents' pain one of its major goals, and both of the pain severity measures are currently included in CMS's publicly-reported quality measures for the five-star system.

In regards to validity, Dr. Saliba and colleagues, in their testing of the development of the 3.0, the kappa from gold standard to facility nurses was high, .96, and gold standard to gold standard nurse, again high, .96, and nurses participating in the study, 88 percent reported that the new items underlying the measure provided better capturing of pain.

Essentially, what has changed from the MDS 2.0 for 3.0 is that it focuses on a resident interview versus the staff assessment. Staff assessment is used only when the resident cannot be interviewed for pain.

And there was concern about, well,
what about cognitively-impaired patients? And
during the development and testing, 89 percent
of residents were able to report on their
pain, and resident pain has been shown to be
significantly more accurate than staff
assessment in determining the pain.

In regards to the pressure ulcers,
the purpose of the proposed measures is to
report the percentage of stage 2 to 3 ulcers
in nursing facilities.

DR. MEIER: Can we not do ulcers
right now?

MS. CONSTANTINE: Oh, okay.

DR. MEIER: Because we are doing
pain.

MS. CONSTANTINE: Oh, sure.

DR. MEIER: So, I think this may
be more content than we should have while we
are talking about pain.

MS. CONSTANTINE: Oh, okay.

DR. MEIER: Is that okay?

MS. CONSTANTINE: Yes.
CO-CHAIR GIFFORD: Yes, we're just doing the pain, 9, 10, and 11. Yes, we will come back to do the pressure ulcers.

MS. CONSTANTINE: Oh, that is fine.

CO-CHAIR MUELLER: Okay, so our primary reviewers?

CO-CHAIR GIFFORD: Actually, you guys flipflop on the different ones. So, you are primary in some. Diane, I think you are primary on 10, or no, on 9, and you are secondary on 10, and you are primary on 11.

DR. MEIER: So, just to frame this, there's three measures. One looks at, basically, short-stay patients, meaning the rehab, the subacute rehab population, and assesses whether there has been improvement or a reduction in either frequency or severity of pain from a baseline measure.

The other two look at an absolute measure percentage with certain level of severity or a certain frequency. So, it is
numerator, under all residents eligible,
numerator with pain that exceeds a certain
threshold, either in terms of severity or
frequency. So, it is not a change measure.
It is an absolute measure.

Then, one of those two absolute
measures is in a short-stay resident
population, and the other is in a long-stay,
long-term care, non-rehab, resident
population.

Would that be accurate?

MS. CONSTANTINE: That is correct.

DR. MEIER: Okay. So, the one we
are talking about now is the short-stay
effective pain management. So, this is
actually put in a positive, in response to
Bill's comments of earlier. And "effective"
means that there's been an improvement from a
baseline.

If we could go to the denominator
and numerator statement, okay, so there's
limitations by power. In other words, if
there are fewer than 20 eligible residents in
the facility, this measure is not publicly
reported. The reasons for that were discussed
earlier, and that makes sense.

So, you are up at numerator. So,
the numerator is the number of short-stay
residents with a 14-day assessment or
discharge assessment who can self-report --
so, this is MDS 3.0 -- and who are on a
scheduled pain medication, reporting a
predefined reduction in pain when compared to
the prior assessment.

Okay. So, first of all, it
excludes people who are not on a scheduled
analgesic, who may well have significant pain.
So, I don't understand that particular
criterion.

And secondly, it is MDS 3.0 self-
report, where we don't have correlations or a
clear comparison in terms of the correlation
between 2.0 and 3.0. Because it is self-
report and because these are residents with,
if not dementia, other reasons for cognitive impairment, such as pain, such as exhaustion, such as delirium, such as transfer trauma, we really don't know.

What we are given here, we have no assessment of level of cognition in the validation sample. It just says, you know, 900 or "X" thousand nursing home residents with no way to know what their cognition was.

So, given that this is nursing home residents we are talking about, who by definition are very frail and vulnerable, whether they are short-stay or long-stay, not knowing the cognitive status of the subjects in whom this measure was tested is a major flaw in my view in the validation data for this.

So, it is both the issue of lack of comparative data between 2.0 and 3.0, not having a sense of either the tests or the validation sample, their cognitive levels and stratification by cognition and performance of
this measure.

Then, my third major concern from the reliability standpoint is the measure developers point out that research shows that prevalence of pain in nursing home populations ranges anywhere from 40 to 60 percent to higher of moderate to severe chronic pain. Yet, the level that we are finding on this measure averages 20 percent, and the range is 3 percent to 40 percent, suggesting that we're teaching to the test.

When people know they are going to be publicly reported, for some reason, they find less pain, and I am very, very concerned that we are not measuring what we think we are measuring. The fact that the gold standard nurse to gold standard nurse has a high correlation is not surprising. The fact that the gold standard nurse to a nurse trained by the gold standard nurse has a high correlation is not surprising.

There is no validation data on the
use of these measures in the standard environment, usual environment, with no extra training, no oversight from the gold standard nurse as compared to the gold standard nurse. So, there is no gold standard comparison.

So, I am pretty worried that we are saying to the public these are accurate measures of pain levels in nursing facilities, when, in fact, they are very likely not to be because of the public reporting and the pressure on facilities to underreport, which is overwhelming. And we have no way of measuring that.

One of the things those of us who live in New York, there was full-time ads that Nursing Home Compare took out in The New York Times comparing quality of nursing homes, and one of the things was pain levels. It was very clear to those of us who work there that the best quality nursing homes had the highest pain scores, and the nursing homes you wouldn't send anybody to had the best pain
scores.

This is the opposite of what we should be doing. You know, it is an unintended consequence, but a predictable consequence of public reporting of this stuff. I think it is having the reverse effect. That is, it is more likely that pain is not going to be identified and addressed rather than less likely.

I think we have a responsibility to at least test that hypothesis before we put forward these measures. So, those are my three primary concerns, the MDS 2.0 to 3.0, assuming that because we have variability on 2.0, we will on 3.0. Self-report versus staff identification are really different measures, particularly in such a cognitively-vulnerable population. The lack of stratification of risk adjustment by cognitive status and facility type, and the impact of public reporting on gaming are a concern with this as well as the other two measures.
MEMBER NAIERMAN: This is Naomi Naierman.

Diane and I have collaborated on this, and I fully concur.

The other thing that I would like to point out is that there is no crosswalk between satisfaction and pain. So, people with moderate pain may feel comfortable with it. It is a very subjective kind of measure, and if they are satisfied, then being medicated any further just to show improvement, as it were, or difference in score, may be more harmful than not.

So, I think some crosswalking between self-reporting and observation, and also with satisfaction, which of course is part of what palliative care is about, is fulfilling the patient's own goals, makes this is a very narrow, if not risky, kind of measure to really assess whether pain is there or not.

DR. MEIER: And obviously, I am
speaking both for Naomi and myself when I say
that there could be nothing more important
than the appropriate relief of suffering in
this particular part of the human population.
Obviously, this is what I do for a living, is
palliative care. So, it is distressing to say
that I don't think the technology has caught
up, the measurement technology has caught up
to the reality of improving care in the
nursing home.

But my biggest concern is not that
these measures are neutral, but that they are
actually having the reverse effect, that they
may actually be worsening quality of care
because there is such a strong incentive not
to identify pain.

MR. BOISSONNAULT: I have --
MEMBER NAIERMAN: I have one more
thing I just want to say. It was startling to
me that there was no mention here of
observational approach to pain management,
given the size of the population in nursing
homes with dementia, notwithstanding the 89 percent validity test of self-reporting among dementia patients in pain. That is very difficult to believe, quite frankly. I would like to see more studies on that, people with dementia reporting on pain.

I would imagine that at least in some cases, in certain dementia levels, there will be some crosswalking with observational approach, and there was no mention of an observational approach, and by the way, with the folks, the nursing home staff that actually spend time with the patients, not just the nurses, but the LPNs and the CNAs.

So, the crosswalking, the self-reporting, and the fact that these measures just do not really apply to people with dementia, which, of course, is most of the patients in nursing homes, most of the residents, I should say.

CO-CHAIR MUELLER: I just want to clarify this is a time-limited measure. So,
you took that into account also?

DR. MEIER: Yes, I could go on with critiques, but it assumes that there is a baseline measure, and there's nothing provided here that says what's the prevalence that somebody comes to a subacute rehab facility with a discharge from the hospital baseline measure. We don't know. My guess is not that many (a), and (b) that the nursing home has zero control over whether it gets a baseline measure from the institution from which the resident is transferred.

So, that is a big concern because it is a change measure. What are you starting with? But that was a lower level.

MR. BOISSONNAULT: Fundamentally, from a consumer perspective, I thought that the move in 2.0 to 3.0 from essentially staff assessment of pain on the part of the patient to the patient's assessment of pain, on the part of the patient, was very positive.

I will, without going point-for-
point to your comments, pain management

perception is reality, notwithstanding that it
is not more pain management or less pain
management, but the right pain management that
you want, which I think was, in essence, one
of your points.

I am sort of concerned about the
unintended consequences of not moving forward
with this, knowing that there's going to be
real problems in the beginning. And I will
give you my example.

When we first started publishing
safety measures, error measures, at hospitals,
it was some of the hospitals with the very
best reputations that had the worst results.
And after several years, we determined that
that was correct.

But we never would have done the
evaluation to find out if that was correct,
had the measures not been published. So,
notwithstanding that I think everything you
said is accurate, I am inclined to opt in
favor of not having the perverse consequences
of not moving forward, period.

DR. MEIER: Can somebody tell me
what are the consequences? I don't understand
that. What are the consequences of not moving
forward? What's the tradeoff of accepting
what we consider not really to be a
scientifically-valid and reliable measure at
this point? What happens?

MR. BOISSONNAULT: I am going to
answer, again, from a consumer's perspective,
and then defer to the Co-Chairs and the staff.

We are sort of early adopters on
the public reporting scene, and we have never
been sensational. We do hospitals, but we do
some nursing homes. We do some insurance
measures. But our thing is hospitals.

But my point is we have heard for
years that the data isn't good enough and the
methodology needs to evolve somewhat. And on
some fundamental measures, it has been our
experience that the measures don't get there
until you start using the data for that type
of measurement.

          So, if you're in The New York
Times and it is real easy for me to say, "You
know what? We're going to have to work
through the kinks," but I just think pain
management is one of the things that nursing
homes are supposed to do. They are one of the
results we are supposed to get.

          I didn't have the same sort of
visceral reaction to the fundamental flaws,
but I only saw the definition of numerator and
denominator here. So, I will stop and just
explain why I will vote how I will vote with
what I have said.

          CO-CHAIR GIFFORD: To answer your
question, what I have seen previously in work
I did with nursing home quality and the
measures is the same issue you talked about,
which is studying to the test and sort of
doing the loopholes of that. It is the same
issues, that those measures that get reported
is what they focus on.

So, whatever the measures are that are being -- any provider, whether they are important or not, that is what they will focus on. So, you will see some improvement.

Those who want to game the system will game the system and find loopholes to game the system, no matter what, whether it is chart abstraction data, whenever reporting data. I mean all of us have an experience where we go to buy something and someone hands us the stuff and says, "This is how you should vote because you're going to get called a week from now from our survey people, and if you answer bad, I'm not going to get paid."

(Laughter.)

So, I mean, I think all of us had had that at some point in purchasing something.

So, really, what it comes down to is, if you don't have any measures at all, it just doesn't get the same level of focus and
attention. So, that is the flip side to what you said.

But just because it is important, we all said it is important. If we use that as the metric, then just put all the measures through and say go with them because they're all important.

Bruce's comment earlier, though, too, is waiting for the data to be perfect means that most of the measures we will never do, and that's a good way to kill the measures in moving forward. So, we have to balance the practicality and balance everything as we go forward on it. I think that is why NQF set up the different areas to talk about that and figure that out.

I have seen measures -- this is my third different panel I have been on, nursing homes and others. I have seen some measures that have gone through that the group just held their nose, but said it's so important, we need to get the measure out there.
Again, as we have said, there is a review process, and it goes up through. One of the things that Christine and I have to do is we have to take it to the full panel and we will present all those issues. Just because we have approved or not approved doesn't mean that it may not still get through the process. I have seen measures that the Committees have put forward, they get turned down. I have seen measures that we have voted down that end up getting approved by NQF.

DR. MEIER: So, here's an even more drilled-down question: these questions are part of MDS 3.0, and they are rolling out in October with or without NQF endorsement. Is that correct?

MS. PACE: The MDS items are, yes, but not the measures.

MR. BOISSONNAULT: Not the mass, but the items.

CO-CHAIR GIFFORD: Yes, the items on the MDS are rolling out in October.
DR. MEIER: Right.

CO-CHAIR GIFFORD: Whether we endorse or not endorse, there will be other people that can take the MDS data and create their own measures and do anything else. They just can't call them an NQF measure.

DR. MEIER: So, tell me what the salience of being able to call it an NQF measure is, as opposed to everything else that is going on out there.

CO-CHAIR GIFFORD: I will defer to CMS, whether CMS would report. I mean CMS has a large cadre of MDS measures that are used for different issues. They have MDS measures that are used in the survey process. They have MDS measures that are in testing for payment-type reform. They have MDS measures that they publicly report, and they have MDS measures they use for research purposes.

I believe -- and correct me if I'm wrong -- will CMS use a publicly-reported measure that is not NQF-endorsed?
MS. PACE: Can I answer one thing, and then let CMS respond? One thing about NQF endorsement, we are considered a voluntary consensus standard-setting organization. Under the NTTA rule, the federal government is supposed to use voluntary consensus standard in lieu of newly-developed standards if they meet their needs. So, to a certain extent, CMS generally uses NQF-endorsed measures versus those that aren't, but there are reasons that they may go forward, and we can have CMS address that as well.

MS. CONSTANTINE: I just want to bring a point up about the measures, not answer for CMS in regards to endorsement. But for the pain management measure, and we probably didn't make it clear enough in the numerator statement, but we assumed that there's a prior admission assessment. So, we were looking at the admission assessment compared to either the 14-day PPS or the discharge assessment.
Then, I guess, secondly, we would be looking for time-limited endorsement with all three of the measures, knowing that even with the development testing that we need to take a look and see what the responses are coming in from validation. But our hope was that this measure was an improvement in regards to eliciting the patient's voice, which for the majority of the time can be elicited in regards to response to pain.

DR. MEIER: Again, everyone agrees this is a critically-important outcome, suffering, among the residents. There's no argument about that.

Everyone also agrees that it is much better and more valid if the report comes from the resident for those who are able to report. There's no debate about that.

The question is, are those two factors sufficient for NQF endorsement?

MS. THOMPSON: This is Darlene Thompson. I just have a couple of comments.
And I agree how important this is, but, first of all, it is making the assumption that pain medication is the only thing you're going to count for effective pain management because that is one of your key questions. I am a firm believer and personally use non-pain medication interventions for my chronic pain, and it does work. So, I think that is a flaw in and of itself.

The second thing is it is looking at, yes, there will be a baseline because the baseline will either be the resident's OBRA admission assessment or their Medicare five-day PPS assessment. Then, you are looking at either their discharge assessment or their 14-day.

What that means is that any short-stay patient, which we have earlier recognized as anybody who lives in a building under 100 days, after day 14 you're on your own; we don't care because you're not being covered in the short-stay measure and you're not being
covered in the long-stay measure. So, you just drop that big group of residents whose pain management improvement may occur after day 14.

If you have a resident come into the facility, they may not be starting therapy by the time you do your five-day PPS MDS assessment. But once they start therapy, depending upon what they are having therapy on, you are going to see either the intensity of that pain go up or the frequency go up. And there's no allocation in that.

When you look at the second measure, short-stay measure, of going from moderate to severe, what I don't understand is why someone didn't sit there and look at, for your short-stay resident, is there effective pain management, from looking at their pain scale from their most current short-stay assessment, whatever that might be, to their prior one? And look at it throughout the continuum of that person's short stay, and not
just look at their 14-day, not just look at
whether they are on a pain medication
management system, but look at, has there been
an improvement in the intensity or frequency
of their pain during their short stay,
comparing their most current short-stay
assessment, whatever that might be, or
discharge assessment, to the prior one.

That is just my comment.

CO-CHAIR GIFFORD: Is CMS ready to
answer the question? I just don't want that
to slip through the cracks.

DR. LING: Well, I will answer a
question; I don't know if it is the question.

And it speaks to this issue of
patients and residents who have cognitive
impairment. When the measure was constructed,
and I have to admit that this is an
assumption, that by relying on J200, should
the pain assessment be conducted, that we
would, by definition, restrict pathway A,
which is the self-reported assessment, to
those who could respond. For those people who could not reliably respond, the objective nursing assessment would come into play.

So, having said that, we still are in the position of having to rely on the data that will be forthcoming, and not on the data -- because we are still talking about 3.0 implementation starting October 1. So, we acknowledge those.

DR. MEIER: So, I guess one question is, should NQF endorse a measure that actually isn't in practice yet, that we have very little on-the-ground opportunities to validate it? Is that true for all of these measures?

CO-CHAIR GIFFORD: Well, actually, for all the RTI measures that are coming forth that are paid for, the funding was paid to RTI by CMS, they are all, I believe they are all coming in as time-limited, right, the MDS 3.0 measures? Is that correct?

So, unless we thought they were so
great, we could up it, but the request from
the measure developers that they be time-
limited is mainly because they test it with
the 3.0 coming forward.

DR. MEIER: Then, the other
question for CMS was the likelihood that you
will continue with public reporting of
measures that are not NQF-endorsed.

MS. TOBIN: As far as the ones
that are going to be tested with 3.0, those
aren't intended to be publicly reported until
they have actually gone through the full
testing and we have those test results. And
then, we would be submitting them for full
endorsement. So, we are talking public
reporting of those really after that stage,
correct.

What will happen is we will
continue to report the 2.0 for a certain
period of time. We will implement MDS 3.0,
collect the data, test the data, and there
will be a pause in terms of public reporting.
Then, when there is sufficient data that has gone through that testing, we will resume in publicly reporting --

CO-CHAIR GIFFORD: Will you report a measure that has not been NQF-endorsed? I mean unless it has some other consensus. A measure that doesn't have consensus -- let me rephrase it -- a measure that doesn't have consensus development support, would you publicly report those measures under Nursing Home Compare?

MS. TOBIN: We would bring it back to CMS and have an internal discussion of where we would want to go with that --

CO-CHAIR GIFFORD: Okay.

MS. TOBIN: -- if that were the case, and for what purpose we might use it, whether it is for the research. I can't say definitely yes or no.

CO-CHAIR GIFFORD: Okay. Yes, I know in Rhode Island and several other states you are seeing more and more in the statutes
for public reporting that they have to be NQF
or consensus or similar to just the language
CMS has.

We are a small, little State, so
it doesn't really matter a great deal. But if
we don't have an NQF-endorsed measure, we
can't report it. That is sort of the position
we have taken in the State.

MS. SCOTT: Dave, may I make a
follow-up comment? I want to make a comment
specifically about the staffing measures.

You know, we are being
legislatively mandated to report certain
staffing measures. They are going to go
without NQF endorsement, if they have to,
because we've got a timeline and a legislative
mandate.

I guess I also wanted to say, and
this is not publicly reported, but we will
continue to use in the survey process the
measures that will be useful for the survey
process, which are very different than the
kinds of measures you would publicly report.

MEMBER NAIERMAN: I have a clarification question. If we endorse this today, and the testing is going to go on and will not be reported until it is tested, doesn't that seem a little bit in the reverse? Doesn't it seem like we ought to be reviewing this after the testing goes on between 2.0 and 3.0?

CO-CHAIR GIFFORD: Yes, time-limited approval means it will be NQF-endorsed. So, you could go forward and publicly report it, but it is time-limited, and come back.

So, if you happen to be an organization that is bound by needing to have a consensus-development process, like I won't pick on CMS -- I'll pick on the State of Rhode Island -- we would report it. Then, when the time limit expires, we wouldn't be able to report it anymore. We would stop reporting it until it got NQF endorsement again.
MEMBER NAIERMAN: Okay, but what I am hearing is that CMS is not going to report it publicly until it has been tested.

CO-CHAIR GIFFORD: Right, but they can still -- the question really is whether -- they could test it and find it, and then decide to report it without NQF endorsement or not.

MEMBER NAIERMAN: Well, if we have a time-limited, I am a little confused about the sequence. If they are not going to report it until they test it --

CO-CHAIR GIFFORD: Well, just because it is time -- there are thousands of NQF-endorsed measures that are not being publicly reported by anyone out there. So, just because we endorse it as an organization doesn't mean that CMS or the State of Rhode Island, or anyone else, is bound to have to publicly report it.

MEMBER NAIERMAN: Yes, I'm asking the reverse question. I'm asking, if, indeed,

Neal R. Gross & Co., Inc.
202-234-4433
it is not going to be reported until it is tested, and we endorse it today, then it is not going to be reported anyway until it is tested. And why can't we look at the testing once it is done?

DR. MEIER: What is the salience of NQF endorsement or not?

MR. BOISSONNAULT: Does it allow them to move from the 2.0 data that we know has the fundamental flaw to the test 2003 data? Is that why you submitted it? Because I have a totally different question, but I didn't understand why you said what you said. Do you want this approved?

MS. GAGE: Yes. And, in fact, the concern about the prior testing, this has been --

MR. BOISSONNAULT: Hold it. CMS should answer that question, not RTI, right?

(Laughter.)

DR. LING: Yes, it would be ideal if we could at least get the time-limited
endorsement. But at the same time, we are very interested in your feedback and your input. So, that was part of the reason, although maybe interpreted as premature, to start the process.

DR. MEIER: But could you say why you want NQF endorsement at this stage? What difference will it make for you, for CMS? Could you explain that to me?

DR. LING: That's a really good question.

(Laughter.)

DR. MEIER: Because NQF does have a reputation to protect --

DR. LING: Yes.

DR. MEIER: -- in terms of the validity and reliability of the measures that we endorse, I would think. And therefore, I think that it is clear that MDS 3.0 is going to roll out, and CMS will report, frankly, what it decides to report.

But if NQF leans too far in the
other direction of saying this is very important, we want to hold their feet to the fire, so we are going to endorse the measure, despite all of the lack of validation and reliability studies that everyone would agree scientifically really ought to be required, I think there is a serious risk of losing that bully pulpit in terms of the rigor and quality of the measures.

That is not to say these are not important things to address. We all agree they are all really important to address. But is that really our role, is to highlight things that are important to address or is it to really assess the validity of the measures?

MR. BOISSONNAULT: Diane, I don't think everyone agrees that it isn't ready enough for a 12-month endorsement. I think that is premature.

I have a question, though, of the technical person. Is that you?

And I apologize I'm not looking at
the full definitions. "Percent of short-stay residents" -- this is 009 -- "who are on a scheduled pain medication regimen at admission and" -- all in caps -- "who report lower levels of pain."

So, I think if this is done one way, what that would mean is we have given you a script, and has it helped? Is that what this measures? Because if it does, then I am all for it. But if it doesn't, then I don't know what it means.

In other words, there was a comment before that sometimes what we try to do is deliver pain management without medicine. I think that is irrelevant to this measure. I think this is, hey, we're giving out the scripts. Are they doing any good or are we just passing out pills for the fun of it?

Is that what you are trying to get at here?

MS. CONSTANTINE: The focus of the
measure, when we discussed it at the last Technical Expert Panel, was looking at this particular population, the short-stay population, and taking a look at, on admission, their pain level. As you said, they are giving a script. Then, at either the 14-day or at discharge, being able to say that their pain has been reduced since, as you mentioned, being on a prescribed pain medication.

MR. BOISSONNAULT: Well, if not, take them off. But my question is, does the numerator require that the center, that the provider will have given the script or in some way is that a change? Because if you are just saying, hey, how many people are on pain medication, and it went down even though we didn't change anything, is that noise in there?

In other words, do you have some patients who have been on a pain medication for a year come in, you say, "Yes, you're on
a pain medication," and 14 days later you do
the assessment and nothing has changed? Well,
of course, nothing has changed because nothing
has changed. They are on the same medication.

Is that noise going through this
measure? I should ask you, Diane.

DR. MEIER: The issue here is that
there are many things that cause pain to go
down 14 days or a month after admission to a
subacute rehab. Most importantly, it is
healing of whatever the acute injury was; it
is time. That has much more salience than
Tylenol or morphine or anything else you give,
as well as things like them starting to feel
safe in the environment and feeling well-
cared-for and having the appropriate type of
wheelchair and cushioning devices.

So, you can't separate those
things out. That is the problem. That is why
I have concerns about the denominator
requirement.

MR. BOISSONNAULT: Right, but this
seems to be -- is this the reverse of that?
Because is this, hey, we gave them pain
edication and two weeks later nothing got
better, so maybe we should get them off of the
pain medication?

MS. CONSTANTINE: Yes.

MR. BOISSONNAULT: I mean, is this
is an overuse measure? Because that would
imply that the only people in the numerator
and denominator are people for whom the
medication is new. If this is people for whom
the medication is -- I don't mean new at an
admission, but new at cause. So, if it is a
fall or something like that, that the primary
care doctor gave them the script three days
before they got there or something. Is that
what you are trying to measure, is essentially
some measure of, gee, we're giving these out
and it's not working?

MS. CONSTANTINE: Yes.

MR. BOISSONNAULT: See, actually,
what's the issue with that?
DR. MEIER: You asked a good question, but it is certainly not clear in the specifications that that is what it is about.

MR. BOISSONNAULT: All I am looking at is the little summary thing. But if that is it, I'm still a believer.

DR. MODAWAL: The issue was really subreporting of pain, you know, the person seeking medications, you know. I think we all agree that pain is important and medication needs to be used. But the issue is whether they should go away from the professional assessment to the patient satisfaction and patients seeking the medication.

Isn't that the main of your question? I thought the first question, the description, is this is the one? You know, that is the main issue really, that we are empowering the patients to be reporting the pain and asking for medications.

Then, if that is so, the two issues are safety because of the professional
judgment, how much to give. I know certain populations really, no matter what you do, will be asking for medication or will overreport their pain as well. There is variation in the nursing homes as well in terms of the mix of the patient populations.

So, if that is the consideration, then, certainly, it can be tested and then assessed later on, that this is a new measure which is basically empowering the patient population to really report their pain and ask. Otherwise, we are doing everything professionally.

You know, every time these are all mandated, it is a vital sign, the first vital signs. They say the pain is reported, and now the measure is that five hours after the pain tablets are given gain is reported. All that is there. It is just removal of the emphasis from professionals to the patient. Is that the intention of this thing?

MS. CONSTANTINE: The intent of
the measure, when we discussed it during the TEP, we wanted to focus on a positive measure for the short stay. And given that they come from post-acute with a lot of the quality measures, your concern is, oh, is it something that, for lack of a better word, you are being dinged for that is actually something that the patient has come with, say an infection or something like that from the acute care facility?

This was an attempt in discussions during the TEP to say, well, if the patient comes in -- and for the short stay, many of the patients come from an acute care facility. They come in, they have an assessment. They have a pain assessment, are prescribed a medication, and then that pain has improved before they are either discharged or the 14-day assessment.

The reason for the focus, there was a lot of discussion about one assessment versus another. Why can't you go further out?
In looking at the short-stay population and their general length of stay, it was to give the facility credit that the pain was assessed, it was addressed, and there was improvement in the patient's pain.

MS. BERNARD: Can I add something to that from the RTI?

MS. CONSTANTINE: Sure.

MS. BERNARD: Given this discussion, I think it is very clear, as you said earlier, that this is a very important measure. The intent of this particular measure is not to address all effectiveness of pain. It is a very conservative measure in saying we know this is a very important issue. We can't measure everything that is related to this, but let's take a small subset of residents who, at the time of admission, were able to say that they had pain, and to look at 14 days later or a discharge to say, has the pain decreased?

If they said they had pain and
were started on pain medicine, was that effective? Is this enough to assess effectiveness of pain management? No. Is this a start to begin to address issues of effective pain management in long-term care facilities? Yes.

So, think of it that way, as a conservative measure to begin to address a problem that we all know is there. This is on the road towards evaluating the effectiveness of pain management, but it is not sufficient in terms of addressing all effectiveness of pain management.

CO-CHAIR GIFFORD: All right.

DR. ZOROWITZ: I'm going to talk.

CO-CHAIR GIFFORD: Yes.

DR. ZOROWITZ: Several points. First of all, I think we all recognize this is somewhat of a departure for a quality measure, and it is a first attempt at actually showing improvement on an individual basis.

Most of the quality measures are
cross-sectional measures which show how the population is doing at a given point of time. This is an early attempt to show some change and to show effectiveness on an individual basis, which I think is a good thing and I think is an important thing.

But, as we can see, there are potential flaws to it, and it has not been well-tested, which gets back to the meaning of the term "endorsement". I'm not sure that endorsement is really the proper term.

Probably, if we asked, "Do you think we should go ahead and test this, not publicly report it, but test it first, and see how it works and see if it has validity and reliability," probably we would all agree. It may not be a perfect measure, but it is a start at getting to what we really want to be measuring with appropriate pain management.

But I think the term "endorsement" is sort of throwing us off because we are not ready, I don't think anybody here is ready to
endorse it as a publicly-reported measure that
we feel confident really means something
because we don't know yet.

If I were asked, would I vote to
go ahead and say NQF says it's okay to go
start testing this, I would probably say yes.
If I were asked, do you endorse it as a
measure that should be reported to the public,
I would say no, because I don't know how it is
going to work yet.

MEMBER NAIERMAN: What's the
question?

CO-CHAIR GIFFORD: So, actually,
let me rephrase it, then, because we have to
make some stuff up as we go along here.

(Laughter.)

A small thing. NQF doesn't
develop or test measures. So, it wouldn't be
that we're testing it forward.

But I think what I hear is a
motion on the table that we vote to approve
the measure time-limited with the caveat, the
condition attached to that time-limited that it not be publicly reported until such time as sufficient reliability and validity testing is done and it comes back to NQF.

If I could summarize what you said, Bob, that would be a motion to put on the table. I mean we don't need to vote it, but I am going to put a motion on the table for a discussion. Yes, they are going to say, no, you can't do that, but I don't care.

(Laughter.)

MEMBER NAIERMAN: But may I add one more thing?

CO-CHAIR GIFFORD: That's why they picked me.

MEMBER NAIERMAN: What I want to ask is something related to another caveat that I would like to consider. Is there a way that we can know -- this isn't mentioned here -- that the self-reporting is going to be done, that we are going to stratify between those who can self-report and those who
cannot? In other words, can we add some kind of a risk or stratification aspect to it, so we are not assuming that all of the patients, residents, that are going to be included in this testing --

CO-CHAIR GIFFORD: How about if you add it in that we are recommending an endorsement of time-limited with sufficient validity and reliability testing, including the information on the cognitively-intact and not intact, people who can report and not report, understanding that?

So, rather than saying it has to be stratified and bucket them in there, we just want information understanding that.

Yes, Dede, do you want to add a third condition?

DR. ORDIN: Well, I think there's several conditions. I always find this a problem when people put the numerator before the denominator. Because when I look at the denominator, the numerator, you have to have
had a medication, right? But the denominator
is everybody.

DR. MEIER: No, I don't think so.

They're the same denominator. The denominator
is everyone who has been on the pain medicine.

DR. ORDIN: Okay, got it.

MR. BOISSONNAULT: That would be a
real problem though.

DR. ORDIN: There's another
problem. I'm glad that's not a problem
because that would be a huge problem. There's
a small problem that I think is applicable to
a lot of measures of what to do when you have
missing data. My feeling is always the
missing data people should fail. I mean not
the people --

DR. MEIER: The facility.

DR. ORDIN: Yes.

CO-CHAIR GIFFORD: So, I heard a
couple of conditions to modification before we
vote. One is it is time-limited without
reporting; that reliability and validity
testing come back, which includes the issue of being able to self-report and not self-report; what to do with missing data.

And let me add something Bruce said early on. Understanding the information of when, since this is a change measure, to Bob's point, when the measure doesn't change, but it is 1/1, some understanding because the self-report is on a 0-to-10 scale. So, if you stay at 1/1, you don't get counted in the numerator; you don't look like you improved. I think all of us might say, well, I'm 1 out of 10, 1 out of 10, and I'm on analgesia; I'm okay with that.

So, understanding that the range of 0 to 10 is not necessarily linear as we go forward in that part of the reliability testing --

DR. MEIER: I have to add to that.

CO-CHAIR GIFFORD: Yes.

DR. MEIER: And I think Mary Jane mentioned this before, as did Naomi. There
are people who would rather have their pain at
a 4 or a 5 than be on an opioid, and we don't
allow for that. And we don't allow for that.

This whole issue of measures that
start with what the resident chooses or wants
and go from there is completely lacking in
this whole measure set. But it is
particularly important in pain management
because a facility will get dinged for someone
whose pain goes from a 3 to a 5, even though
the resident may have said, "I tried that
stuff. I don't want it. I would rather live
with this level of pain." That is good
quality care, but the facility will be
punished for it. And that is a big problem
with these measures.

MR. BOISSONNAULT: Actually, if it
goes from a 3 to a 5, or just stays a 3 to a
3, I think they get equally dinged. The point
is they have said, "We want the drugs."
They've had the consult with the doctor, who
has said, "Okay, give them the morphine," and
it hasn't helped. Their pain score hasn't improved. That is the moving part here: did the pain score improve or not as a result of the intervention?

I think the only thing that needs to be really thought through is, when is the intervention? Again, if treatment is started before the patient arrives at the door, it seems to me those are the folks who should be complaining about being dinged.

To make sure I understood your point, what was the amendment that you just made? Because it was real important.

DR. ORDIN: What to do with missing data.

MR. BOISSONNAULT: And the assumption is, if there's a reward for gaming, you should try as much as you can to not have the bad news simply be eliminated by leaving it blank. I completely agree.

CO-CHAIR GIFFORD: Bob, and then Gil.
DR. ZOROWITZ: I was just going to say I think we have to be careful. There's a lot of different individual resident stories, that we talk about whether someone is going to get dinged or not, but we are not looking at individuals here. We are looking at a population.

While there are residents who prefer not to be on opioids or to be on minimal opioids and to have more pain, we don't know yet how this is going to look as an overall measure until it is tested.

Likewise, remember that to put this in context, we are looking at three measures here. We are not only looking at this measure, which is a measure of change, but we are also looking at the two prevalence measures of moderate to severe pain in short- and long-term patients, which could be high or low, depending on the facility and also depending on how well the facility manages its pain. And you have to look at the first
measure in context with those measures which
actually have been recorded now for several
years.

I think, in all candidness, this
is an experimental measure, and it should be
recognized as such until it is tested. The
other two measures I think have a little bit
more history to them. But whether it can be
gamed, whether an individual patient's choice
might ding a facility, I am not so much
worried about that.

If you document in the chart they
don't want this, this is why, they have had
informed consent, on an individual basis, the
state is not going to come in and say, "You're
not treating pain appropriately" because I
have documented that this is patient choice.

But I am more concerned about the
validity of the measure for a population. I
think it is experimental at this point.

CO-CHAIR GIFFORD: All right,
Heidi, and then we will take a vote on this
measure.

MS. GIL: Yes, just some mixed thoughts about this. Diana, when you said the great organizations, the five-star program being affected and it's not being reality, and then Bruce saying that those strong organizations were sort of pushed to dig deeper and to do better, I have seen particularly the high-end, short-term rehab organizations that are doing an exceptional job on the long-term and short-term side really struggling.

Pain is, obviously, as you all know, one of the biggest hot buttons, which is a good thing, which is good for those we serve. I think the gaming is going to go on, but I do think that we need to make certain that we look at, like you said, the timeframe. We are seeing part of the biggest problem is that patients are coming in before they come into the door, as you mentioned, Bruce, in pain because they are not being pre-medicated.
before they are leaving the hospital, as just
a simple solution.

So, there is a lot of complexity,
as we know, in all of this. But I do think
that the public reporting, as much as it pains
me to see good organizations not come out
strong, is doing its magic. It is creating
the best of organizations to go deeper with
their innovation.

CO-CHAIR GIFFORD: All right,
Darlene, 10 words or less. You said it was
short.

MS. THOMPSON: It's short, but
it's more than 10 words. I'm sorry.

I just want to make sure everybody
understands that the way that measure is
written is that it is either the frequency or
the intensity could go down, equates to
effective pain management. So, my frequency
could go down to rarely, but my intensity
could go up to horrible, and that is
considered effective pain management.
CO-CHAIR GIFFORD: Okay. Make sure that's in the notes, Suzanne, in feedback to RTI.

Okay, so we will vote on it.

DR. ORDIN: May I --

CO-CHAIR GIFFORD: No, vote on the table. No. Vote on the table because we are going to get through the day.

DR. ORDIN: This is just a question for everybody and for all the measures. How are we going to explain this to the public? Because I mean I think it is something to see it because of usability. The usability issue is something that should be addressed in the testing.

CO-CHAIR GIFFORD: So, the caveat there, so the vote on the table is time-limited without public reporting, because it is not ready for public reporting. We want to see reliability/validity testing, usability testing, understand the cognitive testing, missing data; this issue of the Darlene/Bruce
issue of the intensity, frequency, the actual amount on it.

Then, if all those are met, we still reserve the right to ask for additional validity testing. That doesn't mean you meet all those and then it gets NQF endorsement.

MEMBER NAIERMAN: So, the bottom line is we are not voting for endorsement?

CO-CHAIR GIFFORD: No, we're voting for a time-limited endorsement that is not allowed to go forward on public reporting. These guys are going to say you are creating a new category. That's fine. It may get modified as it goes up through.

I have a good feeling on how we are going to present this to whatever -- what's the Committee? -- CSAC. It seems like they're going to drop the bomb any day, but CSAC, as we go forward on the pain measures out there.

I mean you can vote against this.

The current motion that I am putting before
the group is that, if you don't support that
motion, and you want another motion, you can
vote against it. Then, it would be
actually -- not everybody wants it to go up;
it would probably go down to vote no at that
point.

MS. PACE: One thing, usually with
conditions, we first go back to the measure
developer to see if they agree to the
conditions or give a response to the
Committee. Then, you can say, again, you have
that option.

So, we would tell them what your
conditions are, and they would give a response
that you would then say yea or nay.

CO-CHAIR GIFFORD: And some
withdraw after they see the conditions, say,
no, we can't do that; it's not feasible or
anything else.

Okay. Do I need to restate the
motion on the table?

(No response.)
Okay. All in favor of the motion on the table?

(Show of hands.)

MR. BOISSONNAULT: Which is the time-limited --

CO-CHAIR GIFFORD: Time-limited, not reporting -- Bruce, you are the one who said I didn't have to mention it again.

(Laughter.)

MR. BOISSONNAULT: With the applicable conditions.

CO-CHAIR GIFFORD: Yes. Okay. Any opposed?

(Show of hands.)

One, two, three, four. Four opposed.

Any abstaining?

Okay, do the opposing people want to, just for the record, dissenting opinion?

DR. MEIER: Just to say my name?

CO-CHAIR GIFFORD: No, why you have dissenting opinion. You would vote to
say not even --

    DR. MEIER: Not ready for endorsement.

    CO-CHAIR GIFFORD: Not ready for primetime.

    DR. MEIER: Yes.

    CO-CHAIR GIFFORD: So, the four people are not ready for primetime. Okay. That is helpful to know.

The other two measures, can we knock those off quickly, so people can get a quick bathroom break, or do we need to take a bathroom break?

    All right, the other two measures.

    MEMBER NAIERMAN: This is Naomi Naierman.

    I really think the issues are very similar. They are not identical, but they are very similar.

    So, all those conditions I would apply to it, and I would make it, if I can call it a provisional endorsement, I am
willing to go that way. But I don't know what
you can call it by your rules.

MR. BOISSONNAULT: It's limited.

MEMBER NAIERMAN: Limited.

CO-CHAIR GIFFORD: It is a time-
limited that can't be publicly reported --

MEMBER NAIERMAN: Yes.

CO-CHAIR GIFFORD: -- is the
closest thing to a provisional endorsement.

MEMBER NAIERMAN: And my interest
is to move it along. I really buy into the
whole public reporting part.

The notion that the measure
developers will have a chance to actually
reexamine and even redefine this is very
encouraging to me. If it doesn't go to the
public, it means that it is going to move
along and we are going to get some benefit out
of it, as opposed to letting it go to sleep
and become dormant. So, I am encouraged by
that approach.

CO-CHAIR GIFFORD: So, the next
two measures, we are going to vote
collectively together, which is time-limited,
no reporting. We want to see
reliability/validity testing, the issue about
individuals who can and can't respond, missing
data. They are not change measures, so we are
not going to look at the change measures, but
I do think we want to know about the intensity
of measures because they do vary. Well, one
already takes in intensity concept. And we
reserve the right to ask for additional things
in the future. It is not blanket endorsement,
once they are all met.

DR. MEIER: There's just one
monkey wrench I want to throw into the works
here, and I actually put this into my written
comments for both of my measures. That is
that, if you actually look at data, and I know
this is like challenging an article of faith,
that assessment of pain has not been
correlated with improved pain outcomes.
Several systematic reviews have looked at
this. Pain as the fifth vital sign has had no impact on pain outcomes in hospitals.

MR. BOISSONNAULT: What do you mean by pain outcomes?

DR. MEIER: Levels reported by patients. That is what we are looking at here. That is what we are looking at, and frequency or intensity, prevalence of pain.

My point is, why would we measure it if we didn't think it was actionable, right? We don't want to measure things just for the sake of measuring things. We want to measure things that are actionable.

So, that assumed link between the process and the outcome, the outcome being the patient-reported level of pain, has not been demonstrated in the scientific literature.

CO-CHAIR GIFFORD: So, are you saying there's nothing we can do, as a clinical community, to manage pain?

DR. MEIER: Well, measuring it with patients, while a component of it, the
most important thing is workforce and
education of workforce. That is, obviously,
not in our purview. But the assessment of
pain in rigorously-designed studies has not
been shown to improve pain outcomes.

    MS. PACE: But treating pain --

    DR. MEIER: Treating pain does,
but the assessment doesn't lead to treatment.
That's the problem.

    MS. PACE: But this is just, what
is the pain level? And if it is not good,
then that is what you would expect facilities
to act on.

    DR. MEIER: That is a rational,
absolutely rational assumption.

    MR. BOISSONNAULT: But this is so
basic. We are paying money and putting
patients at risk to give them these pills.
And does the patient report, self-report, that
it is better?

    DR. MEIER: Just trying to add
some of the data from the literature to the
CO-CHAIR GIFFORD: Diane, I think you are saying that the process measures haven't included outcome. This is an outcome measure. You could interpret it as a process measure, which is an assessment; this is an outcome measure. This is measuring the amount, the level of pain. Now you can say it is a bad outcome measure because it is not well-correlated, it doesn't address it, but this is an outcome measure that we have here.

DR. MEIER: But do we want outcome measures that are not actionable?

MR. BOISSONNAULT: Take them off the meds. That's the action. If there is not improvement, give them different meds or take them --

DR. ZOROWITZ: Well, I don't think the question is whether it is actionable. I think here's where I might disagree a little bit.

I think it is an actionable
outcome, but I think the interventions necessary to reduce pain require a level of knowledge and expertise that are not widely disseminated, for whatever reasons, without being too critical of providers. Not everybody knows how to manage pain and use that information in order to reduce pain.

I think for those that do have the expertise, and that is why we have a whole field of palliative medicine, and I think anybody who is a good practitioner of palliative medicine will tell you that the vast majority of those who have pain can be successfully treated.

The fact that we are not doing a job of it in many, if not most, of our facilities doesn't mean that it can't be done, nor does that mean that we shouldn't be measuring it. Because certainly if we don't measure it, they are going to have no incentive to improve care.

I think that itself is not a
reason to not measure it. I think it is not
our job to figure out how to make 15,000
facilities in this country adequately treat
pain, but I do think it is our job to
determine whether this is a valid outcome
measure that should be measured.

CO-CHAIR GIFFORD: Okay, the
motion on the table is --

MR. BOISSONNAULT: We've already
voted.

CO-CHAIR GIFFORD: You voted on
these last two? No, we haven't.

MR. BOISSONNAULT: Oh, no, not on
10 and 11.

CO-CHAIR GIFFORD: For 10 and 11,
time-limited, not ready for public reporting.
Give us more reliability/validity data with
additional caveats of understanding between
individuals who can self-report/not report,
how to treat missing data, and the different
intensities out there.

All in favor of that?
(Show of hands.)

All opposed?

(Show of hands.)

Two opposed.

Any abstaining?

The two opposing, do you want to give your dissenting, just for the record, so we understand it?

DR. MEIER: Not adequate reliability and validity testing for the measure.

CO-CHAIR GIFFORD: Okay, we will take a 10-minute break, and we'll come back and we will do pressure ulcers.

(Whereupon, the foregoing matter went off the record at 1:46 p.m. and went back on the record at 2:03 p.m.)

CO-CHAIR MUELLER: All right, thank you, everyone, for taking your seats.

We are going to get started.

We are two measures behind time schedule. So, we do need to move along.
The measures that we are going to be discussing right now have to do with pressure ulcers, both with short stay and long stay.

We will begin with an overview of the measures by the stewards. Then, we will go to the reviewers.

MS. CONSTANTINE: Okay, thank you very much. Yes, my microphone is on.

In regards to the pressure ulcer measures, the proposed measures report the percentage of stage 2 to 4 pressure ulcers in nursing facilities in both the short-stay and long-stay residents, but they do it in two different ways.

The short-stay measure reports on the percentage of pressure ulcers that are new or have not improved, and the long-stay measure reports the prevalence of pressure ulcers in the high-risk population. That is defined by patients with impaired mobility, transfers, or comatose.
Pressure ulcers, as we know, are a very serious medical condition. They are one of the most important measures in the quality of care in nursing facilities. They are high-volume and can be high-cost events across the spectrum of healthcare settings from acute hospitals to home health.

They may cause a patient discomfort and can lead to serious life-threatening infections, which substantially alter the resident's quality of life and increases the total cost of care.

Indicative of the importance of this on a national level is numerous healthcare organizations that have ongoing guideline and educational efforts. This is not an exhaustive listing, but the Joint Commission on the Accreditation of Healthcare Organizations, the Institute of Healthcare Improvement's 5 Million Lives Campaign, CDC's National Center for Health Statistics and National Nursing Home Survey, On-Time Quality
Improvement for Long-Term Care Program from AHRQ.

Also, NQF is sponsoring the National Voluntary Consensus Standards for developing a framework for measuring quality for prevention and management of pressure ulcers, and the Advancing Excellence Campaign, again, for nursing homes has this as one of the top goals.

So, obviously, this is important on a national basis as a clinical issue.

Again, the proposed items from the MDS 2.0 to 3.0 have changed significantly. Specifically, the MDS 3.0 items have utilized the definitions of the National Pressure Ulcer Advisory Board and also has the input of the Wound, Ostomy and Continence Nurses Society.

Essentially, the MDS 3.0 eliminates reverse staging, which doesn't reflect the true pathophysiology of healing of a pressure ulcer. It is based on the deepest anatomical stage. Unstageable pressure ulcers
are now a separate item.

The number of pressure ulcers that were present on admission is now collected for each stage. And again, probably most important, the definitions are now based on best practices and in accordance with the National Pressure Ulcer Advisory Board.

We heard very anecdotally that a lot of nursing facilities were actually reporting or assessing the patient based on 2.0, but then, also, utilizing the National Pressure Ulcer Advisory Panel's definition, and sort of assessing two different ways for pressure ulcers.

In regards to validity, with the development testing, the kappas were high, .92. And in terms of usability, certainly, this is one of the most important clinical issues for facilities to monitor and, hopefully, improve in terms of their rates.

Then, in regards to feasibility, again, this is a CMS-mandated data collection.
So, it is very feasible for facilities to collect this data.

CO-CHAIR MUELLER: Thank you very much.

The primary reviewer for this is Dr. Koren.

DR. KOREN: I think that this was probably one of the most comprehensively-documented of the measures that probably came before any of you. It was like really impressive to see the amount of evidence that has been accumulated over many years in support of this as a measure.

I think that we all agreed that we were going to accept the importance of it, and I think that you really highlighted that, both from a quality perspective and a cost perspective.

Looking at it, and I will just sort of reiterate a little bit what I think Roberta, if that's your name, Roberta said.

MS. CONSTANTINE: Yes.
DR. KOREN: You know, this is a very clear measure. I think that moving from MDS 2 to MDS 3 will even further clarify it because it is very difficult and there's a lot of sort of subjectivity in stage 1. So, this is now saying stage 2 to 4.

It also is something that the data shows that there's huge room for improvement. There is a huge spread in terms of performance between some facilities and others, sort of between 8 percent and 18 percent for pressure ulcers. So, there is a lot of room for improvement.

As was also mentioned, MDS 3 finally acknowledges the fact that there is no physiologic basis in reverse staging, which is a real relief. And also, one of the things they did in their sort of background lit review was there is no contradictory evidence to this. So, there is nobody out there that sort of says this is questionable or we shouldn't be looking at this.
In terms of the weakness of this particular measure, though, I should notice that at this point it is not yet harmonized with the way pressure ulcers are mentioned in other settings, although it was noted that Deb Saliba and others who developed this measure really have taken this under advisement; they are working on it. To the extent that they were able, they have started to try to utilize the same terminology and the same measurement mechanisms.

The other thing that was noted was that the pressure ulcer rate does fluctuate in a manner that appears to be independent of care. So, if you look at pressure ulcer rates, you will see seasonal variation. This also occurs with other things, such as weight loss and a couple of other clinical measures.

Usually, it is worsening in the winter months. So, one can speculate perhaps that it is related to sort of the burden of respiratory disease, or whatever. Maybe the
denominator is changing relative to the
denominator of the acuity of the population
during those periods.

And another question that I had,
and maybe somebody can explain this, is if one
comes in with the expectation that you are a
short-stay resident and you develop a pressure
ulcer, let's say, 50 days into your stay, and
you end up staying more than 100 days, are you
still counted as a short-stay person who has,
in fact, developed a pressure ulcer?

So, that was something that I was
wondering about from sort of an accounting
perspective, because you could well be tipped
over into, oh, now they're a long stay, so we
don't count that, but, in fact, they are
short-stays who have developed something. So,
I think that that is something to be looked at
a little bit.

They also noted that pressure
ulcers are not well-correlated with other
quality measures, but that is not a new
finding. We know that. Many researchers have kind of looked into that and tried to do aggregations, but it has been very difficult.

There was also a question that I had which appeared on page 15, and maybe, Roberta, you can answer this. It says, "While the variation in rate among states makes it difficult to compare facilities between states, the measure remains a valuable guide between facilities within the same state."

And I didn't understand that at all. So, that would be very helpful, if you could explain that. That is on the bottom of page 15.

MS. CONSTANTINE: Fifteen? And is that the short stay or the long stay?

DR. KOREN: That is on the short stay.

MS. CONSTANTINE: Okay.

DR. KOREN: And you don't have to answer it now, but, anyway, it was something that kind of jumped out at me.

So, if I briefly went through sort
of my voting on this, by and large, obviously,
as I said, I thought it completely answered
the question about opportunity for
improvement, that there is huge amounts of
evidence for this particular thing. What
else?

Obviously, it focuses on an
outcome, not a process measure. And let's
see, others? Maybe it would be just easier to
say that, except for that one area, that there
are a couple of not applicables. Comparable
or multiple data sources was felt to be not
applicable. I don't disagree with that.

So, generally speaking, I think
that this really, except for the harmonization
issue, I think that this pretty completely
meets the kind of criteria that you would want
to see in a measure.

I did talk briefly with Lisa, but
I will let her speak for herself on this one.

MS. TRIPP: Yes, Mary Jane and I
did speak about this. I agree with really
everything that she said.

This is an unusual situation because we know we have a better method for doing something. We know the staging method is better. And we also had, I think, a clearer issue that we are testing by eliminating stage 1.

So, we are lucky that we got this one -- because I think it is a clear winner, so to speak. I gave it completes on all four criteria, and I believe Mary Jane did as well.

CO-CHAIR MUELLER: Great. Thank you very much.

Do you want to answer some of the questions she posed before we open it up to the group?

MS. CONSTANTINE: Sure. One of your questions had to do with seasonal variation. We did discuss that in our initial TEP, but it didn't seem like there was such substantial seasonal variation. With other measures, what we have done is actually report
on the quarter and take six months of data, but that is certainly something that we could take back and consider.

DR. KOREN: We've been tracking pressure ulcer rates for Advancing Excellence. While the trendline has been going down, we do see that seasonal variation because we now have three years of data, and we see it there, too.

MS. CONSTANTINE: Sure, we could certainly do that.

And in regards to harmonization, I think everybody who has had to address pressure ulcers and has worked on assessment improvement, it is ongoing; it is almost as soon as you write something, something else might be happening in terms of a measure.

We look at what NQF had in regards to a paper coming out, and we would expect that going forward we would attempt to harmonize with anything for NQF.

DR. KOREN: One other comment I
would make is that, having been working with this particular measure on Advancing Excellence, as well as several other things, this has been an area that has been particularly resistant to improvement. So, while it is useful and helpful to count the numbers, we really have to start focusing on why it is not going down.

You know, there's been sort of marginal improvements, and it has improved a little bit in some places. But even in some states where it appeared to be improving, it has gone back up again.

Part of that, we have also tried to look at the denominator. If you track the denominator over three years, the overall denominator for acuity of nursing home residents is rising. So, part of the resistance to change may well be that we are seeing a different population than we had three years ago. As I said, we have been tracking that. But, nevertheless, it really
hasn't gone down to the extent that we know it
probably could go down.

MEMBER NAIERMAN: Can I just ask a
quick question to follow up to that? Is it
related to anything like staffing mix or
staffing patterns?

DR. KOREN: I don't have the
answer to that. I don't know.

CO-CHAIR MUELLER: Okay. There is
a study, though, by Susan Horn that looked at
the relationship between pressure ulcers and
staffing, and there was a relationship between
RN staffing, and better RN staffing is fewer
pressure ulcers.

Other comments from the Committee
or questions, issues?

(No response.)

Really?

(Laughter.)

DR. MODAWAL: Did I hear stage 2
and 4? Why not the first stage?

MS. CONSTANTINE: Oh, what about
the first stage?

DR. MODAWAL: Yes.

MS. CONSTANTINE: When we initially had our Technical Expert Panel, we asked specifically about that because there's a lot in the literature in regards to whether stage 1 is really reliable, especially assessing in darker-skinned patients. And also, we found that, in a sense, you are sort of, for lack of a better word, dinging facilities for recognizing stage 1 ulcers. Also, some of the literature, like, for example, Dr. Joanne Lynn, who has done research with pressure ulcers, has mentioned that you could almost look at a stage 1 as high-risk.

So, as we brought this to the TEP, and after discussion, it was thought the important thing was to focus on the stage 2 to 4 and let the stage 1 go in terms of reporting.

DR. MODAWAL: Well, you know, as a
quality measure, if you are looking at the impact, and we are not making much progress unless we have some NASA technology and become rate-free, the pressure ulcers will always happen. They are preventable up to a certain extent.

But I think if you are really thinking of prevention and improvement in the care overall, all stages should be included because everything starts with stage 1. And if you miss it, then it may be too late. This is similar to what happens with falls. It doesn't matter whether it is minor or major; you have to have all the processes in place.

CO-CHAIR MUELLER: Any other comments?

DR. ZOROWITZ: I would just like to add to that. I think part of the problem with stage 1's is that they can be overdiagnosed sometimes. I think there is a lot of confusion between stage 1 ulcers and candidal rashes and minor bruises. So, I
I think the reliability is in question.

I think this should be sufficient.

If a stage 1 is found and it is quickly treated, they are usually pretty easily reversible, if it is really a stage 1. If it becomes a stage 2, then it is going to be counted, and I think a quality measure is going to be a lot more accurate, excluding stage 1's, and I don't think including stage 1's would improve the measure that much. I think it would hurt it. So, I would agree with the way the measure is written.

DR. SCHUMACHER: And just a comment. I am not sure the question that Dr. Koren posed about state variability was addressed. I think it related to validity. I think the point that was made in there was that there is a lot of variability from state to state. So, that when you are trying to compare a facility in one state to a facility in another state, that there might be some difficulty there, but that within the same
CO-CHAIR MUELLER: Mary Jane, has Advancing Excellence seen any variation in states?

DR. KOREN: We do. I mean, obviously, there are very high pressure ulcer states and there are very low pressure ulcer states. Some of what we are finding is that the impact of sort of a coalition of stakeholders kind of really focusing on this problem and really working on it really does seem to have an effect, but it is a very hard effect to continue and to sustain.

We saw this problem in New Jersey, for example. They had sort of come together and decided that pressure ulcers was not solely a problem of a single setting. So, they got the hospital people and the ER people and the ambulance people and home care people, and everybody together to kind of help together solve the problem, and the numbers went down. Then, the thing fell apart, and
now the numbers are going up again. So, it is
one of those things that you have to
continuously stay on top of.

MS. CONSTANTINE: I was going to
mention one thing that we saw time and time
again in the literature, is that it is the
ongoing monitoring and surveillance and the
constant sort of day-in and day-out and the
focus, an ongoing focus, which is difficult
for the facilities for sure, but so important.

CO-CHAIR MUELLER: Okay, are we
ready for --

DR. KOREN: One other comment to
make is that we assume that it is all about
pressure, but it is as much about management
of skin moisture, hydration, nutrition, a
number of other factors, even use of lift
devices in facilities. In places that are
using mechanical lifts, there's less because
they are not dragging people on sheets.

So, there are a lot of things that
we really need to start to think about that
could prevent these things that we are
ignoring because we think it is all about
pressure.

CO-CHAIR MUELLER: Very good
point.

Are we ready for a vote?

This is a vote for endorsing a
time-limited measure, which means it has not
been tested because it is based on the 3.0,
and that it satisfies most of the evaluation
criteria. I think our reviewers have
essentially said it satisfies all the
criteria, except for the harmonization.

So, given that, all those in favor
of supporting this as a time-limited
endorsement, please raise your hand.

(Show of hands.)

All those no?

Abstain?

Great.

So, we'll go to the second
measure. That is for the long-stay residents,
and I believe, Dr. Zorowitz, you are the lead on that.

You are okay? You've said everything you needed to say?

MS. CONSTANTINE: Yes.

CO-CHAIR MUELLER: Okay. Okay, go ahead.

DR. ZOROWITZ: I'm very fortunate because Dr. Koren has prefaced hers with many of the same remarks I would make myself.

So, this is percent of high-risk residents with pressure ulcers, long stay defined as 100 days or greater. It is already being measured in the current set of quality measures based on MDS 2.0, but has many of the problems which I think Mary Jane mentioned, such as addition of stage 1, reverse staging, et cetera, which have now been eliminated.

I think the nice thing about the MDS 3.0 is that it is consistent with NPUAP standards and with the way that most reasonable nursing homes are staging their
ulcers and identifying them. So, I do think that it is ready for primetime.

Importance, I think I don't need to say very much about. I think we would all agree that it is an extremely important measure of quality.

I do want to point out the evidence for interventions is, while accumulating, and there's a fairly extensive literature on prevention and treatment of pressure ulcers, it is not completely persuasive. There are facilities that do better jobs and there are facilities that do worst jobs, but there's still plenty of studies that show that, even with comprehensive programs to prevent and treat pressure ulcers, that they are not 100 percent preventable and they are not 100 percent curable.

But that notwithstanding, I think we would probably all agree that there is tremendous potential, based on current
literature, for improvement in treatment and management of pressure ulcers.

The guidelines that are out there, one of the more current guidelines is AMDA's guideline, are quite extensive, and there have been guidelines for many years. They are technically clinical guidelines.

I know the AMDA guideline, which is excellent, doesn't really rate the evidence that it uses for its guideline. It is based more on clinical expertise and consensus than it is on the strength of evidence. But I think that if you actually look at the literature backing it up, it is fairly strong qualitatively.

Scientific acceptability, therefore, I said was partial, but I think it is more positive than negative. Complete I think would require that there really be rigorous, double-blind randomized studies that we could point to that say, yes, this is preventable and this is treatable 100 percent,
but we don't quite have that yet.

One question I had was that the high-risk population, now I guess we are doing away with the percent of low-risk residents because of a variety of issues. This is high-risk residents, which are defined as those who are comatose, impaired in-bed mobility, or transfer or suffering from malnutrition. That has been fairly well validated in MDS 2.0.

But I don't know whether that has been correlated with the Braden or the Norton scales or other commonly-used scales of risk.

And the issue that both Kathleen and I had when we looked at this is that malnutrition is not defined in this except to say that if it is listed as a diagnosis on the MDS, and to the best of our knowledge, it is rarely used as a definition. It is rarely listed as a diagnosis. So, I don't know how good that is going to be as an indicator of a high-risk population.

I should point out, also, that
there is an item on the MDS 3.0 asking whether a risk assessment has been done, yes or no. That doesn't come into play at all with identifying patients at risk, which I found a little bit surprising. Well, maybe not surprising because it hasn't been tested, but that is something that probably ought to be tested going forward.

So far as usability, I think we agreed that this met the criteria completely. I think this meets the standard of identification and classification of pressure ulcers. There's nothing in the MDS 3.0 that shouldn't be consistent with the way most facilities should be identifying pressure ulcers now. And feasibility we also felt was complete.

We did have one concern, and this I think is also true of the current system, that residents who are admitted with very large, very bad stage 4 ulcers, which may not be expected to heal within 100 days, are going
to end up counted in this number. So, I think that is a weakness of this. How much that is going to impact, I don't know, but that is a weakness. I didn't see a mechanism for excluding such ulcers on admission. That is not in the exclusion criteria.

All that having been said, though, let me go to my other comments. I think I pretty much covered everything.

Strengths, we said that the data is fairly easy to collect since it is part of the usual assessment of patients. Weaknesses, MDS 3.0 hasn't been rolled out yet. It is still unclear whether there will be discrepancies in completion of the skin care items, but that is common with all of these measures that are going to be based on 3.0.

Having said all that, we decided that we would recommend the measure for endorsement.

CO-CHAIR MUELLER: Kathleen, anything to add?
DR. NIEDERT: No, I think our main concern is those people that are on end-of-life process that come in that have come in with stage 4's and, yet, we are going to get dinged on that, even though there's probably nothing that we are going to do about it.

Obviously, being a dietician originally in my career, the malnutrition issue was extremely a high impact because of anemia and all of the things. You know, people always assume malnutrition means essentially sarcopenia, when really obesity can be malnutrition. I think a lot of times we think of that person that is anorexic, cachectic, not the person that is a bariatric-type situation, where we really need to be watching because part of the time we can't even find the open areas, I mean sadly.

DR. ZOROWITZ: I hope in the future that there will be further study on the MDS 3.0. There are probably a number of items on the MDS 3.0 that cumulatively will give a
better indication of high risk. I think this is a fairy simplistic definition of high-risk patients, but I think it is what we have now, and I would not stop the measure for that. But I do hope that in the future perhaps it can be a little bit more precise.

DR. NIEDERT: We expand the definition.

DR. ZOROWITZ: Yes.

DR. NIEDERT: The description.

CO-CHAIR MUELLER: Thank you for the nice overview.

Any comments from the Committee or questions?

DR. ORDIN: Yes, I have a question. Would you recommend that an element be added to 3.0 to actually have a risk score or to say whatever scaling score used, you know, is there a way to add whether the person is at high risk, scores at high risk? Would that be helpful?

DR. ZOROWITZ: Well, right now
there's an element yes or no whether a risk assessment has been done, and that is really it. I think if you took -- and I'm just doing this off the top of my head -- I suspect that if you took an established, a validated risk instrument such as Braden and looked at MDS 3.0, you would probably be able to test out some of the items to see if there were correlation. But that is just off the top of my head.

That is the kind of research I would recommend going forward. But would I like to see a full risk assessment on the MDS 3.0?

DR. ORDIN: No, I wasn't suggesting that. Was the risk assessment done, yes/no? What did it show? High risk --

DR. ZOROWITZ: It doesn't. It doesn't say --

DR. ORDIN: No, but I'm saying, I mean --

DR. ZOROWITZ: Well, the question
was, was the patient at risk or not? The question is, was the patient at risk or not? And it is not stratified as to low risk, medium risk, high risk. It is just, are they at risk or not, is the way the question is worded, I believe. I don't have the MDS in front of me.

CO-CHAIR MUELLER: We'll let our comment from --

DR. NIEDERT: Well, the other issue is probably, as an administrator in a nursing home for several years, I don't know of any nursing home that is not doing a risk assessment for pressure ulcers when they first come in, whether it is the Briggs form, you know, something. We are doing something to say that that person is at risk, and using the overlays or air relief mattresses, or whatever. I'm not a nurse, so I can't tell you all the things that nursing uses, but I know that it is done.

DR. LING: So, your memory is
intact because item MO150, is the resident at risk of developing pressure ulcers? It is a yes or no. And the instructional guidance includes the recommendation to determine if the resident is at risk for developing a pressure ulcer.

If the medical record reveals that there's currently a stage 1 or greater pressure ulcer, scar, or bony prominence, et cetera, and review formal risk assessment tool to determine if the resident, what their risk score is, and review the components of the clinical assessment conducted for the evidence of pressure ulcer risk. So, all that is kind of rolled into and lumped into yes or no.

CO-CHAIR MUELLER: Thank you, Shari.

DR. ZOROWITZ: But I don't know how helpful that is because, as I said, it is not stratified. So, we are talking about high risk, and high risk is not identified in that question. It is just, are they at risk, yes
or no?

MR. BOISSONNAULT: As it relates to CMS, some nursing homes probably are going to have populations that are tougher. I'm really not actually interested in recommending personally a risk-adjusted rate for this, because if you know you have a patient that you need to do more for to keep them from getting a pressure ulcer, we actually would kind of hope you wouldn't say, well, they are not going to count against us anyway because we risk-adjusted them out.

If at some point we can identify who is absolutely going to get them or who has a 90 percent chance, I would love to say, you know, this person is over 400 pounds or their BMI is 72, or something, and therefore, we are going to throw them out of the sample. But I think risk adjustment of this measure might be risk adjusting away something we would actually like the staffs to do.

DR. ZOROWITZ: And I don't think
it is possible. I think there are places that
have very high-risk residents that don't get
pressure ulcers. Even within a facility,
there are high-risk residents that are free of
pressure ulcers and high-risk residents that
get them, and there are so many factors, as
Mary Jane pointed out.

We don't always know why the one
that got them got them, other than: did you
turn and position them? Were they on a
pressure-reducing mattress? How's their
nutrition, hydration? We could look at all
that, but sometimes we just don't know. I
don't think the science is at the point where
we can predict with any accuracy someone is
definitely going to get them or someone is
definitely not going to get them.

CO-CHAIR MUELLER: I remember at
the end of our agenda tomorrow there is a
place where we can talk about recommendations
for future research. So, we would want to
hold that thought.
Any other comments?

SISTER HEERY: I think those comments, you know, those questions, are they at risk, or just to stop and point out that you should be care planning at that point. I don't think it is to pull it all together. It is just a pointer that you need to stop as a clinician and look deeper. So, I think that is what the MDS 3 is intending on those questions.

CO-CHAIR MUELLER: Lisa?

MS. TRIPP: Yes, I was just wondering, what is the rationale for limiting this to high-risk residents only?

MS. CONSTANTINE: Well, initially, there were two reported measures, both the high- and the low-risk. When we addressed it with the TEP, the low-risk, the mean was 2.3 percent. I think it was based on 2007 data, and the standard deviation was 2.8 percent. At the 50th percentile, it was like 1.9 percent was the triggering rate, and for
facilities that had zero percent, it was like about 40 percent.

MS. TRIPP: If you had to translate that into a different type of speak, what would you be saying?

(Laughter.)

MS. CONSTANTINE: I'm sorry.

MS. TRIPP: That's okay.

MS. CONSTANTINE: Essentially, in regards to the reportability of the measure and how usable it would be, for low-risk patients it was, you know, really in terms of measurement, not enough facilities could even report their low risk. So, henceforth, the focus on the high-risk patients.

MS. TRIPP: Okay, thank you.

DR. ZOROWITZ: I believe it will still remain a sentinel event if a low-risk patient gets a pressure ulcer. So, the facilities aren't off the hook altogether just because the measure has gone away.

MS. CONSTANTINE: Right, but not
publicly reported.

CO-CHAIR MUELLER: Is the group ready for a vote?

Okay. Again, I would remind you, first of all, our two reviewers have indicated complete on all four criteria.

DR. ZOROWITZ: Well, partial on scientific acceptability.

CO-CHAIR MUELLER: Partial on scientific acceptability, which is one of the reasons it is recommended for time-limited endorsement. So, we would be voting on time-limited endorsement for pressure ulcers in a long-stay population.

All those in favor, please raise your hand.

(Show of hands.)

No, raise your hand.

Abstaining?

Okay, we have two. Yes.

We are supposed to take a break, but I think we did that. So, we are going to
be moving on to the immunization measures.
And just let me get my act together here. So,
that would be another representative from CMS.

And our first one is 14-10,
percent of residents who were assessed and
given seasonal influenza vaccination during
the flu season. This is for short stay.

Are you going to speak to all of
the immunization?

CO-CHAIR GIFFORD: Well, actually,
let's just do the influenza --

CO-CHAIR MUELLER: Oh, okay.

CO-CHAIR GIFFORD: -- short and
long stay together.

CO-CHAIR MUELLER: Okay.

CO-CHAIR GIFFORD: Then, we will
do pneumococcal short and long stay together.
Some of the timing issues may be the same, but
I think some of the other stuff is different.

MS. BERNARD: Yes. Some of my
comments will be very similar, but I will
begin with the influenza vaccines.
So, I'm Shula Bernard from RTI.

Good afternoon.

The two influenza vaccines, the first one is for short stay; the second one is for long stay. I think short stay and long stay has been defined extensively all throughout the day. So, I won't belabor that.

In deference to the time and Dr. Gifford's request that we not go over and over about the high impact, suffice it to say that frail elders are particularly vulnerable to complications of influenza. According to CDC, more than 200,000 people in the United States each year are hospitalized as the result of complications. Among the adults 65 and older, about 72 percent were vaccinated during the 2006-2007 influenza season, which is below the Healthy People 2010 target of 90 percent for this age group.

The MDS 2.0 data used to publicly report on influenza vaccination, the quality measure, shows that the first quarter of 2007
statewide averages for the short-stay population ranged from 57 percent to 85 percent with a 73 percent national average. So, there is variability in performance on this measure. The Nursing Home Compare, the national average for the percent of short-stay residents given influenza vaccine has increased to 82 percent.

Among the long-stay population, the range is from 76 percent to 96 percent. So, there is a difference between the short-stay and the long-stay proportions, which is an argument for us having two different measures, one for each population.

And also, the current information of the Nursing Home Compare shows the national average for the percent of long-stay residents given the influenza vaccine increasing to 90 percent. So, the public reporting of this measure, whether it is causal or not, has been associated with an increase in the adherence to vaccination.
What I would like to emphasize about this is that this measure is essentially unchanged from the MDS 2.0 going to 3.0 with an exception. The exception is that there are additions to the numerator and denominator that were done in order to harmonize the measure to the NQF vaccine measure.

So, as a result, the 3.0 will be harmonized with the MDS. So, this is a previously-endorsed measure that we think as a result of going to the 3.0 will make it more consistent with the NQF measure.

The other areas of importance, or not importance, but to consideration for this panel is the usability. These measures have a history of being used. Obviously, some of the percentages that I quoted to you showed some association with an increase in vaccination, perhaps as a result of the measure and the reporting of the measure.

The feasibility, data for the measure have been collected and will continue
to be collected in the same manner in the MDS 2.0 and MDS 3.0.

So, I will now leave you to discussion.

MS. PACE: Just one point of clarification. On the numerator component, the standard specifications indicate that those are supposed to be computed and reported separately. It looks as if, at least the way this is written up, that it is all combined into one total numerator.

MS. BERNARD: Combined for the --

MS. PACE: For the different categories. The standard specifications are that you report on those who actually received the vaccine, those who were offered and declined, and those who had medical contraindications.

But the way it looks, the way you have written up the specifications is that you are adding those all up to get one rate. That is not consistent with our standards.
MS. BERNARD: With NQF, yes.

Thank you. We will need to clarify that, to indicate that, what the harmonization is to be consistent with the NQF.

MS. PACE: Right. So that is still going to be possible. I just want to make sure because the prior nursing home measure actually did kind of lay it out that way.

CO-CHAIR GIFFORD: What we have before us in writing is not what you are going to propose then?

MS. BERNARD: No.

CO-CHAIR GIFFORD: I'm confused.

MS. BERNARD: Let me just revisit that a second while we look at it. Let me look at the definition with you and just see what your question is.

MS. PACE: Right. Okay. So, if we look at the numerator statement --

CO-CHAIR GIFFORD: That's in writing.
MS. PACE: Right. Okay.

MS. BERNARD: Okay.

CO-CHAIR GIFFORD: That is not harmonized with NQF? Is that what you are saying?

MS. PACE: Right. So, the elements are. So, those are received during the most recent, either the facility or outside the facility, the number who were offered and declined and the number who were ineligible. The only distinction is in the standard specifications we want each of those computed and reported separately.

MR. BOISSONNAULT: So, one is a separate measure, two is a separate measure, and three is a separate measure, all with the same denominator?

MS. PACE: Correct.

MR. BOISSONNAULT: Which I think is a clarification, not a change.

CO-CHAIR GIFFORD: It's like the staffing measure.
MR. BOISSONNAULT: The commas did not mean -- yes.

MS. BERNARD: Yes, that is the way that it -- so, we would need to clarify that, but it is consistent with the NQF. So, if the commas are not in the right place, they will be.

MS. PACE: Right. Let me just give you a little history about it.

MS. BERNARD: Okay.

MS. PACE: There was a lot of discussion. You know, we had lots of different immunization measures and a lot of different ways that people handled patient refusal. Some were excluding it from the denominator. Some were counting it in the numerator.

And the Steering Committee on that project said that we need to be very transparent about how these are -- and, ultimately, the thing that we are most interested in are those who are actually
getting vaccinated.

So, in order to kind of address all of the issues, so this is a harmonization and a compromise kind of thing, but to actually have those all in the numerator, but separate components. So that you could very clearly see that facilities differ on actual vaccination rates. So, you could actually see those.

MS. BERNARD: Yes, and 2 percent declined.

MS. PACE: Right. Right.

MS. BERNARD: And that's the way this is constructed.

MR. BOISSONNAULT: Just a question. In the NQF specification that we want to harmonize or that I believe CMS wants to harmonize to, is there also a total of one plus two plus three, the overall? Okay. So, it is not one and two and three and the sum. It is just one and two and three with the exclusions and definitions tied tightly to the
NQF definition that already exists.

MS. PACE: Right.

MR. BOISSONNAULT: Okay.

MS. BERNARD: And there's a separate ratio relative to the denominator, which is everyone in a facility, one denominator.

DR. ORDIN: So, I have a question about the NQF consensus recommendations. I mean I know it says you need the three, but is it wrong to add them up? Because, in the end, you really want to know -- I mean, first of all, I always want to shine a light on refusals because we look at this in the VA, and if you don't, the number of refusals go up and they get hidden when they are subtracted from the denominator. So, I think it is really important to have those three.

But for looking at the website and understanding this for the public, I think it is very helpful to have what proportion of the time was the right thing done, whether that is
appropriately not giving it or appropriately giving it.

So, are you not allowed to report it?

MS. PACE: The standard specifications actually do say computed and reported separately and not to be totaled. Because once you total, you start obscuring those things. Discussion at the Steering Committee for that project was that the whole category of patient refusal is a very fuzzy area and practices around that are quite fuzzy on what's counted as a refusal versus -- you know.

So, anyway, they really felt pretty strongly that they needed to be computed and reported separately. This gets into the area of what control NQF has over once measures get out there, but that is how the specifications are, that that is the recommendation.

And if you can't do all of those,
because, for example, claims-based measures
don't know the refusals, then the main thing
is that that element of patient vaccination
actually is consistent. So, at least you can
report that component. That was the thinking
of that Committee.

CO-CHAIR MUELLER: Bruce, you are
the primary reviewer on this. So, would you
like to proceed?

MR. BOISSONNAULT: I gave the
measure all completes. I have just a couple
of remarks.

By the way, I would modify it with
the proviso that was just described, that it
actually be reported in a way that is in
harmony with existing NQF measures, but I
think that is a clarification, not a change.
So, that is sort of for the record.

Interestingly, Diana said
something that I am going to say here. In my
notes, I said there's an opportunity for
gaming. Why exclude the case if it is blank?
I like what we concluded before, which is, in the absence of any underlying, overriding reason rewarding someone for leaving an information cell blank, it seems to me counterproductive. So, whatever mechanism that the Co-Chairs think is reasonable, I would have added that proviso.

CO-CHAIR MUELLER: Don't the guidelines say that?

MS. PACE: It is not part of the standard specification.

MR. BOISSONNAULT: In this, it says blank; it gets excluded.

MS. PACE: No, I understand. I'm just saying the NQF --

MR. BOISSONNAULT: Right, and I think where there's no a reason to do that, I had the same note.

I do have one question, having said all complete. I like the measure. This is a process measure that approaches being an outcomes measure just because of the strength
of the science. And I'm not one to say that often.

But it looks to me like the measure is going to be based on deciles or quartiles as opposed to some sort of significance testing. In my world, sometimes that leads to highlighting differences or distinctions without a difference. That is why we never rank hospitals, because hospital No. 9 is never actually statistically-significantly better than hospital No. 10. So, we always compare to the mean.

So, I don't know if as the measures developer you could talk to why you explicitly sort of excluded the notion of significance testing. That is my report.

CO-CHAIR MUELLER: Patricia, did you have anything to also add?

MS. ROSENBAUM: No, I don't think so. I agree. I agree with that, pretty much what he verbalized about that.

CO-CHAIR MUELLER: Go ahead, Bill.
MR. KUBAT: Yes, just a comment.

Bill Kubat.

Maybe Bruce or Trish can help me with this one. I am supportive of it as well, but it always struck me, even when it came around the first time, and what I see in the documentation seems to bear this out. They talk about guarded validity. It is almost as much more of a public health interest measure than it is a quality improvement measure. It has always been a struggle in terms of facilities and for the public.

The extent to which the measure differentiates good and poor facilities, good and poor care processes, and so forth, and how that reflects in terms of the scientific methodology and the usefulness, because one of the things that we do also with the usefulness is, well, it is already out there. I mean it is already on the Compare website now. CMS wants us to use it for quality improvement. So, therefore, it is useful. Well, I mean it
is grandfathered.

MR. BOISSONNAULT: Could you, because I remember seeing guarded validity, too, and I don't remember what my notes say. Do you have it in front of you by any chance, where it is? Or can you do a quick word search on "guarded"?

MR. KUBAT: It is on page 11.

MR. BOISSONNAULT: I thought "guarded" was referencing a limited piece.

MS. ROSENBAUM: It's the University of Colorado consistently gave "guarded" for a lot of these immunizations, which was a problem for me. I couldn't understand what they meant by that "guarded validity".

MR. KUBAT: It's in 2(b).

MR. BOISSONNAULT: Yes. Or "not to be"; that is the question.

(Laughter.)

MR. KUBAT: "Influenza measure for short-stay residents received a rate of
guarded for validity testing."

MR. BOISSONNAULT: The word "guarded" is circled.

MS. GAGE: It had a level of statistical significance that was a borderline. So, they didn't want to go so far as to say always consistent was statistically-significant, but it was within the area that it was considered strong. But that is why it was identified as guarded.

CO-CHAIR GIFFORD: What metric are they using? It is not U.S. Preventive Task Force. I mean somehow they have "guarded" in quotes. It is some metric of --

MS. GAGE: They had tested the --

CO-CHAIR GIFFORD: No, I'm saying, what metric they used?

MS. BERNARD: They didn't use U.S. Prevention Task Force.

CO-CHAIR GIFFORD: They just created their own rating metric? "Guarded" is their own rating metric?
MS. GAGE: Yes, it is.

CO-CHAIR GIFFORD: Do we know what that metric range is? Is "guarded" at the bottom? Is it at the top? Is it in the middle?

CO-CHAIR MUELLER: Be sure you are using a microphone.

MS. GAGE: Oh, sorry.

CO-CHAIR GIFFORD: Yes, can you guys use a microphone?

MS. GAGE: The expectation was --

CO-CHAIR GIFFORD: The microphone.

MR. KUBAT: And while she is getting to the microphone, just from a simplistic standpoint, the issue or the question to me is, what is this supposed to mean? Or what kind of useful information is it to provide the consumer that helps to differentiate? That's the whole question, not to say that it doesn't, but when I see the word "guarded", and so forth, public health interest is legitimate, but it is different
CO-CHAIR GIFFORD: Before we get attached to this word, it is in quotes. Colorado made up some metric, like the U.S. Preventive grading of A, B, C, D. I just don't know what "guarded" is. "Guarded" could be like the second from the top and the best thing or it could be at the bottom and it could be the worse thing. I just want to know what Colorado says for "guarded" before we jump all over "guarded". We are jumping over a word. We are interpreting a word that is in quotes, and I just want to know what Colorado's metric is; that's all.

MR. BOISSONNAULT: And what aspects of validity and reliability were guarded because it is not the whole topic.

CO-CHAIR GIFFORD: I mean, if it is guarded because it was .049 -- if they wanted to be under .05, then who cares? If it was because it was .9 --

MS. GALLAGHER: The issue was the
variability across the country. So, in the
analysis they did of the influenza
immunization measure for short-stay residents,
the measure was well-correlated with other
immunization QMs. So, they were looking at
how highly correlated it was to other
acceptable immunization QMs. But it was not
related to any other measure of nursing home
quality.

In addition, the measure showed
substantial geographic variation, which may
suggest that the performance was influenced by
factors other than facility quality. So, they weren't ready to go out and say, yes,
definitely, this is a good measure, but it did
appear to suggest that it was a good measure.

DR. ORDIN: And since we are doing
these two together, I assume that it is the
same for the long stay, right, because it has
the same guarded --

MR. BOISSONNAULT: It says for
short-stay patients.
DR. ORDIN: But for the long stay, it says the same thing, "guarded".

CO-CHAIR GIFFORD: So, it sounds like this is the first measure that actually someone tested to see whether it was correlated with quality of all the measures we have done.

DR. ORDIN: Or at least correlated with the other measures.

CO-CHAIR GIFFORD: Yes, that's what I mean. Yes. That's what I mean. So, actually, it is some sort of criterion validity test that no one else has actually even done on any of the measures we have talked about so far.

MS. BERNARD: Or correlated with other nursing home measures. There was a time when the availability of the vaccine was in short supply. So, facilities may have tried to get the vaccine, but couldn't get the full amount of vaccine.

So, that is, I think, what he is
referring to here, is that there may be other external factors to specific facility performance that may impact on the proportion of residents receiving the vaccine that may not have to do necessarily with quality.

MS. PACE: And I will just make a comment about this because the Measure Testing Task Force is addressing some of the -- you know, we haven't given real explicit direction on what reliability and validity testing. I think, as David said, the fact that they actually have addressed this, and the correlations with other quality measures is one way of looking at it.

The fact that this is strongly related to outcomes gives it quite a bit of face validity.

The reliability statistics seem to be quite high, so I am not sure why they even mention "guarded" in relation to reliability.

MS. BERNARD: Well, the kappa statistics for actually being able to measure
this that was done by Saliba and Buchanan were .989.

MS. PACE: Right.

MS. BERNARD: It's reliability.

I'm sorry.

MS. PACE: That's reliability.

That's what I meant. The reliability, you know, the comment about "guarded" is made for both, but --

MS. BERNARD: Well, the comment about guarded, yes, I think he is referring more to validity than reliability.

DR. SCHUMACHER: Can I raise a question about the numerator as it pertains to usability? My question is I completely understand why each of those three items needs to be part of the numerator, but what I am wondering is, Nos. 2 and 3, if we are really trying to get at immunity and protection from infection, what value do Nos. 2 and 3 have on their own in terms of the way we report those to the public? Are those going to have any
meaning to people?

MS. PACE: Well, I will answer for the Committee that came up with these. Again, it is to put things in context. They really are most interested in the vaccination rate, and should someone decide to report only that component, I don't think anyone would have a complaint. But they really wanted to have those other elements done in a standardized way and to be very transparent.

So, their idea was that it provides, you know, for those that are assessing immunization status and offering, that is appropriate care. And it is a different category than actually receiving vaccination. They thought it provides useful information for people to look at where are the differences and what that relates to.

But I understand you point. All I can say is that they are most interested in the actual vaccination rate but thought those other two components provided more useful
information.

DR. ORDIN: You know, the same issue -- I'm a reviewer on the long stay. One of my recommendations to CMS is that they explore this. I mean I think they need to explore what is the best way to display and explain these data to the public.

I think that they are very useful to a facility to look at themselves in comparison to everyone else. I mean, you know, if their proportion of refusals is much higher than everyone else, everyone should be pointing their finger. I personally think everyone should be pointing their finger at them.

But I agree with you. I mean I think that should be something that we recommend to CMS, is that they look into that.

MS. ROSENBAUM: Yes, I think so, too, because that tells you something entirely different. When I looked at the numerator, my guess was they were really trying to find out
about assessment of the condition as opposed to if you have immunization or not.

But when I looked at the sample for the 3.0 MDS, it does pull that out, and you could pull that number out, if you wanted to. So, that made me happy, and I think this other makes them happy.

(Laughter.)

But I think that you are right, though, because this information can be useful for so many other things aside from just getting the immunization, as far as education, as far as family members. I know in long-term care facilities we sometimes include the families because of their resident family programs and immunize family members as well as residents.

MS. THOMPSON: Darlene Thompson.

I agree. I think all three need to be reflected, so that when somebody looks at that, they are not just looking at the number that was given without knowing the
other two. The only suggestion I have to the
reviewers, not the reviewers but the
developer, is that, under 2(a)(2), where it
talks about the numerator timeframe, with the
MDS 3.0, right now it is still that October
1st through June 30th. However, CMS has
indicated that they have left that open
because CDC may change the timeframe of the
influenza. So, they probably want to make
sure that they keep that a little bit more
flexible.

They have now removed that as a
hard stop and a skip pattern in the MDS 3.0.
So, there is a slight indication that there
might be some errors in data coming in because
right now it is a hard stop. You can't answer
it if you are outside those boundaries. Now
they will, unless the people have software
that will automatically turn it on and off,
depending upon what that influenza season is
defined by CDC.

MS. PACE: And the standard
specifications actually say it could be given prior to October 1 if the supply is available. So, in the measure, you know, the specifications that were developed by this Committee were to acknowledge that patients may have received it prior to October 1, and that would count and be very appropriate.

MS. BERNARD: However, there is some concern about giving elderly the vaccine too soon because of how long their immunization would cover them through the flu season.

CO-CHAIR GIFFORD: CDC changed that recommendation this year. Their experts did. I mean that is why we gave out the vaccine in August and September to the elderly. The seasonal this year, they said was a theoretical thing that everyone sort of talked about, and actually, when push came to shove, they said, no, the evidence doesn't support it.

MS. ROSENBAUM: I think part of
that is that it takes a couple of weeks to build the immunization. Of course, with all that was going on in the past year with the H1N1, and so forth, they felt getting that seasonal immunity in quickly would help. I think that it lasts about a year or so. Plus, the next year's strains are going to be different from this year's strains.

CO-CHAIR MUELLER: This year they were dealing with two different vaccine issues.

MS. ROSENBAUM: Right.

CO-CHAIR GIFFORD: Dede, you did the long term. Do you want to add anything? Is anything different for the long term?

DR. ORDIN: Yes, I would say there's one thing, and it is the issue that I brought up before.

CO-CHAIR GIFFORD: Your microphone.

DR. ORDIN: Sorry.

The denominator includes,
potentially includes people who could be there less than 100 days. So, that just has to be fixed.

The second and third parts of the denominator, which are so painful to go into, I will not go into any details, but of people who were discharged during the flu season, but came in before the flu season, and the other way around. Because you are dealing with admission and discharge, it could be less than 100 days. So, that 100-day specification should be in the denominators. It has the same problem that you mentioned, Bruce, about that should be fixed, about people who have data missing should be both, should be in the denominator and the numerator.

MS. BERNARD: Would they be captured in the short stay or are you concerned they will fall through the cracks completely?

MR. BOISSONNAULT: If all you have to do to eliminate all your bad patients is
leave a field blank, then I know what I will figure out how to do.

CO-CHAIR GIFFORD: So, when it is on the table, summarizing it, it would be a motion to approve the measure with modifications. This is not a time-limited measure.

DR. ORDIN: Can I ask one clarification?

CO-CHAIR GIFFORD: Yes.

DR. ORDIN: Because I didn't read the short-term measure. When you say, "falling through the cracks," we just want to make sure that everybody is covered, as opposed to being covered twice. So, I mean, it has to be defined as anyone less than 100 days needs to be in that short stay.

MR. BOISSONNAULT: That, too, yes. Yes, okay.

MS. PACE: The prior Steering Committee, and maybe you could address this, asked why there needs to be two measures.
Because the recommendations for immunization don't vary depending on whether you're short stay or long stay.

MS. BERNARD: Part of it is that you are dealing with two distinct populations within a nursing facility. There is variability in the percent that are being vaccinated in those two populations, as I indicated earlier. So, you are bringing together a performance on two populations and averaging them.

In this way, you can understand whether or not the problem is that the people who are coming in during the flu season or something may not be assessed adequately versus the long-stayers in a facility.

MS. PACE: So, the measure that we most recently endorsed was one measure, but could be stratified by those populations. I mean it ends up to be the same difference.

MS. BERNARD: It's the same difference, yes, whether you call it one
measure stratified or one measure for short
stay and another for long stay.

DR. ZOROWITZ: I can also tell you
that, based on my experience, the process to
vaccinate long-term residents versus short-
term residents tends to be different. Long-
term residents tend to be vaccinated within a
very short time on a regular schedule every
year. Short-term residents really require a
different mindset to make sure that there's a
standing order, an order written, and that it
is done on a regular basis. So, it can
fluctuate over the flu season, whereas the
long-term residents, there really should be no
fluctuation. So, I think it would be
problematic to try to keep them together.

CO-CHAIR GIFFORD: All right. So,
to summarize the discussion, what has been
thrown out in the pit would be a vote on
accepting the measure with three minor
modifications.

One would be that the long-
term/short-term definition be modified to make sure it captures everyone and there's no loophole in the 100-day.

No. 2 would be, and maybe this is more guidance, actually, to CMS on the MDS, which is the ability to expand or contract the timeframe, depending on what the public health recommendations are for administering the seasonal influenza. Because right now it says October, but, as we saw this last year, we all said give it earlier.

And the last would be looking at, if their data is missing, that it be counted as not being administered.

DR. ORDIN: I would say there is one more that --

CO-CHAIR GIFFORD: Okay.

DR. ORDIN: -- I think it might help CMS to have officially added. That is the usability to the public of how you portray these measures needs to be explored.

MS. BERNARD: So, and public
reporting.

CO-CHAIR GIFFORD: Helen? Within NQF, we don't have conditions or statements on how the measures can be used, do we? Because it is not just the CMS.

DR. ORDIN: Oh, no, it is through the developers.

CO-CHAIR GIFFORD: Yes, it is through developers. I mean it is some guidance, but I don't think it is a condition on the measure. I think it is in the notes and everything else.

But I would say, no, it is not a condition for voting because the whole science about how you compare is -- yes, I know where you are trying to go. I would love to go there, too, but --

DR. ORDIN: But if we include it in the recommendation --

CO-CHAIR GIFFORD: It is beyond our scope. So, I would say not accept with minor modifications that I just listed:
missing data, flexibility in timeframe, and
make sure of the denominator for the
timeframe, and harmonizing it with NQF
standards for reporting the measure, the three
new measures. Thank you.

Anyone else like to add conditions
on while we're at it?

MR. BOISSONNAULT: Did you keep in
there the second time, the thing about unless
there's some reason not to, the blank fields?

CO-CHAIR GIFFORD: Yes, blank
fields, yes, missing data.

MR. BOISSONNAULT: Should not be
excluded.

CO-CHAIR GIFFORD: Correct.

MR. BOISSONNAULT: They should be
a problem.

CO-CHAIR GIFFORD: Bank fields or
missing data, timeframe expanded beyond
October, the denominator definition,
short/long term, and the harmonization with
NQF. Those are the four conditions, except
with those four conditions. Okay?

All in favor?

(Show of hands.)

All opposed?

(No response.)

Abstaining?

(No response.)

Beautiful.

CO-CHAIR MUELLER: And we just voted on two?

CO-CHAIR GIFFORD: We voted no, both of them together, knocked off two at once.

CO-CHAIR MUELLER: Okay.

SISTER HEERY: Pneumococcal, short and long term.

MS. BERNARD: Pneumococcal. The proposed measure is, again, the same as the MDS 2.0 with the addition of harmonization with the NQF pneumococcal vaccine measure.

So, using the MDS 3.0, the numerator -- and, hopefully, it is correct this time -- measures
the number of short-stay residents whose pneumococcal vaccine is up-to-date or who were offered but declined the vaccine or who were ineligible because of medical contraindications. It is the same issue of separating it. Otherwise, it is the same measure as the current endorsed measure from the MDS 2.0.

CO-CHAIR MUELLER: Patricia, I believe you were the main reviewer on that.

MS. ROSENBAUM: Right. I am the primary reviewer. Alice Bell and Ron Schumacher are secondary.

The summary, the same issues. I am not going to go into that because we will apply the same to that.

I went through this, and I felt that it was complete for everything, except I had some questions about the scientific acceptability, but we have kind of gone over that because some of the same things that occurred -- I went over the flu, too, and some
of the same things that are in the influenza
are in the pneumococcal with the "guarded",
and so forth.

Plus, I feel like a lot of this
information was from 2006, and so forth, and
we have come a long way since then in this
respect: there's been more education, more
promotion of immunizations, and, plus, now
we're seeing hospitals and the other
healthcare systems all becoming aware and
participating. So, that is going, to me, to
create a different environment now than
existed in 2006. I don't know whether you
feel that way, but I think that 3.0 is
probably going to reflect all that.

MS. BERNARD: Among the short stay
or long stay?

MS. ROSENBAUM: I think for both.
I think for both. People are more aware now,
and they are probably documenting better. I
know in hospitals now this is included in
their admission, standardized admission orders
for pneumococcal and for influenza.

I think there was a harmonized approach as much as I can understand how that worked. I think that that has been done.

The only weakness that I was a little concerned about was the statement on getting the second vaccination. In other words, if the person did not meet the criteria coming in, if they were under 65, or whatever, that was not addressed. I have been trying to remember where I underlined that.

NQF said that they did not want to pursue that. I will just try to find the page for you.

MS. PACE: I think this was an issue of how easily you could implement that into a quality measure. So, certainly, if there's some way that it can be done, that would be fine. But in the standard specifications, the Committee at that time said that's great; we recognize that that's the guideline, but how would you actually
 operationalize that in a measure for which we have data across a lot of different settings? I mean that is from that Committee.

MS. ROSENBAUM: But the expectation would be that that would be pursued by the facility still, right?

MS. PACE: The need for --

MS. ROSENBAUM: For the second vaccination.

MS. PACE: -- the second vaccine?

MS. ROSENBAUM: Because I think that's an important issue with some people.

MS. PACE: I don't believe that that's necessarily addressed by this --

MS. ROSENBAUM: Oh, okay.

MS. PACE: -- measure, but it will be something that we will take a look at.

MS. ROSENBAUM: Yes, I think it should be looked at in light of the fact that pneumococcal pneumonia is responsible for so many deaths and illnesses. Now there is a resistant pneumococcal out there. So that you
want to make sure people are fully immunized against this. So, I think that should be looked at.

And of course, importance, I think it is very important. I'm a big proponent of immunizations. It decreases the pneumococcal pneumonia. It decreases severity of pneumonia. It decreases hospitalizations, and it contributes to the large population immunizations. And it decreases missed opportunities for giving vaccination.

The scientific acceptability, I just told you what my own problems were with some of that validity and testing. I wasn't quite sure I understood how they did it. I wonder about the quality of the information they had at that time to work with.

And the usability I think is wonderful because you can use this in facilities for educational purposes and to decrease and help with investigations like that.
And I think it can be understood by consumers, but I agree with Diana; I think there has to be a way to make it palatable to consumers, so they understand what the importance is and why they should know about that, if they are taking someone to a facility.

And the feasibility, I think that you can implement this easily and get the information you need easily.

DR. SCHUMACHER: So, I was the secondary reviewer on pneumococcal vaccination for short stay.

There was one piece that I picked up on that I thought was a little bit weaker, although overall I thought it was a good measure that met all the criteria. That was around susceptibility to inaccuracies. There were some comments here that the reliability may be stronger for the chronic care measure than the acute care measure, that there was 13 percent of the time the current pneumococcal
immunization measure was assessed differently by different assessors. So, I think there were some issues there with accuracy on the short-term vaccination.

I don't know if anyone has any comments on that.

MS. BELL: Alice Bell.

If I just might ask, because in the description of the measure it speaks to measuring up-to-date status, which would address the second vaccination as well as particularly the short-stay residents, those who might have gotten the vaccine before they were admitted to the center, so who are up-to-date, but don't have the vaccine administered in the center.

So, is the measure up-to-date status or is it administration in the facility?

MS. BERNARD: It is not administration in the facility. It is up-to-date because they are assessing. But I think
the key term here is assessing the residents for the need for the vaccine. And if there is a need for the vaccine, then they provide the vaccine.

But among the short-stay residents, there is, and especially if they are coming from an acute care setting, there is a high likelihood that they would have had the vaccine, especially when you are talking about the pneumococcal vaccine in the acute care setting.

So, obviously, you can't expect the nursing facility to provide a vaccine for someone who is already -- but if the assessment, and if there is a determination of need, be it because they have exceeded the time since the prior one or because they have never had one, that is part of the assessment of what the residents need.

So, I am sorry if I misspoke earlier.

MS. BELL: Thank you.
MS. PACE: So, in this particular data item, it probably already takes into account the need for a second vaccine as well.

MS. BERNARD: Yes, and I'm sorry I misspoke before, because it does. The assessment, the expectation is that the resident will be assessed, and if there is a need, the patient, the resident has been given the vaccine.

MS. THOMPSON: Darlene Thompson.

The facilities are going to determine if the residents' vaccine is up-to-date based on that definition in the RAI manual as to what does up-to-date mean. So, I think it is real important that CMS, they are continuing to refine their manual. They had an excellent seminar last week on the MDS 3.0. I think make that clear.

Also, not all short-stay patients coming from a hospital to a nursing center are even going to be eligible to get the pneumococcal vaccine because it is not
something you give to everybody "just because".

And also, in the manual it needs to say that, if the resident -- we get 19-year-old, 20-year-old kids coming into our facility. So, would they be considered not eligible because it is a medical contradiction or, no, because they are not old enough to get it? But "no" would make it sound like they should have had it when they shouldn't have.

So, really, that falls into that "not offered". So, I think as long as the manual is clear as to what to do in those instances, that that would be helpful in making sure that this measure is clear as well.

MS. BERNARD: Okay, that is a good point. You are talking about refining the eligibility determination.

DR. SCHUMACHER: And I think you brought up 3.0. So, it does say in here that there's more clarity around this in 3.0. And I notice that this one, at least on the short
stay -- I didn't look at long stay -- but short stay is a time-limited. So, is that because it is changed with 3.0 from 2.0 in terms of how the questions are asked? It says the changes are minor.

    MS. BERNARD: They are minor changes to the questions to clarify the way that they are being asked. Now I don't have the copy of the MDS 3.0 here.

    MS. THOMPSON: The changes are more on the influenza one. There are more selections on when it is not offered. I don't really see anything big in the pneumococcal one, but it is going to be in the definitions. That will be in the manual.

    DR. SCHUMACHER: So, why is this one marked as time-limited?

    CO-CHAIR GIFFORD: Yes, actually, I was going to suggest we override the vendors potentially, depending on how the dialog goes. I was going to see how the dialog goes, but, yes, it is a reasonable request.
I was the secondary reviewer on the long-term one. I would say the only thing I would add, and I didn't pick up on it, but it was a good pickup, which is the issue of falling through the cracks that we talked about before.

The only other thing there was that I would say that they really didn't present any, other than content validity, they didn't do any criterion or construct validity-type testing on the measure out there. But most of the stuff we have had hasn't had that out there as a quality measure overall, but, really, there is a lot of good validity testing on the link between the two. So, I wasn't too concerned about that.

And to your question, it is all residents because, generally, when somebody goes into a nursing home, it probably meets the definition of needing to get the pneumococcal vaccine. And if they don't, you know, they still benefit from getting the
vaccine anyway. So, it is so few people, it
is probably not worth the squeeze to try to
exclude them out of the measure.

MR. BOISSONNAULT: To the Co-
Chairs, as we try to harmonize, would it be
worth -- because I think all of the one, two,
three issues that we dealt with in the last
one, do they not apply here, Karen? You know,
the one, two, three issues.

MS. PACE: Yes.

MR. BOISSONNAULT: So, you are
going to rewrite them, essentially, identical,
so that the clarity that it is category 1 and
category 2 and category 3 for three different
measures with I believe the same denominator.
In other words, whatever you do on the other
one, I think you cut and paste on this one,
right?

MS. BERNARD: Yes.

MR. BOISSONNAULT: There's no
reason not to have exactly the same. Okay.

MS. BERNARD: And we will run it
by Karen to make sure that it harmonizes with
the NQF, which is the intent of this.

CO-CHAIR GIFFORD: So, on the
table, then, would be to approve the measure
with conditions. The vendor asked for time-
limited.

I guess, before we do that, why
were you asking for time-limited, not just ask
like for influenza that we just go with this
measure?

MS. BERNARD: We hadn't had the
MDS 3.0 --

MS. GAGE: Typo.

CO-CHAIR GIFFORD: Typo?

MS. GAGE: Typo.

MS. BERNARD: Yes, typo.

CO-CHAIR GIFFORD: Good answer.

Typo.

(Laughter.)

Okay. So, that the group --

MS. BERNARD: Absolutely a typo --

CO-CHAIR GIFFORD: Stop talking.
Stop talking. A typo.

(Laughter.)

So, on the table is to approve the measure with three minor conditions of modification, harmonize with NQF standards for the numerator definition, close the loophole for the short-term/long-term stay, and I am going to add in, Bruce, you may have the same thing with treating blanks is not given. The timeframe we don't have to do that, but that would be it. So, there's three conditions.

Approve with those three minor modifications. All in favor?

(Show of hands.)

All opposed?

(No response.)

Any abstaining?

(No response.)

Wonderful.

You would like to do falls? Or would you like a 10-minute break?

MEMBER NAIERMAN: Can we get an
idea of where we are in the process right now?

CO-CHAIR GIFFORD: We are 10 minutes behind schedule. We should have a break at 3:15, and it is 3:30. So, we're pretty darn close.

Do you guys want to keep going?

We'll do the falls and then we will do the break? Okay, yes.

That was both 16 and 17. We knocked off two again.

Okay, who from RTI is doing falls?

Let me ask you all, let me ask the primary, are any of these under the fall measures section? That's what I call it, the falls measures section. Are there any of these that need to be bundled together, like we are going to vote and group them together, like we just had the dialog here? Or should we sort of break them all out?

DR. MODAWAL: The two I'm primary on, No. 8 and No. 5, they can belong together and be voted together.
CO-CHAIR GIFFORD: No. 8 and No. 5?

DR. MODAWAL: Yes.

MS. CONSTANTINE: Oh, but they are two separate organizations.

CO-CHAIR GIFFORD: They are two different organizations. Oh, so we've got to do them separate, yes. Yes, we have to pick which baby we like better.

(Laughter.)

There's three organizations? We don't like the third. We're just going to pick between the two. Okay.

(Laughter.)

RTI, do you want to start with -- which? You pick. Which one do you want to go first here?

MS. CONSTANTINE: How about falls with major injury?

CO-CHAIR GIFFORD: Falls with major injury.

MS. CONSTANTINE: Hello again.
CO-CHAIR GIFFORD: Number what?

MS. CONSTANTINE: Falls with major injury is NH-008.

CO-CHAIR GIFFORD: No. 8.

MS. CONSTANTINE: No. 8. Okay.

This is a new measure that we are proposing. The purpose of the measure, it is intended to help to monitor the falls, rate of falls, with major injury. That consists of either bone fracture, joint dislocation, closed head injuries with altered consciousness, or subdural hematomas among long-stay residents occurring in nursing facilities.

It is estimated that 75 percent of nursing facility residents fall at least once a year, at twice the rate of their community counterparts.

Saliba and Buchanan tested the proposed MDS 3.0 items, assessing the prevalence of any falls or falls with major injury. Basically, the study sample included
over 4500 residents. They found that during this six-month data collection period approximately 24 percent of patients reported at least one fall since the prior assessment. And among the 24 percent who experienced a fall, 9 percent at least had one fall with major injury.

Research has shown also that falls can lead up to 50 to 65 percent of residents with fear that impacts both their social and functional activities.

The proposed measure is based on the MDS 3.0 item J19C, number of falls with major injury.

RAND examined the agreement between the facility assessors and the gold standard nurses as well as they compared the responses between the peers of gold standard nurses. The reliability of the MDS 3.0 item was substantially better than that of the analogous MDS 2.0 item, which is fell in the past 30 days.
The MDS 3.0 item, the gold standard versus facility nurse kappa, was 0.945, and the gold standard versus gold standard kappa, 0.967 for the MDS, and there was a report in 2001 by Abt. The kappa was .66. Oh, I'm sorry. The kappa was a report of .66 by John Morris and a kappa of .638 reported by Abt in 2001.

So, essentially, with the MDS 2.0 items, they had a checkoff list, check all that applies. It was fell in the past 30 days, fell in the past 31 to 181 days. The 3.0 measure has a checkoff that says, well, it addressed falls since prior assessment, and then the categories of no injury, minor injury, and then falls with major injury.

So, this is a proposed new measure to track the long-stay residents, falls with major injury.

CO-CHAIR MUELLER: Our reviewer on this?

DR. MODAWAL: Yes. I was the
primary reviewer on this.

    Certainly, of course, we agree
with the importance of the thing. In terms of
the scientific validity and reliability, I
gave it a partial. And also, the same for the
usability and feasibility.

    My secondary also agrees that,
basically, this can be recommended for
adoption, though I hope there's another typo.
It is a time-tested recommendation from the
vendor.

    However, there are a few issues
which need to be looked at. In terms of the
title itself, my personal feeling is that it
should be both minor and major because the MDS
3 actually now is categorizing injury into no
injury, minor and major. So, rather than just
major alone, it should be both minor and
major. So, that is one thing.

    The other thing is the duration of
looking back. I think it says like 12 months,
but I think some of the new guidelines,
including some of the Ackrill guidelines, memory for falls is short. So, I think it will be better if it is just the last six months, would be a good timeframe to assess, particularly if you are looking for long stay because of the nature of the problem, and this fact, there's no easy answers in terms of interventions.

Now one other thing I felt was in terms of the scientific validity, that one should look at most recent guidelines coming out, the consensus guidelines from the American Geriatric Society or the British Geriatric Society and the American Academy of Orthopedic Surgeons.

One other key things, actually, they are trying to separate is the typical geriatrics and normal falls, as we know. And in the definition, they actually are very specific. Because I was at a meeting a couple of years ago in England, and they are talking about deleting these falls which have a
history, which have a known or witnessed loss of consciousness. Because your whole line of thinking for a geriatric fall is very different if there's a loss of consciousness.

So, that needs to be looked at before we sort of recommend it fully, because the whole line of assessment and interventions is very different because of the other typical medical causes which are associated with loss of consciousness, like syncope and seizure disorders and others, which are not in the typical syndrome of geriatric fall.

So, I would say that, if those things are addressed, it will be like a category 2 recommendation with these modifications and clarifications and refining.

Darlene would like to comment, who is the second reviewer.

MS. THOMPSON: Thank you.

Under the scientific availability of the measure properties, this is one of the first ones where apparently it is going to be
looking for, according to the numerator, 12 months' worth of MDSes. So, for each resident, it is going to be able to go over anywhere from three to five to six different MDSes to look for that particular injury or major injury, which is a little bit different than what we currently usually are doing when looking at current to prior, or something, but not sitting there saying for every resident there's four to six chances that they might actually have had this injury in the last 12 months.

Secondly, just a definition of major injury, CMS did a good job last week in the training to indicate that the definition you have described is "includes", which means it is not an all-inclusive list. I don't think anybody could write down an all-inclusive list of major injuries.

So, you run into the validity of what I consider to be a major injury for a resident and what somebody else might consider
to be a major injury for a resident. So, the
coding could have some issues in and of its
own right.

The issue under the stratification
where long-stay resident facilities with fewer
than 30 residents are excluded because of the
small sample size, if we are going back a
year, in which case we are also including
discharge assessments, we need to look and see
if over the period of an entire year would a
facility not have 30 long-stay residents.
Because, currently, when we look at them, we
are not looking over the course of an entire
year and gathering a year's worth of
discharges. That is where that added that in,
adding those discharges.

I'm still in 2. One of the
biggest issues falls under this summary of
evidence supporting the exclusion where the
TEP indicated that, because a comatose
patient, due to their physiological stage,
cannot actually fall, they recommend to
exclude that population of comatose patients.

If you look at the definition of a
fall, according to how we answer the MDS, it
is an unintentional change in position coming
to rest on the ground floor or onto the next
lower surface. If I am transferring a
comatose patient and the lift is going to die,
and I am going to put them on the floor, that
is a fall. It is a fall for a non-comatose
patient. An assisted fall is a fall.

So, therefore, why if I drop a
comatose patient, it is not a fall, but if I
drop a cognitively-impaired patient who is not
comatose, it is a fall? So, there is a big
flaw in the elimination of comatose patients
just because they cannot fall on their own.

So, I agree that the scientific
specifications are partially met.

As it relates to usability, again,
I think because of the issues and the
definitions, and the fact that it hasn't been
tested because this is new, that I also
consider that to be partially met.

With regard to feasibility, we do have the electronic transmission of the MDS. So, again, the only issue is going to be if the data is going to be accurate, due to the fact that it is not a concrete definition. So, you could have a wide swing.

You are also going to find in nursing centers that, should a facility receive a citation from a state survey because they failed to identify something as a major injury in the eyes of the surveyors, you are going to see that pendulum swing where they are going to err on the side of calling more stuff major injuries than they are or others will swing the other way. So, I feel there is an issue with that as well.

MS. PACE: And feasibility --

MS. THOMPSON: Partial, yes.

DR. ORDIN: I get the feeling that you were recommending that minor injuries also be included?
DR. MODAWAL: Yes. I mean I think it should be both, one or more falls with both minor and major injury because this is a new categorization in the MDS 3, and the process was not there. Really, it makes sense, you know, in terms of delineating the two, but that doesn't mean that we should not look at the fall overall.

The minor includes abrasions and bruises and some of the soft tissue injuries, and the major is --

DR. ORDIN: Wait. But there is another, "and/or any fall-related injury that causes the resident to complain of pain."

DR. MODAWAL: The pain is not there.

DR. ORDIN: Yes, it is.

MS. THOMPSON: Yes, that is in the definition. It is in the manual.

DR. MODAWAL: It should be, then, we should have some more, we should then specify minor and major.
DR. ZOROWITZ: But Measure 005 is all documented patient falls with an injury level of minor or greater. So, that would be exactly what you are -- that is another measure.

DR. MODAWAL: That is why I wanted to --

DR. ZOROWITZ: So, you are asking that you eliminate this measure.

DR. MODAWAL: No, no. That is why we wanted to discuss it together, the different organizations, you know, who have actually proposed this. That is why we are discussing it separately.

CO-CHAIR GIFFORD: Yes. Just so you know, the process is we are going to vote, since there's two roughly competing measures, we are going to vote each measure up or down, not talking about the two measures. If they both pass, then we have discussion about voting between the two measures.

So, let's just vote right now, if
you can. Think of it that we only have one measure before us, and we are going to set this aside. Then, we are going to take, as if we have not talked about the falls before, and do another measure. So, the voting is independent of the fact that we have another measure out there.

CO-CHAIR MUELLER: So, some clarification about why the measure steward did not include minor?

MS. CONSTANTINE: Yes. During our TEP, in looking at the development of this being the new measure, again, they decided to take a more conservative approach. So, certainly falls with major injury was a step in the right direction; however, to hold off on reporting all falls with minor injuries. So, it was the thought that, with the implementation of the MDS 3.0 and gathering more data, perhaps that we would revisit it.

The reason for the 12 months, even though we would look back on the quarter, was
again given the statistics, to make sure that
we would have enough to be able to actually
report the measure at a facility level.

DR. ZOROWITZ: Let me just throw a
little monkey wrench into this. This is very
interesting, but when you look at the
literature of falls prevention, there's
nothing in the literature to suggest that it
is possible to differentiate between an
injurious and a non-injurious fall.

The goal of falls prevention is to
prevent, therefore, all falls. We cannot
focus on preventing injurious falls. So, in
essence, whether you are counting all falls,
whether you are counting minor or greater
injury falls, or whether you are counting
major injury falls, your intervention is not
going to change. Your intervention is still
going to be to prevent as many falls as you
can.

So, as we are discussing the
differences between these two, I think that is
something to keep in mind. I am not quite sure what was the point of measuring only falls with major injuries.

MR. BOISSONNAULT: I have just a question. Actually, it might be to you, Robert.

Does it seem like the data for major injury falls are going to have a different reliability perhaps than falls where no one was hurt?

DR. ZOROWITZ: Well, falls with major injury, first of all, I would expect it to be fairly small.

MR. BOISSONNAULT: I understand that.

DR. ZOROWITZ: And I don't know how that varies from state to state, from institution to institution. But I would assume it is very small. But, more importantly than that, I don't know how you affect that without preventing all falls in general anyway.
MR. BOISSONNAULT: Agreed. I am actually just wondering if the reason that the MDS 3 and this measure seemed to make a distinction is because it is kind of hard to hide a broken bone. I mean it is actually in version 3. It's there as three different categories. I hypothesize it is because the data is more reliable. When you have a broken bone, it is hard to hide that.

DR. MODAWAL: I think what Robert mentioned before was this may be the number issue because certainly the numbers of fracture and hip injury would be a lot smaller. I think that may be the reason that they thought of a 12-month period as well. If that was the thinking behind it, then really, you know, it has to be tested and it will make sense.

But I just want to say both 8 and 5 are really talking about, as you are saying, it is risk factor assessment and intervention. However, maybe 4, which is patient fall rate,
may deal with the prevention aspects. You
know, there are two parts to it as well. So,
I think both 8 and -- basically, 8 leads with
a risk assessment and intervention, I suppose,
as a measure.

MS. BELL: Alice Bell.

There is one component still,
though, where data is being collected in terms
of injurious falls as it relates to hip
fractures and things like hip protectors and
calcium and vitamin D. So, potentially,
although we don't have all that information
yet, there is potentially a distinction
between major injury specifically as it
relates to fracture and minor injury. So,
that is just one point.

MS. GAGE: That is what I was
going to add, is that, again, as you have seen
throughout the measures that we have
presented, we are trying to take a
conservative approach where there is good,
systematic information rather than subjective
definitions of things. And for a major injury, that can be defined based on the ICD-9 code. So, there is a good, solid, scientifically-based definition of that.

DR. ZOROWITZ: I am trying to think of how this is going to assist facilities in improvement efforts and what is this going to mean when publicly reported. I mean, obviously, a facility that has a higher number of major injuries is going to be looked at unfavorably by the public. No doubt about that. But I am trying to understand what these measures will actually mean to the institution and how actionable are they.

And I understand so far as the specificity of the definitions make it easier to look at major injuries versus minor injuries, and certainly looking at all injuries rather than all falls, especially if you have the low bed to floormat falls, which are still falls but planned falls. But I am trying to figure out exactly what is the point
of this measure; what will we do with it, and
how will facilities respond to it, other than
looking at facilities that are outliers, which
are problematic.

And is there any research looking
at variability among institutions with major
falls, with major injuries, and how that
relates to their total numbers of falls or
other measures?

DR. MODAWAL: There is some
evidence that the number of falls doesn't
matter. It is just ultimately it is the major
injury. I think that information on falls
will be captured in the denominator. So, even
if we are only looking at major injury, we do
have the number of falls for the facility.
So, that has to be seen in relation to the
total falls, which is creating a new specific
quality measure.

Because, as you know, there may be
underreporting or overreporting of falls in
nursing homes. Overreporting is not always
bad, as long as there's a process and plan in place. The bottom line may be just a major injury.

So, that will be a reflection.

You know, if you can look at a denominator and the major injuries, you get a fair idea of what is happening in a nursing facility.

CO-CHAIR MUELLER: We just want to clarify the denominator is all patients?

DR. MODAWAL: All falls.

CO-CHAIR MUELLER: No, all patients.

DR. MODAWAL: It is all patients.

Oh, I beg your pardon. But it should be all falls really, you know. That would be a better measure of quality as compared to all patients.

DR. NIEDERT: I agree with that because, when you are looking at falls meaning lower to the floor or any lower surface, which really to me isn't a fall, but it is a fall by definition, and the ones where you have the
low bed and they roll out of bed, and there's absolutely no injury, but yet we have to count that.

And then you have facilities that don't use any of those mechanisms that many of us use. Yet, because they do roll out of bed and we don't have them restrained with siderails, it seems like we get dinged because, if we have them restrained and they don't fall, then that's okay. But if we have them in a low bed without a restraint with a mat, and they roll out of bed, then we get dinged.

CO-CHAIR GIFFORD: So, I'm starting to hear a number of discussions like we are a fall TEP expert group trying to design our own fall measure. That, to me, is a sign that we have some concerns about the measure, since that at least the information has been presented to us about the measure. So, we may want to start thinking about how we want to formulate some vote or recommendation
on it.

I mean we are not talking about just minor modifications here. We are talking about major changes in this measure. And when we talk about major changes, then we are into the measure development process, and we weren't hired, and your bonuses won't be tied to -- designing new measures out of this group.

DR. ORDIN: I don't think this is the be-all and end-all of fall measures. I mean it probably isn't the only fall measure we need, but I think that it is a very interesting and relevant measure. If I were a facility, I would want to know if I were an outlier. If I were looking for a facility for myself, I would want to know what the falls were.

So, I think while there could be different measures, I think that there's nothing wrong with this measure.

DR. NIEDERT: But is that the
information you are really going to get? Is that the information the public is going to
to get from this measure? Or is it going to get
the number of all those low bed rollouts, all
those lowered to a lower surface?

DR. ORDIN: This is a major
injury.

MR. BOISSONNAULT: This is only a
major injury one. We talked about maybe we
should add others in, but is there ambiguity
about this measure or is there ambiguity when
we start adding things into the numerator that
aren't in this measure? Notwithstanding that
some people think we should do that, is there
ambiguity about this measure, which measures
the percentage, essentially, a rough
percentage of people who fall and are badly
harmed in ways that are easily documented?

Sorry.

MR. KUBAT: There was ambiguity
for me until, Giff, you made the qualifier in
terms of process, that you just consider this
on a standalone. At the beginning, I was thinking about, well, considering this vis-a-vis the other three that we've got. Well, that is not what we are supposed to do. That removed the ambiguity.

CO-CHAIR GIFFORD: Actually, not the other three measures. I am talking about the other fall injury measure. So, this is No. 8 and No. 5, yes.

MS. GIL: I just want to add that I worry from a quality-of-life standpoint with this one in terms of I think about the residents who you are trying to grant wishes, who really want to be live in their own room and have that ability, but also have a tragic fall because of that wish.

Knowing that at times, like Kathleen said, what would happen is organizations might go to that restraint for some reason or alarm because of that just makes me cringe a bit. So, one of my thoughts is whether or not we move to test this, but
not do the public reporting.

MR. BOISSONNAULT: I recommend we move post-haste to get a restraint measure. It's later in the agenda.

DR. MODAWAL: Yes, I concur with that. I think it can be tested as long as it is not public because it will skew the data and it may speak, as we heard before, on some very good facilities, but very bad just because they had a few fractures, you know.

CO-CHAIR GIFFORD: All right. So, what I am hearing is a wide range of opinions. The vendor has asked for, because it is a new measure and it is based on MDS with some additional reliability testing, hopefully, to come from it, that this be a measure that is time-limited.

What I heard was two things that we would like maybe some conditions on the time-limited, would be at least exploring the issue of redefining the numerator to include minor in there as well as the issue of what it
means if you excluded comatose, and how many
comatose are in there. Is it meaningful?
Maybe the comatose is so small it is
insignificant exclusion.

MS. THOMPSON: It is not so much
the comatose patient.

CO-CHAIR GIFFORD: Yes, right.

MS. THOMPSON: It is the
definition you can drop a comatose patient and
it doesn't count.

CO-CHAIR GIFFORD: Right. Okay.

MS. THOMPSON: If you drop anybody
else, it does.

CO-CHAIR GIFFORD: Yes. So, I
think those would be the two conditions that
I have heard so far with this. I have a
feeling we are going to come back and take a
bite at this apple with the two different
measures out there.

Yes?

MS. TOBIN: Judy Tobin from CMS.
I just wanted to offer one other
reason why we would want to separate out major injury from minor injury. One, with a rehab population, where you may have falls and non-injurious, but with major injury as well, as CMS, we would want to be able to look at those because there is a whole sequelae that can occur afterwards. You have a major fall. You have a fracture. Now somebody is catheterized, UTI. I mean there's a whole sequelae that can occur, and you can be talking about very different scenarios.

So, we would make the case that we would not include the minor injuries in this fall.

CO-CHAIR GIFFORD: So, I think the condition is not that we are saying they have to be combined. We just wanted the vendor to look at the data and give us more data on why you would or wouldn't combine it, and what it would look like with the two combined. I think that is the condition we are looking at.

So, again, it is a time-limited
approval with feedback and to address the
question about should minor and major be
combined together, why they should or
shouldn't, and the removing of the comatose as
an exclusion of that. That would be what our
recommendation would be like. That is what we
are sort of voting on. There's a lot of
differing opinions out there.

Do people want to comment on that
before we vote?

DR. ORDIN: Yes, I'm not clear
what we are voting on. Are we voting --

CO-CHAIR GIFFORD: You're voting
to --

DR. ORDIN: What does it address?
What does it address? You're saying address
the implications of adding minor injury.

I personally am against asking
them to do anything about minor injuries. I
think we should take this measure as is.

CO-CHAIR GIFFORD: As is. Okay.

DR. ZOROWITZ: If I can add
something, I am reading this for the first
time and trying to figure out. Again, we
mentioned it before. Having not read this
before, it is hard to become familiar with it
very quickly.

But, according to the summary of
evidence, it says, "1800 people living in
nursing homes die each year from falls. About
10 to 20 percent of nursing falls cause
serious injury; 2 to 6 percent cause
fractures."

So, that percentage, I mean if it
is 10 to 20 percent, that is a significant
enough number that it should show up fairly
consistently if data is gathered. And I
suspect that the reason that this measure is
being considered is because there is variation
in the way falls are defined from institution
to institution, even though there is a CMS
definition of what a fall is. To measure all
falls, which I think would be the best way to
go, is logistically difficult because of that
fact.

So, this is sort of a proxy measure meant to indicate the quality of an institution's falls prevention program. Whether or not it works, I don't know because I don't know whether it has been correlated as such. But if that's the case, then it may make sense to restrict it to major injuries. But I have to defer to the developers to see whether that is correct or not.

MS. CONSTANTINE: Yes, again, this was something that was debated at the TEP, and the thought was, given it is a new measure, to take a conservative approach and examine the falls with major injury.

Also, in regards to the usability, based on the literature, although there's a little bit of mixed results, the thought was that many patients actually come into a nursing facility because they have been falling at home and they can't live independently. There is sort of a multi-
interventional approach that you can utilize
to take a look, for example, at their
cardiovascular medications, their history of
falling, think about physical therapy,
occupational therapy to help them improve
their balance and their gait to prevent falls.
So, that is what we had in mind in developing
the measure.

CO-CHAIR GIFFORD: Go ahead,

Darlene.

MS. THOMPSON: One thing I think
that some people are forgetting, this is a
long-stay measure. It is only total residents
who have been in the building for 100 days.
They are not going to be counted in -- and
you're absolutely right; you do get residents
that come to the facility because they fall a
lot at home. But, hopefully, within those
first 100 days, we might be able to handle
that, although it does make you go back and
look in time.

So, I think some of the short-stay
people aren't going to show up in this measure anyway, and that 100 days does give us some time to work on the residents that come in that will eventually be long-stay residents.

CO-CHAIR GIFFORD: So, let me clarify to Dede's comment, that we are not asking them to change this. It is to ask to go back to their TEP or give us some more information as to the pros and cons of why they may or may not merge the two together. That would be it.

So, it is a time-limited approval or as defined with the question to them: what would it look like or why, because we are not all fall experts around the table? They have a TEP and they have a process to come back and say that we had questions about why they shouldn't combine the two. They may come back and say we want two separate measures that complement each other. I don't know. But it will give them an opportunity to come back; plus, the issue with the comatose, and ask
them to go back and revisit understanding the
definition of MDS and the logic behind it.
So, that is really what we are asking them to
do.

Are you okay with that? Yes.
So, voting in favor of that issue?
(Show of hands.)
Okay. Opposed?
I want to say, "restrained". I
mean, abstaining?
(Laughter.)
Okay. So, can we have ANA up to
hear about your measure?

MS. MONTALVO: Good afternoon.
I'm Isis Montalvo, the Director of
the National Center for Nursing Quality.
The question that I have for
clarification, are we doing falls and then
falls with injury or just falls with injury
initially?

CO-CHAIR GIFFORD: I'm sorry. I
wasn't listening.
MS. MONTALVO: That's okay.

CO-CHAIR GIFFORD: I wasn't listening. I was having a sidebar conversation.

MS. MONTALVO: We have two measures proposed, falls and then falls with injury. Should we do one and then the other sequentially?

CO-CHAIR GIFFORD: Let's do falls with injury --

MS. MONTALVO: Okay.

CO-CHAIR GIFFORD: -- and then I have a feeling we are going to take a break. Then, we will come back.

MS. MONTALVO: Okay. And I also have Dr. Nancy Dunton on the phone, who is our technical expert with our measures.

This particular measure --

MS. PACE: Can we just clarify? We are talking about 005?

CO-CHAIR GIFFORD: Yes, we are talking about 005.
MS. MONTALVO: This particular measure is not a new measure.

CO-CHAIR GIFFORD: Just a second.

What?

MR. BOISSONNAULT: Somebody is talking on the phone.

CO-CHAIR GIFFORD: It's God.

(Laughter.)

You're hallucinating, Bruce. We need a break.

(Laughter.)

MR. BOISSONNAULT: Dementia.

MS. TRIPP: There is somebody who is trying, I think, to communicate with us right now, but they are not speaking very loudly or we can't hear them.

MS. MONTALVO: Nancy, are you on the phone?

MS. TRIPP: Someone from RAND is on the phone as well.

MR. WENGER: Right. We've been holding.
MS. TRIPP: Okay. Could you identify yourself, whoever is on the phone?

MR. WENGER: Neil Wenger and also Carol Roth.

CO-CHAIR GIFFORD: Neil, you're on a different measure, not 005, are you?

MR. WENGER: No, we were 003.

CO-CHAIR GIFFORD: So, you have to wait a little bit, Neil. Is that okay?

You're three hours behind us, so you can wait. Are you guys stuck? Are you stuck? You are able to wait or do we need to take you out of schedule?

MR. WENGER: When do you think you might take us, so that we can rearrange?

CO-CHAIR GIFFORD: We will take you -- what's your measure on?

MR. WENGER: 003.

CO-CHAIR GIFFORD: Physiotherapy? We want to do this 005 right now because it links in with the previous discussion. Then, we can take your measure. I don't know if we
are going to take a break after this, either. 
But if you're time-pressed, we can slide you 
in now.

MR. WENGER: Well, no, if you tell 
us when, we can try to get back on.

CO-CHAIR GIFFORD: 4:45 our time.
So, it will be 1:45 your time.

MR. WENGER: Okay. I don't know, 
Carol, is that possible for you?

MS. ROTH: Yes, it's okay.

MR. WENGER: Okay. Very good.
Thank you.

CO-CHAIR GIFFORD: Sorry, Neil.

MR. WENGER: No, no problem.
Thank you.


MS. MONTALVO: Nancy, you're still 
on the phone?

DR. DUNTON: I am, yes. Thank 
you.

MS. MONTALVO: Okay. This 
particular measure is not a new NQF-endorsed
measure, falls with injury. In fact, this was well-tested in the acute care setting and actually went before the Mental Health Steering Committee, who recommended that it be considered for other settings due to the harmonization focus for NQF measures, and to provide consistency across settings related to definitions.

So, with that, I will turn it over to Nancy related to our criterion.

DR. DUNTON: Thank you.

The falls with injury measure, the definition is the number of falls with injuries of minor or greater per thousand resident days. It meets the importance criteria because falls is a National Priorities Partnership priority. It affects large numbers of residents in home care settings with some studies showing as many as 2.5 falls per person per year, of which 10 to 20 percent result in injury, functional decline, and other sequelae.
There's variation across studies in the rate of falls, and there's been established in the research literature a relationship to nurse staffing.

In terms of scientific acceptability, the measure is well-specified with a precise definition of the numerator and the denominator and inclusion and exclusion criteria, and it is risk-stratified by setting.

We have not conducted validity or reliability studies in the long-term care arena, but we have done so in the acute care setting with criterion validity as measured by sensitivity and specificity around 90 percent.

It is the case, as has been discussed, not all fall situations are clear. The measure specification is that, to determine the actual injury level, residents should be followed for 24 hours to determine injury level, if it is not immediately apparent.
Falls are being publicly reported for acute care settings at the state and federal level. They are used by many care settings for quality improvement programs.

The data come from incident reports, which are supplemented with training on data collection guidelines on falls, include both assisted and non-assisted falls.

MS. MONTALVO: Nancy, can you repeat that? There was a breakup, and we are having a hard time hearing you.

DR. DUNTON: In terms of feasibility, the data are captured by incident reports and will be in a new common format. The reliability of the data is supported by specific data collection guidelines and training, and we collect in falls and injurious falls both falls that are assisted and those that are not assisted.

And that is sort of the summary of the scientific acceptability as well as importance from the documentation that was
submitted to the National Quality Forum.

CO-CHAIR MUELLER: Dr. Modawal, you were the primary reviewer?

DR. MODAWAL: Yes, thank you.

Yes, I think just like the previous case with injury, of course, the importance and the description includes minor and major. I think for scientific validity and reliability for the issues we heard, in terms of lack of data, my assessment was partial. The same for the usability and feasibility. There are many unknown answers there.

The few things, you know, which I had questions were the calculation, you know, the numerator and the denominator, as we heard that they were tested in different settings, you know, just not the nursing home, and how that needs to be modified at home or in assisted living facilities or some other place.

So, those were the main questions.
Of course, some of the data has been extrapolated from hospital settings and applied to the nursing home and other settings.

So, I think the vendor sort of recommends time-limited endorsement, and I would agree with that with some, of course, clarifications and modifications and refinements.

And, Robert, do you want to comment?

DR. ZOROWITZ: Yes. You know, I don't think it is feasible for nursing homes to gather data and report from incident reports. That is No. 1. I think we really have to rely on the MDS for any information, and the numerator and the exclusions I think are problematic. The numerator is falls with fall injury level of 2 minor or greater, but on the MDS J1900, it is B or C. So, I am not sure whether this really jibes with how it is worded on the MDS.
Excluded populations, I understand excluding visitors and students. I haven't done an MDS lately on a visitor or a student, although I am asked to do it.

But an excluded population also is falls by patients from eligible reporting unit; however, patient was not on the unit at the time of the fall. Now that may make sense in a hospital, but that makes no sense in a nursing home in which a fall, no matter where they fall, it is a fall because we encourage them to be throughout the facility. So, the numerator I think is problematic.

The denominator is fine, patient days during the calendar month. But I think right off the bat, the fact that this is supposed to be gathered from incident reports and the way the numerator is defined, I don't think this is something that I would recommend go forward unless it were redefined.

DR. GRIEBLING: This is Tomas Griebling.
We were discussing there are some issues with the denominator. It appears this actually is based more on the inpatient acute hospital settings rather than long-term care or nursing homes.

CO-CHAIR MUELLER: I also have some concern about measuring it by units because I don't believe we have the capability right now with the MDS to determine where things are happening. We just know it is happening in the nursing home.

DR. GRIEBLING: In terms of on-the-unit versus off-the-unit, was the intention for the developer, is it in the facility versus, say, they are going out of the facility with family or something like that, and they have a fall, to exclude those types of falls?

DR. DUNTON: Yes, it would be, if a patient were being transferred to a community setting, a doctor's appointment, something like that, those would be treated
according to the definition. I agree that falls in the therapy room, in the dining area, et cetera, those would be included.

CO-CHAIR MUELLER: I was wondering if the developer would have any comments on the fact that we have the MDS 3.0 with fall measures or fall items, and then what's being proposed as incident reports. Was that just an oversight or could you see that it could be harmonized using a different measure?

DR. DUNTON: Certainly, I think using MDS is an option. This measure was submitted to be in harmony with measures in the acute care setting as opposed to other indicators in the long-term care setting. So, if it were to be measured through the MDS, you are correct that sections would have to change to reflect that source.

CO-CHAIR MUELLER: Any other questions or comments? Or are we ready for a vote?

DR. ORDIN: I just have a
question. I mean, is there a movement among
nursing homes to have a standardized incident
report?

DR. ZOROWITZ: Every nursing home
has a different format for the incident
report. My own opinion is that we should be,
for nursing home measures, we should use data
sources which are currently collecting data.
I'm sure I know we and many facilities do
collect data from incident reports and report
them internally, but if we are going to be
reporting nationally, I think we ought to use
data sources which we all use uniformly.

CO-CHAIR MUELLER: I will just ask
one more clarification of the developer
because it sounded like you had been to the
group with mental health, who seemed to think
this measure worked well for them. Do they
also use incident reports or what was their
reaction to that?

DR. DUNTON: Could you just repeat
that?
CO-CHAIR MUELLER: We do have, for example, the definition of psych units. So, we represented this is a mental health unit. The Steering Committee, they thought it was a good measure that could be applicable to other settings.

For example, within the database that we manage, we also do have like long-term care units as an option within that setting. So, it is, again, taking a look at different settings that could use that measure for harmonization, so there is consistency.

And perhaps the NQF staff might have something else to add.

DR. DUNTON: The one thought that I had was I don't know what the current status of the format is for incident reports, but it could lead to the standardization of reporting across home care settings. So, that seems to be a long time, but the elements that are in the common format would support this.

CO-CHAIR MUELLER: I don't know; I
wasn't at that meeting, but I assume the context was inpatient mental health facilities?

MS. PACE: Psych units.

CO-CHAIR MUELLER: Psych units within hospitals? So, you are talking still about acute care hospitals. So, that it is more consistent with how you are using it for the non-psychiatric units.

So, in terms of our approach on harmonization or our interest in harmonization, it is definitely to have measures that are consistent across settings. We recognize that different data sources may require some differences, but what we would like to see, and we would need to look at in terms of, if you are using MDS and the items on MDS, and the measure in the hospital, how close can they get, so that you can have the same interpretation?

Not that at this stage that people have to change data sources. You know, the
future with electronic health records, we may
get closer to having one measure that works
across all settings in terms of the data
items.

But having said that, we are still
very interested in having measures that have
some consistency of interpretation across
settings. So, is a fall in this setting the
same as a fall in another setting, and are we
reporting on it in the same way?

MR. KUBAT: Maybe on a related
point -- this is Bill -- and too simplistic,
but I think in terms of the harmonization
issue, what is almost more compelling here is
within the venue, not across venues. I think
it would be problematic if we had multiple
falls measures related to long-term care, but
different data sources.

CO-CHAIR GIFFORD: Do you guys
have any reliability testing between
facilities on incident reports? And also,
what is the reliability if the incident report
is in MDS? What do you gain by adding
incident reports over the MDS?

MS. MONTALVO: We don't have the
data related to comparing MDS and incident
reporting, but we certainly have done validity
and reliability studies related to incident
reports across facilities.

Nancy, can you speak to that?

DR. DUNTON: Yes. We are just
completing a study, a validity study on the
rating of incidents to either a fall or not a
fall, across 600 units in acute care settings.
We looked at a group of experts as well as
clinicians and identified their ability to
identify a fall or an incident as a fall with
the sensitivity and specificity above 90
percent. So, there is some reliability around
the definition of most fall areas.

CO-CHAIR GIFFORD: Nancy, did you
say that was in the acute care setting?

DR. DUNTON: It is.

CO-CHAIR GIFFORD: Have you done
it in a long-term care setting?

DR. DUNTON: We have not. In the acute care setting, versus what we get to long-term care, in the acute care setting, we also capture rehabilitation units, the facilities.

MS. TRIPP: I have a question about the measure we looked at a moment ago only included falls with serious injuries. Your measure includes falls with minor injuries as well. So, I was hoping you could speak to why you chose to use minor and major injuries.

I also want to point out, I think in the beginning of this meeting we were told that this might be the last site-specific-type meeting. And if we are going to try to transcend location and preserve our interest in harmonization, if other measures, you know, exist right now that cover minor and major injuries, if we pick one that only covers major injuries, we are going to be in
disharmony in a sense with how these issues are being looked at in other settings. So, I just want to throw that out there for something for us to think about. Let us know why you included minor and serious injuries.

MS. MONTALVO: Nancy can speak to the differences between the two.

DR. DUNTON: Sure. We collect injury level of all falls, so that we report them back to the hospitals for quality improvement purposes as none, minor, moderate, major, or death. Actually, we combine major and death because they are rare in acute care settings.

So, of course, it would be overly complicated to report all of those levels using public reporting. So, minor distinguishes something happened physiologically which could also had psychological sequelae, but other people think of major and moderate as cutpoints. So, we concentrated on something happened to the
patient that incurred extra cost. CMS is now
not reimbursing hospitals for treatment of
injuries or those with some disabilities.

So, I can understand why there
would be discussion around which injury level
to report, but we capture whatever the injury
level is. And of course, the major injury and
death rates are, even in hospitals are
extremely low. So, the measure is somewhat
more stable for care settings that have 20 or
30 patients in them as in them being a long-
term facility, if you include all injuries.

CO-CHAIR GIFFORD: All right.
Maybe I was confused and maybe I did some
assumptions.

When I read the numerator, it
talks about minor injuries at a level 2. I'm
just assuming that was off the MDS. It is off
the NCI. Okay.

MS. PACE: They have a scale.

CO-CHAIR GIFFORD: I got you. So,
that would be minor and major then. Okay.
DR. ZOROWITZ: No, and it would require that facilities develop incident reports that have a level 2, 3, or whatever. I mean I don't even recognize this. That's why I think the feasibility is low.

MR. BOISSONNAULT: Due to harmony, right? I mean there's a certain disharmony with the sort of hospital-based report that this is sourced off of from the MDS, is my understanding of what's --

DR. ZOROWITZ: Apparently.

MR. BOISSONNAULT: Yes.

DR. ZOROWITZ: But I don't know how hospitals report, but evidently they don't, I know they don't use the MDS, and I know what's on the MDS, and I know what's going to be on the MDS 3.0. And I don't even know whether CMS is going to want us to be submitting data from another source in order to report it.

So, I think there are a variety of reasons that this isn't going to work. To me,
it brings up the whole issue of whether we just need to go back and rethink the best way of finding a measure that reflects the quality of attempts to reduce falls in facilities. I think we are identifying some gaps in scientific knowledge and validity of these measures that I am not sure we are able to answer today.

But I don't think this measure as written is going to work at all. I understand the motivation behind it and the rationale. But given the way nursing homes collect and report information on falls and injuries, I think this is logistically impossible. That doesn't mean it's not a very important measure, but I don't think we have really come up with an ideal way of reporting a quality measure on falls, based on the two proposed measures so far.

MS. GIL: I was just going to say I think this is an important lesson in terms of harmonizing with acute care. I am
constantly working with acute and long-term
care to bring them together. Language is just
so key in everything we do. The next one that
Alice and I will be going over, just getting
through the language of it was a challenge
because it didn't sort of fit in my head.

So, I think that the process of
getting nursing homes and acute care together
from the beginning is real important in terms
of really looking at a solid proposal. I
appreciate the effort.

DR. MODAWAL: Yes, I think the
intentions are good, and I think it is an
important topic, we all agree.

I think this as a measure as it is
written is too broad because they have
hospice, long-term acute care, hospital, and
nursing homes, skilled nursing facility,
rehabilitation facility.

As we are hearing, the
transportability of these measures, the tools
from one side to another may not work. That
is the difficulty we face right now.

CO-CHAIR MUELLER: So, it sounds like on the face of it, when you just read the title of the measure, it sounds great. But when you actually look at how it is measured and what the data sources are to measure it, it doesn't fit to long-term care. It is a square peg going in a round hole, or vice versa.

So, on that alone, it doesn't sound like there's a lot of enthusiasm for this measure. Are we ready to vote on the measure as proposed?

MR. BOISSONNAULT: Do we need to get the "C's" and the "N's" and all that stuff from the folks? Or are they already on the record?

CO-CHAIR GIFFORD: Did you guys submit? Did the reviewers submit?

CO-CHAIR MUELLER: No, I don't think they did.

CO-CHAIR GIFFORD: Turn off their
microphones, someone.

Did the reviewers already turn in their stuff to NQF with their ratings?

DR. MODAWAL: Yes, we have.

CO-CHAIR GIFFORD: Then, we have them on record. So, we don't have to go through them, unless anyone would like to go through them. Would you like to go through them and vote on them all?

DR. MODAWAL: Well, you know, for the scientific -- I think it's all partial and minimal for the research and scientific and minimal for the usability, and also for feasibility it was partial.

CO-CHAIR MUELLER: Thank you.

DR. ZOROWITZ: I think he's being polite.

(Laughter.)

The importance, I think it is completely.

Scientific acceptability, I think it's partial because it hasn't been tested in
long-term care facilities.

But usability and feasibility, I am debating between minimally and not at all.

CO-CHAIR MUELLER: Okay.

DR. ZOROWITZ: But I'm leaning towards not at all, just because of the data sources.

CO-CHAIR MUELLER: Thank you.

So, we have now heard the reviewers' recommendations. I think we are probably ready for a vote right now.

And this is a time-limited measure. So, based on its being a time-limited measure, we would be voting to -- let's see, how do we do this?

You can kill it in time-limited, too.

Okay. So, all those in favor of the measure raise your hand.

(No response.)

All those not, raise your hand?

(Show of hands.)
All those abstaining?

(No response.)

Okay. So, this measure does not pass our muster.

CO-CHAIR GIFFORD: It doesn't pass muster at this time. We encourage the developers to work and figure out how to harmonize it with MDS and come back because there clearly is an interest in looking at that.

CO-CHAIR MUELLER: Thank you.

CO-CHAIR MUELLER: We have RAND calling back in at 4:45. It is 4:32. Do you want to do the other fall, the other restraint? Do we want to do that? But when RAND calls back in, we are going to have to take them. We already kicked them out once.

CO-CHAIR MUELLER: Well, we have 004, which the ANA is also proposing that one, the patient fall rate.

MS. BELL: And I would say, as primary on that one, the issues are identical
to the previous measure. So, we might be able
to move through it rather quickly.

CO-CHAIR GIFFORD: Okay.

CO-CHAIR MUELLER: That's what I
was thinking, yes.

CO-CHAIR GIFFORD: Then, let's do
004. You guys have a hungry appetite.

(Laughter.)

MS. MONTALVO: Well, a lot of the
information that was said previously related
to the introduction and the importance has
already been stated.

Nancy, is there anything else that
you want to add related to the importance of
measuring overall patient falls?

DR. DUNTON: No, other than I
think that capturing through the MDS or
wherever, capturing the total fall rate is
important, not just the injury fall rate.

MS. BELL: Alice Bell.

And as the primary reviewer, I
would agree that it is important, but we
struggle with the same issues in terms of definition, data capture, the tools that would be used, and the fact that they are incompatible with long-term care at this point.

And also, we kind of went back and forth a little bit in this measure between looking at fall rate and also some reference to looking at fall risk assessment and intervention. And it wasn't clear to me exactly, although fall rate was the focus, some of the assessment was based on other criteria.

But, most pointedly, the issue is in and around feasibility and usability with different tools to measure the data.

CO-CHAIR MUELLER: Any other comments? Go ahead.

MS. GIL: As a secondary reviewer, I concur with Alice. I don't think anything more needs to be said.

I think, obviously, this
information across settings has incredible value. I encourage you to keep on plugging away to harmonize this.

And in terms of, obviously, its usability, to bring together your performance improvement strategies that you laid out, I thought that was nicely done and, again, could bring such strong value.

I guess the other thing that I would mention is that, through the feasibility, it spoke to the electronic medical record. Certainly, acute care is far more advanced in that vein as well. So, I would hope you would consider that as well.

CO-CHAIR MUELLER: Any other comments about this measure?

(No response.)

Okay. Are we ready for a vote?

Okay. So, all those in favor of endorsing this time-limited measure 004?

(No response.)

All those not, raise your hand.
(Show of hands.)

Abstain?

(No response.)

Okay, thank you. Thank you so much.

Now it's a break, right?

CO-CHAIR GIFFORD: Yes, why don't we take a 10-minute break? At 4:45, be back promptly; 10 minutes.

(Whereupon, the foregoing matter went off the record at 4:37 p.m. and went back on the record at 4:46 p.m.)

CO-CHAIR GIFFORD: All right.

Neil, 003, on physical therapy/assistive device for new balance. You've got 20 people around the table here eager to hear why we should approve this measure.

MR. WENGER: Wonderful. Thank you.

So, this is a process-of-care measure, which I think is sort of different than most of the measures that you have been
looking at today.

It is predicated upon a large body of evidence that shows that people at risk of falling can have that risk minimized through intervention. The body of evidence on this usually looks at multimodal interventions, which are not measurable through most means of collecting data. This focuses on two of the most common components of those interventions that are physical therapy and exercise and use of assistive devices.

This is a composite measure that uses data from MDS together with administrative data, both of which are generally available and can be combined.

The demonstration that someone should be in the denominator for this measure is that they have a new or worsening balance problem based on serial MDS measures. Therefore, one needs at least two quarterly serial MDS measures to qualify for this measure.
The numerator is based on either MDS or claims data demonstrating that there was physical therapy ordered or that a new assistive device was initiated.

We have demonstrated that this measure can be implemented in a large cohort of about half of the high-risk eligibles in California. The published data show that the combination of MDS with administrative data is feasible, and, indeed, the pass rate is relatively low, with about a third passing.

This measure itself has not been directly linked to clinical outcomes of decreased falls or deceased injuries. However, this measure, when measured by chart review, combined with a series of other companion measures that aimed at falls, does demonstrate that improved quality in the outpatient setting is directly related to a decrease in the Tinetti fear-of-falling scale over a one-year study period.

I think I will stop there and
CO-CHAIR GIFFORD: Okay. Who is the primary reviewer? Yes, Alice?

MS. BELL: Alice Bell. I had a couple of issues. First of all, I think it is very important, and there's a lot of excellent things in this measure.

My concerns relate to treating physical therapy intervention and the issuance of an assistive device as being equal interventions because, in reality, the issuance of an assistive device without proper training, fitting, and assuring that it is the appropriate device, actually creates increased risk for falls. So, they are not like interventions. That is one issue.

So, I would look to look at perhaps just the provision of physical therapy services and not the provision of an assistive device as a separate and equal intervention strategy.
The second issue that I had was the exclusion of patients with severe dementia, given that dementia is a risk factor for falls, and that I believe intervention strategies are demonstrated through the evidence that patients even with severe dementia can have their fall risk managed, and particularly when we are looking at a new or worsening balance problem, and you are looking at consecutive MDS quarterly assessments, even though patients with severe dementia who present now with a new or worsening balance problem, I think it is indicated to provide the intervention and attempt to remediate that worsening condition, which may or may not be related to their dementia.

So, those are the two issues. I would say that, in terms of importance, as I said, I rate it as complete. In the other areas, I rated it as partial, simply because of that treating an assistive device as the same value as therapy intervention and the
exclusion of patients with dementia, with
severe dementia.

CO-CHAIR GIFFORD: And usability
and feasibility?

MS. BELL: Partial also, for those
same reasons.

CO-CHAIR GIFFORD: Okay.

MS. BELL: Actually, no, let me
change that. Usability, complete, because I
do think access to the data elements is fine.
I think it is easy to capture what we are
looking to capture here.

But feasibility, based on the
equal measure of an assistive device, I think
is problematic, partial.

CO-CHAIR GIFFORD: Before I turn
to Neil to comment on that, the secondary
reviewer?

DR. MODAWAL: Yes, Arvind Modawal.

Yes, I agree with what Alice has
said. There are basically two things, and it
is too broad, and combining them may not be
the right way because issues of compliance
with the assistive devices. Also, it may be
part of nursing interventions as well, if they
have had the physical therapy intervention
already in place.

So, I think half of it really
looks good, you know, as a physical therapy,
if it can be modified. Physical therapy for
any balance problem makes sense.

So, otherwise, in terms of
scientific validity and usability/feasibility,
it will be all partial for me.

CO-CHAIR GIFFORD: So, Neil, do
you want to comment on why you guys thought PT
and assistive devices should be together in
the numerator?

MR. WENGER: I think that those
are good points, but I had a difficult time
hearing the second speaker. But let me
address the first two points.

I don't think that we have good
evidence at this point how to allocate or
apportion which intervention works best for
patients with falls. In fact, the real way to
do this, which I think is beyond the current
scope of measurement, is to identify different
types of patients with different types of
lesions and to direct the interventions
specifically to the type of patient. But
given that we are attempting to develop a
measure, such specificity, at least in today's
world, I think is beyond us.

I think it is a good point that
not everyone will benefit from assistive
devices. I think the same is true for
physical therapy. It wouldn't be impossible
to actually report this measure dividing up
the numerator into assistive device or
physical therapy or both, if the panel felt
that that would be more valuable. Certainly,
these are separate components that can be
easily constructed.

When we developed this measure
with our expert panel, they included both
physical therapy and assistive devices for different types of falls problems.

To address the second issue, we recently convened a panel to consider advanced dementia with specific quality measures. Let me note that this is only advanced dementia that we are excluding here, not all dementia. It doesn't mean that undertaking these interventions would be a mistake with someone with advanced dementia, but it does mean that there are many patients with advanced dementia, at least in the view of our expert panel, that would not be able to adequately benefit from either an assistive device or physical therapy. And therefore, they didn't feel that it stood as a quality measure to require using these interventions for a patient with advanced dementia.

CO-CHAIR GIFORD: Neil, how do you define advanced dementia?

MR. WENCER: It is defined based on the algorithm that we listed, which is
taken from several variables within MDS. This is a validated algorithm developed by others. I can look it up for you here.

CO-CHAIR GIFFORD: It's a CPS?

MS. BELL: It is based on a number of different MDS criteria combined.

CO-CHAIR GIFFORD: Okay.

MS. BELL: Combined results.

MS. PACE: On the tool?

MS. BELL: Yes.

CO-CHAIR GIFFORD: Okay. So, Alice, go ahead. A question?

MS. BELL: Sure. I think two points. One is the distinction I am making is I think if you combined, if you said physical therapy and an assistive device or physical therapy with or without the use of an assistive device, that would be one thing. But when you look at simply the provision of an assistive device to a patient, not knowing who provided the device, what criteria was used for determining what device, whether any
training in the use of the device was
provided, and whether the device was even
fitted to the patient, that is a much lesser
level of intervention.

So, that is the issue I have, is
to say physical therapy or an assistive device
being equal interventions. If you wanted to
compare those two, you could look at physical
therapy with or without the issuance of an
assistive device and the issuance of an
assistive device independent of therapy. I
think that would be interesting to see, but
combining them I don't think makes the measure
meaningful.

I understand your statement about
the distinction of severe or advanced
dementia, but, again, I would say the
literature does indicate that even patients
with advanced or severe dementia, depending on
the presenting problem that has resulted in
their balance deficits, one of which might be
the issuance of an inappropriate assistive
device, may, in fact, benefit from therapy
intervention and may, in fact, see a reduction
in fall risk.

CO-CHAIR GIFFORD: Neil?

MR. WENGER: I certainly
understand what is being said. I guess I
don't have the literature at my fingertips
concerning what proportion of patients with
advanced dementia would not benefit and,
therefore, the measure would be inappropriate
for them.

When we posed this exact question
to our group of experts, they felt that the
patients with advanced dementia should be
excluded. Perhaps someone can shed some light
by presenting some literature to show that a
preponderance of patients with advanced
dementia would benefit from these
interventions, and we can also search for
that.

DR. ZOROWITZ: This is Bob
Zorowitz.
I am just wondering, the elements
to define advanced dementia or poor prognosis
are based on MDS 2.0, is that correct?

MR. WENGER: They are currently.

We developed based on 3.0.

DR. ZOROWITZ: So, this is just a
procedural question. I guess if we were to
decide to endorse this measure, would that be
conditional on its being changed to reflect
MDS 3.0?

CO-CHAIR GIFFORD: Yes.

MS. PACE: Right, and, actually,
your conditional recommendations, we want to
have the measure developer take care of before
it goes farther for even voting. So, from
what I'm understanding, 3.0 is advanced enough
that they could identify the elements now. Is
that correct?

DR. ZOROWITZ: I believe so. I
mean it is in a final enough form that it
could, but I don't know how well-validated the
data elements together are, because 2.0 has
been worked over pretty well over the years.
So, I don't know about 3.0.

CO-CHAIR GIFFORD: Yes, but many
of the items from 2.0 are just carrying over
into 3.0 with some changes.

DR. ZOROWITZ: But there's the
brief interview of mental state in the 3.0.

CO-CHAIR GIFFORD: Right.

MR. WENGER: We have already
looked at the elements in 3.0 to correspond to
the basic elements within this measure, but we
have not yet looked at that specific scale,
which was actually developed elsewhere. We
can do that.

MS. ROTH: Now I actually have
looked at the elements, and many of them are
unchanged. There's I think one where there's
a very minor change, and probably it is in the
physical functioning item where there are more
response categories that would have to be
taken into consideration. I think the poor
prognosis item actually has been improved from
what it was in 2.0. So, some of it is unchanged, and some of it there are some changes.

DR. ZOROWITZ: Getting back to the issue with the assistive device, I mean in my facility, in my experience, an assistive device is rarely given out without accompanying physical therapy anyway.

When you developed this, was there a discussion of any data on how often an assistive device such as a cane or a walker is distributed without some sort of instruction? I mean, in other words, are these always -- obviously, physical therapy often includes giving an assistive device, but I don't know how often giving an assistive device excludes physical therapy.

MR. WENGER: Right. We measured those two things separately. The expert panel that included assistive device as satisfying the measure did have a discussion concerning advice that was required along with the
administration of the device, but recognize
that there is no way to know how well-done
that was.

CO-CHAIR GIFFORD: No, I think,
Neil, the question is, if you measured this
with PT only and then you add in PT or
assistive device, how many new residents get
counted into the numerator?

MR. WENGER: That is a good
question that I don't know the answer to off
the top of my head.

Carol, do you know?

MS. ROTH: No, I don't.

CO-CHAIR GIFFORD: Because if it
is not significant, then you don't need -- you
know, if the PT and assistive device, if PT is
highly, highly correlated with the assistive
device, then it doesn't add much. If they are
very different, then I think some of the
questions come up here.

DR. ZOROWITZ: And my concern is
that a facility, especially since physical
therapy, although it can be Medicare Part B reimbursed in some facilities, depending on how their reimbursement is, it may be more of a cost to them. They may be tempted to just give an assistive device to somebody rather than provide the service, and they would get their little chit on the quality indicator.

MS. BELL: And I think that is one. The other, I agree that I don't think it is a significant number or shouldn't be. And again, the reality is that a device issued without training, without proper fit, actually increases risk for falls. So, even if it was a small number, it could negatively impact measuring the impact of the intervention.

I don't believe the issuance of an assistive device independent of anything else is actually an intervention to address fall risk.

MR. BOISSONNAULT: And that was actually to my point, which is one dimension of validity. And maybe it was in the lit
review. I was wondering if anyone could
mention it from either RAND, who I have found
does very fine work, but one of the things
that I look for in terms of dimension of
validity is, if this happens, is there any
evidence that it actually improves what you
are trying to improve, which is falls
reduction? Was that correlation made well in
either the submission or do the folks from
RAND have any evidence that doing this the way
you are measuring it actually reduces falls?

MR. WENGER: So, this measure
itself as measured in a nursing home, we do
not have any link to outcome. The same
measure, based on chart review, within an
intervention study among community-based
patients is related to a decrease in fear of
falling. And when combined with several other
falls-based measures, because this is, of
course, the treatment part of measures that
include history and exam-taking, together
those are very much related to improvement in
fear of falling, but we have not linked it to falls or injury.

MR. BOISSONNAULT:  Did you say "fear of falling" or actual falling?

MR. WENGER:  Yes, we are using the Tinetti's fear-of-falling scale.

DR. ORDIN:  I'm sorry, I might have missed this. This is Dede Ordin.

This uses both administrative and MDS data. I assume that is the rationale for restricting it to the over 65, because it would seem like under 65, you know, the same issues would apply. I am having trouble understanding how the production of that measure would happen and whether the administrative data truly are needed, given data elements in 3.0.

I looked real quickly. Obviously, the G(5)(a) must be for 2.0. I don't know what 3.0 has about assistive device, but I am sure it has something.

MS. THOMPSON:  Darlene Thompson.
I've got a couple of questions. I am assuming since we are going 65 or older, you are taking it from the birthdate from somewhere, either from the MDS, the birthdate that is on there, or from the administrative claim.

The second part, I need you to scroll it back down. I'm sorry. Thank you.

But I am confused. I'm trying to figure out what this is actually measuring because the numerator is -- now I lost it. Numerator details is residents who have a new balance problem which would be identified in the last seven days off the ARD date who received a new assistive device or physical therapy in the prior four months.

I am trying to figure out, if a resident had therapy four months before the ARD date, and on this new assessment I say they have an increase in their balance problem, I am trying to figure out what we are trying to measure here because the therapy was
four months before we identified they had a new balance problem.

MR. WENGER: The denominator is a comparison between two quarterly reports. Therefore, it is possible that the decrement in either balance or gait could have occurred anytime during that interval. Therefore, a physical therapy that occurred -- let's say, for instance, that the balance change occurred two-and-a-half months ago, two weeks after the prior MDS report. Therefore, physical therapy initiated at that time would be two-and-a-half months prior to current MDS, but would have, indeed, been the appropriate clinical maneuver.

MS. BELL: And I think a bit of the struggle is the four-month, and what they do is they give a 30-day window prior to the previous MDS.

MR. WENGER: Right, and the reason for that is that in our experience balance problems don't occur all of a sudden. If
physical therapy is being initiated, the 
thought is that they are identifying an 
abnormality, and therefore, they are 
interacting clinically to attempt to 
ameliorate it.

The thinking is that we are 
attempting to include all reasonable clinical 
intervention for a worsening gait or balance 
problem.

CO-CHAIR GIFFORD: So, let me 
throw something into the pit here for this 
discussion. I would put forth to the group, 
given the dialog, that we vote on any time-
limited approval, ask for a crosswalk to the 
MDS 3.0, that comes back with a little bit of 
the data literature that Neil said they would 
look at both ends: why severe dementia was 
excluded or any data that would suggest severe 
dementia actually is helpful in this group, 
and some data on whether the assistive 
devices, how much it actually adds to the 
measure and whether you need to actually split
it or not with some recommendation back to the
group. But a time-limited approval based on
that.

That sort of summarizes the
comments. Do you want to discuss that at all?
Bill?

MR. KUBAT: Well, just a comment.
I mean somewhat my reaction is, are the
qualifiers so substantive as to make it
problematic, hard to support?

MS. BELL: And I would just, to
that point, say that I think it would be
difficult to support with the alternative of
therapy or an assistive device as being
treated as equal interventions.

MS. THOMPSON: I've got one other
question. Is there an exclusion for if a
resident refuses therapy?

MS. BELL: I apologize. The
criteria was they actually received therapy
through CPT code.

MS. THOMPSON: All right. So, if
they refused therapy --

MS. BELL: They wouldn't --

MS. THOMPSON: -- they wouldn't be counted.

MS. BELL: That is correct.

MS. THOMPSON: So, then, that measure would show that you potentially -- because I am assuming this would be the higher the number, the better, supposedly, the measure is.

MS. BELL: Right.

MS. THOMPSON: So, you could have a low measure because you have a lot of residents that are refusing to take the therapy.

MS. BELL: Now what I don't know is number of days, duration of therapy intervention. There's nothing to indicate that. It is basically, if therapy is billed, they qualify as having received therapy.

MR. WENGER: Correct.

CO-CHAIR GIFFORD: So, based on
those comments, let me modify the time-limited approval. The time-limited approval as PT only with them coming back with data as to really justifying why assistive devices need to be added in.

Then, the stuff we talked about before, the MDS 3.0 crosswalk and the information on exclusions of dementia, see where they need to modify that.

Is that a reasonable approach? Or you guys still don't feel comfortable with it?

We are suggesting a modifying, dropping the assistive device, with them to come back with data to see whether they should include it or not. Because what I am hearing from them is their concerns with leaving assistive devices is, if it doesn't add much to the measure, you would drop it anyway. But if it adds a lot, then they have to figure out how to justify to us why they would want to put it in with better reliability, but that the PT alone would be sufficient with all the
data that was suggested and presented to us.

That is the way I am summarizing it, but I could be summarizing it wrong.

I am seeing head nods.

DR. ZOROWITZ: Yes, I think that sounds reasonable. I mean, for the most part, the standard of care for a new balance problem is to have a physical therapy assessment. So, I mean, my gut feeling is that a physical therapy assessment alone should be adequate, but I didn't do the research, and I would trust that the Technical Expert Panel did, but perhaps they just don't have that data on hand.

So, I would agree. I think, otherwise, it is a fairly sound measure.

CO-CHAIR GIFFORD: All right. All in favor of time-limited approval with PT, excluding assistive device; ask the developers to come back with information about assistive device; see the literature review on exclusions for dementia -- but right now it
excludes severe dementia -- and the crosswalk
with MDS 3.0? All in favor?

(Show of hands.)

All opposed?

(Show of hands.)

Three opposed.

Any abstaining?

(Show of hand.)

One abstaining.

Can I just ask -- never mind. You can abstain for any reason. You don't have to give a reason.

MS. TRIPP: Well, I would like to.

CO-CHAIR GIFFORD: Okay.

MS. TRIPP: I just would like, I think I've said this a few times, but more time to review this would be helpful. I am sure that is clear, but that is what I am saying.

CO-CHAIR GIFFORD: And the three dissenting votes, dissenting opinion?

MR. BOISSONNAULT: I would like to
see evidence that the process actually links to the desired outcome, which is fewer falls and not fear of falls.

CO-CHAIR GIFFORD: Bill?

MR. KUBAT: The same point.

CO-CHAIR GIFFORD: Darlene? And exclusion for refusals is why you -- good.

Now you got all that? You got all this feedback?

MR. WENGER: Yes.

CO-CHAIR GIFFORD: Okay. Thank you, guys.

CO-CHAIR GIFFORD: The next measure, 021, RTI.

MS. CONSTANTINE: Hi. This is the last time I will be at the table this afternoon.

Okay. The last measure that we will be discussing is physical restraints. The purpose of the proposed measure is to report on the percent of long-stay residents
who were physically restrained daily during
the seven days prior to the resident
assessment. Again, I will sort of summarize
and highlight just the pertinent, important
points.

Physical restraints may be used in
nursing homes to control people whose
behaviors are judged to be disruptive,
aggressive, or dangerous, including patients
with cognitive impairment. It also poses
serious risk for nursing home residents,
including pressure sores, decreased mobility,
depression, agitation, and social isolation.
Also, residents who experience greater use of
restraints also experience an increased risk
in hospitalization.

Restraints reduce the residents' autonomy and their dignity. According to the
OBRA act of 1987, it specifically grants residents the right to freedom from undue
physical restraints.

The associated guideline from CMS
states, "The resident has the right to be free from any physical or chemical restraints imposed for the purpose of discipline or convenience and are not required by the resident's medical symptoms."

Concerns in regard to restraint use have been voiced by various organizations, such as the National Citizens Coalition for Nursing Home Reform, the Alzheimer's Association, the American Physical Therapy Association. And the Advancing Excellence Campaign in America's Nursing Homes has made the reduction of physical restraints one of their major goals.

Essentially, there's very little difference between the MDS 2.0 and 3.0 items. The difference is in MDS 2.0 it indicates whether trunk restraint, limb restraint, or chair prevents rising was utilized daily during the seven days prior to the assessment. However, for the proposed measure, it makes a clarification and eliminates a little bit of
the confusion regarding whether it was used in bed or whether the restraint was also used in a chair or out of bed. So, that is the additional categories.

They were designed to eliminate some confusion about the definition of restraint and enhance, including accuracy.

Essentially, the kappas during development testing with the MDS 3.0 from gold standard to gold standard nurses ranged from .86 to .93; in gold standard to facility nurses, .66 to .87.

And looking at the variability that still remains across for this measure, again, using 2.0 data and looking at July through September of 2009, the national average for daily physical restraint use was 3.3 percent with the range going from a minimum of 0.2 percent to a high of 6.7 percent.

MS. TRIPP: Actually, I think I am the primary on this. Yes. Okay, great. It
is late in the day.

Yes, I think this is a fairly simple issue. So, clearly, this is of high importance. It is responsive to a core public policy goal, as expressed in OBRA '87 and CMS regulations implementing OBRA.

Reducing restraints I think is a principle that is agreed to by almost all the stakeholders involved in this process. So, it is clearly of high importance.

I will just tell you what the numerator and denominator are for this. The numerator is all long-stay residents who are physically restrained daily during the seven days prior to an annual or quarterly significant change or a significant correction in MDS 3.0 assessment during the selected time window.

The denominator is all long-term-stay residents who have had an annual or quarterly significant change or significant correction in MDS 3.0 assessment during the
selected quarter and haven't been excluded.

A resident is excluded if the selected MDS 3.0 assessment was conducted within 14 days of admission or if there is missing data in relevant questions in the MDS. So, those are the exclusions.

The reliability appears to be very high for this. There were a couple of studies that were referenced in the material. There was no discrepancy in the day two study using MDS 2.0.

There was a national pilot test for the proposed MDS 3.0 measures that showed good reliability with a little evidence of confusion. Okay?

Validity, there wasn't a whole lot of data presented on the validity of the measure. So, I don't know if you could speak to that just briefly.

MS. CONSTANTINE: Sure. The University of Colorado evaluated validity of the current measure, and they did it in a
couple of different ways.

First, they examined the expected positive influence of public reporting on the quality of care by assessing the degree to which the quality measure was triggered and whether it has been improved over time. They also, again, looked at convergent validity, where you examine how the quality measure compared and it correlates to the other quality measures.

They also wanted to see whether the quality measure triggering rate was influenced by factors unrelated to the facility, such as seasonal variation in the triggering rates across. They looked at 13 quarters of data in 2006, and also looked at the amount of variance in the triggering rates explained by the state where the facility was located.

So, essentially, for public reporting, it seems that the measure is having some effect, as evidenced by the decline in
the triggering rate from 8 percent in the third quarter of 2003 to 3.5 percent in the second quarter of 2009.

And in regards to the convergent validity, the correlations with other clinical measures are weak, which might reflect more the limited clinical relationship of physical restraints to the other measures.

There's little evidence of seasonal variation, and 19.6 percent, though, of the variance in the reported rate for this measure was explained by the state in which the facility existed. So, there is definitely a difference between states. However, it also does allow a facility within that particular state to examine how they perform versus other facilities within the state.

MS. TRIPP: Okay. All right, thank you.

So, in terms of the usability, it seems like this is a highly usable measure.

CMS is expecting nursing homes to utilize the
measure as a tool to decrease the use of restraints. And the Advancing Excellence in America's Nursing Home Campaign supports the measure.

And real progress in reducing the use of restraints has been made since the measure has been used since 2002. So, it seems highly usable.

The feasibility seems to be quite easy as well, since it comes from MDS data, 3.0, and there's very little difference between 2.0 and 3.0 with respect to this. So, because of this, I gave it -- I mean there wasn't a whole lot of validity data to rely on, but I found that the items were completely met.

Ron Schumacher is the secondary reviewer.

DR. SCHUMACHER: Yes, as the secondary reviewer, I would concur with all of that. I thought this one was also relative straightforward. I really couldn't find a
significant weakness in this one. So, I would recommend that we go forward with it.

CO-CHAIR MUELLER: Any comments or questions?

DR. MODAWAL: Yes, I just have a comment in terms of how in the new MDS 3 physical restraints are defined. How is it categorized?

MS. TRIPP: It is categorized by either you could have a trunk restraint, a limb restraint, or chair prevents rising. It could be used while in a bed or out of bed in a chair. So, they refined the categories to clean up the definition a little bit and make it more understandable.

DR. MODAWAL: What is the rationale for the seven days before the MDS? Why was the seven-day cutoff chosen?

MS. TRIPP: Oh, that is basically a standard look-back period. There's a couple of items or quality measures that use a little bit different, but a standard seven-day look-
back period is what is utilized in many of the quality measures, taking a look seven days to see how often the restraint was used, and it was used with other measures.

MS. PACE: I was just going to ask to make sure I am understanding this right, in the seven days the restraints had to be used every day of the prior seven days in order for it to trigger?

MS. TRIPP: Yes.

MS. PACE: So, someone who is in restraints five out of the seven previous days --

CO-CHAIR GIFFORD: They're okay.

MS. PACE: Okay. And what was the rationale for that decision?

MS. CONSTANTINE: Well, I think that the focus was that it had to be something that happened daily, and then how would you be able to track, although I guess you could make differences in one to two days, two to three days, you know, four to five days, but --
MS. PACE: So, it was because the MDS item only asked if it was done daily in the past seven days or?

CO-CHAIR MUELLER: Section (P). Not used, used less than daily, and used daily.

MR. BOISSONNAULT: Karen and I were more or less on the same wave length. My question has to do with the research finding that you put out there that I found interesting.

You said, since '92, we have seen that measurement has had an impact. So, when you looked at the data, you saw that the folks who are restrained every day for the past seven days went down. Did they just move into the six-or-fewer-day category or did we find ways to get some people completely off restraints? Did you look at that?

Is there any thought, so that you don't squeeze the balloon from here to here, is there any thought about looking at all
three buckets?

MS. CONSTANTINE: That is a good question, and, no, not to my understanding did we look at other than daily to sort of stratify and look at it, but that is something we could definitely consider.

CO-CHAIR GIFFORD: Yes, Mary Jane.

DR. KOREN: We have been working, as you know, with Advancing Excellence on reducing restraints and really have gotten the national rate down quite a bit. At this point, CMS I think is sort of thinking, should we be on to bigger and better things? We've gotten them really down pretty far.

But it does raise the question, I think Bruce raised it, which is maybe now is the time to really change the criteria and say, not more than two or three days or something like that, or whatever. I don't know the exact buckets for the MDS. But maybe this is an opportunity to take the next step.

MS. CONSTANTINE: And push it
further.

DR. KOREN: Yes.

MS. GIL: I would like to see it look at the reduction in alarms.

(Laughter.)

CO-CHAIR GIFFORD: Yes, I would like CMS to actually define alarms as a restraint.

(Laughter.)

DR. MODAWAL: I had just a question in terms of adjustment. You know, restraints are used for a reason, and I think the most common reason being delirium and confusion and agitation, which sometimes is hard.

We haven't reached a point where, other than a person sitting with a patient, we can make the person safe in terms of falls and things like that. So, I wonder if some adjustment is needed, raising the same question, seven days and every day, a few days, to sort of factor in what is acceptable
and what is not in terms of adjustment for the behaviors and other difficult agitation or delirium.

I mean, as you know, once delirium starts, it is 30 days the person will need some kind of help. It may not be physical restraints, but maybe some alternative ways other than alarms, of course, of helping the person.

DR. SCHUMACHER: Well, doesn't that raise another question about when you talk about where did the people go who are using the restraints? Are we shifting, as an unintended consequence, to chemical restraints as opposed to physical restraints?

CO-CHAIR GIFFORD: My question is, why also the 14-day exclusion?

MS. CONSTANTINE: The 14-day exclusion?

CO-CHAIR GIFFORD: Yes. The 14-day, I mean, why? This is restraints for any period. I mean the literature is pretty clear
on the harm restraints cause overall and the fact that they induce delirium when used early. I am not sure why this isn't just a flat-out measure straight across the board.

MS. CONSTANTINE: If I could just take a look at that --

MS. GAGE: Roberta, was this the population that the short-stay patient would have lines and things, and so patients are sometimes restrained post-surgical in order to protect them from pulling out their lines, whereas that is not true with the long-stay population?

MS. CONSTANTINE: Okay, "assessment indicating it is an overadmission conducted" --

CO-CHAIR GIFFORD: I guess I'm questioning, why make this a long-stay measure? Why is this just a nursing home stay? Frankly, the hospitals would benefit from doing what the nursing homes do out there.
MS. CONSTANTINE: Well, yes, there was some concern during the TEP about, again, a patient coming straight from an acute care facility, and when in doubt, you know, if the patient had been restrained, until you assess the patients and figure out maybe what an underlying condition might be, that maybe a med reduction or meds given could help the patient or a change in their going from an acute care facility to a nursing facility. Just sort of acclimation might make a difference.

So, they didn't want to focus on the short-stay population, but I can certainly take your point.

CO-CHAIR GIFFORD: So, I'm hearing approve the measure actually as is, but the concern of the group is that they would like to see this measure, other measures, go further and expand to why it is short term. Why not go beyond daily? Add noise alarms as a form of restraint, and you almost need to
complement this with medication as a restraint.

But, as it is structured, I think it would be approval as is with no conditions other than we would really, I think, strongly word something for CMS to do more than just this. Give RTI some more money to do some more measures.

(Laughter.)

It's my taxpayer dollars.

(Laughter.)

MS. PACE: David, this one also has an exclusion for missing information. I just want to see if that is a concern for this measure as well. That was brought up in --

CO-CHAIR GIFFORD: Oh, sorry, yes.

MR. BOISSONNAULT: It is the issue that we have talked about where, if you leave any of the key things blank, they throw it out instead of assuming against you. So it is an incentive to leave it blank.

CO-CHAIR GIFFORD: So, we have to
amend the motion that we actually include
those as counting, count them in the
numerator?

MR. BOISSONNAULT: We have with
the last, with the caveat that unless there's
some compelling research, argument to go
otherwise, excluded data should mean that we
assume that they were restrained, not that
they weren't.

CO-CHAIR GIFFORD: So, it is
approved with that condition, and then the
other recommendation we had. Okay.

All in favor?

(Show of hands.)

Any opposed?

(No response.)

Abstaining?

(No response.)

Wonderful.

All right, we are through our
schedule to public comment and NQF member
comment.
Sandy? You don't have to say
anything if you don't want to, Sandy.

(Laughter.)

MS. FITZLER: I am, and maybe this
is something that you already have, but it is
just a few comments on the pressure ulcer
measure. That is because there wasn't much
discussion on it, and I don't have access to
the information that you have. So, you
already might have it in your information.

CO-CHAIR GIFFORD: We don't have
access to the information we have, either.

(Laughter.)

MS. FITZLER: Well, the issue is
it was identified that there's a lot of new
things to pressure ulcer assessment in MDS 3,
but one of the things that I did not hear
mentioned was we, for the first time, will be
looking at ways to code DTIs and unstageable
ulcers.

So, given that, when it comes to
the short-stay ulcer, or the short-stay
measure, if that individual has an unstageable
and we recognize it on admission, and then you
are looking at the measure, the assessment on
discharge, and by that time we can code it, is
that being considered a new measure or is this
an exclusion? So, that is No. 1.

And then, secondly, on that short
stay, where we are looking at the admission
assessment and then the discharge, currently,
the average length of stay is 29 days. Some
of those folks will be discharged much sooner
than that. We have a short period and we may
not always see healing in an ulcer in some of
those individuals. So, I can see that that
would be problematic, too.

MS. EDELMAN: I'm Toby Edelman
with the Center for Medicare Advocacy. I
would like to make a few brief comments.

First, I have been somewhat
troubled by what I have heard today. It seems
to me that a very significant portion of the
Steering Committee represents the nursing home
industry and there's very limited representation of consumer or beneficiary interest. I think that is an inappropriate balance on this Committee.

And the result I think is that a lot of the discussion, or a significant amount of discussion today has been how facilities will look when a measure is publicly reported. We heard a lot of discussion about not wanting facilities to be dinged. God forbid they look worse than they should.

Not a lot of discussion about whether the measure would be useful to nursing homes for quality improvement purposes, and certainly not discussion about whether consumers really want to hear about this information that is useful to them.

I know from working with residents and their families and advocates for residents that what people really care about is staffing. The literature we know indicates that the most important predictor of high
quality of care is the staff, the nursing staff in the nursing home, particularly registered nurses, but also the paraprofessional staff. And consumers understand that and, yet, the Committee voted down the two measures that were considered for staffing.

At least we are going to get that from Congress. Who would have thought it's easier to get something like that through Congress than through a committee?

My final points: I was on the TEP, and I think we had a very significant amount of enthusiasm for the chemical restraint issue that a couple of people raised just now here at the end.

We know that there's an enormous amount of anti-psychotic drug use in nursing homes. The MDS for the fourth quarter 2009 indicated 26 percent of residents are receiving anti-psychotic drugs. The general numbers, like 25 to 30 percent of residents
get anti-psychotic drugs. As many as half
don't have a diagnosis that would justify the
use of the drug. So, theirs is a lot of off-
label use.

Since 2005, the Food and Drug
Administration has had black box warnings,
first, for the atypical anti-psychotics, then
for the conventional anti-psychotics, talking
about an increase in morbidity for residents
with dementia.

And there was testimony by the
Food and Drug Administration in Congress in
2007 that approximately 15,000 residents are
dying from the inappropriate use of anti-
psychotic drugs.

Our TEP was interested in this,
and maybe RTI could get more money to look
into this because I think it is a very
important issue. I think people that
understand that physical restraints are a
problem, but the chemical restraints I think
are really replacing the physical, and it is
killing a lot of people.

Thank you.

MS. MONTALVO: Isis Montalvo from the American Nurses Association.

I just want to reiterate, I think, some of the key points that were made earlier. When we think about patients across settings, patients moving from the acute care setting to the long-term care setting, and we are looking at measures that are going to evaluate the care across settings, that it would really benefit us as providers, as consumers, to have those measures harmonized.

So, that way, you can follow that patient from the acute care setting to the long-term care setting, regardless of whether it is a fall, whether it is a pressure ulcer, regardless of staffing. Certainly accommodating what needs to be accommodated for that specific setting, but realizing the value in being able to measure that care across settings.
CO-CHAIR GIFFORD: So, CMS, can you put the MDS into the hospital setting? It would be helpful.

Any other comments?

(No response.)

We are ahead of schedule. So, I am going to take a quick moment.

MS. THOMPSON: I don't want to throw a monkey wrench in, but did I miss -- did we do 4?

CO-CHAIR GIFFORD: Did I miss something?

MR. BOISSONNAULT: I think what happened --

MS. THOMPSON: Did we do 004-10?

We did the 5.

CO-CHAIR GIFFORD: Oh, you're right, we didn't do fall rate. I apologize. Yes, we did. That's right, we did do it.

Yes.

MS. THOMPSON: Okay, I am sorry.

CO-CHAIR GIFFORD: Alice did it.
That's right, yes.

So, you're going to take us to
dinner somewhere, right? So, there's a
shuttle outside at six o'clock to take us to
dinner. Those who are staying there at the
hotel, at the Sheraton, can't get back to the
hotel unless you come to dinner with us. So,
those who are not staying at the hotel and
drove here, I guess you don't have to come to
dinner with us, if you don't want, but they're
welcome to come, right? Yes. Okay.

I want to take a quick moment. We
have time on the agenda tomorrow at lunch, but
I know some of you will probably be bolting
out of here. I just want to take a moment
just to go around the room, and each of you
can just sort of mention -- we are talking
about functional measures tomorrow. So, I
don't want to get into tomorrow's measures,
and we can talk about it afterwards.

But particularly in some of the
areas that we looked at today, which were
pain, pressure ulcers, prevention, staffing, and the mental health area, and others, just to comment on some areas that you would like to see some measures developed, because we are constrained by what actually gets submitted by the vendors out there, and also constrained by what they have actually decided to do.

As I say, we are not a measurement group, but we do have an opportunity to at least give some guidance to where we would like to see some additional measures. So, just I would like to go around the room, and since we only have 20 minutes, and there's 20 of us, you've got to keep your comments pretty short. We will have time to talk about it a bit tomorrow.

Mary Rose?

SISTER HEERY: I think psychotropic medication would be an excellent measure to look at. I think that impacts probably, that would be a domino effect on most of the measures we talked about today,
and we see negative outcome from the extended use of that. So, I would be a proponent of that.

I also think another measure I would like to see -- well, it is on tomorrow with the ADLs and things, but that would be my primary measure.

Thank you.

DR. ORDIN: I would say the CAHPS measures.

MR. KUBAT: I think I would echo that comment about CAHPS or at least about satisfaction or experience of care, and so forth.

From the first time serving on the first Steering Committee, it was identified then. It has been an absolute frustration to me to see what the experience has been since then because I saw the development of nursing home CAHPS.

I had conversation with AHRQ and whatnot about that. They developed the tool
to put it up in the public domain for everybody to ignore. And yet, at the same time, you have hospital CAHPS, home health CAHPS. Home health CAHPS did go through the NQF process, and so forth.

And the only thing I ever really wanted or hoped that CMS would do is to do with CAHPS or with satisfaction or experiences of care what they have done with MDS, which is just define the specs and let existing vendors embed it within their processes.

MEMBER NAIERMAN: I would like to echo the CAHPS idea, but I would like to add a couple of nuances to it.

First of all, given how many patients/residents there are with dementia, I would like to see someone do some research on surrogate reporting, where it is the professional or the family caregiver.

I would also like to ask we consider looking at end-stage dementia as a possible life-limiting illness with the
possibility that that might lead to more
palliative care and less aggressive care.

There has been some recent literature about
that that has to do with, I think,
appropriateness of care, waste, and a lot of
related kinds of things.

So, end-stage dementia, can we
consider it a life-limiting illness? In that
case, is hospice and palliative care more
appropriate than life-prolonging care or
aggressive kinds of treatments?

MS. BELL: And I would agree with
everything that has been stated and add a
couple.

One, beyond just like psychotropic
meds, but looking at management of
polypharmacy as a whole and, additionally,
looking back to the fall issue, looking at
identification of fall risk factors and care
planning to address individualized risk
factors.

MS. FRANDSEN: I know we are
talking about it tomorrow, but incontinence;
there's so much prevalence in nursing homes.
So, that is important.

I would also like to see something
about person-directed or surrogate-directed
care.

DR. NIEDERT: And along the same
lines as patient satisfaction, I would like to
see something about texture-modified diets,
including the use of thickened liquids. They
lead to dehydration. Most of the time none of
us in this room would drink them, either, but
yet we expect our residents to do it. It is
a quality-of-life issue.

And many physicians will not
change the order because they are concerned
about lawsuits and litigation, and all of
that. Yet, our residents are suffering
terribly because they are cupping their hands;
they are doing all kinds of behaviors. Then
what do we do when they do behaviors? Then we
put them on meds, and it is just a vicious
circle.

So, I would like to see something about dysphasia, swallowing.

CO-CHAIR GIFFORD: Meds that are anticholinergic and dry out their mouths, so they need to drink more.

DR. NIEDERT: That's right.

DR. ZOROWITZ: I'm still worried about the staffing issue. I am sorry we were not able to get a measure that was workable, but I think that we need to somehow figure out how to appropriately and accurately measure staffing, given that there is diversity in how staff are allocated at various nursing homes. It is a difficult issue, but I don't think it is one that is going to go away.

DR. MODAWAL: Yes, I think I agree with some of the measures sort of mentioned before which would make a difference. My interest would be to see something on delirium. I think the problem is prevention is important and management is important, but
we don't understand the mechanism of delirium. That is why we can't have concrete interventions or management approaches to it.

We brought up the polypharmacy and dementia and falls. So, I think it is a major area which needs to be studied in nursing homes because that is where the future studies will be done. The time for studying delirium in hospitals is over or at least it will be. In terms of understanding the life history of delirium, I think the future studies of delirium will be in nursing homes. Some approaches should be made as quality indicators in this area.

MS. TRIPP: Yes, I also want to talk about anti-psychotic drugs in the long-term care setting. If it is okay, and I hope you don't mind the intrusion, but I am going to email a white paper to everyone on this Committee tonight. Tomorrow I will bring a basically one-page kind of talking points that summarizes some of the data. So, I will bring
that in tomorrow. But I share that concern.

DR. KOREN: We have touched on person-centered care, but we really have done nothing around culture change. And it is really too bad. I think that one of the things that has inhibited the field is that we haven't had metrics, but we are starting to get metrics. Now we need to get them tested.

One of the things that we have done, I think, in Advancing Excellence that speaks to person-centeredness is we are looking at the issue of consistent assignment because we know from focus groups with residents that the thing they value the most highly are relationships with their nurses' aides. So, figuring out ways to measure this, and I think we finally have a way to objectively measure it from the resident's perspective.

We also have started to try to collect some data about including residents in setting goals for their care and participating...
in care planning. Questions about how do you
give life meaning in a nursing home, and we
are very focused on you can get up anytime you
want, but if there is nothing to get up for,
what are we doing?

So, I think that there are things
that we should be starting to look for
metrics. We may have to be pretty creative
about it, and then start to test them, if we
are really going to start to measure quality
in nursing homes beyond just physical care.

MS. GIL: I absolutely ditto what
Mary Jane is saying. I think it is such an
important issue for us to tackle and not an
easy one whatsoever in terms of looking at
quality of life and truly looking at how we
are able to really fulfill lifestyle
preference and choice.

I also like the idea of CAHPS. I
think there's a lot of quagmires that they are
experiencing in other settings that we can
learn from, but I think it is a real important
piece as well.

And again, on all the alarms, I do think it really is a restraint in a horrific way. We have seen really great studies going on with decreasing alarms without any increase in falls. So, I will make that a plug for the alarms.

MS. ROSENBAUM: Well, infection control and prevention is where I'm at. So, I would like to see more done with especially communication between healthcare facilities about multi-drug-resistant organisms and the residents that ping-pong back and forth between the hospital and the nursing home, and also more judicious use of antibiotics because we all know that the multi-drug-resistant organisms are just continuing to appear and appear. We have to look at how we treat our residents in the nursing home.

DR. SCHUMACHER: So, I would echo the thoughts about polypharmacy and anti-psychotic use. I will throw out a couple of
others.

One that people kind of touch on, advanced care planning. Is there a way that we can measure at least attempts to have discussions around advanced care planning with residents?

Then, the last one would be inappropriate hospital admissions. I think that is something we need to look closely at.

MR. BOISSONNAULT: Yes, I think it was Chuck Darby, the late Chuck Darby's dream to have a unified way of measuring patient experiences of care, and CAHPS was it. So, I am glad you brought that up.

By the way, in the process of getting that passed, there was a sort of political deal to drop all the coordination-of-care questions, which are the only ones that actually have a tie to clinical outcomes. So, I would love to see that go back in.

And there may be things that we measure on a CAHPS for this population that
aren't relevant in the hospital, sort of a well-being scale, a usefulness scale or something, a happiness scale. I don't know.

I love the idea of, you know the infection control people said it, the reason MRSA is not going down is because we are trying to fix it the same way we fixed heart attacks, which is one hospital, one unit at a time, when, in fact, infection control is no stronger in any community than the weakest link. Our data is real clear on that.

So, MRSA would be something I would go after, but I would go after it not only in a harmonized way, but actually in a coordinated way with one set of measures over different settings, which is more than harmonization.

Then, on polypharmacy, I kind of like how it intersects with chemical restraints. There is one other factor that folks developing a measure could consider, which is the P450 pathway, overwhelming that.
I actually think it would be sort of a risk-adjuster as to how many is too many that would be easy to deal with. Certain drugs need that.

But we talked about advanced directives, and I think I'm there.

MS. THOMPSON: I keep crossing things off my list here, but I think one that would be nice to look at is return-to-community and transition planning.

DR. GRIEBLING: As a surgical specialist, I have a couple of thoughts on how our care interacts with people in nursing home care.

So, I would support things related to nutrition, not just weight loss but nutrition, because it impacts wound healing and a number of other things.

Certainly polypharmacy and delirium.

I think the issue about advanced directives is critical in terms of, as Naomi
said, you know, utilization of care and resources, especially at end of life and things like that.

And then another area, and Lisa may have some comments on this, but one of the things I don't think we have touched on are sort of the legal and financial aspects of care, and how that influences families, family caregivers. I mean I know from my own practice in nursing homes I have seen couples have to divorce and things in order to reach spend-downs and things, and how those kinds of outcomes, which I think are going to be hard to capture, but how that impacts families in their interactions, their spiritual needs, those types of things.

CO-CHAIR MUELLER: I am just going to amplify two. One has to do with measures related to culture change. So, ways to measure organizational practices that promote person-directed care.

And then, the other one I want to
amplify is the nurse staffing measure or measures, particularly a measure, measures of turnover and stability, and also, specifically, turnover and stability of the director of nursing and the administrator.

CO-CHAIR GIFFORD: I would like to see more non-MDS measures. I think we have let the tail wag the dog long enough.

So, I will re-amplify quality of life. You know we focus on the clinical. We need to do quality of life. So, whether it is CAHPS, whether it is culture change, structural measures -- you know, if you give me a medication at 4:00 in the morning and stick a needle in me to draw blood at 5:00 in the morning, I am going to swat you and then be restrained and put on chemicals.

(Laughter.)

But I also think things like flexibility in when people eat, when they bathe, noising in there. It is at the infancy. I thank the Commonwealth for funding
that type of work. If you can fund more of it
to get measures out there, Mary Jane, it would
be great, but I think we need to move in that
direction.

The other would be
rehospitalization, the ping-ponging. The
hospitalization rate is just staggering. If
not just for the cost control, we know that
the hospitals are dangerous for our patients
when they go there, if we can keep them out of
the hospital, and a lot of it goes to the end-
of-life discussion. So, it is not just the
PDA.

So, if we can really look at
rehospitalization rates, I mean it is just --
you know, the fact that one out of four go
back within 14 days is just such a bad sign of
their healthcare system.

DR. KOREN: Giff, just one thing.
You stimulated a thought, as did the other
lady who talked about transitions.

You know, there is an NQF
transitional care measure, the CTM-3. There is no reason that that could not be used for the discharges of the post-acute care patients/residents.

Because at least then you would see whether or not there was some value in the post-acute care and whether or not, once they got into the community, they stayed there.

CO-CHAIR GIFFORD: Yes, excellent point.

Then, I just want to re-emphasize staffing. You know, I, too, am sad that we couldn't get something on staffing, but, to me, I am more interested in and I think the greater impact is not necessarily the staffing levels and everything else. While there is good data on it, it is consistent assignment and turnover. If we can get those, that would be very valuable.

DR. BURSTIN: That was a spectacular list. Obviously, there is lots more work to do.
I think the idea of the CTM-3 is a great idea. We will try to make sure we bring those specs for you to take a look at tomorrow. That would be a relatively easy one for us to go to Eric Holman and have him look at it -- he is a geriatrician as well -- to see whether it is easily applicable. It wouldn't require any other work other than the fact that it is already endorsed and in use in multiple states as well.

DR. KOREN: We are actually piloting its use in home care as for discharge from home healthcare into the community.

I was talking to Alice Bonner, who is in Massachusetts with the Department of Health. They are willing to test it in a couple of nursing homes.

CO-CHAIR GIFFORD: Yes, I would just go back to the beginning comments. While a lot of work in CMS really shapes the direction, NQF-endorsed measures can be and will be used by many groups outside of CMS.
So, it doesn't have to be MDS-based. You know, there are states that are hungry to try to do some of that.

CMS wants to make a comment.

DR. LING: Hi. I'm Shari Ling.

CO-CHAIR GIFFORD: You are CMS, yes.

(Laughter.)

DR. LING: I'm intimidated.

Just thank you so much for your comments and suggestions. They are extraordinarily helpful. We have an open ear and a collective open mind.

I think it is important for you to know that we are just getting started. These measures that you have been presented today are from the MDS 3.0. There are other measures still that could be built from the MDS 3.0, taking full advantage of the enhancements of the instrument.

But we are also interested in facilitating the development of measures that
are not necessarily originating in the MDS 3.0

So, speaking to the intent of taking a
systemwide approach, the coordination of care,
the transfer of information and of that care,
I think those are important concepts that they
are on our radar screen. The concepts of
healthcare-associated infections and how to
look at things from a system point of view,
not just within facilities or a setting, that,
too, is on our radar screen.

So, I am very encouraged by your
comments and suggestions. I really sincerely
thank you.

DR. BURSTIN: Certainly, based on
the comments of the Steering Committee, we
will try one more time to go back to AHRQ and
CMS on the CAHPS issue because we really were
hoping to have it submitted to this project.

CO-CHAIR GIFFORD: So, a couple of
housekeeping comments.

I lied before. Yes, the magic bus
is not out there at six o'clock. It is out
there at 6:20. So, you have 20 minutes to do
whatever.

What is the address of the
restaurant? I don't know. The restaurant?
MS. THEBERGE: The shuttle is
leaving at 6:20, is what I believe the
schedule says.

It is Clyde's restaurant in Chevy
Chase.

CO-CHAIR GIFFORD: And there is a
change for tomorrow. The shuttle, despite
what was the confusing stuff slid under our
doors, those staying at the Sheraton, and we
were trying to keep you from coming; that's
why.

(Laughter.)

And despite the different agendas,
the shuttle is leaving at 8:10 tomorrow.
Right?

MS. THEBERGE: That is what my
schedule says, 8:10.

CO-CHAIR GIFFORD: At 8:10
tomorrow from the Sheraton. So, be down by
8:05 or we will leave you out.

The meeting starts at --

MS. THEBERGE: 8:45.

CO-CHAIR GIFFORD: -- 8:45.

MS. THEBERGE: With a working
breakfast.

CO-CHAIR GIFFORD: We will start
at 8:45, not 8:46 or 8:47, but 8:45 tomorrow
morning.

Thank you all very much.

MS. THEBERGE: Thank you,
everyone.

(Whereupon, at 6:01 p.m., the
proceedings in the above-entitled matter were
adjourned for the day, to reconvene the
following day, Thursday, April 22, 2010, at
8:45 a.m.)
employees 161:11
empowering
241:19 242:10
enabled 49:11
enactment 146:17
encourage 403:11
420:6 423:2
encouraged 86:20
263:20 497:11
encouraging 263:16
ended 168:17
endorse 19:10
21:11 171:16
184:19 222:3,3
228:11 232:3
233:17 234:2
235:18 236:3
247:17 436:8
endorsement 20:17
38:13 81:4 121:11
124:9,22 131:21
157:2 165:20
167:22 232:12
338:18 344:7
495:9
endorse 20:8
20:8,9 21:22
24:17 34:1,8 76:1
81:21 82:17
120:11 121:13
127:19 134:19
150:11 166:9,11
166:22 170:3
171:3 172:3
221:15 223:3,15
224:2,20 229:15
231:15 232:22
233:7 234:7 235:1
235:7 236:18
246:10,11,20
249:8 259:6,8,10
262:3,22 263:9
264:12 290:16
296:20 306:12,13
402:6
endorsements
20:19
endorses 127:21
endorsing 290:7
423:20
ends 338:20 445:17
end-all 382:11
end-of 297:2
end-stage 53:8
480:21 481:7
end-users 36:3
energy 95:14
184:11
engaged 29:4
England 365:21
enhance 454:7
enhancements 47:2
496:20
enormous 473:17
ensure 32:8 54:19
ensured 33:16
ensuring 138:11
enter 117:9
entered 106:2
entertain 131:6
190:18
enthusiasm 417:11
473:14
entire 18:20 54:7
368:10,13
entirely 59:17
331:20
environment 21:13
141:2 210:2,2
239:15 345:12
epidemiology 8:13
15:7
episode-based
27:19
equal 92:12 427:11
427:21 429:14
434:7 446:15
equally 57:18
252:19
equates 257:18
equity 53:15
ER 288:18
Eric 84:16 495:5
er 370:14
ter 125:2 216:13
ters 111:16
133:8 333:15
especially 23:7
30:19 33:1 51:20
198:22 202:13
285:7 351:6,9
378:19 439:22
487:10 491:2
essence 197:2
216:5 374:14
essentially 162:22
203:16 215:18
240:17 273:18
290:12 297:12
305:9 310:2
356:12 363:9
383:16 453:15
454:8 457:20
established 299:5
399:3
estimate 98:20
estimated 361:15
et 24:15 95:14
158:12 291:18
301:9 405:3
etheral 17:12
evaluate 3:17 21:20
69:22 475:10
evaluated 20:20
175:20 456:21
evaluating 61:1
65:5 245:10
evaluation 3:8
12:20 25:21 30:3
64:6 75:15,17,21
166:20 190:9
216:19 290:10
event 305:18
events 272:5
eventual 191:20
eventually 144:17
190:8 392:4
Evercare 15:10
everybody 72:11
102:12 128:17
151:20 173:2
250:2 257:15
258:10 260:4
268:6 282:13
288:20 337:14
353:1 480:2
evidence 29:21
30:10 32:9 20:22
4:19 47:10,11
108:17,19 109:4
114:10 134:4
136:14,20 137:5
165:13 167:9
182:1,8 202:11
275:11 276:19
280:5 292:8 293:9
293:12 301:13
334:20 368:19
379:11 389:7
425:3,5 428:6
430:22 441:6,10
451:1 456:14
458:9
evidenced 457:22
evidently 414:14
evolve 217:20
exact 435:12
463:20
exactly 36:19
142:12 150:13
164:10 170:20
195:2 356:21
372:4 378:22
422:11
exam 42:21 72:5
examine 183:2
390:14 457:8
458:16
examined 124:5
362:15 457:2
example 27:11 28:8
28:14 33:9 39:19
39:21 40:4 62:19
84:10 101:11
183:3 216:11
285:13 288:15
318:1 391:2 407:2
407:7
exam-taking 441:21
exceeded 351:16
exceeds 206:2
Excellence 203:1
273:7 282:5 283:3
288:3 453:11
459:2 463:9
485:10
excellent 86:14
293:9 352:17
427:7 478:19
494:9
exception 197:22
310:4,4
exceptional 256:10
excited 55:3 84:4
exclude 318:22
356:3 369:1
404:17
excluded 106:1
145:9 152:20
177:9 319:13
320:15 342:14
368:6 386:1 403:1
403:5 435:15
445:18 456:1,2
469:7
excludes 152:7
181:14 207:14
438:16 450:1
excluding 101:12
153:6 287:8 296:5
314:15 403:2
432:7 449:19
exclusion 89:14
100:19 102:21
117:20 296:6
368:19 386:4
388:5 399:8 428:2
429:1 446:17
451:7 465:17,19
468:13 471:6
exclusions 177:21
315:22 402:17
448:8 449:22
forbid 472:10
force 36:18 108:11
323:13,19 328:8
foregoing 179:4
270:15 424:10
forgetting 391:12
forgive 187:16
forget 166:7
form 47:10 187:11
300:15 436:20
467:22
formal 301:10
format 134:15
400:14 406:5
407:17,21
former 105:16
forms 18:2 60:6
61:12 184:13
formula 116:17
156:5 160:3
formulas 156:4
formulate 381:22
forth 37:13,22
63:11 109:14
111:12 114:11
123:17 125:4
140:21 141:1
228:17 321:15
324:21 335:4
345:3,5 422:7
445:12 479:14
480:5 487:13
forthcoming 228:6
fortunate 291:8
Forum 1:1 401:1
forward 17:20
29:16 30:16 34:12
35:1,17 40:17
43:3 47:17 54:8
56:2 57:4,13
58:20 60:18 88:13
114:13 129:2
132:17 143:6
146:19 168:16
169:4,8 171:11
172:20 186:1
193:15 196:3,4
211:12 216:8
217:2,6 220:12,14
221:9 223:11
229:4 232:12
247:19 251:17
259:11,19 282:20
295:8 299:12
403:20 460:2
found 48:17 49:16
88:9 97:7 133:22
138:5 285:9 287:3
295:4 362:1 441:2
459:15 462:10
Foundation 5:23
14:7 137:16 138:5
147:4
four 31:21 41:5
73:14 74:16 75:13
97:18 184:4
186:20 194:6
198:11 261:15,15
262:7 281:10
306:6 342:22
343:1 367:10
443:16,18 444:1
461:22 493:16
fourth 75:22
473:19
four-month 444:17
fracture 361:10
376:13 377:15
387:8
fractured 38:7
62:22
fractures 377:10
385:10 389:11
frail 208:12 308:11
frame 23:13 205:13
framed 47:4 126:1
framework 273:5
Frandsen 1:21 4:14
5:6,12 14:10,11
90:1,2 139:11
171:10 180:10
181:9 186:21,22
200:5 481:22
frank 185:3
frankly 108:10
214:4 235:20
466:20
free 123:12 125:4
125:15 199:14
303:4 453:1
freedom 452:20
frequency 91:1
205:18,26 206:4
226:11 227:4
257:17,19 259:1
265:8
friend 115:22
front 300:7 322:5
frustration 37:15
479:17
FTE 162:7
fulfill 486:17
fulfilling 212:18
full 20:7 121:12
161:5 221:4
229:12,14 237:1
299:13 327:20
496:19
fully 116:18 202:17
212:4 348:1 366:6
full-blown 68:15
full-time 210:15
fun 237:18
function 27:12,14
41:6 45:3
functional 39:21
52:11 55:7 66:13
362:11 398:21
477:18
functionality 54:1
63:8 133:5,7
functionally 53:4
functional/cognit... 53:17
functioning 64:21
139:19 202:20
437:19
functions 45:12
152:20
fund 4:5 6:19 15:2
493:1
fundamental
192:11 217:21
218:11 234:10
Fundamentally
215:16
funded 21:2
funding 185:18
228:18 492:22
funnel 34:19
further 24:14 42:3
49:4 75:18 182:14
212:11 243:22
276:3 297:20
464:1 467:20
future 39:6,10
149:21 150:6
168:8 171:18
186:7 264:12
297:20 298:5
303:21 409:1
484:7,11
fuzzy 317:11,12

G

Gage 4:11 16:14,14
83:22 84:2 90:19
91:6,9,13 94:11
94:19 96:11,17,22
97:4,14 98:15,19
99:8,19 100:18
101:5 104:12
105:11 107:1,16
107:20 108:1
109:11 111:6,21
112:11,16,20
113:1 118:1,16
119:1,6 122:20
123:21 127:10,16
175:21 234:15
323:4,15 324:1,8
324:11 357:13,15
377:17 466:7
gain 18:15 242:18
410:1
gait 391:6 444:6
445:8
Gallagher 4:23
<table>
<thead>
<tr>
<th>Page 559</th>
</tr>
</thead>
<tbody>
<tr>
<td>158:2</td>
</tr>
<tr>
<td>2(a)(8) 155:10</td>
</tr>
<tr>
<td>157:18,21</td>
</tr>
<tr>
<td>2(b) 322:17</td>
</tr>
<tr>
<td>2(e) 163:16</td>
</tr>
<tr>
<td>2.0 41:18 42:4 43:6</td>
</tr>
<tr>
<td>44:13 49:9 85:17</td>
</tr>
<tr>
<td>88:19 105:16</td>
</tr>
<tr>
<td>203:17 207:21</td>
</tr>
<tr>
<td>208:19 211:13,15</td>
</tr>
<tr>
<td>215:18 229:19</td>
</tr>
<tr>
<td>232:8 234:9</td>
</tr>
<tr>
<td>273:13 274:11</td>
</tr>
<tr>
<td>291:15 294:9</td>
</tr>
<tr>
<td>311:2 343:19</td>
</tr>
<tr>
<td>344:8 354:3</td>
</tr>
<tr>
<td>362:21 363:9</td>
</tr>
<tr>
<td>436:3,22 437:4</td>
</tr>
<tr>
<td>438:1 442:17</td>
</tr>
<tr>
<td>453:16,17 454:15</td>
</tr>
<tr>
<td>456:11 459:12</td>
</tr>
<tr>
<td>2.3 304:18</td>
</tr>
<tr>
<td>2.5 398:20</td>
</tr>
<tr>
<td>2.8 304:20</td>
</tr>
<tr>
<td>2:03 270:17</td>
</tr>
<tr>
<td>20 3:7,9 74:18</td>
</tr>
<tr>
<td>102:6 175:4 177:7</td>
</tr>
<tr>
<td>207:1 209:9 389:9</td>
</tr>
<tr>
<td>389:13 398:21</td>
</tr>
<tr>
<td>413:10 424:15</td>
</tr>
<tr>
<td>478:13,13 498:1</td>
</tr>
<tr>
<td>20th 32:13</td>
</tr>
<tr>
<td>20-year-old 353:5</td>
</tr>
<tr>
<td>200,000 308:13</td>
</tr>
<tr>
<td>2001 142:21 143:2</td>
</tr>
<tr>
<td>363:5,8</td>
</tr>
<tr>
<td>2002 459:7</td>
</tr>
<tr>
<td>2003 234:10 458:2</td>
</tr>
<tr>
<td>2004 21:9 143:20</td>
</tr>
<tr>
<td>173:22</td>
</tr>
<tr>
<td>2005 474:5</td>
</tr>
<tr>
<td>2006 345:5,13</td>
</tr>
<tr>
<td>457:16</td>
</tr>
<tr>
<td>2006-2007 308:17</td>
</tr>
<tr>
<td>2007 304:19 308:22</td>
</tr>
<tr>
<td>474:13</td>
</tr>
<tr>
<td>2008 137:19</td>
</tr>
<tr>
<td>2009 454:16 458:3</td>
</tr>
<tr>
<td>473:19</td>
</tr>
<tr>
<td>2010 1:9 118:17</td>
</tr>
<tr>
<td>136:4 308:18</td>
</tr>
<tr>
<td>499:17</td>
</tr>
<tr>
<td>2011 27:12 39:20</td>
</tr>
<tr>
<td>2012 39:20</td>
</tr>
<tr>
<td>202 5:17,18</td>
</tr>
<tr>
<td>203 5:19</td>
</tr>
<tr>
<td>207 5:21</td>
</tr>
<tr>
<td>21 1:9</td>
</tr>
<tr>
<td>214 5:23</td>
</tr>
<tr>
<td>215 5:21,23</td>
</tr>
<tr>
<td>217 5:21,25</td>
</tr>
<tr>
<td>22 499:17</td>
</tr>
<tr>
<td>24 35:22 36:11</td>
</tr>
<tr>
<td>117:7 167:16</td>
</tr>
<tr>
<td>362:3,5 399:20</td>
</tr>
<tr>
<td>25 40:20 473:22</td>
</tr>
<tr>
<td>26 3:10 473:20</td>
</tr>
<tr>
<td>263 6:2,4</td>
</tr>
<tr>
<td>264 6:5,9</td>
</tr>
<tr>
<td>27 91:11</td>
</tr>
<tr>
<td>272 6:8,11</td>
</tr>
<tr>
<td>273 6:12,15,17</td>
</tr>
<tr>
<td>277 6:19</td>
</tr>
<tr>
<td>283 6:21</td>
</tr>
<tr>
<td>284 6:17</td>
</tr>
<tr>
<td>285 6:19</td>
</tr>
<tr>
<td>286 6:22</td>
</tr>
<tr>
<td>29 471:10</td>
</tr>
<tr>
<td>293 6:23 7:2</td>
</tr>
<tr>
<td>299 7:5</td>
</tr>
<tr>
<td>3 68:9,12 71:21</td>
</tr>
<tr>
<td>75:20 198:16</td>
</tr>
<tr>
<td>204:9 209:10</td>
</tr>
<tr>
<td>252:10,18,18,19</td>
</tr>
<tr>
<td>276:3,14 304:9</td>
</tr>
<tr>
<td>329:18,20 356:14</td>
</tr>
<tr>
<td>364:16 371:4</td>
</tr>
<tr>
<td>376:3,6 414:3</td>
</tr>
<tr>
<td>460:6 470:16</td>
</tr>
<tr>
<td>3-generated 174:20</td>
</tr>
<tr>
<td>3.0 41:18 42:5,8</td>
</tr>
<tr>
<td>43:6 44:12,12</td>
</tr>
<tr>
<td>47:3 49:9 55:1,3</td>
</tr>
<tr>
<td>72:7 76:14,15</td>
</tr>
<tr>
<td>79:6 87:17 109:21</td>
</tr>
<tr>
<td>112:19 121:4</td>
</tr>
<tr>
<td>127:5,7 203:9,17</td>
</tr>
<tr>
<td>207:9,18,21</td>
</tr>
<tr>
<td>208:19 211:13,15</td>
</tr>
<tr>
<td>215:18 221:14</td>
</tr>
<tr>
<td>228:7,20 229:4,10</td>
</tr>
<tr>
<td>229:20 232:9</td>
</tr>
<tr>
<td>235:19 273:13,14</td>
</tr>
<tr>
<td>273:18 290:9</td>
</tr>
<tr>
<td>291:20 295:1,13</td>
</tr>
<tr>
<td>296:13,17 297:21</td>
</tr>
<tr>
<td>297:22 298:17</td>
</tr>
<tr>
<td>299:7,14 310:3,8</td>
</tr>
<tr>
<td>310:11 311:2</td>
</tr>
<tr>
<td>332:4 333:5,13</td>
</tr>
<tr>
<td>343:21 345:14</td>
</tr>
<tr>
<td>352:18 353:20,21</td>
</tr>
<tr>
<td>354:3,9 357:12</td>
</tr>
<tr>
<td>361:20 362:13,19</td>
</tr>
<tr>
<td>362:13 373:19</td>
</tr>
<tr>
<td>405:6 414:17</td>
</tr>
<tr>
<td>436:5,10,16 437:2</td>
</tr>
<tr>
<td>437:5,7,10 442:17</td>
</tr>
<tr>
<td>442:20 445:15</td>
</tr>
<tr>
<td>448:7 450:2</td>
</tr>
<tr>
<td>453:16 454:9</td>
</tr>
<tr>
<td>455:17,22 456:3</td>
</tr>
<tr>
<td>456:13 459:11,12</td>
</tr>
<tr>
<td>496:17,19 497:1</td>
</tr>
<tr>
<td>3.0-based 44:6</td>
</tr>
<tr>
<td>3.3 454:18</td>
</tr>
<tr>
<td>3.5 458:2</td>
</tr>
<tr>
<td>3.15 359:4</td>
</tr>
<tr>
<td>3.30 359:4</td>
</tr>
<tr>
<td>30 19:21 20:18</td>
</tr>
<tr>
<td>74:18 175:5 177:7</td>
</tr>
<tr>
<td>178:8,13 362:22</td>
</tr>
<tr>
<td>363:11 368:6,11</td>
</tr>
<tr>
<td>413:11 465:5</td>
</tr>
<tr>
<td>473:22</td>
</tr>
<tr>
<td>30th 333:6</td>
</tr>
<tr>
<td>30-day 444:18</td>
</tr>
<tr>
<td>300 7:2,7</td>
</tr>
<tr>
<td>309 7:8,9,10,13</td>
</tr>
<tr>
<td>31 363:12</td>
</tr>
<tr>
<td>310 7:16</td>
</tr>
<tr>
<td>314 7:18</td>
</tr>
<tr>
<td>321 7:19</td>
</tr>
<tr>
<td>323 7:18</td>
</tr>
<tr>
<td>338 7:21</td>
</tr>
<tr>
<td>339 7:18</td>
</tr>
<tr>
<td>345 7:22</td>
</tr>
<tr>
<td>346 8:2,6,9</td>
</tr>
<tr>
<td>347 8:11</td>
</tr>
<tr>
<td>352 8:14</td>
</tr>
<tr>
<td>353 8:15</td>
</tr>
<tr>
<td>357 8:17</td>
</tr>
<tr>
<td>359 8:15</td>
</tr>
<tr>
<td>361 8:19</td>
</tr>
<tr>
<td>362 8:20</td>
</tr>
<tr>
<td>363 8:21,24</td>
</tr>
<tr>
<td>366 9:2</td>
</tr>
<tr>
<td>369 9:4</td>
</tr>
<tr>
<td>373 9:6</td>
</tr>
<tr>
<td>38 49:17</td>
</tr>
<tr>
<td>39 3:13</td>
</tr>
<tr>
<td>396 9:7,8,10</td>
</tr>
<tr>
<td>424 9:20,22,24 10:2</td>
</tr>
<tr>
<td>425 10:4</td>
</tr>
<tr>
<td>426 10:5</td>
</tr>
<tr>
<td>427 10:6,9</td>
</tr>
<tr>
<td>430 10:10</td>
</tr>
<tr>
<td>432 10:12</td>
</tr>
<tr>
<td>433 10:14</td>
</tr>
<tr>
<td>44 3:13</td>
</tr>
<tr>
<td>45 3:14</td>
</tr>
<tr>
<td>4500 362:1</td>
</tr>
<tr>
<td>453 10:15</td>
</tr>
<tr>
<td>454 10:16,19</td>
</tr>
<tr>
<td>458 10:21</td>
</tr>
<tr>
<td>460 10:19</td>
</tr>
<tr>
<td>461 10:21</td>
</tr>
<tr>
<td>463 10:22,24</td>
</tr>
<tr>
<td>472 10:25</td>
</tr>
<tr>
<td>473 11:3,6</td>
</tr>
<tr>
<td>474 11:9</td>
</tr>
<tr>
<td>478 11:12</td>
</tr>
<tr>
<td>480 11:17,19</td>
</tr>
</tbody>
</table>

Neal R. Gross & Co., Inc.
202-234-4433
<table>
<thead>
<tr>
<th>600</th>
<th>410:12</th>
</tr>
</thead>
<tbody>
<tr>
<td>61</td>
<td>4:4</td>
</tr>
<tr>
<td>638</td>
<td>363:7</td>
</tr>
<tr>
<td>65</td>
<td>308:15 346:9</td>
</tr>
<tr>
<td></td>
<td>362:9 442:11,12</td>
</tr>
<tr>
<td></td>
<td>443:2</td>
</tr>
<tr>
<td>66</td>
<td>363:6,7 454:12</td>
</tr>
<tr>
<td>67</td>
<td>3:24</td>
</tr>
<tr>
<td>685</td>
<td>87:2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>7154:2 180:7</td>
</tr>
<tr>
<td>70 4:4,5 52:7</td>
</tr>
<tr>
<td>72 302:17 308:16</td>
</tr>
<tr>
<td>73 4:6 309:3</td>
</tr>
<tr>
<td>75 66:11 361:15</td>
</tr>
<tr>
<td>76 309:10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>8276:11 359:21</td>
</tr>
<tr>
<td>360:1 361:4,5</td>
</tr>
<tr>
<td>376:19 377:3,3</td>
</tr>
<tr>
<td>384:9 458:1</td>
</tr>
<tr>
<td>8:05 499:2</td>
</tr>
<tr>
<td>8:10 498:18,21,22</td>
</tr>
<tr>
<td>8:45 499:4,5,9,9,18</td>
</tr>
<tr>
<td>8:46 499:9</td>
</tr>
<tr>
<td>8:47 499:9</td>
</tr>
<tr>
<td>80 174:12</td>
</tr>
<tr>
<td>82 309:8</td>
</tr>
<tr>
<td>84 4:8</td>
</tr>
<tr>
<td>85 4:9 202:15 309:2</td>
</tr>
<tr>
<td>86 4:11 454:11</td>
</tr>
<tr>
<td>87 454:12 455:5</td>
</tr>
<tr>
<td>88 92:4,5 203:13</td>
</tr>
<tr>
<td>89 204:2 214:1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>992:3,7 93:11</td>
</tr>
<tr>
<td>134:9 205:2,11</td>
</tr>
<tr>
<td>320:10 325:21</td>
</tr>
<tr>
<td>362:6</td>
</tr>
<tr>
<td>9:00 1:12</td>
</tr>
<tr>
<td>9:12 12:2</td>
</tr>
<tr>
<td>90 4:13 178:10</td>
</tr>
<tr>
<td>302:15 308:18</td>
</tr>
<tr>
<td>309:18 399:15</td>
</tr>
<tr>
<td>410:16</td>
</tr>
</tbody>
</table>

Neal R. Gross & Co., Inc.
202-234-4433