THE NATIONAL QUALITY FORUM

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STEERING COMMITTEE ON NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR NURSING HOMES

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MEETING

+ + + + +

WEDNESDAY

APRIL 21, 2010

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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

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to see developed

1 P-R-O-C-E-E-D-I-N-G-S
2 9:12 a.m.
3 MS. THEBERGE: We are so glad to
4 see you all in person finally.
5 My name is Suzanne Theberge. I am
6 the Project Manager for this project. I would
7 like to ask my colleagues here to introduce
8 themselves.
9 MR. CONYERS: Thank you.
10 Good morning. My name is Del
11 Conyers. I am the Assistant Managing Director
12 of Performance Measures at NQF.
13 DR. BURSTIN: I am Helen Burstin.
14 I am the Senior Vice President for Performance
15 Measures at NQF.
16 I also want to add my welcome.
17 MS. PACE: Good morning.
18 I am Karen Pace. I am the Senior
19 Program Director at NQF and work with measure
20 evaluation and methodology and also some other
21 projects.
22 MS. NOCHOMOVITZ: Hi. I am Emma

1 Nochomovitz, NQF Research Analyst.
2 Nice to meet you all.
3 MS. THEBERGE: And I would also
4 like to ask our Co-Chairs to introduce
5 themselves real quickly.
6 CO-CHAIR MUELLER: Hi. I am
7 Christine Mueller, and I am at the University
8 of Minnesota School of Nursing.
9 CO-CHAIR GIFFORD: I am David
10 Gifford. I am the Director of the State
11 Department of Health in Rhode Island.
12 MS. THEBERGE: We went over some
13 of these slides earlier in the orientation
14 call. So, I am just going to skip through
15 them all real quickly, at least what is NQF.
16 Okay. So, let's go around and
17 introduce everyone else.
18 CO-CHAIR GIFFORD: Mary, we will
19 start with you.
20 SISTER HEERY: Hi. I'm Sister
21 Mary Rose. I am from Columbus, Ohio.
22 DR. ORDIN: And I'm Dede Ordin,

1 Office of Quality and Performance, VA.
2 MR. KUBAT: Hi. Good morning.
3 I am Bill Kubat from the Good
4 Samaritan Society in Sioux Falls, South
5 Dakota.
6 MEMBER NAIERMAN: I am Naomi
7 Naierman, American Hospice Foundation.
8 MS. BELL: Alice Bell, American
9 Physical Therapy Association.
10 MS. FRANDSEN: Betty MacLaughlin
11 Frandsen from AANAC.
12 DR. NIEDERT: Kathleen Niedert
13 from the Western Home Communities in Cedar
14 Falls, Iowa.
15 DR. ZOROWITZ: Bob Zorowitz from
16 Village Nursing Home in New York.
17 DR. MODAWAL: Arvind Modawal from
18 the University of Cincinnati Medical Center in
19 Cincinnati.
20 MS. TRIPP: Hi. I'm Lisa Tripp.
21 I am with the John Marshall Law School in
22 Atlanta, Georgia.

1 DR. KOREN: I am Mary Jane Koren.
2 I am with the Commonwealth Fund.
3 MS. GIL: Good morning.
4 Heidi Gil from Planetree from
5 Connecticut.
6 MS. ROSENBAUM: Pat Rosenbaum,
7 infection control and epidemiology consultant.
8 DR. SCHUMACHER: Hi. I am Ron
9 Schumacher. I am from the United HealthCare
10 and Evercare.
11 MR. BOISSONNAULT: Bruce
12 Boissonnault, Niagara Health Quality
13 Coalition.
14 MS. THOMPSON: Darlene Thompson,
15 Kindred Healthcare.
16 DR. GRIEBLING: Good morning.
17 I am Tomas Griebling. I am at the
18 University of Kansas in the Department of
19 Urology, the Center on Aging, and also with
20 the American Urological Association.
21 CO-CHAIR GIFFORD: Okay. Can we
22 hear from the peanut gallery?

1 MS. DOWELL: Robin Dowell from
2 CMS.
3 MS. MANDI: Stacy Mandi from CMS.
4 DR. LING: Shari Ling, CMS.
5 MS. GALLAGHER: Rita Munley
6 Gallagher, not CMS, the American Nurses
7 Association.
8 (Laughter.)
9 MS. TOBIN: Judy Tobin, CMS.
10 MS. FITZLER: I'm Sandy Fitzler
11 from the American Health Care Association.
12 MS. CONSTANTINE: Roberta
13 Constantine, RTI.
14 MS. GAGE: Barbara Gage, RTI.
15 MS. SCOTT: Jean Scott from CMS.
16 MS. BERNARD: Shula Bernard from
17 RTI.
18 MS. VANCE: Jackie Vance, American
19 Medical Directors Association.
20 MS. EDELMAN: I am Toby Edelman,
21 Center for Medicare Advocacy.
22 CO-CHAIR GIFFORD: Do we have

1 anyone in the black box at all today? Anyone
2 calling in? Do we have some people in the
3 black box? I always want to know what's in
4 the black box?
5 (Laughter.)
6 Anyone out there want to speak?
7 MS. BERRY: Ellen Berry, CMS.
8 CO-CHAIR GIFFORD: Ellen, you're
9 just like coming in as a voice. There's not
10 even a black box.
11 (Laughter.)
12 So, very ethereal today. Oh,
13 there's the black box, yes. It's more a
14 rectangle.
15 Anyone else?
16 (No response.)
17 Okay. We are going to skip over
18 the disclosure of interest. We are not going
19 to disclose any interest out there. So, we're
20 going to keep it secret as we go forward for
21 the rest of the day.
22 (Laughter.)

1 I think everyone has filled the
2 forms out and done it all and everything, yes.
3 No, Helen is rolling over. See,
4 you shouldn't have picked me as a Co-Chair.
5 But we are going to go through a
6 quick overview, Suzanne. So, I will hand it
7 over to Suzanne.
8 MS. THEBERGE: All right. So, as
9 we talked about on the phone, NQF is a
10 private, nonprofit, voluntary, consensus
11 standard-setting organization with over 400
12 member organizations.
13 We are here today to do our
14 consensus-development process. We are going
15 to gain consensus about which measures and
16 practices should be national voluntary
17 consensus standards for nursing homes. We
18 have public and private sector representation
19 on our governing board and our focus is on the
20 entire continuum of healthcare.
21 I wanted to go a little bit over
22 the consensus-development process as it

1 relates to you folks on the Steering
2 Committee. This is a schematic of part of the
3 CDP, and you folks are in the yellow box.
4 After we go through today and
5 discuss the measures, the next step is that
6 NQF staff will draft a report on the
7 recommendations. Then, we post that for
8 review and member and public comment.
9 After we receive comments on the
10 measures that you have voted to endorse, then
11 we will submit the comments back to you for
12 consideration and have a conference call later
13 this summer to discuss these comments. The
14 Steering Committee may respond to comments by
15 revising the report or submitting comments on
16 the comments.
17 Once the Steering Committee has
18 reviewed the comments and revised the report
19 as necessary, the NQF member body will vote on
20 the final version of the Steering Committee
21 recommendations. The voting period lasts 30
22 days and will happen in late August through

1 September.
2 Candidate consensus standards that
3 are approved by the NQF membership will
4 proceed to the next step, which is the
5 decision by the CSAC. The CSAC reviews the
6 recommendations of the Steering Committee and
7 the voting results and then either grants full
8 endorsement, time-limited endorsement, or
9 denies endorsement. Our CSAC vote will happen
10 in mid-October.
11 Finally, the NQF Board of
12 Directors will affirm or deny the CSAC's
13 decision, and the Board meeting will happen in
14 December. After the Board ratifies the
15 consensus standards, they are, then, posted to
16 the NQF website.
17 Appeals can be filed on endorsed
18 standards only within 30 days of the Board's
19 endorsements, and appeals are reviewed and
20 evaluated by the CSAC, and they make a
21 recommendation for action to the Board, which
22 needs to happen within seven calendar days.

1 The Nursing Homes Project is
2 funded by the U.S. Department of Health and
3 Human Services. We are going to be focusing
4 on measures and patient experience-of-care
5 surveys that specifically address nursing home
6 quality measures for public reporting and
7 quality improvement. This is a followup to
8 the Nursing Home Project that was completed in
9 2004.
10 The goals are to identify and
11 endorse measures for public reporting and
12 quality improvement in the nursing home
13 environment. Here's the project timeline with
14 some more specific dates for some of the
15 processes that I mentioned earlier. As you
16 can see, we are on the third step now, the
17 Steering Committee in-person meeting.
18 The role of the Steering Committee
19 is to come together as a group of experts to
20 evaluate the measures in-depth and to make
21 recommendations to the NQF membership for
22 endorsement, and then give us your expertise.

1 Then, again, as I mentioned earlier, you will
2 respond to the comments submitted during the
3 review period.
4 The Co-Chairs, upfront here with
5 me, will represent the Steering Committee when
6 the CSAC meets. The other role of the
7 Steering Committee is to respond to any
8 direction from the CSAC.
9 Your in-person obligation is
10 limited to this meeting, but if we are unable
11 to finish going through all the measures in
12 the next two days, we will hold a conference
13 call to follow up and finish that. Then, we
14 will also have a call in the summer to discuss
15 anything that comes up in the commenting
16 period.
17 As you all know, you were assigned
18 a few measures to review. We worked hard to
19 assign them to you based on your areas of
20 expertise or because we thought you would
21 bring a valuable perspective to this
22 particular measure.

1 You will be leading the discussion
2 that you were the primary reviewer for. So,
3 once we call your measure, we will ask whoever
4 the primary reviewer was to speak to that.
5 You should share your rating of each
6 subcriteria, and the secondary reviewer should
7 chime in as necessary, especially if you
8 disagreed about something. We definitely want
9 to hear about that.
10 Your review should be concise and
11 provide the expert view for the Steering
12 Committee. Listed below are some talking
13 points that should help you frame your
14 discussion.
15 You should introduce the measure
16 by referencing the measure ID and a brief
17 description. Then, you should talk about
18 whether the specifications are complete. Were
19 they clearly stated? Is all the necessary
20 information there to reproduce the measure?
21 What are the strengths? What are the
22 weaknesses?

1 One of our criteria, is this
2 important? Is this measure important to
3 measure and report? Is it scientifically-
4 acceptable? What are the results about the
5 quality of care? Is this measure usable?
6 Would the results of the measure be
7 understandable to the intended audience and
8 likely to be useful for decisionmaking? And
9 is this measure feasible?
10 And finally, you should mention
11 any revisions or clarifications that you see
12 necessary and your recommendation with any
13 caveats, if you think the measure is not ready
14 yet, if you think it needs further
15 specifications, et cetera.
16 Now I am going to turn this over
17 to Helen to talk about our endorsement
18 criteria.
19 DR. BURSTIN: Great. I spend
20 enough time with these Steering Committees,
21 you would think I would have mastered the
22 microphones.

1 In fact, we have one next door, in
2 case you saw lots of other people with little
3 NQF name tags. This is day two of our
4 Outcomes Steering Committee. So, I will be
5 popping in and out between the rooms, but
6 Karen Pace, who introduced herself at the
7 other side here, is our lead methodologist and
8 the one probably most grounded in
9 understanding our criteria.
10 I just wanted to really emphasize
11 a few things that Suzanne mentioned, really
12 making the case that we really are trying to
13 stay very grounded in those criteria. This is
14 intended to be a really thoughtful review
15 process of those measures. The more we can
16 stay grounded in those criteria and
17 subcriteria, the more objective we can be.
18 So, we tried to as much as
19 possible objectify the process, make it as
20 clear as could be. We have updated our NQF
21 evaluation criteria almost a year and a half,
22 almost two years ago, Karen. It seems like

1 just yesterday.
2 The intent of that was several
3 reasons. First of all, we really wanted to
4 strengthen the criteria to make sure we were
5 really bringing in the right set of measures
6 that could help both for public reporting as
7 well as improving quality.
8 The other thing was there was a
9 sense that we wanted to raise the bar. We
10 wanted the measures to be getting better and
11 better, so that we are really assessing true
12 quality.
13 So, when you are going to be
14 seeing a mix today of process measures and
15 outcome measures, process measures certainly
16 still have a place, even in light of the
17 Committee meeting next door for the next two
18 days, but we really do want to make sure that
19 those process measures clearly have a link to
20 outcomes. They should be strong enough, they
21 should be fairly proximal to the outcome, as
22 opposed to very distal and far away from the

1 actual outcome. So, that if you actually
2 tried to work on that process measure, you
3 could actually move the needle on our ultimate
4 goal, which is really improving care and
5 outcomes for patients.
6 We also wanted as much as possible
7 harmonized measures within sites of care,
8 across sites of care. Now this is probably
9 one of our last Steering Committees that is
10 setting-specific. We are really going to try
11 to move towards, for example, probably in
12 2011, a Committee that is focused on function,
13 that allows us to, in fact, harmonize a lot of
14 the measures that look at function or some of
15 these issues across hospitals, nursing homes,
16 home care.
17 The divisions are not that
18 helpful. You really want to be able to take
19 a broader, more episode-based view of care.
20 These very narrow, setting-specific measures
21 aren't necessarily, I think, where we want to
22 be in the long-term.

1 For where we are right now, there
2 is a specific purpose and a need for these.
3 These measures, the nursing home measures,
4 have been around for a while and clearly in
5 need of updating. We were really pleased when
6 we got the updated measures from CMS.
7 But you should think about
8 harmonization issues. For example, if you
9 know there is a similar measure in home
10 health, and it is just kind of off, it would
11 be very helpful to raise those issues and say,
12 does this really need to be different? Or,
13 actually, there will be an issue coming up
14 later, for example, of a falls measure that
15 was just looked at in the Mental Health
16 Outcomes Project where they said, you know, we
17 don't really need a separate falls measure for
18 psych facilities. Can't we just have a falls
19 measure?
20 So, again, I think those are the
21 kind of issues we will be bringing to you on
22 harmonization, again, as much as possible, a

1 stronger emphasis on outcomes, and I mentioned
2 the outcome link thing.
3 For those of you who have been
4 engaged in our process to date, here's a
5 couple of the highlights of what's different.
6 The first thing is the importance to measure
7 and report is now a must-pass criterion.
8 Basically, if you are not going to get useful
9 information out of it to really drive
10 improvement, you could stop right there.
11 There are three subcriteria embedded within
12 importance to measure and report.
13 First of all, is it one of the
14 national priorities and goals, the National
15 Priorities Partnership that NQF has convened,
16 has put forward? Is it clearly an area of
17 high impact in terms of mortality, morbidity,
18 impact on the population, whatever the case
19 may be? And the third piece that we are doing
20 a fair amount of work on, that Karen is
21 leading as well, is, is there strong evidence
22 to support the measure focus?

1 If those three areas aren't
2 satisfied, there's no need to proceed with the
3 rest of the evaluation of the measure. We
4 will stop right there. So, that is a must-
5 pass criterion. That is a new change for us
6 compared to the prior years.
7 The next three are just a few
8 highlights. Scientific acceptability is
9 really about the measurement properties. The
10 evidence is under importance to measure and
11 report.
12 Here we are really looking at
13 issues particularly of reliability and
14 validity. You do have some untested measures
15 in your midst today. The only way those could
16 go forward is as time-limited measures. Carol
17 will be for you a resource to help you
18 understand some of those nuances.
19 Usability, really especially
20 important, I think in some ways, for nursing
21 homes because these data are publicly
22 reported. We really do want patients and

1 families to be able to have measures they can
2 use to understand and make better decisions
3 about their care, to say nothing of providers
4 and others who also help make those decisions.
5 Usability also includes the
6 subcriterion harmonization. So, that is where
7 we would really want you to emphasize that
8 point.
9 And lastly, not surprisingly,
10 given where we are going and a whole lot of
11 money on the table for HIT at the moment, we
12 also want to see how feasible it is to collect
13 these data using electronic data. I realize
14 nursing homes has got a dataset attached to
15 it, but over time, as the transition happens
16 to broad-based electronic systems that are
17 interoperable, how much of these data could be
18 collected through routine care, through the
19 natural process of care?
20 Next, and just lastly, there are
21 four conditions for our consideration. Even
22 if a measure is not in the public domain,

1 we've got to have a measure steward agreement
2 signed to allow others to use the measure.
3 With this measure steward, there is always a
4 requirement that the measure steward has to
5 agree that they are going to maintain and
6 update the measures.
7 We have a regular maintenance
8 process to ensure that measures stay current.
9 Evidence changes so quickly that, literally,
10 yesterday we were looking at diabetes measures
11 and saying, "But the ACCORD trial came out
12 March 15th." Okay, guys, it's April; it's
13 April 20th.
14 (Laughter.)
15 But there is clearly a need to
16 make sure we are staying current. So, we have
17 a process that allows us to look at that. But
18 part of that means the steward has to agree,
19 yes, I'm going to maintain this measure; I'm
20 going to keep up on the evidence base, and
21 make sure this measure, in fact, maintains the
22 currency of the evidence.

1 The third one is especially
2 important and, again, not as much an issue for
3 nursing homes because there's a natural path
4 for public reporting of nursing home measures.
5 The intent is these measures should be usable
6 for both public reporting and quality
7 improvement. So, there may be measures that
8 would be very useful internally within nursing
9 homes, for example, but wouldn't necessarily
10 rise to the level of saying you would be able
11 to understand differences between nursing
12 homes by publicly reporting that measure. We
13 really want to look at the measures that would
14 allow you to do both.
15 Then, finally, the staff have gone
16 through and at least ensured that what we have
17 submitted to you for your consideration at
18 least is complete. So, we didn't get into the
19 nuances of reading things; we leave that to
20 you, but at least we have gone through it and
21 worked with the developers to make sure you've
22 got a complete submission.

1 Time-limited endorsement is
2 something you are going to spend a fair amount
3 of time on today, depending on how many of
4 those measures come up. We are, again,
5 working through some of these issues. There's
6 still a little bit of uncertainty, I think,
7 from measure developers about our intent of
8 time-limited endorsement.
9 The original idea was that there
10 were measures out there that were so important
11 the field really wanted them, but they hadn't
12 yet gone through testing. So, we put forward
13 this ability to bring through untested
14 measures under a categorization called time-
15 limited.
16 We have recently passed a change
17 in our time-limited process with the Board of
18 Directors. There's really a sense that we
19 want to narrow the funnel of untested measures
20 that come to NQF.
21 There is some criteria that we
22 have set up for what time-limited measures

1 could come forward. The idea would be that
2 there's no currently NQF-endorsed measure that
3 can accomplish this, and therefore, bringing
4 in this in an important area makes sense.
5 The second thing is there's a
6 critical timeline. There's a legislative
7 need. There's a regulatory need to have these
8 measures in place.
9 The third, I think, is really
10 important as well, is that the measure is not
11 complex. I think there's a general comfort
12 level that a fairly simple process measure is
13 going to get tested over time. You are not
14 going to see perhaps a huge amount of change
15 based on testing, but a complex measure with
16 risk adjustment or a composite, we don't feel
17 comfortable putting forward as time-limited.
18 So, I think we have already gone through the
19 process of pulling out anything we think
20 didn't work in that case.
21 The last thing is we used to allow
22 up to 24 months for measure developers to test

1 their measures. We are finding it difficult
2 to get the testing in a timely manner. I
3 think it is also difficult for end-users to
4 feel comfortable using some of these measures
5 if they are still untested.
6 So, the Board has recommended, and
7 we are in this interim transition period at
8 the moment, that we would like to try to get
9 the testing results back within 12 months,
10 rather than we were seeing almost all the
11 developers, of course, waiting until month 24
12 to bring that in. I think the sooner we can
13 bring in those testing results, the more
14 comfort we have in the fidelity of those
15 measures for people to use them for public
16 reporting.
17 Karen is also leading a testing
18 task force we are doing right now that is
19 helping us think through exactly what we mean
20 by different levels of reliability and
21 validity, what's going to be required at
22 submission versus what will be required at

1 that testing point.
2 I think I turn it back to you now,
3 yes? And I give this back to Suzanne.
4 Any general questions for Karen or
5 me?
6 MR. KUBAT: Yes. Bill Kubat.
7 Maybe sort of a question or a comment.
8 DR. BURSTIN: Yes.
9 MR. KUBAT: But I had the
10 privilege of serving on that first Steering
11 Committee. One of the things that I have
12 noticed, and some of it is the pace, and so
13 forth, by which the work here has been done,
14 but I just have to acknowledge I have felt a
15 little bit of frustration in the work here.
16 Because one of the things that we
17 did in that first Steering Committee, and I
18 realize it was the first one, but we spent a
19 considerable amount of time at the beginning
20 identifying what measures should be on there.
21 What are the domains and the kinds of measures
22 that should be reported, and so forth?

1 Here what we have done has just
2 been responding to what's been submitted and
3 responding very quickly and responding to a
4 very narrow band.
5 DR. BURSTIN: Yes.
6 MR. KUBAT: And it feels very
7 fractured. When I have thought about
8 harmonization -- and I like that word; I have
9 been intrigued with that. I like the word.
10 I like the thought. I like the concept.
11 But I think in terms of
12 harmonization not just in terms of NQF-
13 endorsed measures, but I think in terms of
14 what is publicly reported. NQF-endorsed and
15 publicly reported are not synonymous.
16 I think in terms of not only what
17 is on Nursing Home Compare, but Nursing Home
18 Compare vis-a-vis Home Health Compare vis-a-
19 vis Hospital Compare vis-a-vis Dialysis
20 Compare, and they are consistently, I mean
21 they are dramatically different tones in terms
22 of the measures, in terms of the wording, in

1 terms of the domains. And there is no
2 platform to be able to address that.
3 So, I just need to say that.
4 DR. BURSTIN: Yes, and actually
5 you do have one platform, although I think the
6 issue is it will operate in the future, which
7 is that one of the things we would really like
8 this Committee to say is, what didn't you get
9 that we should make sure comes in in the
10 future?
11 I think the issue is these sets of
12 measures were getting old. They needed to be
13 updated. CMS has been working with their
14 developer to update those measures. They
15 clearly needed to get cleared up, and that is
16 the intent of this.
17 But we very much would like you to
18 identify what those measure gaps are. As we
19 think towards, for example, this Committee
20 maybe in 2011 or 2012, where we are going to
21 do functional status, for example, across the
22 settings of care, or, also, I know there was

1 some concern, and certainly David and
2 Christine expressed it strongly, a strong
3 desire to have nursing home CAHPS come to the
4 table, for example, as a patient experience-
5 of-care survey.
6 We did speak with CMS. We also
7 invited AHRQ to potentially submit it on their
8 own. That hasn't happened yet. We are still
9 sort of seeing if that is a possibility.
10 But, again, if there are
11 measurement gaps that we can put out to the
12 field to say, if you are working on things
13 over the next two years, please do these, that
14 is a really important role for the Steering
15 Committee. Even if you couldn't do it in
16 advance, let's help set the field going
17 forward.
18 Does that help? Good.
19 MS. THEBERGE: Okay. So, we had
20 25 measures submitted to the Steering
21 Committee for review. We have broken those
22 measures out into some categories for a little

1 easier review.
2 Mental health, we have two
3 measures. Staffing, we have two measures.
4 Pain and pressure ulcers, we have five.
5 Vaccination, we have four. Falls, we have
6 five, and function, we have eight measures.
7 The way this is going to work is
8 we are going to ask the measure developers to
9 speak very briefly, about three minutes for
10 each measure developer to talk about the
11 measures in that section, what their intent
12 was. Then, you will go through each measure,
13 and the measure developer for the measure you
14 are discussing will be sitting up here and
15 able to answer any questions that come up.
16 Before we begin, CMS is going to
17 spend a few minutes speaking about the
18 transition from MDS 2.0 to 3.0.
19 Then, also, we have two similar
20 measures in the falls category. So, we will
21 be discussing that later. Then, we have one
22 measure that is up for maintenance.

1 So, now we are going to start
2 looking at our measures, unless there's any
3 further questions.
4 MR. KUBAT: Maybe related to 2.0
5 and 3.0, a naive question, but I did
6 understand from the train-the-trainer sessions
7 of last week that there are changes being made
8 even as we go to 3.0. So, does any of that
9 impact what we are doing here?
10 DR. BURSTIN: Sounds like a
11 question, hopefully, CMS will be able to
12 address for us. But just as one more thing to
13 add, if the measures change in the interim, so
14 if there is a significant change made on one
15 of these measures, even before the next
16 window, and we will do maintenance on these
17 measures, NQF does have an ad hoc maintenance
18 process.
19 If the evidence base changes, if
20 there is a material change to the measure, we
21 can go with an off-cycle review and exam it
22 for maintenance whenever, as necessary. So,

1 if there are changes that happen, it doesn't
2 have to be a static thing. We can actually
3 move this forward as well.
4 CO-CHAIR GIFFORD: Does everyone
5 around the table know, feel comfortable with
6 what the MDS 2.0 is or 3.0 is? Does anyone
7 not and you would just like two seconds of
8 what MDS is?
9 (No response.)
10 Okay, good.
11 I'm getting whispers from both
12 ears, and I can't do it. I can't even hear
13 whispers from one ear.
14 (Laughter.)
15 Are we doing it now or later?
16 DR. LING: Hi. Good morning.
17 My name is Sheri Ling. I am a
18 medical officer with CMS in the Division of
19 Chronic and Post-Acute Care.
20 Any ophthalmologists in the house?
21 I may need one. Okay. Then, I am in trouble.
22 All right.

1 So, I am a medical officer with
2 the Division of Chronic and Post-Acute Care in
3 the Quality Measurement and Health Assessment
4 Group at CMS.
5 I just want to take a couple of
6 moments to tee-off the 3.0-based measures that
7 you will be hearing about, and RTI will be
8 speaking on behalf of CMS about providing you
9 with the details of the candidate measures
10 submitted for your consideration.
11 But just as a prelude, to speak a
12 little bit about 3.0, MDS. 3.0, and to take us
13 back to 1995, so why 1995? The MDS 2.0 has
14 been and served a primary data collection
15 vehicle through which we have obtained
16 comprehensive information on our nursing home
17 residents.
18 1995, if you think about where you
19 were and what you were doing in 1995, and what
20 we have witnessed since 1995, in that brief
21 time interval, we have witnessed the
22 introduction of effective therapies to abort

1 myocardial infarctions, translated more
2 recently to preservation of neurologic
3 function, averting stroke. We have witnessed
4 AIDS converting from a terminal illness to one
5 that can be survived. We have also witnessed
6 treatment of peptic ulcer disease and blood
7 ulcer disease with antibiotics. These are
8 things that were just unfathomable in 1995.
9 With these changes in medical
10 technology and with the medical practice, we
11 have also observed a shift in the way that our
12 system functions in how we deliver care to our
13 residents, to our patients, and with that
14 shift also has been a shift in the sample that
15 resides in the nursing home. We no longer
16 have a homogenous sample of residents. We
17 have residents who are either under our care
18 because they are recovering from an acute
19 illness or because they do have more chronic
20 care needs.
21 So, these are two different
22 subpopulations that we have, for all intents

1 and purposes, lumped into the category of
2 nursing homes. Now it was necessary for the
3 MDS to change to accommodate some of those
4 shifts in our population.
5 Importantly, it has also changed
6 to integrate state-of-the-art assessment
7 techniques. It has also changed to
8 importantly represent the residents' voice.
9 And it has, importantly, changed with the
10 burden of care in mind to be an efficient and
11 comprehensive and standardized data collection
12 vehicle. So, these are changes that are
13 implicit in the measures that you will be
14 presented today.
15 So, my concluding statements about
16 the measures that are submitted for your
17 consideration are that they are grounded on
18 the concept of importance. They are important
19 because they represent clinically-important
20 conditions that we are charged with the care
21 and keeping of our residents and our patients.
22 They were considered important by consensus

1 through our technical experts panels.

2 They incorporate the enhancements

3 of the 3.0 instrument. Along that line,

4 importantly, the measures are framed, we have

5 taken a stab at redefining subacute from

6 longer or more chronic care. You will see

7 that, that the measures are distinguished,

8 subacute or post-acute versus chronic.

9 It is also important to know that

10 there is evidence in the form of literature

11 supporting the concept and, also, evidence

12 that the instruments from which these measures

13 arise have been tested and it has been

14 validated.

15 The final concept being that it is

16 our intent at CMS to publicly report the

17 quality measures that are put forward. It is

18 important this public reporting meets the

19 original intent of OBRA, the origin of the

20 resident assessment instrument and of the MDS.

21 So, that is actually all I have to

22 say. Thank you for your attention.

1 DR. ORDIN: Sheri, can I ask a
2 question?
3 DR. LING: Yes.
4 DR. ORDIN: I mean I think it came
5 up in my review and, also, in my co-reviewers.
6 How are you defining long stay versus short
7 stay? Because at the beginning of the measure
8 it said 100 days.
9 DR. LING: Yes.
10 DR. ORDIN: And maybe you could
11 elucidate that?
12 DR. LING: Yes. And we toiled
13 over this definition. The reason that we took
14 a crack at redefining, based on the 100-day
15 cutpoint, is because when we actually analyzed
16 using the old criteria, just making that
17 distinction, we found that there are people
18 who met the criteria in both buckets.
19 So, we are trying to be clearer
20 about who is in which bucket and, in that
21 sense, taking into account or at least
22 acknowledging that the two subpopulations may

1 be meaningfully different, different issues.
2 So, we drew the line in the sand at 100 days
3 as a starting point.
4 I think RTI can further elaborate
5 on that.
6 MS. CONSTANTINE: Good morning.
7 I am Roberta Constantine from RTI.
8 One of the improvements in the MDS
9 2.0 to 3.0 has been the addition of the
10 comprehensive discharge assessment. That has
11 really enabled us, also, to make improvements
12 in looking at the quality measures from the
13 short-stay population to the long-stay
14 population.
15 Based on analyses that were
16 performed by CMS, it was found that
17 approximately 38 percent of residents were
18 discharged within 14 days. So, prior, with
19 the current measures, often a patient would be
20 discharged before -- you couldn't look at them
21 at another point in time.
22 So, this is a great improvement

1 because it now allows us to really take a look
2 at patients before they are discharged. So,
3 I just wanted to add that.
4 DR. LING: Thanks, Roberta.
5 MS. THOMPSON: This is Darlene
6 Thompson.
7 I don't know if this is the time
8 to ask this or not. But in the two measures
9 I have, which are considered long stay, there
10 is no definition as to how you are calculating
11 that 100 days. Are you taking it from the
12 date the stay began, A1600, versus the
13 reference date, the assessment reference date,
14 or the discharge date? Or what are you using
15 to calculate that 100 days?
16 Thank you.
17 DR. LING: For those who are
18 listening and for the record, it was based on
19 the admission date.
20 CO-CHAIR MUELLER: Are there any
21 other questions from the group for CMS?
22 (No response.)

1 DR. LING: Thank you all.
2 MS. THEBERGE: All right. We
3 would like to ask the measure developers for
4 the mental health measures to come up. That
5 would be AMDA and RTI.
6 We are going to start with Measure
7 001, assessment of dementia, and then 025,
8 percent of residents who have symptoms of
9 major depression.
10 MS. VANCE: Good morning.
11 I am just adjusting my chair, so
12 the light doesn't blind me. Thank you.
13 Should I begin? Thank you.
14 Good morning.
15 I am Jackie Vance and with AMDA,
16 the association that is dedicated to long-term
17 care medicine. We are very pleased to present
18 this dementia measure to you.
19 We firmly believe that this
20 measure is of national importance, especially
21 in relation to quality improvement. This
22 measure addresses a process that is

1 strategically important in maximizing the
2 health of large populations of persons within
3 the long-term care continuum. It addresses
4 the important medical condition, as defined by
5 high-prevalence incidence, morbidity,
6 mortality, and disability.
7 Up to 70 percent of nursing home
8 patients do carry a diagnosis of dementia.
9 Yet, it is believed that this disease is
10 underdiagnosed. Dementia carries a range of
11 behavioral, cognitive, functional, and mood
12 impairments that can significantly affect
13 patient-centered outcomes and quality of life.
14 The measure also addresses a
15 clinical condition that requires high
16 expenditures in both in-patient and acute
17 care. Due to the current variability in
18 practice, many patients may either have
19 unrecognized dementia upon admission to the
20 nursing home or patients have a diagnosis of
21 dementia that was never screened with a
22 validated instrument, leading to an

1 appropriate diagnosis or not having the
2 dementia staged, leaving that practitioner to
3 basically guess where the person is
4 functionally and cognitively within that level
5 of dementia, causing poorly-coordinated care
6 across many settings and the potential for
7 inappropriate and non-compassionate care for
8 these patients with end-stage dementia, and
9 overuse of aggressive, inappropriate care.
10 This measure also ties in all six
11 dimensions of healthcare performance
12 improvement within the IOM's report "Crossing
13 the Quality Chasm". That is safety,
14 effectiveness, patient-centeredness,
15 timeliness, efficiency, and equity.
16 Because once the physical
17 functional/cognitive psychosocial domains have
18 been assessed from this measure, the results
19 assist the practitioner, the care team, the
20 patient, and their family in creating a
21 patient-centered plan of care that is not only
22 appropriate for this stage of dementia that

1 they are in, but the functionality within that
2 level of dementia.
3 So, in other words, this measure
4 was taken from the American Medical Directors'
5 Guideline on Dementia from that second step.
6 And the second step within that guideline is
7 how you create that entire care process, how
8 you move forward from there. So, it is
9 extremely useful in decisionmaking for that
10 person.
11 We do know that the IOM, CMS, and
12 others stress that healthcare should be
13 patient-centered. The individual patient's
14 culture, their social context, their specific
15 needs deserve respect, and the patient and
16 their families should play an active role in
17 making decisions about their care. We believe
18 a measure such as the one we are proposing is
19 necessary to ensure patient-centered care with
20 a person with dementia.
21 In the handout that I passed out
22 to you, I have given you sections of the MDS

1 3.0 that are relevant to the areas that we
2 stress that should be assessed. With the MDS
3 3.0, we are very excited because the data that
4 we are asking to be assessed can be captured
5 electronically. The brief interview for
6 mental status, renewed interview which is the
7 PHQ-9, the behavior section and the functional
8 status sections are all rated very high on
9 kappa statistics and highly validated. Now
10 this will allow for both electronic data
11 capture while using a validated tool, which
12 are goals for our measure.
13 So, I guess, in closing, we ask
14 that you would consider our measure as
15 suitable. We are certainly open for
16 discussion.
17 Thank you for your consideration.
18 CO-CHAIR GIFFORD: Thank you,
19 Jackie.
20 A couple of points. I am the
21 primary reviewer on this, but before going
22 there, I just have a couple of things to

1 comment on for some groundrules as we go
2 forward.
3 One, we are going to have the
4 measure developers give a very short, two-
5 minute-type overview. Then, the primary
6 reviewer gives an overview, and we will let
7 the secondary reviewer elaborate on the
8 primary reviewer, if they have any other
9 additional comments.
10 Then, really have an open
11 discussion. I would like to try to get as
12 much input from people as possible. Try to
13 keep it on the topic because I would like to
14 get quickly to an up-or-down vote. We may
15 want to do it in a staggered way, which is we
16 have different criteria. We can vote as is,
17 vote with some modifications, vote time-
18 limited, or turn down altogether.
19 I certainly will give a priority
20 of anyone at any point who wants to sort of
21 call the question, call the vote, if we are
22 beating a dead horse. There is no need to sit

1 here and beat the dead horse and say the same
2 stuff over and over again. So, if someone
3 wants to call the question, I will let people
4 call the question, so we can get forward on
5 it.
6 We have a lot of measures to go
7 through today and tomorrow. Some of these
8 measures I think will be relatively quick.
9 So, while it is an interesting topic, like on
10 this topic I might feel really a lot about,
11 but we can move quickly or we can take a long
12 time on this one, or vice versa, going
13 forward.
14 So, I think all the topics are
15 incredibly important to the population of
16 nursing home residents. We will take that off
17 the table right now. I don't think there is
18 any measure that wasn't equally important to
19 the nursing home population. So, I think it
20 is going to be more into the other aspects.
21 The last comment is that, as we
22 talk about particularly usability and

1 feasibility of the measure, remember that
2 while many of these are being sponsored by
3 CMS, no insult to CMS, but they pay for a
4 majority of the nursing home care. They are
5 a driver in many areas.
6 But many of the NQF measures are
7 used by many other people. There are some of
8 the organizations around here. There's a lot
9 of the nursing home chains that are starting
10 to use these measures. States are starting to
11 use these measures. Advocacy groups are using
12 these measures. Researchers are using these
13 measures, and other payers besides CMS are
14 starting to use these measures, too.
15 So, as we think about this, this
16 is not just about measures for CMS and for
17 Nursing Home Compare. These are measures that
18 could be used for other purposes. So, I want
19 to make sure that is part of the dialog as we
20 go forward. Because certainly, as measures
21 are developed, they are developed for
22 different purposes.

1 Any sort of comments or
2 suggestions or additions on the groundrules?
3 Yes, Kathleen?
4 DR. NIEDERT: I have a question,
5 and this is my first experience in this group.
6 Could I have just a brief explanation of how
7 the verbiage came about to explain the
8 different areas that we have, who wrote it,
9 how it was developed? Because some of it I
10 feel needs some wordsmithing if it is to go
11 out to the public.
12 CO-CHAIR GIFFORD: Suzanne, do you
13 want to answer that or do you want me, not
14 involved, to answer it?
15 MS. THEBERGE: Are you speaking to
16 the text of the measure? The text of the
17 measure was entirely written by the measure
18 developers.
19 I'm sorry.
20 DR. NIEDERT: In the measure I
21 reviewed, there were some questions. There
22 were actually some questions within the

1 verbiage, as if they had a thought, but they
2 didn't complete the thought. So, I just was
3 curious as to how that came about and whether
4 it just was an oversight when it was being
5 developed and sent out.
6 CO-CHAIR GIFFORD: Yes, the forms
7 that we have were completed by the measure
8 developers. We did not go back and edit it
9 for clarity. If something didn't make sense,
10 we might sometimes ask people to put
11 information in, but the language is all from
12 the measure developers.
13 I don't believe this language, I
14 mean NQF is sort of public; everything is
15 public, but this is not necessarily what's the
16 type of information that might go into a
17 technical report that goes out there for use
18 on something as we go forward. I am not sure
19 we need to spend time editing the language of
20 the reviewers out there.
21 CO-CHAIR MUELLER: I would add
22 that, if that resulted in any concern about

1 the measure as you were evaluating it, we have
2 our measure developers here. So, there could
3 be some dialog.
4 DR. NIEDERT: Thank you.
5 CO-CHAIR GIFFORD: Yes, we are not
6 working for the measure developers. If they
7 want to hire us outside this room, they could
8 hire you outside the room to help with the
9 language, but we are not working for the
10 measure developers.
11 MS. PACE: Just one other thing.
12 In those forms, it is clearly identified if
13 there were any questions from the staff that
14 they wanted you to consider. So, that is a
15 whole separate section. We have done that
16 purposely, so that you know everything is
17 coming from the measure developer, except if
18 there was a specific item that said it was
19 supplied by staff or a question by staff.
20 MEMBER NAIERMAN: May I ask a
21 general question about dementia?
22 CO-CHAIR GIFFORD: Yes.

1 MEMBER NAIERMAN: The two notions
2 that we have just talked about, dementia and
3 then short- and long-term stays, what is the
4 cross between the two?
5 The reason I ask is because I was
6 asked to review the pain measures. It is
7 pertinent to know if, indeed, the short-term
8 stay folks are less likely to be with dementia
9 or not. Is there some kind of an intersection
10 between the two that can be predefined or
11 assumed in advance?
12 MS. VANCE: Dementia, it really
13 doesn't matter whether short- or long-term
14 stay.
15 MEMBER NAIERMAN: So, the post-
16 acute or subacute folks can also be with
17 dementia?
18 MS. VANCE: Absolutely. For
19 example, let's say that someone has a certain
20 level of dementia, and they were in an
21 assisted living setting and they fell there
22 and fractured a hip, and they came to your

1 nursing home for rehab, but their plans are to
2 go back to the dementia assisted living.
3 These are the people which really, for us, we
4 feel that would benefit from this measure.
5 The measure would cause people to
6 truly look at the person with dementia and
7 assess them, and find out where they, within
8 that dementia, what is their functionality to
9 develop a strong plan of care for them.
10 Because these are people that are moving back
11 and forth across the continuum of care, and
12 let's not guess where they are in the
13 dementia. Let's validate where they are
14 within the dementia.
15 DR. MODAWAL: I'm sorry, I have a
16 question related to that about dementia and
17 short stay and long stay.
18 MS. TOBIN: May I make a request?
19 Could each speaker introduce themselves, so
20 that we know who is speaking and, also, for
21 people on the phone to know who is speaking?
22 DR. MODAWAL: Thank you. Yes, I'm

1 Arvind Modawal. I'm a geriatrician and
2 professor of family and community medicine at
3 University of Cincinnati Medical Center.
4 My question is similar to what was
5 mentioned earlier on. There are differences
6 in the population and our evaluation is short
7 term and long term. Because as a nursing home
8 physician, basically, acute stay or short
9 stay, which we are calling as part of the MDS,
10 is really kind of a rehab crisis situation.
11 You know, these patients are coming from
12 hospitals, and after the CMS-mandated three-
13 day stay, and they are delirious and confused
14 and all. At that time, actually, we can
15 suspect that they may have underlying dementia
16 because of the rehab and the recuperation that
17 is taking place after UTIs and pneumonias and
18 other medical problems.
19 The emphasis at that point is
20 really to give them rehab, get them
21 functioning, let them provide the baseline,
22 and then pass it on to the primary care

1 physician and the community when they go home.
2 So, I think, as part of the
3 nursing home staff and the management,
4 including clinicians, it will be a big task to
5 start evaluating dementia when we have a
6 bigger problem with delirium, which has a
7 mortality which is as high as having MI or
8 sepsis.
9 So, we really need to tease that
10 out. We can actually suspect underlying
11 dementia, but we cannot -- and I say "cannot"
12 -- objectively diagnosis dementia in the
13 presence of confusion and delirium. So, that
14 is the difficulty the staff and the physicians
15 will face. That is the importance of
16 diagnosing.
17 CO-CHAIR GIFFORD: This is a
18 wonderful discussion we could spent all day
19 on. It turns out it is probably not germane
20 to the measure. So, I am going, as the
21 primary reviewer on this measure, and since we
22 don't have other dementia measures before us,

1 actually, this distinction between long-term
2 and everything else, I will give you my
3 review, and you will discover it probably
4 doesn't really matter what you are saying.
5 Clinically, I agree with
6 everything you just said. I am a geriatrician
7 in a nursing home, too.
8 Let me give you my quick view as
9 the primary reviewer. This measure, as was
10 previously described, was to assess the
11 percentage of patients over 75 that had
12 current signs and symptoms of dementia, were
13 assessed in the physical, functional, and
14 psychosocial domains with a valid instrument,
15 and documented in the medical record. That is
16 the way it is described there.
17 From an importance standpoint, I
18 think we all heard that dementia is a very
19 prevalent illness in the nursing home
20 population. It has profound impacts on the
21 quality of life and the clinical outcomes.
22 So, in that sense, it is an important domain

1 to be measured.

2 In the description of the measure,

3 though, it is unclear how the measure is

4 actually defined. I could not really figure

5 out how it was defined in there. There's no

6 description on how to define signs and

7 symptoms of dementia for the denominator. It

8 is not described. The numerator and

9 denominator appear to be described as

10 presented to us by CPT codes, which don't

11 build into the validated instruments, nor does

12 it list the validated instruments that are to

13 be included out there.

14 On reliability and validity

15 testing, there was no reliability/validity

16 testing presented.

17 From a usability standpoint, it is

18 unclear, given the previous issues, how usable

19 the measure is because it needs to be worked

20 on, but it potentially could be usable.

21 From a feasibility standpoint, it

22 doesn't appear very feasible because it is

1 lacking too much definition out there.

2 Based on that sort of quick

3 summary and overview, let me ask, Mary Jane,

4 if you have anything to add before my

5 recommendation.

6 DR. KOREN: I basically concur

7 with what Giff has outlined.

8 I would also add that the new MDS

9 3 actually does have some cognitive screening

10 items on it that seem to be fairly well

11 correlated with other validated instruments.

12 So, I think that in the development of MDS 3

13 there was really an effort made to screen.

14 And as I said, it is a minimum dataset and it

15 is not a thorough full-blown assessment.

16 But there is a way now to screen

17 people on admission for dementia. So, I would

18 concur with Giff's assessment.

19 CO-CHAIR GIFFORD: So, therefore,

20 based on my review and Mary Jane's comments,

21 I would recommend to the group that we vote

22 not to approve this measure as is. I would

1 say that the amount of work that needs to go
2 into it is so great that we are not measure
3 developers; we are not here to develop
4 measures as our duty today. It would take us
5 all day to figure out how to develop the
6 measure, though it is an incredibly important
7 topic.
8 That would be my recommendation to
9 the group.
10 CO-CHAIR MUELLER: Any comments
11 from the members?
12 (No response.)
13 CO-CHAIR GIFFORD: All in favor of
14 the recommendation?
15 MS. PACE: Before, one of the
16 things just that we need to be able to
17 document is how your recommendation relates to
18 our criteria.
19 CO-CHAIR GIFFORD: Do you want us
20 to do it by each one?
21 MS. PACE: Well, what we generally
22 do is ask the Committee to evaluate

1 importance, scientific acceptability,
2 usability, and feasibility. Now, if you could
3 state on which of those criteria it fails and
4 the group agrees, we could just say that that
5 was unanimous. But, in general, we need to
6 have that documentation of how the
7 recommendation fits the criteria.
8 CO-CHAIR GIFFORD: Okay. Then, I
9 will break down my recommendation.
10 MS. PACE: Okay.
11 CO-CHAIR GIFFORD: I would say,
12 for importance, I would recommend that it
13 passes for importance.
14 From reliability/validity, it
15 fails.
16 From usability, it is hard to
17 determine. I just can't determine because of
18 the way it has been presented.
19 And from a feasibility with what
20 is presented, it fails.
21 And I would just, for speed on
22 this measure, I would just bundle those

1 together then for a pass, but I think some of
2 the subsequent ones we may want to get more
3 into the detail of everything, I would agree.
4 And, Jackie, as an AMDA member, it
5 pains me to give that feedback to AMDA.
6 DR. NIEDERT: So, what I am
7 hearing from you is that we are not saying the
8 measure is not important. We are saying it is
9 truly important; it is just that this measure
10 needs more work?
11 CO-CHAIR GIFFORD: That is a kind
12 way of putting it.
13 DR. ZOROWITZ: Bob Zorowitz,
14 Medical Director at Village Nursing Home, also
15 a member of AMDA. So, I sympathize with
16 Jackie.
17 When I read the numerator and the
18 denominator, the problem is not the importance
19 of the measure, as you have said. It is how
20 it is described here.
21 And actually, if the MDS 3 is
22 done, you are going to have 100 percent of

1 your residents at least having a basic screen
2 for dementia, and a brief interview of mental
3 status has pretty good correlation with other
4 standard screens for dementia, such as the
5 Folstein mini mental state exam and other
6 instruments.
7 So, I think the MDS 3.0 itself is
8 going to solve a lot of this problem. I am
9 not sure, if you were to go and say what
10 percentage of patients have been screened for
11 signs and symptoms of dementia, if everybody
12 has had the MDS done, you are going to have
13 100 percent, at least basic. What they do
14 with it is a different issue.
15 But I would agree with the way
16 this measure is described is not very helpful.
17 DR. MODAWAL: Yes, Arvind Modawal.
18 I would just like to say, I mean
19 this is an incredibly important area
20 clinically. I think those measures, I don't
21 know whether we are going to hear this in the
22 long stay as well, but it would be very

1 relevant for the nursing home population as
2 opposed to short stay.
3 MS. TRIPP: This is Lisa Tripp
4 with the John Marshall Law School.
5 I think I want to echo what Bill
6 said earlier. I think, as a process matter,
7 at least for me, it is very difficult to sort
8 of get two minutes of a discussion and then be
9 asked to sort of vote on whether something
10 meets these criteria with just minutes to
11 think about it really. I think we got a list,
12 I think we got all of the measures with the
13 feedback maybe yesterday by email at about
14 four o'clock in the afternoon.
15 So, I don't know what other
16 processes are available, but at least for me,
17 it is difficult to think about these things
18 and respond in seconds. So, I just want to
19 throw that out there.
20 CO-CHAIR GIFFORD: It is a good
21 point, and probably this is not the best
22 measure to start with. I mean I think you are

1 going to see much more lengthier presentations
2 by primary reviewers and secondary reviewers.
3 I mean I was a secondary reviewer on another
4 one; I would do it very different.
5 This measure fails. Mary Jane, do
6 you want to elaborate? I mean both Mary Jane
7 and I are big believers in the topic and
8 everything else.
9 Mary Jane, do you just want to
10 give some confidence to the group that I am
11 not glossing over it and saying just fail it?
12 DR. KOREN: No, I --
13 CO-CHAIR GIFFORD: I think we will
14 have a much lengthier discussion on a lot of
15 the measures. I am trying to move us, and I
16 am cognizant of time. We've got four measures
17 to try to get done by 11:30, and it doesn't
18 mean we have to spend 20 minutes or 30 minutes
19 on each measure. There's going to be some
20 measures that we are just going to go through
21 like that.
22 That is why we have to have some

1 reliance and confidence in our colleagues
2 around the table, that they have done a good
3 job with their primary and secondary reviews.
4 But we do have the other measures
5 to get into greater detail. I know on some of
6 the other measures we are going to spend a lot
7 of time and debate on them.
8 DR. KOREN: Right. No, I have
9 nothing to add to Giff, except to also say I
10 am an AMDA member. So, I am sorry that we
11 can't recommend it, but it just isn't there.
12 CO-CHAIR MUELLER: I would just
13 remind the members that we actually have four
14 voting options. One is that it satisfies the
15 evaluation criteria.
16 The other is that the measure
17 satisfies some of the evaluation criteria,
18 requires further information, clarification,
19 and refinement. That is No. 2.
20 No. 3 is do not recommend because
21 it does not satisfy the evaluation criteria.
22 And then, the fourth is a time-

1 limited endorsement.
2 MR. BOISSONNAULT: Bruce
3 Boissonnault.
4 So, importance and usability are
5 not the issue, as you saw it? Is it the
6 actual math?
7 CO-CHAIR GIFFORD: Yes. I mean,
8 in the name, it doesn't specify any of the
9 aspects in the name of the title. I mean the
10 name and the description is that it is the
11 percentage of patients who present with signs
12 and symptoms of dementia. That is not defined
13 anywhere in the material they submit. Now I
14 know how I would do it with the MDS 3.0, in
15 MDS 3.0, but it is not defined anywhere.
16 Then, the numerator is that they
17 were assessed with a reliable instrument.
18 None of the reliable instruments are defined,
19 how you would actually collect that.
20 And actually, the numerator is
21 defined by the CPT codes that physicians would
22 use in billing patients there. So, if they

1 billed at a moderate or high level, it seems
2 to be assumed there was. The denominator,
3 though, seems to be defined by CPT codes as
4 well. So, it looks like I can't even figure
5 out how to calculate the measure.
6 But even if that was all there,
7 there's no reliability, zero reliability in
8 validity testing at all. So, once you have
9 failed that, I can't even figure out how to
10 get into usability or even feasibility.
11 But even if the feasibility, the
12 definition in the description everywhere is
13 that this should be documented in the medical
14 record. We can spend a lot of time debating
15 whether the MDS is part of the medical record
16 or not, but it doesn't even rely on the MDS
17 for its measure specification.
18 MR. BOISSONNAULT: Would guidance
19 to the developers, then, be the title of the
20 measure is somewhat inconsistent with the
21 mechanics of the measure?
22 CO-CHAIR GIFFORD: Jackie, I hate

1 to be --

2 MS. VANCE: If I may say

3 something --

4 CO-CHAIR GIFFORD: It's not

5 inconsistent. It just isn't there.

6 MS. VANCE: But if I may say one

7 small thing in our defense, and if it is an

8 option, and then it may fail, to allow a

9 refinement and let the Committee reconsider

10 it. Because I have to be honest, the way the

11 question was written about the CPT coding, it

12 did not look like it was a numerator. So, we

13 misunderstood that question, and I have to be

14 honest. That was not our intent to make CPT

15 coding a numerator. So, I will be honest.

16 And this was our first attempt at

17 ever submitting a measure. We are not

18 methodologists. We are just passionate about

19 clinical care.

20 So, we did not understand that,

21 and also understand that it was in the middle

22 of a blizzard, that everything was shut down

1 when we were creating this measure.
2 (Laughter.)
3 So, no, I'm not making -- I'm just
4 letting you know that it was a really weird
5 situation.
6 Then, the MDS 3.0 all came out.
7 In the midst of this, we were allowed to make
8 refinements as far as data capture, but we
9 weren't allowed to change the original how we
10 put the first measure out. And if we would be
11 allowed to submit a refinement for
12 consideration, and then if you still wish to
13 fail it, at least we would be given a chance
14 to do that.
15 CO-CHAIR GIFFORD: I mean I think
16 this comes down to we are dealing with the
17 information presented before us.
18 MR. BOISSONNAULT: I got that.
19 CO-CHAIR GIFFORD: I go back to my
20 original thing. We are not measure
21 developers. We are not working for the
22 measure developers here. Our task is to up-

1 and-down vote these with what we have
2 presented before us.
3 Now if we think there is enough to
4 give guidance back, I mean I think Jackie
5 heard a lot of feedback on it to help revise
6 it. I would concur with part of her excuse.
7 I know how I would give advice for it back,
8 but I would just say, given this measure, it
9 probably was not a good measure to start with
10 because of it; I would still stick with the
11 recommendation that it fail.
12 MS. PACE: I would just like to
13 make a clarification, too. The recommendation
14 with conditions is for a very narrow aspect of
15 the measure, if there are codes that are
16 missing. It is not to totally define a
17 measure.
18 So, it really is for narrow
19 aspects of a measure that need to be adjusted,
20 relooked at. So, that is not a general -- you
21 know, we really aren't advocating that.
22 The other thing that hasn't come

1 up, but just so you know, I think Helen
2 mentioned it a little bit. But we are moving
3 to a new cycle of looking at measures, both
4 measures that are endorsed, plus bringing in
5 new measures on fairly regular cycles. So,
6 that gives measure developers time, if a
7 measure doesn't pass, then from the feedback
8 of the Steering Committee, they can look at
9 really spending some time on developing the
10 measure and bring it back to NQF at that time.
11 CO-CHAIR MUELLER: This measure
12 was not submitted for testing, is that
13 correct? I haven't checked to see.
14 CO-CHAIR GIFFORD: Yes, they
15 expressly say that it has not been tested for
16 reliability/validity.
17 CO-CHAIR MUELLER: But it wasn't
18 submitted? Because there is that criteria
19 where you can submit for testing.
20 MS. PACE: No, there is time-
21 limited endorsement --
22 CO-CHAIR GIFFORD: No, you have

1 time-limited, yes.

2 MS. PACE: -- for untested

3 measures, but if you have a measure that is

4 not even specified well --

5 CO-CHAIR MUELLER: Okay, got it.

6 MS. PACE: -- again, you get into

7 measure development versus you've got a

8 measure that is well-specified and ready to go

9 to testing.

10 CO-CHAIR MUELLER: So, maybe this

11 was a good one to start with, so that we can

12 kind of just learn all the things we have to

13 think about.

14 Are we ready for a vote?

15 Okay. So, what has been proposed

16 by the measure reviewers is to not recommend

17 the measure for endorsement.

18 Do we do hands? How do we do

19 this? Yes, okay.

20 So, all in favor of that

21 recommendation, please indicate by raising

22 your hand.

1 (Show of hands.)
2 Those not in favor, please
3 indicate.
4 (No response.)
5 Do we abstain? Is that an option,
6 to abstain?
7 Any abstentions?
8 (No response.)
9 Okay. So, it appears that it is
10 unanimous that this measure not be
11 recommended.
12 CO-CHAIR GIFFORD: I think,
13 Jackie, the message you hear is dementia is
14 very important. We would love to see
15 something revised and worked on, and we
16 appreciate the complexity of the application
17 process.
18 The next measure is, I guess we
19 get two minutes from RTI, the measure
20 developer, and then we will hear from the
21 reviewers.
22 MS. GAGE: There we go. Is that

1 better?

2 Barbara Gage from RTI. Thank you

3 for having us here today. We are really

4 excited.

5 As Dr. Ling mentioned, there is a

6 whole series of CMS measures that are designed

7 to better reflect the patient voice in terms

8 of measuring quality of care. This first one

9 that we will be looking at is a perfect

10 example of that.

11 The work that we are presenting

12 has been based on several technical expert

13 panels before this. Many of you know the

14 members, people like Dr. Deb Saliba, who has

15 been working closely with us on all of these

16 measures, as well as Eric Tangalos and members

17 of AMDA and members of the associations,

18 members of the different research communities.

19 So, we thank and recognize all of

20 them for their input. Members of the clinical

21 community as well, Dr. Levenson from Genesis,

22 as well as members from other healthcare

1 providers, including the Kindreds and a few
2 others who are at the table here today.
3 So, thank you for having us.
4 This measure that I am presenting
5 is on the percent of residents who have
6 symptoms of major depression. This is for the
7 long-stay population. It is based on the
8 numerator is the PHQ-9 item, which has been
9 heavily tested in the research communities.
10 I can say more about that, if you would like,
11 but it is a summative score identifying about
12 nine different areas that might be a
13 reflection of depression in the patient. That
14 is the numerator. The denominator is any
15 admission in the nursing facility.
16 So, it is an improvement on what
17 was in the MDS 2.0 measure because it now
18 looks at any patient, any resident in the
19 nursing facility, rather than just looking at
20 worsening of depression within the nursing
21 facility.
22 Its importance, this is probably

1 not a group I need to speak to the importance
2 of identifying depression in the long-stay
3 nursing facility community, but it is
4 expensive, complicated, and, most importantly,
5 it is treatable. So, identifying it and
6 dealing with it is considered to be very
7 important. There is a series of studies we
8 have put in the materials documenting the
9 importance.
10 The usability, or I'm sorry, the
11 reliability and the validity, the scientific
12 acceptability, these items have all been
13 tested. In some of the work that Dr. Saliba
14 did earlier, the reliability was excellent on
15 the individual items. The average kappa
16 between the gold standard nurses for the PHQ-9
17 resident interview was .935, and between the
18 gold standard and facility nurses it was .96.
19 So, this is an item where the
20 patient voice is encouraged, but the staff
21 voice can be used if the patient voice can't
22 be captured.

1 The validity was also quite good.
2 The kappa was .685, which is a fairly high
3 kappa on a measure like this. So, the
4 proposed quality measure is a ratio
5 constructed from those two tested items. So,
6 we feel good about the scientific
7 acceptability.
8 The usability, whether this item,
9 is it really a practical item that would be
10 used in the nursing facilities? Yes, it is
11 important to identify depression, and this is
12 a scientifically-acceptable way to identify
13 and decrease the prevalence in the nursing
14 facility population.
15 The feasibility, the good thing
16 about the measures that our team is presenting
17 today is that they are tied to the MDS 3.0.
18 So, when it comes to implementation, all of
19 these items will be collected on all of the
20 nursing facility residents in the U.S. as of
21 October. So, feasibility seems pretty
22 feasible.

1 (Laughter.)

2 That's inarticulate there.

3 CO-CHAIR GIFFORD: Thank you,

4 Barbara.

5 Sister Mary Rose, you're the

6 primary reviewer.

7 SISTER HEERY: Yes, I was. My

8 name is Sister Mary Rose.

9 I found this a very good proposal.

10 I thought it was well-thought-out. I thought

11 it was well-presented. I thought the

12 literature supported it. From a nursing home

13 perspective, I am looking forward to using

14 this tool because I think it will be very good

15 when we report quality that we will all be

16 reporting the same thing, no longer apples and

17 oranges.

18 We will be moving away from the

19 2.0, where we had ability to look at what

20 assessment we would use. That sometimes

21 didn't give the public a good comparison

22 because we were able to, I don't want to say

1 present the wrong thing at times. The way we
2 collected our data was not consistent.
3 So, I think the PHQ will give us
4 good data to collect. It will also help us to
5 bring information back to the families and the
6 physicians, and we can, then, have the
7 treatments working and be more proactive.
8 So, I felt, reading through it, it
9 did -- I would ditto what she said -- it
10 passed the criterias needed. I think it would
11 be a very usable tool for both the facility
12 and the public and help us to compare.
13 The only thing I didn't
14 understand, one question was the exclusion.
15 People didn't rate three of them. That was my
16 only concern. But other than that, I thought
17 it was really well done.
18 CO-CHAIR MUELLER: Betty, you are
19 the second reviewer. Would you like to
20 comment?
21 MS. PACE: We need to turn off
22 some of the microphones.

1 MS. FRANDSEN: There we go. Okay.
2 I'm Betty Frandsen, and I was the
3 secondary reviewer. Sister Mary Rose and I
4 did confer on this in advance, and I agree
5 with her assessment. I had independently come
6 to the same conclusion.
7 I felt that it passed on all the
8 criteria. It was actually a pleasure to read,
9 and it came across as very usable, very well
10 done, clear, and with great benefit to
11 residents.
12 MS. THOMPSON: This is Darlene
13 Thompson. May I ask a question? Because I
14 agree with Lisa; I didn't have an opportunity
15 to read all the other ones.
16 Can you tell me what the summary
17 score has to be for the resident to count in
18 the numerator?
19 MS. GAGE: Yes. The PHQ-9 is an
20 existing item. So, the calculation of the --
21 MS. THOMPSON: I understand how
22 you calculated. You calculated off the

1 frequency. But it is a 0-to-27 score for the
2 resident. What is the cutpoint that counts
3 the resident on the numerator as falling into
4 this measure? Any number? So, if you are not
5 a zero, you are possibly --
6 MS. GAGE: Yes, it is a summative
7 score.
8 MS. THOMPSON: I know, so any --
9 MS. GAGE: So, yes.
10 MS. THOMPSON: If I have a 1, I'm
11 as depressed as a sum of 27, according to this
12 measure?
13 MS. GAGE: You are not as
14 depressed. In terms of the quality, in terms
15 of measuring -- I don't want to misspeak. So,
16 let me pull this out.
17 MS. THOMPSON: Okay, I am trying
18 to read it on the board there. So, it is not
19 going from the total?
20 CO-CHAIR GIFFORD: No, it looks
21 like --
22 MS. THOMPSON: It is going from

1 particular questions?

2 CO-CHAIR GIFFORD: It looks like

3 they have a PHQ score of 9 or 10, and it may

4 give it a sensitivity of 88 percent and a

5 specificity of 88 percent.

6 MS. THOMPSON: Okay. So, if the

7 total score is less than 9, they don't count

8 it on the numerator in this particular

9 measure? Is that what you are saying?

10 CO-CHAIR GIFFORD: At least that

11 is under the testing of the current use.

12 MS. THOMPSON: Greater or equal to

13 10, okay.

14 SISTER HEERY: They were broken

15 down as a category.

16 CO-CHAIR GIFFORD: Let me ask.

17 Everyone has laptops. Does everyone have the

18 thumbnail drive with all the measures on it.

19 Does anyone have the thumbnail with all the

20 measures on it?

21 Because people that don't have

22 their laptops, if you want to just come up and

1 look over my shoulder and read through it, I
2 am fine with that. But if we want to just
3 share some of the laptops, so people can look
4 at and read certain sections of the measure,
5 if you want to look at it, it would be
6 helpful. It is also up here, if you want to
7 look at it.
8 SISTER HEERY: Darlene, it was
9 levels of depression that they looked at, and
10 they had different scoring systems. So, I
11 believe it was under 9 that wasn't considered
12 depressed.
13 MS. THOMPSON: Okay, because the
14 only reason I am asking is I understand that,
15 if the resident can't complete it, you do the
16 staff one, and the staff one has one
17 additional question. So, there's three
18 additional points on the staff one. So, there
19 is a little bit of discrepancy in the
20 numbering. So, I was just trying to figure
21 out where is that cutpoint, because on the
22 staff one they could be, but, I mean, if the

1 resident finishes it, they may not. So, for
2 validity.
3 MS. PACE: I don't think it is
4 clear that, at least in the numerator
5 statement that it is clear what counts as
6 depression.
7 CO-CHAIR MUELLER: Right. That is
8 what is missing from the definition.
9 MS. THOMPSON: And I didn't even
10 read this one, and I couldn't figure it out.
11 MS. GAGE: The logic is under the
12 2(a)(3) with the numerator details, yes.
13 CO-CHAIR GIFFORD: But it doesn't
14 tell you a total score.
15 MS. THOMPSON: So, then it is not
16 total; it is a combination of these items?
17 CO-CHAIR GIFFORD: It is not the
18 actual PHQ; it is a subset of the PHQ?
19 MS. GAGE: Yes, and it is a ratio
20 measure. So, if you go to the -- five or
21 more, okay, that was the definition. I hate
22 to speak from memory.

1 But if you go back up, you have to
2 have five or more of the items on the bottom
3 and at least one of the items on the top as
4 true in order to trigger the numerator, in
5 order to be counted in the numerator. So, at
6 least one of the following is true.
7 The PHQ-9 is a series of nine
8 statements asking about whether the patient --
9 in the past two weeks, has the patient had
10 little interest in this, little interest in
11 pleasure? There is a whole series of issues
12 for concentration, self-value, responsiveness,
13 patience, decreased aptitude, decreased mood,
14 energy, et cetera.
15 So, you go through the interview
16 item with the patient. Then, if the patient
17 responded as true to at least one of the
18 following, where their score was at least five
19 times a week or higher, five times in the last
20 two weeks or higher, that they have had either
21 at least, one, little interest or pleasure of
22 doing things, feeling down, depressed, or

1 hopeless half or more of the days over the
2 last two weeks. So, they have at least one of
3 those and five of the others. Then, that
4 score goes into the numerator.
5 Then, the denominator is the sum
6 of the residents in the facility, and the
7 level of the score, the thresholds -- did we
8 think about the thresholds?
9 MS. PACE: So, it is not really a
10 summative thing? It is just --
11 MS. GAGE: The numerators are
12 summative. The numerator, the PHQ-9 is the
13 numerator.
14 MS. PACE: Right, but you said you
15 would get into the numerator if one of the
16 group of --
17 MS. GAGE: The two on the top or
18 the five --
19 MS. PACE: If one of those is
20 present and five of the following, but it is
21 not saying you add up the scores?
22 MS. GAGE: Oh, correct.

1 CO-CHAIR MUELLER: It appears the
2 numerator is not the score of the PHQ.
3 Rather, it is the items are --
4 MS. GAGE: Yes. Thank you.
5 So, it is a facility measure that
6 identifies the proportion of the patients, the
7 percent of the residents who have been found
8 to have depression based on --
9 CO-CHAIR GIFFORD: I think the
10 question, it is not clear in the document as
11 to how you are defining who is having
12 depression. At some point, you have to make
13 a cutpoint.
14 MS. GAGE: Yes.
15 CO-CHAIR GIFFORD: And it is not
16 clear how you define -- I mean I think what we
17 are asking is, what is the score? It is a
18 complicated score. It is two of these, four
19 of these, three of these, and two of those.
20 But, at some point, you add those all up, and
21 what's that number? I think that is what the
22 group is looking for, to understand this

1 better.

2 Is that a fair summary? Darlene,

3 is that what you are looking for?

4 MS. THOMPSON: Yes, and, also,

5 because on the staff one there's three

6 additional points. And depending on what that

7 cut is, there is a discrepancy between the

8 validity of whether that numerator is going to

9 be the same.

10 CO-CHAIR MUELLER: The way I read

11 it, it does not look like it is a cutpoint

12 issue. It looks like the items on the PHQ

13 are, if any one of these nine items are a

14 positive, then you count in the numerator.

15 MS. GAGE: Right.

16 CO-CHAIR MUELLER: It is not about

17 the total score or a cutpoint score. Is that

18 how --

19 MS. GAGE: That's correct. It is

20 a prevalence estimate. My apologies for the

21 additive score. I was thinking more of the

22 PHQ-9 and how it is used, but in the quality

1 measure it is an identification of the
2 presence of the depression.
3 MS. PACE: So, the description of
4 the numerator statement said that it is based
5 on the total sum severity score, which I think
6 is leading people to think you are adding up
7 numbers and coming up with a score.
8 MS. GAGE: We should clean that
9 up.
10 MS. PACE: It is maybe a little
11 discrepancy between how it is described and
12 how it is actually done.
13 CO-CHAIR GIFFORD: Dede?
14 DR. ORDIN: I have a question.
15 Obviously, this tool is used a great deal, and
16 it is being incorporated into measures.
17 Is this the same definition of
18 positivity that is used in other measures?
19 MS. GAGE: Yes, it is. It is.
20 This measure comes out of Dr. Saliba's work,
21 which is the same work that is feeding into
22 the VA work and the other settings. So, yes.

1 Our goal in having such a diverse
2 team is to create greater harmony across the
3 different efforts that are underway in related
4 measures.
5 DR. ORDIN: I also have a
6 denominator question, and it came up, I think
7 it is going to come up a lot because it came
8 up in my two other measures.
9 It looks like in the denominator
10 it is possible to get people who were there
11 for less than 100 days. So, that is why I
12 asked the 100-day question before. I mean
13 because you are looking at a quarterly MDS or
14 you are looking at an MDS that could happen
15 less than 100 days after admission. This is
16 true of a lot of the measures, not just your
17 measure.
18 MS. GAGE: Yes. For the long-stay
19 population, there are exclusion criterias
20 built in.
21 I am going to turn to my colleague
22 Roberta, who can recite all of the short-

1 stay/long-stay differentiators.

2 Roberta?

3 MS. CONSTANTINE: Well, some of

4 them are more --

5 MS. GAGE: Roberta, you have to go

6 to a microphone.

7 MS. CONSTANTINE: Hi.

8 In some cases, really it depends

9 somewhat on the measure as well as what

10 particular assessments that you are referring

11 to. For example, in a lot of the long-stay

12 measures, you are excluding the admission over

13 assessment, but then, on the other hand, you

14 are including a quarterly or an annual or a

15 significant change or a significant correction

16 assessment. But it is somewhat measure-

17 specific at times.

18 MS. THOMPSON: This is Darlene

19 Thompson.

20 I think the discussion we had

21 earlier about the resident being in the

22 facility 100 days and using that as a guide,

1 that should be the guide for all the long
2 stays. Because even with what you indicated,
3 that you don't count the admission, you don't
4 count PPS, but you count a significant change,
5 a managed healthcare patient could have a
6 significant change assessment done in day 20
7 or day 6, or whatever, of their stay. Then,
8 they are going to be thrown into that long-
9 stay measure.
10 So, I think one of the things to
11 look at is that, if we are talking long stay
12 and everybody thinks a resident has to be in
13 the building or be a resident for 100 days,
14 and we are going to go by that date the stay
15 began, then that should be added to the
16 denominator of all the long stays. Then, I
17 think we won't have this confusion across the
18 board, because both of mine are the same as
19 well.
20 DR. ORDIN: Okay. So, it would be
21 an exclusion if someone is less than 100 days?
22 MS. CONSTANTINE: That is a good

1 point. We tried, in sort of writing the
2 measures, to say it is the long-stay
3 population and, therefore, the long-stay
4 population would have a stay of 100 days or
5 more, and then refer to the assessments,
6 whether they are the quarterly, the annual,
7 the significant changes, significant
8 correction assessment.
9 But thank you for bringing up that
10 point. We will try to be sure that we make
11 that clearer in the measure itself.
12 CO-CHAIR GIFFORD: I have a
13 question. On the validity testing, it appears
14 that it is related to the sensitivity and
15 specificity of this for detecting depression.
16 I have a different validity question.
17 This is really a quality measure
18 or a measure used for quality improvement.
19 What I didn't see was, and understanding there
20 is no perfect measure, so we can fail all the
21 measures because none of them are perfect, but
22 I didn't see validity testing as a quality

1 measure, that a facility that scores high on
2 this is doing worse quality than a facility
3 that is scoring low on it, nor did I see
4 validity testing that showed that, if I did
5 better management, my score would change.
6 SISTER HEERY: I believe it was in
7 the literature review that they did talk about
8 that validity and how the score would change
9 if you were more proactive in your approach to
10 treating depression, is where they had a lot
11 of information.
12 MS. GAGE: The use of the
13 quarterly assessments identifies that change
14 at the facility level, and the use of the
15 quality measure, these items were tested for
16 their validity, and in terms of the depression
17 being identified, the literature suggests that
18 reducing prevalence was a good indicator of
19 quality, of improved quality, as this is a
20 treatable condition.
21 I think a lot of this comes down
22 to the fact that depression is treatable, and

1 a good nursing home shouldn't have growing
2 problems with depression. They should be
3 treating the conditions, and it should be
4 going down over time.
5 CO-CHAIR GIFFORD: But isn't this
6 measure just a cross-sectional measure? I
7 mean, if it is measuring quality and change,
8 and that is the focus, shouldn't it be a
9 change measure, instead of a cross-sectional
10 measure?
11 MS. GAGE: It is at the facility
12 level. If you think about how the MDS items
13 are used and how they are collected every
14 year, every facility will have an item
15 collected at that point in time.
16 The former item on the MDS 2.0 was
17 actually a measure of the percent of patients
18 whose depression worsened or the percent of
19 patients in the facility, the change in the
20 percent of patients in the facility with
21 depression.
22 The construction of it was not

1 really a good, valid measure. It excluded
2 populations who could have entered that group
3 over time.
4 So, by measuring the percent of
5 all nursing facility residents with the
6 depression, based on the measures, at a point
7 in time, you can see at a facility level
8 whether that percent has changed over time.
9 And this is the long-stay population. So,
10 there is a bit of a presumption that it is not
11 due to case mix changes.
12 DR. MODAWAL: I have a question
13 related to that. In terms of the validity, I
14 think it is a very important question because,
15 is this tool a screening tool or is it as good
16 for management and followup as well? I don't
17 know how these things -- I mean I have used it
18 in an office setting, but I don't how
19 applicable will it be as far as the protocols
20 for MDS goes and the follow up of our
21 patients, and using it as a quality measure.
22 They are not interchangeable sometimes.

1 MS. GAGE: No, they are not.
2 Where the quality measures usually target the
3 overall effectiveness of a provider, this gets
4 at that issue of, is there a quality issue?
5 The care-planning aspect, which I think you
6 are referring to in terms of how to treat, is
7 not captured here. This is not intended to go
8 that far. It is only intended to identify the
9 prevalence of the problem.
10 DR. MODAWAL: So, if the
11 prevalence of the problem is a question that
12 needs a screening in a facility, you know,
13 then should we put some time limits, okay,
14 once a year or every six months, rather than
15 a routine MDS feature?
16 MS. GAGE: Yes.
17 DR. MODAWAL: Just like we are
18 talking about falls, you know, that we should
19 ask about it once a year.
20 MS. GAGE: Yes.
21 DR. MODAWAL: Can that be put in
22 to make it more usable and feasible?

1 MS. GAGE: Yes, and this will be
2 used; the assessments that are used in the
3 identification are the annual, the quarterly,
4 and the significant change. So, there is an
5 annual measure at the facility level. A good
6 question.
7 MS. PACE: I think I just want to
8 clarify something. The question about
9 validity that came up is an important question
10 for you all to think about. Frankly, it is
11 something that the Measure Testing Task Force
12 that Helen mentions is working on. For both
13 reliability and validity, it is kind of at two
14 levels, at the data level and, then, at the
15 computed performance measures score level.
16 So, what David is asking about is
17 what evidence, if any, does the computed
18 measure score? Obviously, depression and the
19 evidence regarding depression and treatment is
20 good, but that is not about the measure score
21 as it has been presented.
22 So, one of the questions -- and I

1 think it relates to many of the measures, that
2 you might want to talk about the philosophy of
3 this idea of cross-section prevalence being a
4 quality measure versus what the evidence is
5 talking about is actually identifying
6 individuals and treating individuals and
7 seeing that.
8 I think that goes across several
9 of these measures, if you could maybe talk a
10 little bit about the general philosophy there?
11 MS. GAGE: Sure. Thank you,
12 Karen.
13 The measures that we are bringing
14 forth for CMS are a set of measures to monitor
15 quality of care in the nursing facilities for
16 the beneficiaries, the residents that are
17 being treated in the nursing facilities.
18 While they rest, while the measures rest on
19 the individual items which are what can be
20 tested in terms of reliability and validity,
21 the MDS 3.0 items, we have not yet had the
22 chance to test the new measures because the

1 data collection just begins in October.
2 So, we are using the reliability
3 and the validity that have been tested in past
4 research, which is how you approach scientific
5 acceptability: have these items been used
6 well? Does this make sense? Are they
7 carrying through statistically?
8 So, the application of the items
9 into a standardized measure for the annual
10 assessment in monitoring the program and the
11 quality of care in the individual facilities
12 is built on the work that has been done at the
13 item level.
14 MS. PACE: So, I guess one
15 question that gets at some of these issues is,
16 so only patients that have been at the
17 facility longer than 100 days will be in the
18 denominator. So, it is really the presumption
19 that the nursing facility has had time to
20 identify and treat depression. So, the
21 prevalence of depression in your patients
22 post-100 days indicates that the nursing home

1 or nursing facility has not really been
2 identifying and attending to.
3 So, is that kind of the basic
4 assumption of why you can use this as a
5 quality measure?
6 MS. GAGE: Yes, that is correct.
7 This is a treatable issue.
8 CO-CHAIR GIFFORD: Bill?
9 MR. KUBAT: Yes, a question. The
10 discussion has been helpful. But particularly
11 in light of the measure and the validity
12 discussions, and so forth, is there any
13 additional significance?
14 Two of them that I always
15 gravitate to, one of them is 4(d),
16 susceptibility to inaccuracies, errors, and
17 unintended consequences, and there's nothing
18 there. No research could be identified.
19 Can you comment on that in light
20 of the discussion we have had thus far?
21 MS. GAGE: My understanding of the
22 item is whether an item could be

1 misinterpreted when being applied, when being
2 used in the facility by the clinicians. With
3 the PHQ-9, this has been so heavily tested in
4 so many communities, the language is quite
5 clear. So, it is not applicable. Or "no" I
6 guess would be a better answer.
7 MR. KUBAT: I think, actually,
8 ultimately, this measure is a measure of the
9 facility, not the individual, but it is an
10 aggregate of individuals.
11 MS. GAGE: Correct.
12 MR. KUBAT: What is presented here
13 is high kappa, high reliability testing, high
14 sensitivity and specificity at the individual
15 level.
16 MS. GAGE: Yes.
17 MR. KUBAT: Nothing is presented
18 at the facility level because it hasn't been
19 calculated just based off MDS 3.0.
20 MS. GAGE: Correct. Yes.
21 MR. KUBAT: Is that a fair summary
22 of that?

1 MS. GAGE: That is.
2 MR. KUBAT: So, that is why your
3 answer that we don't know.
4 DR. ORDIN: I think part of the
5 thing that would be helpful in looking at
6 potential adverse impact of this measure is to
7 look at it over time with the use of
8 psychotropic drugs, because one of the things
9 that could happen is overuse in response to
10 that.
11 So, that is one of the reasons for
12 testing it as a measure rather than as -- you
13 know, it has been totally validated as a
14 screen for an individual patient.
15 CO-CHAIR GIFFORD: All right. So,
16 I am going to call the question on the
17 different components. So, the importance of
18 this measure, people feel it completely meets
19 everything -- I am going to say, just
20 summarize the recommendation before the group
21 that you are voting on, that we vote, the
22 completeness, it passes. We are happy with

1 the completeness of this.

2 Everyone in favor of that? Show

3 of hands. We just need to see it.

4 (Show of hands.)

5 Anyone abstaining?

6 (No response.)

7 Anyone against?

8 (No response.)

9 Okay. On reliability and validity

10 of the scientific evidence of this measure,

11 what I would put forth to the group would be

12 that it recommends passing with the caveat

13 that Darlene has brought forward, that the

14 definition of 100 days be modified to really

15 be 100 days. There's no loophole in there.

16 So, there is actual calculation back to the

17 admission date. I think that that is probably

18 what is before the group.

19 Yes, Ron?

20 DR. SCHUMACHER: Ron Schumacher.

21 Just a question on that. Is there

22 a potential loophole there if there are

1 hospital admissions during the time the person
2 is in the nursing facility? Does the clock
3 start again on a new admission?
4 CO-CHAIR GIFFORD: The way the MDS
5 is filled out -- of course, I haven't filled
6 one out in a while, about five years. So, I
7 apologize. But it depends on how the
8 admission occurs.
9 If they are officially discharged
10 from the hospital and going back over it, if
11 they come back, then they need a new MDS
12 filled out. So, it should change it, I
13 believe.
14 But I think the reviewer, Darlene,
15 or anyone close to the MDS, RTI, is that
16 right?
17 MS. CONSTANTINE: Depending on the
18 definition and what occurred, it could be a
19 significant change assessment.
20 CO-CHAIR GIFFORD: You need a
21 microphone. Sorry.
22 MS. CONSTANTINE: My best friend.

1 Hi.

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

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

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

20 DR. SCHUMACHER: So, I was just
21 worried about unintended consequences
22 resulting in increased hospitalization for

1 depression, so that the clock could start
2 ticking again.
3 MS. THOMPSON: This is Darlene
4 Thompson.
5 With the definition for doing the
6 MDS, if the resident is discharged even for an
7 observational stay that is over 24 hours, then
8 they have to be discharged. When they come
9 back, you would enter the new data into A1600.
10 So, what you are discussing about
11 a long-stay patient that took a short stay in
12 the hospital now becoming a brand-new clock is
13 correct. However, you could put a caveat in
14 there by looking at, if the prior assessment
15 was a discharge with return anticipated, and
16 the resident comes back, because you do have
17 to answer a question if it was a re-entry.
18 So, I think that if the
19 individuals would go back and look at the
20 exclusion for the denominator to cover those
21 instances, I think that is going to take care
22 of your issue.

1 MS. GAGE: Thank you.

2 CO-CHAIR GIFFORD: Any other

3 comments on reliability and validity?

4 (No response.)

5 So, what we have before us would

6 be voting that it does meet

7 reliability/validity except for the small

8 modification. So, we are in that modification

9 range of defining the 100 days more clearly.

10 Any others? Yes, Dede?

11 DR. ORDIN: I would just like to

12 bring up for consideration that perhaps we

13 would like to do a time-limited one on this

14 and ask for a study of the validity of the

15 measure.

16 MS. GAGE: We will be, as we go

17 live in the October 2010 data collection, we

18 will be testing all of the measures.

19 CO-CHAIR GIFFORD: Barbara, I

20 don't know if you realized what you just said

21 yes to. That means we were voting this is a

22 time-limited measure.

1 MS. GAGE: Oh, no.
2 CO-CHAIR GIFFORD: So, the
3 measure, this is a time-limited measure, and
4 change their submission to a time-limited
5 measure, is that right, Barbara?
6 MS. GAGE: No. No, no, no. This
7 is an improvement on the previously-endorsed
8 measure.
9 DR. ORDIN: I agree that it is an
10 improvement on the previously-endorsed
11 measure, which was very problematic, but I am
12 concerned about potential adverse impacts.
13 And is this really measuring quality and
14 there's a way that you could look at the
15 medication that is going on? At the
16 individual level, what is the change in the
17 measure? I mean use it as the clinical tool
18 to validate that, yes, this is, indeed,
19 reflecting quality of care in a facility.
20 I know you guys know how to
21 validate this.
22 (Laughter.)

1 CO-CHAIR GIFFORD: Are you
2 suggesting a modification of the vote before
3 the Committee or a vote --
4 DR. ORDIN: Yes.
5 CO-CHAIR GIFFORD: Okay.
6 DR. ORDIN: I am suggesting that
7 we consider --
8 CO-CHAIR GIFFORD: Use time-
9 limited with the 100-day change?
10 MS. THEBERGE: I believe the staff
11 had marked this as time-limited endorsement
12 only.
13 CO-CHAIR GIFFORD: You did? Oh,
14 okay.
15 DR. ORDIN: Here I thought I was
16 being so radical.
17 MS. PACE: Let me just make a
18 clarification.
19 Again, this is where NQF has not
20 been real clear about accepting data
21 reliability and validity versus measure score.
22 So, we could go either way with this. So, I

1 think it is an issue of what the Committee
2 thinks are the dangers or potential dangers or
3 need for more information as the
4 implementation of MDS 3.0.
5 So, it certainly can fit in either
6 category. We need your guidance on that.
7 I think there was also a need to
8 put a clarification in the numerator, so that
9 it was clear how that was actually computed.
10 The other thing I will just
11 mention about measures that are endorsed,
12 whether it is time-limited or full
13 endorsement, that as it is implemented, if the
14 community identified issues with it, that is
15 something that could be brought back to NQF
16 for ad hoc review.
17 So, there are other options, but
18 certainly the time-limited is, under these
19 circumstances, something for your
20 consideration.
21 CO-CHAIR GIFFORD: Comments from
22 the Committee counter to the proposal on the

1 table or in the pit? That is the way we are
2 organized here.
3 (Laughter.)
4 Arguments not to time-limit it?
5 Anyone?
6 (No response.)
7 Okay. So, what is before us is
8 time-limited approval with the caveat to
9 modify the 100-day definition more clearly.
10 Any other comments before we vote?
11 (No response.)
12 Everyone in favor of that?
13 (Show of hands.)
14 Anyone abstaining?
15 (No response.)
16 Anyone opposed?
17 (No response.)
18 For the record, I vote for it,
19 yes.
20 MS. GAGE: Thank you.
21 CO-CHAIR GIFFORD: Yes?
22 MR. KUBAT: Bill Kubat here.

1 Maybe this is just a general
2 question, and I don't mean this as a
3 distraction. So, if it is, you just tell me.
4 And I don't know if this is a question for the
5 developer, for NQF, or if it is a question for
6 CMS.
7 But there are a number of measures
8 where you could ask this question. How is it
9 considered whether or not the measure is
10 appropriately-worded as is or worded in the
11 positive? I mean you could take this measure
12 and say it is a percent of persons "free of".
13 And the reason I ask that
14 question, and to me it is a harmonization
15 question, is that you see that kind of
16 language throughout much of Hospital Compare,
17 and so forth.
18 So, how does that relate to what
19 we are about here? This measure and, again,
20 you could relate it to any number of others.
21 MS. GAGE: Shari, would you like
22 to answer?

1 The CMS measures in general have
2 the approach -- that is why you are seeing it
3 in all of the Compare. CMS is moving towards
4 a positive interpretation of whatever is being
5 examined. So, these are all consistent with
6 that approach also.
7 MR. KUBAT: So, that means that
8 CMS would, then, as they are using these
9 endorsed measures for purposes of Nursing Home
10 Compare, what have you, they have the latitude
11 or the sense that they will invert them and do
12 them in the positive? I mean, what does that
13 mean?
14 CO-CHAIR GIFFORD: No, the measure
15 we have before us is the percentage with the
16 diagnosis. If the diagnosis is viewed as a
17 negative, then it is worded in the negative;
18 it is a, quote, "negative" measure. If having
19 the diagnosis is a positive thing, then it is
20 worded in a positive thing. But it is worded
21 in the percent with this activity.
22 You know, NQF has endorsed

1 different types of measures. I mean a lot of
2 the medical error measures are all in the sort
3 of the negative, if you use that term, versus
4 the "free from". So, we flip back and forth.
5 Many of the original measures were
6 measures in the process measures, which tended
7 to be processes that were supposed to be done.
8 So, they were viewed as in the positive. As
9 we move more to outcome measures, the outcome
10 measures are more of the disease of interest.
11 So, one could argue that they may be viewed in
12 the negative.
13 But, next door, they are doing a
14 lot of outcome stuff, and the outcomes are not
15 free from disease. They are the outcome often
16 of interest. So, it is an interesting issue.
17 As far as what you do with
18 reporting it, I mean the validity in reporting
19 and the structure of this is as is, which is
20 percent with the disease or with the measure
21 of interest. Here, the goal would be to have
22 very few people depressed, and therefore, you

1 would argue that it is framed in the negative.
2 To flip it around and to the
3 reciprocal, you know, I guess anyone can do
4 anything with any measure. It is not just
5 CMS. Anyone could do that. So, it is really
6 tested and structured in the way it is
7 presented to us, and we are voting on it the
8 way it is presented to us.
9 MR. KUBAT: Well, and I don't want
10 to belabor the point, but I do think it is an
11 important one. So, as I understand it, then,
12 if CMS does invert it or use the reciprocal,
13 then that is not an NQF-endorsed measure?
14 CO-CHAIR GIFFORD: Correct.
15 MS. TOBIN: Judy Tobin from CMS.
16 The Compare site is a public-
17 facing site meant to word the measures in such
18 a way that the general public can understand
19 and interpret them. So, some of the wording
20 is changed for that general public digestion
21 of the measure.
22 DR. ORDIN: I have a question.

1 This is Dede Ordin. I have a question for
2 NQF.
3 I know you said it, but what does
4 time-limited mean, because there is no way
5 that this can be tested until 3.0 has been
6 used for probably a year?
7 MS. PACE: And when is 3.0 being
8 implemented?
9 DR. ORDIN: October.
10 MS. GAGE: It is being implemented
11 in October. We have plans to begin testing in
12 the January period, after a quarter of data
13 have come in and people have experienced --
14 DR. ORDIN: Right. I mean our
15 current policy is testing within 12 months.
16 MS. GAGE: And that is not
17 possible here.
18 MS. THEBERGE: The final
19 endorsement won't be until December though.
20 So, that would be 12 months from December when
21 the Board endorses.
22 CO-CHAIR GIFFORD: Yes, we are

1 just at the beginning.

2 (Laughter.)

3 These measures haven't graduated

4 yet.

5 Okay, the next one would be on

6 usability. What I heard from the group was

7 that the usability was probably --

8 MS. PACE: voted already, didn't

9 we?

10 CO-CHAIR GIFFORD: We voted on

11 importance of reliability and validity. I'm

12 just following the rules. I just do what

13 people tell me to do. The time-limited and

14 that was all related to the reliability and

15 scientific aspects of it, right?

16 CO-CHAIR MUELLER: I think

17 everybody thought we were voting on --

18 CO-CHAIR GIFFORD: All right. I'm

19 very good at misleading people. It's what I

20 do for a living these days.

21 I will lump usability and

22 feasibility together because I am assuming

1 everyone felt that that was reasonable to move
2 forward on. Any caveats to that?
3 (No response.)
4 All in favor?
5 (Show of hands.)
6 Any abstaining?
7 (No response.)
8 Any opposed?
9 (No response.)
10 Then, I would take the whole
11 measure as a whole set. Now the whole set,
12 which is to approve it time-limited with 100
13 days out there.
14 Any abstaining?
15 (No response.)
16 Any opposed?
17 (No response.)
18 All in favor?
19 (Show of hands.)
20 To make sure you guys are
21 listening, I changed the order.
22 (Laughter.)

1 Okay, Christine?
2 CO-CHAIR MUELLER: All right, our
3 next set of measures is staffing measures in
4 the nursing home, and our steward is the
5 American Nurses Association.
6 I am the primary reviewer on one,
7 and Betty is the secondary on that same one.
8 Then, she is the primary reviewer on the
9 first.
10 Rita, I don't know if you're --
11 CO-CHAIR GIFFORD: 11:45 is the
12 break, Dede, 11:45, right there on paper. We
13 are doing what everyone says. We are not
14 varying. We are going right through on this.
15 CO-CHAIR MUELLER: Yes, although I
16 wish otherwise.
17 I'm sorry, I have too many papers.
18 So, what do you mean by No. 6?
19 MS. GALLAGHER: This is Nursing
20 Home 006.
21 CO-CHAIR MUELLER: 006, and both
22 of these measures are quite related, and the

1 documentation was the same for both measures.
2 So, I don't know how you are planning to
3 approach that.
4 MS. GALLAGHER: Well, I think
5 that, at the pleasure of the group, it might
6 be best to entertain them together.
7 Karen, is that --
8 MS. PACE: Yes, I would have them
9 hear comments about both of them, and then
10 they can discuss them individually. But I
11 think it would be easier for you to just talk
12 about both of them.
13 MS. GALLAGHER: Okay. I am Rita
14 Munley Gallagher. I'm a Senior Policy Fellow
15 with the National Center for Nursing Quality
16 at the American Nurses Association.
17 I am here to follow on to the
18 comments earlier made by Helen Burstin
19 regarding ANA's willingness to work to expand
20 the 0204 and 0205, which are currently
21 endorsed NQF measures, to reflect
22 appropriately the nursing home setting.

1 As you heard earlier, the Mental
2 Health Steering Committee in its deliberations
3 in the recent past two weeks, I guess it was,
4 requested that that activity take place. And
5 how that will be operationalized is that a
6 work group will be empaneled, and members of
7 the Steering Committee will be invited to
8 participate in the definitions that need to be
9 included in the expanded measure. That would
10 be the same suggestion for this group.
11 NDNQI's principal investigator,
12 Dr. Nancy Dunton, is on the telephone, and she
13 would be pleased to speak to you about any of
14 the technical aspects of the measures. I am
15 here merely to express the measure developer's
16 willingness to expand the measures and move
17 forward with them for additional settings.
18 So, Nancy, are you there?
19 DR. DUNTON: Yes. Thank you,
20 Rita.
21 Good morning, everyone.
22 I think it is appropriate to

1 review these measures together, total nursing
2 hours per resident day and skill mix. They
3 are structural measures that have been shown
4 in the research literature to be significantly
5 related to improved functionality of short-
6 stay residents and decreased probability of
7 death, improved resident functionality, and
8 fewer medical errors and survey deficiencies,
9 and reduced adverse outcomes and cost.
10 So, the specifications of the
11 measures are as they were for the hospital
12 setting in that the total nursing hours for
13 patient day or per resident day in this
14 instance is defined to include hours provided
15 by all categories of nursing licensure status,
16 and resident days in this instance would be
17 the patient census.
18 The reliability and validity of
19 these measures have not been studied by us in
20 the nursing home setting, although we have
21 conducted criterion validity studies of both
22 measures on the hospital setting and found

1 them to have very high ICCs, in the range of
2 .95.
3 The measures, there is sort of
4 limited evidence of usability in that these
5 concepts are represented on Nursing Home
6 Compare, although the measures that are
7 proposed here differ in source from the
8 measures reported there, which come from the
9 annual or the 9 months or 15 months annual
10 surveys of nursing homes, as opposed to from
11 payroll records and patient censuses.
12 The data collection is feasible
13 because, of course, there are payroll data and
14 patient census data in nursing homes,
15 generally in electronic format, although
16 certainly not from a medical record or from
17 the MDS.
18 So, we are asking for time-limited
19 endorsement of these measures because we know
20 that their reliability and validity testing
21 need to be conducted in long-term care
22 settings, and the NQI has the ability to do

1 that because there are skilled nursing
2 facilities, rehab units, and nursing homes
3 affiliated with member hospitals who will be
4 willing to serve as testbeds for the
5 demonstration of feasibility of data
6 collection and the reliability and validity
7 testing.
8 CO-CHAIR MUELLER: Okay. I am the
9 primary reviewer on this one. We are going to
10 be, first of all, talking about the skill mix
11 by RN, LPN, and nursing assistant.
12 The way that measure works is it
13 is the proportion of the direct-care nursing
14 staff that are providing 50 percent or more
15 direct care that are RNs and the proportion
16 that are LPNs and the proportion that are
17 nursing assistants. Then, there is also a
18 measure, a complementary measure, about those
19 that are contract or agency-type staff.
20 So, my assessment is that this is
21 really important, an important measure. We
22 can go back to 1970-something when there were

1 hearings on the Hill about staffing and
2 quality in nursing homes. So, when we think
3 about the fact that this was in 1970 and we
4 are in 2010, and what we are still wondering
5 about is staffing and quality in nursing-
6 homes-related, it does puzzle me a bit.
7 But, regardless, there has been a
8 great body of literature on nursing staffing
9 and quality in nursing homes, and that was not
10 probably as well-represented in the
11 presentation of this measure as I know of the
12 body of literature that is out there. So, it
13 was a little struggle for me to check, yes,
14 this is important because the evidence to
15 support the importance wasn't as strong in the
16 measure that was presented.
17 So, I would just hope, I expect a
18 number of you are quite familiar with that
19 literature and know that we have a good,
20 growing body of evidence; particularly RN
21 staffing and nursing homes is probably the
22 strongest.

1 We tend to see in many of the
2 studies that there is this inverse
3 relationship between staffing and quality;
4 when it comes to practical nurses and CNAs,
5 the evidence is somewhat uneven. So, I would
6 support it as being important.
7 In terms of the rest of the
8 criteria that we need to look at, as was
9 mentioned by the developer, there has been no
10 reliability and validity testing about the
11 measure in nursing homes. There is very
12 limited reliability and validity testing.
13 There was a study, and I hope that
14 our CMS colleagues might end up commenting on
15 this, with a contract with the Colorado
16 Medical Foundation, where they were testing
17 different measures of nurse staffing and
18 nursing homes and have a report out that came
19 out in 2008. That was not referred to in the
20 measure that was presented. There are some
21 recommendations from that body of research
22 about what might be reliable and valid

1 measures.

2 The usability and feasibility,

3 what is being proposed is that it is payroll

4 data. In this study that CMS contracted the

5 Colorado Medical Foundation, they found that

6 it was very uneven about whether nursing homes

7 could, indeed, systematically and consistently

8 have valid payroll data. So, the feasibility

9 is questionable.

10 I don't know, being a time-limited

11 measure, how we are going to go about ensuring

12 that we get good payroll data from nursing

13 home staff. Having said that, I also know

14 that in the newly-passed Health Reform Act

15 there is some legislation language in there,

16 or language in there, about testing these

17 measures and getting nursing homes to submit

18 reliable data for staffing.

19 So, it is about the timing of all

20 of this and when, indeed, it would be we would

21 have data that could be actually collected and

22 then tested for reliability and validity. So,

1 it just kills me, having done most of my
2 research in nurse staffing and quality in
3 nursing homes, to say at the end I don't know
4 if, even in a time-limited way, this measure
5 is ready for testing, but I would be anxious
6 to hear the responses from the rest of the
7 Committee. Some comments from CMS and ANA, of
8 course, would be very helpful.
9 But before we do that, I would
10 like to defer to the second reviewer, Betty.
11 MS. FRANDSEN: Likewise, I felt
12 that it was a very important measure.
13 However, the other three criteria, I felt the
14 information that was provided were lacking.
15 I couldn't understand how to translate what
16 was presented as having been usable in a
17 hospital setting, how it was going to
18 translate to long-term care as it currently is
19 functioning in capturing this information that
20 is provided in the OSCAR reports.
21 Therefore, it is hard for me to
22 say, when I think it is so important, that I

1 think that the idea is probably ahead of the
2 usability and feasibility that was presented.
3 CO-CHAIR MUELLER: Bill?
4 MR. KUBAT: Yes, Bill Kubat.
5 I echo both of those comments.
6 I'm going to remember from the first Steering
7 Committee meeting thinking about the
8 importance of domains. Staffing was one. But
9 the issue then is the same issue now: how do
10 you consistently and reliably gather the data?
11 It doesn't exist.
12 Now some other things I think that
13 were named then, but are even more significant
14 I think now, is the issue of how you -- I
15 don't know if it is necessarily a risk
16 adjustment, but how do you account for acuity
17 and differences in acuity in relation to
18 staffing?
19 Then, secondly, in terms of some
20 of the definitions, now with more of an advent
21 with culture change, and so forth,
22 appropriately accounting for versatile

1 workers, and so forth. So, it is a more
2 complex environment now than it was then, but
3 it is still a very important issue.
4 CO-CHAIR MUELLER: Okay. I see
5 Mary Jane, and then I see someone from CMS,
6 and Lisa. Did you have your hand up first,
7 Lisa?
8 MS. TRIPP: Oh, I will cede it to
9 Mary Jane.
10 DR. KOREN: This is very quick. I
11 think that Bill raises a very interesting and
12 important point, which is that with some of
13 the innovation that is going on in nursing
14 homes, we want to be careful that we don't
15 choose a measure that straitjackets us or
16 prevents really some innovations and trying
17 new models, and doing things like that.
18 So, while I echo the importance of
19 licensed and other staff in nursing homes, I
20 just want to be careful it is not an
21 unintended consequence.
22 MS. TRIPP: If I might also add, I

1 think there's an issue of harmonization as
2 well. There is going to be a new CMS quality
3 measure with regard to staffing. It is
4 required by the new law. So, there is going
5 to be data collected electronically from
6 payroll and, also, from cost reports and other
7 auditable sources. So, that data is going to
8 be a lot of data.
9 Actually, Janet Wells is here with
10 NCCNHR, who has been heavily involved in this.
11 If you wanted to explain a little bit about
12 what exactly is going to be the information
13 that is going to be gathered, I think it would
14 be helpful.
15 CO-CHAIR MUELLER: So, it looks
16 like CMS is deferring to NCCNHR right now,
17 huh?
18 (Laughter.)
19 MR. WELLS: Yes, maybe I don't
20 need to say anything since Jean is here, but
21 in 2001 the CMS issued phase 2 of a monumental
22 report on appropriateness of nurse staffing

1 ratios in nursing homes. As a continuation of
2 that contract, since 2001, CMS has been
3 developing quality measures and a data
4 collection system for nurse staffing.
5 It hasn't been implemented because
6 CMS has not moved forward with regulations to
7 collect the data electronically from payroll.
8 That will happen now under the healthcare
9 reform law.
10 I just want to say, from a
11 consumer perspective, we think it is
12 extraordinarily important to have quality
13 measures for nurse staffing. The healthcare
14 reform law requires measures based on hours
15 per resident day, turnover and retention
16 rates, which we think are very important. It
17 also authorizes collection of other types of
18 staffing data as well.
19 So, we hope that there will be
20 quality measures. In 2004, NQF recommended
21 that there be a staffing measure when data was
22 available. We hope we are not waiting another

1 six years before there are recognized quality
2 measures for nurse staffing, but we do think
3 it is very important to recognize the work
4 that has already been done at the University
5 of Colorado.
6 CO-CHAIR MUELLER: Go ahead. I
7 can't see your name.
8 MR. BOISSONNAULT: I'm Bruce
9 Boissonnault.
10 I am the secondary reviewer with
11 Betty on the next measure, but I would echo
12 what the Committee seems to be opining. There
13 is another harmonization issue for me, which
14 is this measure implies that more is always
15 better, that there is not diminishing marginal
16 returns when you reach a certain point.
17 With what I hope CMS is eventually
18 going to do, we can use the same data that
19 gathers the hours to tie back to the
20 productivity piece because just measuring
21 hours without also looking at productivity in
22 the same database I think is a tragic mistake.

1 And the other point that I wanted
2 to make is the way the denominator -- it is a
3 sort of detailed thing -- but the way the
4 denominator is defined, to me, straitjackets
5 us from the perspective -- I think basketball,
6 sort of man-on-man coverage versus zone
7 coverage. We don't know which one is going to
8 work, but a lot of the zone coverage players
9 are excluded in counting hours. I think that
10 is potentially problematic. Nonetheless, I
11 think the importance of knowing staffing can't
12 be overstated.
13 CO-CHAIR MUELLER: Jean?
14 MS. SCOTT: Yes, I'm Jean Scott
15 from CMS.
16 I guess I would like to make
17 several comments, first of all, having to do
18 with the healthcare reform and what we are
19 actually required to do, and what we are
20 actually doing at CMS vis-a-vis the collection
21 of staffing data.
22 The health reform bill actually

1 requires us to collect not only nursing care,
2 nurse staffing data, but, also, therapist data
3 and other medical personnel data. So, that is
4 what we will be collecting.
5 The work has begun with this. We
6 have had an IT contractor for about a year
7 building the requirements for the system to
8 collect these data. Now, obviously, when you
9 put a new data collection in under the CMS
10 data collection system, the amount of
11 bureaucracy is incredible with it because you
12 have to make sure you don't crash everything
13 else, because it will be under the big
14 computer system.
15 So, it is taking some time, but we
16 will have this up and going as required within
17 two years of enactment of the health reform
18 law. So, we do expect that to happen, and it
19 is moving forward.
20 I wanted to say a word, too, about
21 what has been done and what hasn't been done
22 with the validity testing and a word about the

1 feasibility testing of collecting the data.
2 I also was the government task
3 leader for the study that is being talked
4 about with the Colorado Foundation for Medical
5 Care. That study did, in fact, develop a
6 database of more than 1400 nursing homes for
7 which we had a year's worth of payroll data,
8 but we had purely a payroll data dump. So, it
9 was a different thing than asking the
10 facilities to give us the data themselves and
11 to do an extract of the data.
12 With the data from the data dump,
13 so to speak, there actually was a measures
14 development effort, and those were tested
15 against some of the quality measures and also
16 against things like for the short-stay
17 population for discharge back to community,
18 for rehospitalization for the long-stay
19 population. So, there has been some measure
20 development. It is not this measure that was
21 tested, though. It was measures that were
22 developed under that contract which get to

1 some of the same things.

2 We have not done any testing of

3 measures that include physical therapists or

4 other medical personnel. We have, however,

5 done some work beyond that study to look very

6 carefully at what could and couldn't be done

7 with an invoice-based system to bring in

8 contract staff, which also is an important

9 piece to this, particularly with the therapy

10 staff. We are looking at that.

11 We have also had some

12 conversations with Dr. Katz from AMDA, who is

13 helping us think through other medical

14 personnel, because that does include

15 physicians. We are going to be looking at

16 physician extenders. We want to look at

17 advanced practice nurses as a separate group.

18 And one word about the feasibility

19 study that was done, because we think that

20 that sort of misrepresents how feasible this

21 really is to do. The feasibility study that

22 was done was a targeted feasibility study. We

1 only included nine facilities in that, and it
2 was a targeted study, in that we were trying
3 to identify what the problems would be.
4 I mean, if you look very carefully
5 at that study, and it is on the CMS website
6 still, if you look very carefully, we went to
7 facilities on things like Indian reservations
8 to really try to pick up the mom and pops who
9 would be difficult. We know this is quite
10 feasible with payroll vendors, and it is
11 feasible for facilities that have a good IT
12 department. It is going to be more difficult,
13 and we are taking that into account in
14 designing the new system.
15 MS. PACE: I just want to make one
16 comment to the Committee. In terms of your
17 decisions, it should be about the measure as
18 presented, not about what may happen in the
19 next three years. You have the option of
20 approving this measure based on the criteria
21 or not. In the future, if a new and better
22 measure is available, they have the

1 opportunity of submitting that, and NQF is
2 interested in the best in class.
3 So, I just want to lay that out in
4 terms of you should make your decision on this
5 measure based on how well it meets the
6 criteria. And in the future, if better
7 measures are available and are brought to NQF,
8 certainly, we welcome that.
9 MR. BOISSONNAULT: The best we
10 could do, though, is a 12-month limited
11 endorsement based on the application itself,
12 correct?
13 MS. PACE: Exactly.
14 MR. BOISSONNAULT: So, we are
15 already --
16 MS. PACE: Right, right.
17 MR. BOISSONNAULT: -- at a certain
18 threshold.
19 MS. PACE: Right.
20 MS. THOMPSON: This is Darlene
21 Thompson.
22 I was just going to indicate that

1 the fact that, even though payroll data is
2 electronic, most payroll data does not break
3 out productive from non-productive. They are
4 either by job title, which could be held by a
5 licensed personnel and non-licensed personnel,
6 or they will be by the criteria or their
7 credentials, which, then, wouldn't indicate
8 whether in the productive or non-productive
9 state.
10 So, the feasibility of being able
11 to gather this data, even though we have
12 electronic payroll data, there's no way that
13 would be able to occur.
14 MR. BOISSONNAULT: I was just
15 going to say, if CMS writes rules that says
16 submit the data this way, then I think the
17 payroll systems will very quickly respond.
18 MS. THOMPSON: I agree, but it
19 will take work on the payroll systems because
20 not everybody uses the same one. So, there
21 will be that outlay to the centers, plus some
22 time to wiggle out the issues that are going

1 to come up with that. So, might as well allow
2 that to happen before we even look at being
3 able to pull productive time.
4 CO-CHAIR GIFFORD: Can you help
5 me? I'm confused by the measure. I want to
6 go back and look at the numerator.
7 It excludes all non-clinical
8 people, and the numerator says it has to have
9 greater than 50 percent of their shift in
10 productive time to be included in the
11 numerator. Then, it reports the number of
12 hours. And the denominator is all RNs, LPNs,
13 and UAPs.
14 So, I'm not sure; what is this
15 measure? Is it percentage of total hours of
16 individuals who spend more than 50 percent of
17 their productive time providing direct patient
18 care? Is that --
19 MR. BOISSONNAULT: And certain
20 matrixed functions I think are excluded that
21 might actually in some settings be care. So,
22 if you move to a matrixed organization, you

1 could be penalized by this measure, the way I
2 read it.
3 CO-CHAIR GIFFORD: Well, before we
4 get there, I am just trying to understand the
5 measure itself. Why isn't it close to 100
6 percent? When you start excluding everything
7 out -- or is the key here productive hours,
8 and they don't define productive hours?
9 MR. BOISSONNAULT: The key is the
10 denominator, which is patient days. So, in
11 other words, are you flying the airplane with
12 only one pilot or do you have three?
13 CO-CHAIR GIFFORD: The denominator
14 is hours.
15 MS. PACE: Multiple numerators.
16 CO-CHAIR GIFFORD: Oh, the
17 denominator is not days; it's hours.
18 MS. PACE: Right.
19 MR. BOISSONNAULT: But it's
20 patients. So, it is how many --
21 CO-CHAIR GIFFORD: No, it's LPNs.
22 That is why I am confused.

1 MR. BOISSONNAULT: Okay, sorry.
2 I'm on 7.
3 CO-CHAIR GIFFORD: I'm looking at
4 this measure here. The denominator is LPN,
5 RN, UAP hours, and the numerator is hours.
6 So, the denominator is all hours of this group
7 that does something divided into the
8 productive hours there. I can't figure out
9 where they come --
10 CO-CHAIR MUELLER: Okay, I'm going
11 to give it a try.
12 So, first of all, you get in the
13 numerator if you are 50 percent or more
14 providing direct care.
15 CO-CHAIR GIFFORD: Just is it
16 zero/one or is it hours?
17 MR. BOISSONNAULT: Zero/one,
18 right?
19 CO-CHAIR MUELLER: Yes.
20 MR. BOISSONNAULT: You either are
21 more than 50 percent --
22 CO-CHAIR MUELLER: Or you're not,

1 right.

2 DR. ORDIN: Could I ask a favor?

3 Could you start with the denominator?

4 CO-CHAIR GIFFORD: Yes, yes.

5 CO-CHAIR MUELLER: Yes. The

6 denominator would be anybody who is 50 percent

7 or more and all the hours of those people.

8 CO-CHAIR GIFFORD: But that's not

9 what they say in there.

10 Can you put up 2(a)(8)?

11 CO-CHAIR MUELLER: 006.

12 CO-CHAIR GIFFORD: Am I on the

13 wrong measure? I am on 006. Yes, I am on

14 006.

15 CO-CHAIR MUELLER: Yes.

16 CO-CHAIR GIFFORD: The denominator

17 says, data elements, LPN and LVN hours, hours,

18 hours, hours, hours. It seems to be hours.

19 CO-CHAIR MUELLER: 006 is hours.

20 So, let's say you have 10 people in the

21 nursing home that are 50 percent or more

22 providing direct care. It would be, the

1 combination of all their hours would be the
2 denominator.
3 Then, the numerator would be,
4 there's a variety of formulas you will get.
5 You will get one formula of the percent of RNs
6 or the number of RN hours divided by the
7 denominator, and that will give you the
8 proportion of RN hours that this facility
9 provides.
10 CO-CHAIR GIFFORD: Yes, but I am
11 still confused. So, if you take all RNs who
12 are doing direct patient care, do they have to
13 be more than 50 -- this denominator doesn't
14 say the 50 percent cutoff.
15 CO-CHAIR MUELLER: Right. No.
16 CO-CHAIR GIFFORD: This is just
17 all RNs everywhere, right?
18 CO-CHAIR MUELLER: Okay.
19 DR. DUNTON: This is Nancy Dunton.
20 Can I --
21 CO-CHAIR MUELLER: Yes, could we
22 have the ANA person say something?

1 DR. DUNTON: This measure, it is
2 currently endorsed for hospital settings. It
3 includes in the numerator all hours provided
4 by, let's say, RNs who spend at least 50
5 percent of their time in direct patient care.
6 In the denominator are the same kind of hours
7 for staff who spend at least 50 percent of
8 their time in direct patient care of RNs,
9 LPNs, or LVNs, or nursing assistants. So, it
10 is a proportion.
11 CO-CHAIR GIFFORD: But that is not
12 what is before us. At least what I am
13 verbally hearing isn't, right? Am I reading
14 it wrong?
15 DR. DUNTON: Yes, I think you
16 might be reading it wrong because --
17 CO-CHAIR GIFFORD: Well, can you
18 look at 2(a)(8)?
19 MS. PACE: So, what they are
20 saying is, in 2(a)(4), it is the total number
21 of productive hours, and 2(a)(8) is the same,
22 which --

1 CO-CHAIR GIFFORD: All right,
2 2(a)(4). Yes.
3 MS. PACE: Total number of
4 productive hours worked by all of those staff.
5 CO-CHAIR GIFFORD: Yes.
6 MS. PACE: And then, the numerator
7 is not adding those up, because you're right,
8 they will add up to 100 percent. The
9 numerator is looking at the skill mix. So,
10 what percent of those total hours are RN
11 hours? What percent of those total hours are
12 LPN hours, et cetera?
13 So, it is designed to be, the
14 numerator categories are designed to be
15 computed separately. But if you would add
16 them up, you would get 100 percent, yes.
17 CO-CHAIR MUELLER: So, you would
18 get three QIs, RNs, percent of RNs, percent of
19 LPNs.
20 CO-CHAIR GIFFORD: Oh, I've got
21 you. Okay.
22 MR. BOISSONNAULT: Let me ask --

1 CO-CHAIR GIFFORD: So, it is a
2 distribution?
3 MR. BOISSONNAULT: Right, it is
4 the weighting of RNs versus LPNs versus --
5 CO-CHAIR GIFFORD: So, it will add
6 up to 100 percent?
7 MS. PACE: Right.
8 CO-CHAIR GIFFORD: I've got you.
9 Okay.
10 MR. BOISSONNAULT: Which is why we
11 were both getting to 100 percent.
12 MS. PACE: Right.
13 CO-CHAIR GIFFORD: I've got you.
14 MS. PACE: Right. So, the idea is
15 to look at the mix of the personnel providing
16 care. But it is still the question of what's
17 good and --
18 MR. BOISSONNAULT: The commas
19 don't mean pluses; they mean one each.
20 CO-CHAIR MUELLER: Yes.
21 MS. PACE: Right.
22 CO-CHAIR MUELLER: Okay.

1 MS. GIL: This is Heidi Gil.
2 I just wanted to mention that,
3 obviously, with this formula, the concern,
4 given the current state of short-term rehab
5 and nursing homes, the fluctuation in staffing
6 based on census, and making certain that,
7 obviously, the public reporting piece of this
8 would be for any consumer to understand, as
9 well as I know that the nursing homes are all
10 really getting good at reporting better on the
11 annual survey the staffing because of the
12 five-star rating. But that is just coming
13 about as five stars come about. So, to see
14 the accuracy come with this kind of system
15 really scares me.
16 DR. MODAWAL: Yes, Arvind Modawal.
17 I just still have a comment
18 related to that. Why this 50 percent came up?
19 Because, as you are saying, a lot of staffing,
20 they are working less than 50 percent. So,
21 there should be a simplistic way that we would
22 look at all hours for individual categories

1 and then hours worked in the clinical setting,
2 you know.
3 CO-CHAIR MUELLER: I think, if I
4 am hearing you correctly, what the 50 percent
5 means is you have somebody who works full-
6 time, but they spend 50 percent or more of
7 their time in direct care.
8 DR. MODAWAL: Yes.
9 CO-CHAIR MUELLER: Okay.
10 DR. MODAWAL: What I am saying is
11 that a lot of part-time employees are working
12 less than 50 percent, yet contributing to the
13 mission of care in the nursing home. So, they
14 are maybe there, you know, one day a week or
15 a half-day a week, or something like that.
16 So, that is also an RN level or LPN level, and
17 it should also be accounted for because they
18 may not find RNs or LPNs who are able to give
19 that degree of time because they are agency
20 nurses; they are nurses coming in just
21 interested in part-time work.
22 CO-CHAIR MUELLER: Well, I think

1 it would account for those. It is, if you are
2 there for that day and you are spending 50
3 percent or more of your time in direct care,
4 it counts.
5 DR. MODAWAL: Okay.
6 CO-CHAIR MUELLER: It is not an
7 FTE.
8 DR. MODAWAL: Oh, I see.
9 MS. GALLAGHER: Perhaps if we were
10 to conceptualize the 50 percent as meaning you
11 were actually providing care as opposed to you
12 were the Director of Nursing?
13 DR. MODAWAL: Yes, I think it
14 needs some clarification.
15 MS. GALLAGHER: Sort of a
16 categorization of the person, not how much
17 time they spend all together in the activity,
18 but, rather, that they are providing care as
19 opposed to supervising others. That is the
20 aegis of the issue.
21 MR. BOISSONNAULT: So, if you are
22 looking at the ratio, essentially, it is the

1 ratio of RN, LPN, and UAP of the total direct-
2 care hours. They don't risk-adjust it. Why
3 wouldn't you want to risk-adjust this? Or
4 stratify by patient acuity? Because we know
5 that there are nursing homes, I mean we have
6 seen by the long-term stay, the short-term
7 stay, and the number that gets kicked out, and
8 everything else, you would probably want to
9 risk-adjust this, I would think.
10 DR. DUNTON: This is Nancy Dunton
11 again.
12 The intention in the documentation
13 is that it would be risk-stratified by type of
14 care, unit type.
15 CO-CHAIR GIFFORD: I just need a
16 2(e), which says risk adjustment. For
17 outcomes, it says not available, not
18 available, not available.
19 MR. KUBAT: And it says, under
20 2(a)(12)-(13), no risk adjustment necessary.
21 CO-CHAIR MUELLER: What about
22 stratification?

1 CO-CHAIR GIFFORD: Stratification
2 is risk adjustment.
3 CO-CHAIR MUELLER: Right.
4 MS. GALLAGHER: The intention is
5 stratification by unit type, which is how it
6 is currently operationalized in the hospital.
7 As I indicated earlier, what we will be doing
8 as we add the behavioral health aspects, we
9 will be working with an expert panel to define
10 what exactly their units would be, and we
11 would expect that the nursing home community
12 would provide input into what their units
13 would be also.
14 CO-CHAIR MUELLER: Okay. I would
15 like to see where we are right now, a straw
16 vote.
17 All of those that would be ready
18 to vote on this measure, could you raise your
19 hand?
20 MR. BOISSONNAULT: Ready to vote
21 or ready to vote yes or no?
22 CO-CHAIR MUELLER: Ready to vote.

1 (Show of hands.)
2 All right, it looks like we have
3 the majority that are ready to vote.
4 So, the recommendation is that
5 this measure, the first one, not be accepted.
6 I have to go back to my notes here. That is
7 the recommendation on 006.
8 Sorry. We will go through the
9 criteria.
10 So, the idea, the first is that it
11 is important, and the assessment is that this
12 is a very important measure. The testing of
13 the measure is that there is no evidence of
14 that, and we do have to keep in mind this was
15 intended to be a time-limited measure.
16 The third is usability and
17 feasibility. That was also assessed not to be
18 adequate.
19 So, the conclusion is that,
20 therefore, this cannot be an endorsed measure.
21 Any comments before we would go to
22 a vote in regards to what I just said?

1 MS. PACE: So, you are not even
2 recommending for time-limited? You're saying
3 to vote it down? That's fine. That's fine.
4 I just want to clarify.
5 CO-CHAIR MUELLER: Well, she just
6 whispered in my ear this is time-limited. So,
7 I forgot that.
8 MS. PACE: So, the vote could be
9 time-limited endorsement, yes or no? So, it
10 really would only be eligible for time-limited
11 endorsement. So, if you vote yes, it would be
12 yes for time-limited status. If you vote no,
13 it is just not going to be recommended at all.
14 Does that make sense?
15 CO-CHAIR MUELLER: Yes, and time-
16 limited, this is on the memo that all of you
17 got and I didn't, so I am catching up today.
18 There's three strategies we can
19 use. One is time-limited for measures that
20 satisfy most of the evaluation criteria or the
21 other is recommended for time-limited
22 endorsement with conditions or do not

1 recommend for time-limited.
2 My concern with time-limited is I
3 don't know if they can be pulled off in a
4 year. So, that is where my hesitancy is.
5 Any comments on that?
6 MR. BOISSONNAULT: Madam Chairman,
7 I think time-limited implies that we are all
8 very comfortable with the measure and are just
9 waiting for the evidence to support what is
10 common sense. So, when we call the vote, that
11 would be my read of the situation, if we vote
12 yes for time-limited.
13 CO-CHAIR MUELLER: Okay. So, we
14 need not worry about that 12-month thing?
15 MS. GALLAGHER: Well, first of
16 all, the change from 24 months to 12 months is
17 rolling in. That is what is going on now.
18 The consensus-development process has moved to
19 12 months in consideration of time-limited.
20 I think that, first of all, it is
21 not likely that this measure would even be
22 endorsed until the end of the year. Is that

1 correct, Karen?
2 MS. PACE: That's the --
3 MS. GALLAGHER: Yes, probably
4 December. So, it is really a longer
5 timeframe. Obviously, we would begin work
6 earlier rather than later. So, I guess we are
7 talking closer to 18-19 months, if we were to
8 begin in the near future.
9 CO-CHAIR GIFFORD: But I think, to
10 Bruce's point, you're right, time-limited is
11 that we think it is a good measure; we think
12 it just needs a few little things sort of
13 worked out. It is not at the level, on the
14 previous one, where we could say, okay,
15 Darlene said just change the 100-day thing and
16 we think it's fine to go forward. I mean we
17 ended up modifying it for another reason, but
18 I think we felt much more comfortable as a
19 group.
20 Time-limited is more of that
21 category. So, if there needs to be
22 substantial work in it, you know, if we

1 really, really like it and think it is
2 important, and there's promise that it can be
3 done in a short timeframe, yes, we should move
4 forward on it. But if it is not, then it
5 should get voted down.
6 It doesn't mean that they
7 shouldn't continue to work, it's not
8 important, or it should go forward on it. I
9 go back to the point that we are not measure
10 developers around the table, as much as we
11 would like to.
12 MS. TRIPP: If I could just make
13 the point on harmonization, this is certainly
14 a very important issue; there's no doubt.
15 Federal law is going to mandate that this data
16 be collected, in light of federal mandates it.
17 CMS is doing it right now. I worry, and this
18 is not to take away from the effort that was
19 put into this, I just worry that it would
20 generate more confusion with the public to
21 have dueling measures. I think that is a
22 significant concern.

1 CO-CHAIR MUELLER: So, we are
2 calling the vote on recommendation for a time-
3 limited measure, a time-limited endorsement.
4 MS. TRIPP: I'm sorry, Madam
5 Chairman, did you give your recommendation as
6 the reviewer, referencing the time-limited?
7 Because I don't know that I heard it, if you
8 did.
9 CO-CHAIR MUELLER: Yes, my
10 recommendation was based on needing to know a
11 little bit more from CMS because I needed to
12 hear what they had to say to know what box to
13 check, actually. And the conversation here,
14 I think, was somewhat helpful, too.
15 MS. PACE: So, that is just what
16 you are voting on. She is not saying that is
17 what she is recommending. You're recommending
18 yes or no on --
19 MS. TRIPP: That is what I was
20 just trying to figure out, exactly what your
21 recommendation was.
22 CO-CHAIR MUELLER: Yes. So, well,

1 I guess I would say that it would perhaps be
2 worth our while to recommend it for time-
3 limited endorsement. So, that's where I'll
4 stand.
5 DR. ORDIN: Can I hear from the
6 secondary reviewer?
7 CO-CHAIR GIFFORD: I'm not the
8 secondary.
9 Yes, Betty?
10 MS. FRANDSEN: My recommendation
11 would be not to move it forward as it was
12 presented. It's not that it's not important,
13 but there's too many gaps in what was
14 presented.
15 CO-CHAIR GIFFORD: So, the vote
16 before us is to endorse it with time-limited
17 without any conditions, but to hear back more
18 data in the future.
19 So, I guess any abstaining?
20 (No response.)
21 All in favor of it?
22 MR. BOISSONNAULT: All in favor

1 of?

2 CO-CHAIR GIFFORD: Of time-limited

3 endorsement? That is what is before us.

4 (Show of hands.)

5 All opposed?

6 (No response.)

7 CO-CHAIR MUELLER: I will abstain.

8 CO-CHAIR GIFFORD: Christine

9 abstains.

10 CO-CHAIR MUELLER: Yes.

11 CO-CHAIR GIFFORD: I'm looking at

12 the time. We are behind a little bit. We

13 would like to take a comment from any of the

14 members of the audience who are on the phone.

15 Then, we will take a quick break to grab

16 lunch, come back in, and we will resume. So,

17 we are behind a little in the schedule, but I

18 think as we get the gist of how to move

19 through this, we will pick up speed as we go

20 forward and feel more comfortable with the

21 process.

22 MS. TRIPP: I just have a quick

1 clarification question. I don't mean to slow
2 everybody down.
3 Was that vote on 06 and 07 because
4 they --
5 CO-CHAIR GIFFORD: Just 06.
6 MS. TRIPP: Just 06?
7 CO-CHAIR GIFFORD: We are going to
8 come back to 07 and talk about 07.
9 MS. TRIPP: Okay.
10 CO-CHAIR GIFFORD: Sandy?
11 While Sandy walks up to the
12 microphone, anyone on the phone who would like
13 to make comments?
14 (No response.)
15 Okay.
16 MS. FITZLER: I have a few
17 comments.
18 First of all, I would like to
19 thank Bill Kubat. AHCA has been greatly
20 involved in trying to get as many issues
21 stated in the positive. Since we had the
22 first measures in 2004, we have been working

1 on this, and CMS did assure me that we were
2 going to get as many as possible stated in the
3 positive. So, I would like you all to keep
4 that in mind because I'm not seeing a lot of
5 that.
6 My second issue, with the
7 specificity of some of the measures like the
8 percent of residents who have symptoms of
9 major depression, long stay, the denominator
10 size in many facilities can be quite small.
11 We have some facilities who are currently at
12 80 percent short stay, some of them close to
13 100 percent short stay. I mean you look at
14 the trending of care in long-term care
15 facilities; we are seeing more and more of
16 this.
17 Given this, currently in MDS 2
18 measures, if the denominator is too small, we
19 just don't see the measure. Is that still
20 going to be the same for the MDS 3-generated
21 measures?
22 MS. CONSTANTINE: Hi. Roberta

1 Constantine again from RTI.
2 Yes, for public reporting
3 purposes, the short-stay measures, if a
4 facility has less than 20 residents, it is not
5 publicly reported and 30 for long-stay
6 residents, given the issues with HIPAA and
7 also looking in regards to the validity of the
8 measure statistically with small numbers.
9 MS. FITZLER: I would just like to
10 respond. My concern is -- and, Dr. Gifford,
11 you said this early on when you started --
12 that we have to look at the measures and where
13 the measures are being used or all the
14 potential areas where they are going to be
15 used. It is very difficult, then, when you
16 are looking at five-star and assessing quality
17 or in a value-based purchasing program, how
18 can you assess, then, quality, if not all the
19 measures can be reported by the facilities
20 being evaluated? So, it makes it difficult.
21 MS. GAGE: It can still be
22 monitored. You just don't want to publicly

1 report.

2 MS. FITZLER: Barbara says it can

3 still be monitored. You just don't want to

4 publicly report. But the reason why we don't

5 publicly report is because there's an issue

6 with validity. Am I correct?

7 MS. TOBIN: Privacy.

8 MS. FITZLER: Just privacy?

9 MS. TOBIN: As you get down to a

10 small sample, when you have so many

11 characteristics identified on a patient, it

12 becomes more and more possible to identify who

13 you are reporting on. So, it becomes, in

14 part, a privacy issue as well.

15 MS. FITZLER: Okay. So, the

16 sample size, then, is not the issue here?

17 CO-CHAIR GIFFORD: Any other

18 comments from the audience before we break for

19 lunch? If you want to stand between the

20 Committee voting on the measures and lunch,

21 make a comment.

22 (Laughter.)

1 If not -- yes?

2 MEMBER NAIERMAN: I just have one

3 quick question. Approximately what percentage

4 of nursing homes are that small?

5 MS. FITZLER: What do you mean

6 small?

7 MEMBER NAIERMAN: Well, 20 and 30,

8 respectively, number of patients. How many,

9 when you say ones will be excluded?

10 MS. FITZLER: Somebody here from

11 CMS may know the numbers, but currently, under

12 MDS 2, there's quite a few homes that don't

13 produce all the measures right now. I am just

14 looking at some of the measures that we have

15 as we see the transition to more and more

16 post-acute care, and seeing that become more

17 problematic.

18 I don't have the number. Does

19 anybody?

20 CO-CHAIR GIFFORD: A lot of the

21 sample sizes are by all the exclusions that

22 get you down in that problem. Actually, in

1 Rhode Island we have 92 licensed nursing
2 homes, and I think there is less than 10 that
3 are under 40 by total bed size. Because,
4 actually, financially, you can't make it when
5 you are under 40 beds. It is almost
6 mathematically impossible at the current
7 reimbursement rates for Medicaid and Medicare.
8 MS. THOMPSON: And the number 30
9 for a long stay, I've got a 150-bed facility
10 that 90 percent of their residents are short
11 stay. So, therefore, they never get enough
12 measures to hit the long stay because they
13 don't have 30 residents consistently that are
14 in the facility for more than 100 days. So,
15 it is not necessarily the size of the
16 building. It is the length of stay of the
17 residents in the building.
18 CO-CHAIR GIFFORD: What I would
19 like to do is lunch is ready outside, right?
20 Lunch is ready outside. We are going to do a
21 working lunch. Collect lunch, go to the
22 bathroom, check your BlackBerry, check your

1 emails, come back. We will do 10 minutes of
2 sort of eating at 12:15, and we will start
3 back up with a working lunch in here. Okay?
4 (Whereupon, the foregoing matter
5 went off the record at 11:52 p.m. for lunch
6 and went back on the record at 12:18 p.m.)
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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,

1 the measure has the same items presented. In
2 my review of it, I felt that it contained the
3 same issues that we dealt with in reviewing
4 No. 6. Although it is a very important
5 measure, I did not feel, as it was presented,
6 that it met the other criteria.
7 CO-CHAIR MUELLER: I would just
8 add this is time-limited also.
9 MS. FRANDSEN: Yes, it is.
10 And my secondary is Bruce.
11 MR. BOISSONNAULT: Very briefly,
12 it meets the importance criterion, hands down.
13 Scientific acceptability was sort of a maybe
14 with caveats. It excludes certain teams, the
15 issue we already discussed about man-to-man
16 coverage versus zone coverage, the implication
17 of a linear relationship between staffing.
18 And as far as usability, I had
19 yes, with some "but's". The measure does in
20 the end, though, it would measure what it says
21 it will measure.
22 My other concern was the sort of

1 lack of evidence that it would move the bar on
2 all of the things that it said it would move
3 the bar on. In other words, there was an
4 explicit statement in the application that it
5 would improve quality, undefined.
6 Coordination of care and safety,
7 and I did see what I thought was enough
8 evidence on the safety indicator, but the
9 others weren't in the app.
10 So, my recommendation was, because
11 it is a time-limited application, it was no,
12 notwithstanding that I think the importance of
13 the measure is unquestioned.
14 CO-CHAIR MUELLER: Further
15 comments from the Committee?
16 DR. KOREN: I didn't read these
17 particular reviews, but there's one thing I
18 was thinking that I heard in the discussion
19 before, which is the idea of parsing out what
20 nurses in nursing homes do as productive
21 versus unproductive time. I think maybe that
22 comes from a hospital model.

1 But, you know, I think that we
2 really have to examine what the role of an RN,
3 for example, is in a nursing home, and to
4 argue that maybe some of the most productive
5 time they have is when they are supervising
6 and serving as team leaders to the care team.
7 So, I think we should be really
8 careful utilizing terms like productive and
9 unproductive. Their job is to do assessments.
10 Their job is to lead a team. Their job is to
11 be a resource, being leaders.
12 So, I think we need to really be
13 careful about the terminology and not just
14 sort of bring it wholesale out of an acute
15 system.
16 CO-CHAIR MUELLER: That is a good
17 point, or even to have a definition of what
18 productive means.
19 Any other comments?
20 (No response.)
21 Okay.
22 CO-CHAIR GIFFORD: So, we actually

1 were admonished at lunch for not following the
2 rules. We actually need to go back and make
3 sure we do this, not only vote on each of the
4 four categories, the importance of scientific
5 usability and feasibility, but we make sure we
6 are voting on whether we think it is complete,
7 partial, minimal, or needs lots of work.
8 And for the measure developers in
9 the room, having been a previous measure
10 developer, I understand the amount of time and
11 energy and resources it take to develop a
12 measure and validate a measure and to fill out
13 these forms. That said, I know there's no
14 perfect measure.
15 So, there is going to be a lot of
16 criticisms and comments, but I think the
17 responsibility of the group here is to go
18 through a process, I think a well-thought-out
19 process by NQF, to endorse a measure that has
20 some meaning behind the NQF measure. That
21 doesn't mean that I think the work that you
22 all have done has not been recognized and

1 everything else, but to move along, I am going
2 to push, and if you can't tell, have some very
3 frank and quick discussions about it.
4 Part of the reason, I am not in
5 Rhode Island, so I don't have to worry about
6 being politic anymore. Just to say it is what
7 it is on some of the measures, so we can go
8 through and get everything, but it doesn't
9 mean that the measures that we haven't done
10 aren't incredibly important.
11 I think all of us, as I said,
12 think almost all the measures before us, we
13 can almost all vote right now -- what's the
14 term we use? We can sort of bundle them all
15 together and just all vote that they are all
16 important, and most of them meet the
17 importance metric. You wouldn't have invested
18 the time, you wouldn't have had the funding to
19 get to that time, they wouldn't even be before
20 us if they didn't even pass that measure.
21 It really is getting into the
22 scientific usability and feasibility. That is

1 going to be really hard as we go forward on
2 that.
3 So, just understanding that, just
4 because a measure gets voted down, it doesn't
5 mean that it is not important and that it
6 shouldn't be worked on and shouldn't come back
7 to the group for our future stuff, because I
8 think we want to see those types of things.
9 All right, that said -- yes?
10 CO-CHAIR MUELLER: So, we do a
11 vote for each, we ask for a show of hands for
12 complete? Is that how we would do that,
13 Suzanne? Okay.
14 So, for the importance to measure
15 and report for 007, we have a show of hands
16 for -- all right, we are redoing our thing
17 here.
18 So, we would like the reviewers,
19 the two reviewers, to go through each and give
20 your rating for each of the four criteria.
21 MS. FRANDSEN: This is Betty
22 Frandsen again.

1 For importance, I scored it
2 partial.
3 For scientific acceptability, the
4 reliability and validity, I put minimal.
5 For usability, partial.
6 And for feasibility, as it is
7 written, minimal.
8 MR. BOISSONNAULT: All right.
9 There's a couple of submeasures that actually
10 have that.
11 I'm confused because on the form
12 it says, "Was the threshold importance met?"
13 That's a yes/no.
14 MS. PACE: Importance is yes/no.
15 MR. BOISSONNAULT: Okay. So, yes.
16 Then, forgive me, my copious notes
17 here. To be or not to be.
18 CO-CHAIR GIFFORD: Can I put a
19 motion on the table that, for all the
20 measures, we vote that they all were important
21 for a yes? Is there anyone from any of the
22 primary reviews who would like to argue that

1 their measures were not addressing an
2 important topic and had enough material
3 presented to meet the importance criteria?
4 (No response.)
5 So, if we bundle that, that will
6 move us along. Then, we only have to vote on
7 the three things each time. Okay.
8 All in favor of all the measures
9 being important?
10 (Chorus of ayes.)
11 All right. Okay. Good.
12 I always wanted to do that. I see
13 it before committees every night, the
14 legislature, and they always bundle everything
15 together. I have always wanted to do that.
16 So, thank you.
17 (Laughter.)
18 MR. BOISSONNAULT: The scientific
19 acceptability, I said partial.
20 The usability, I actually thought
21 it would be usable. So, a "C".
22 And feasibility, I think it is

1 certainly feasible.
2 CO-CHAIR GIFFORD: So, that would
3 be a complete, partial, or minimal --
4 MR. BOISSONNAULT: No, a "C".
5 CO-CHAIR GIFFORD: Complete, okay.
6 MR. BOISSONNAULT: Yes, a "C".
7 CO-CHAIR MUELLER: Okay. So, we
8 will vote on scientific acceptability. All
9 those that would be in favor of being
10 complete, raise your hand.
11 (Show of hands.)
12 Partial, raise your hand.
13 DR. NIEDERT: I'm not comfortable
14 with that, when I haven't had a chance to
15 actually review the measure, to go ahead and
16 vote on each one. I've not looked at the
17 citations. I've not looked at any of the
18 information except what five minutes that we
19 have had here.
20 MS. PACE: We generally like to
21 get the Committee's assessment of each of
22 those criteria because your vote to recommend

1 or not recommend needs to be grounded in the
2 criteria. So, if you want to, by consensus,
3 say the reason under those criteria that it is
4 not going to pass that particular criterion,
5 we can talk about that.
6 But, basically, where things go
7 from here is out to public comment and
8 eventually to voting. Your recommendations
9 need to be justified in the evaluation
10 criteria. So, what we have been doing as a
11 general approach is having the Committees vote
12 on whether the measure meets the criteria, and
13 then, ultimately, that should lead you to your
14 decision about the recommendation.
15 So, if someone has another
16 approach, so that we can make sure that these
17 recommendations are grounded in the criteria,
18 we can certainly entertain that.
19 DR. SCHUMACHER: I think it would
20 really help us if, as it is stated in some of
21 the materials that we got prior to coming in
22 here today, if the primary reviewer and the

1 secondary reviewer could just tell us if they
2 reached consensus on it, and if they can tell
3 us what their ratings were. I mean that is
4 about all we have to go on because we didn't
5 review all these topics.
6 So, if they reached consensus,
7 that's great. I am more likely to agree with
8 that. If they didn't, let's talk about the
9 areas where they disagreed.
10 MS. PACE: And I would say that
11 what is more important in terms of
12 understanding the decision is the reason, not
13 necessarily the rating. So, if the primary
14 reviewers will go through the criteria and
15 say, "This is why I think it was not
16 important" or "This is why I think it did not
17 meet scientific acceptability," if the group
18 agrees with that, we can work with that in
19 terms of being able to present something to
20 the public of the reasons for your eventual
21 not recommending.
22 David, do you think that can work

1 to at least make sure we understand under each
2 criteria the reason, what the concern is?
3 CO-CHAIR MUELLER: Yes, I think
4 so, too. Then, we would not have to do this
5 one by one?
6 MR. BOISSONNAULT: Well, on this
7 one, to Kathleen's point, the issues in 6 were
8 very similar. I actually think they were sort
9 of out there. We could argue about whether
10 the research exists or not, but there were
11 some fundamental sort of
12 harmonization/usability issues and some
13 scientific issues that came up, I think, that
14 apply here.
15 So, for acceptability and
16 usability, that was where I think we had
17 issues.
18 MS. PACE: So, this is the other
19 option. Because, as, hopefully, you
20 understood all along, these decisions are
21 Committee decisions, not individual reviewer
22 decisions. If, on a particular measure, you

1 don't feel capable of voting, then don't vote
2 on that measure.
3 But we really do need to have
4 these decisions grounded in the criteria.
5 That is what the criteria are there for, and
6 we want to get a sense that the Committee has
7 addressed those and, also, that the final
8 recommendation makes sense. So, if the votes
9 on the criteria are different than --
10 CO-CHAIR GIFFORD: But we don't
11 need to know how many think it is complete,
12 partial, minimal, or non-responsive?
13 MS. PACE: Well, generally, we
14 have been doing that. If you want to put
15 forward a particular rating, based on the
16 primary reviewers, and see if people agree
17 with that, we can work with that as well, but
18 we still need to have these decisions grounded
19 in the criteria.
20 MS. TRIPP: I actually had a
21 suggestion that might speed it up. Certainly,
22 where there's unanimity among both reviewers,

1 we could simply make a motion that we adopt
2 their rationale, you know, we adopt their
3 rating. We could do that. Then, if people
4 disagree, they could opt out, maybe disagree.
5 But it does seem very time-consuming to go
6 through each one of these and give four
7 options for each one.
8 CO-CHAIR GIFFORD: Diane?
9 DR. MEIER: Oh, sorry. Diane
10 Meier.
11 We were intended to be pretty
12 intimately familiar with all the measures in
13 order to be able to vote at this level of
14 detail. So, you know, had I known that
15 perhaps, and we had enough time to do that,
16 then this might have been a reasonable
17 request. But I don't want to vote in any
18 direction on something I haven't read other
19 than, you know, on this level of detail. We
20 have to trust each other and the work.
21 Otherwise, we should all be reviewing
22 everything.

1 DR. NIEDERT: This is Kathleen.
2 That is exactly, that was my point
3 to begin with. I think that all of us in this
4 room are either researchers or have done
5 research. Most of us in this room are PhD's
6 and MD's, at least at the MS level. So, I
7 think we should have had more, if you wanted
8 us to vote on every one of these issues,
9 usability, feasibility, scientific, then we
10 should have had adequate time to have reviewed
11 it.
12 I agree that we can go along with
13 the two reviewers.
14 CO-CHAIR GIFFORD: Well, let me
15 suggest a modification to what Lisa, I think,
16 presented. Hear the recommendation from the
17 two reviewers, but I think we should, and if
18 you want to put it in the record, you can put
19 down what they voted there, but I think the
20 vote, ultimately, we are really voting
21 collectively as a group on this.
22 I think we should have the

1 discussion, so we know where it is. So,
2 clearly, it is going to be the up-or-down vote
3 or the vote on whether this should go forward
4 as is, should go forward with modifications,
5 time-limited, with or without modifications,
6 or it is not ready for primetime.
7 Then, use the two reviewers'
8 comments to reflect the Committee's work of
9 what is out there, but then not go through
10 each of the votes. It is not a good use of
11 our time, and it is not productive. We are
12 going to spend less time actually talking
13 about meaningful reasons why we have concerns.
14 I think that would be a more meaningful way.
15 So, I mean, what I would say,
16 then, on this, for this measure, is that we
17 had a lot of similar discussions before, I
18 think as Bruce said, and there is some
19 disagreement about usability and feasibility,
20 which we may want to hear a little bit more
21 about. But let's sort of take their two
22 comments. They can go in, but let's really

1 have a broader up-or-down vote on the measure
2 itself because, in essence, that is where,
3 when I tried to break it out before, you all
4 thought we had voted on the whole thing
5 anyway. So, I think it makes more sense to
6 move in that way. That would be more
7 productive use of our time.
8 I see a lot of head-nodding.
9 Okay.
10 Janet can call me and say ban me
11 from NQF after this.
12 MS. PACE: I think as long as we
13 get specific comments about the criteria, as
14 you have been doing, as you have been going
15 through, that we can put that together.
16 CO-CHAIR MUELLER: So, it may be
17 useful -- between Betty and Bruce, you just
18 had some discrepancy in usability and
19 feasibility that I think we should sort out a
20 bit.
21 MR. BOISSONNAULT: With the
22 exception of the fact that I am a definitive

1 no overall, what I submitted, I don't know if
2 that is acceptable, but what I submitted on
3 the measure in writing stands.
4 I'm looking at Karen because I
5 think there's a process here. We are all
6 learning.
7 MS. PACE: Right, and we are, too.
8 With every project, we learn something new.
9 MR. BOISSONNAULT: I mean, do you
10 want me to list them off again because I
11 have comments on all four?
12 MS. PACE: No, I don't think that.
13 I think the question is that you thought it
14 was --
15 MR. BOISSONNAULT: I thought it
16 was 2 and 3.
17 MS. PACE: -- completely usable
18 and --
19 MR. BOISSONNAULT: Excuse me.
20 Completely feasible, completely important, but
21 scientific acceptability and usability
22 especially, period, those two were much more

1 problematic.
2 CO-CHAIR MUELLER: Okay. I'm
3 sorry, I misunderstood. I thought you had
4 said complete for usability.
5 MR. BOISSONNAULT: Well --
6 CO-CHAIR MUELLER: So, the
7 discrepancy is just feasibility.
8 MR. BOISSONNAULT: Scientific
9 acceptability and usability, I am going to say
10 I had concerns about that were very specific.
11 CO-CHAIR GIFFORD: Bruce, I'm
12 going to hold you to the same standard I do
13 with my son. I reserve the right to change my
14 opinion at any time. So, you feel free to
15 change your opinion on that.
16 MR. BOISSONNAULT: By the way, I
17 know what you are referencing, and you are
18 correct, but as far as my remarks that I have
19 made through this, scientific acceptability
20 and usability are the issues for me.
21 CO-CHAIR GIFFORD: So, the measure
22 overall would be --

1 MR. BOISSONNAULT: I recommend no.
2 CO-CHAIR GIFFORD: You recommend
3 no.
4 Betty?
5 MS. FRANDSEN: I recommend no.
6 CO-CHAIR GIFFORD: So, overall
7 recommendation is no.
8 Any discussion on that?
9 (No response.)
10 In favor? In favor of no?
11 (Show of hands.)
12 In favor of the vote before us,
13 double negative.
14 Any abstaining?
15 Any against?
16 Okay. The next measure then, pain
17 measures. RTI is going to give an overall of
18 the pain measures.
19 Well, amongst the primary and
20 secondary reviewers, are there any of these
21 measures, short- or long-term -- some of you
22 came up to me during the break that we should

1 bundle together and talk about and maybe
2 discuss together. I know that there's been a
3 lot of talk about the immunization measures,
4 to do long- and short-term together, each one,
5 because of the similarity and the nature of
6 it.
7 You would actually recommend all
8 of these be done together? Concerns are going
9 to be identical, okay.
10 Any other primary reviewers on the
11 pain measures agree with that, bundle them all
12 together? Okay. Are you guys the only two
13 primary and secondary reviewers on all the
14 pain measures? No one else doing any? You
15 didn't share the pain? Okay.
16 Go ahead. RTI, are you going to
17 give a quick overview of them? Okay.
18 MS. CONSTANTINE: I will be giving
19 an overview on the group of the measures, so
20 both pain and pressure ulcers. Also, I will
21 try to limit my discussion of importance and
22 cut to the chase, in the interest of time and

1 what Dr. Gifford had to say.
2 In regards to these measures, the
3 purpose of the pain measures specifically is
4 to monitor and report on the percentage of
5 both the long-stay and short-stay residents
6 who have moderate to severe pain, and the new
7 measure we are introducing to report the
8 percent of short-stay residents with effective
9 pain management.
10 In regards to importance, you
11 know, the evidence definitely suggests that
12 pain is consistently undertreated in nursing
13 facilities, especially with residents with
14 cognitive impairment. At least 40 to as many
15 as 85 percent of nursing facility residents
16 have persistent pain, and pain is often not
17 fully documented.
18 In regards to the Omnibus Budget
19 Reconciliation Act of 1987, the mandate was to
20 promote maximum practicable functioning among
21 residents and, hence, pain and pain management
22 is very important.

1 Also, the Advancing Excellence in
2 America's Nursing Homes has made management of
3 residents' pain one of its major goals, and
4 both of the pain severity measures are
5 currently included in CMS's publicly-reported
6 quality measures for the five-star system.
7 In regards to validity, Dr. Saliba
8 and colleagues, in their testing of the
9 development of the 3.0, the kappa from gold
10 standard to facility nurses was high, .96, and
11 gold standard to gold standard nurse, again
12 high, .96, and nurses participating in the
13 study, 88 percent reported that the new items
14 underlying the measure provided better
15 capturing of pain.
16 Essentially, what has changed from
17 the MDS 2.0 for 3.0 is that it focuses on a
18 resident interview versus the staff
19 assessment. Staff assessment is used only
20 when the resident cannot be interviewed for
21 pain.
22 And there was concern about, well,

1 what about cognitively-impaired patients? And
2 during the development and testing, 89 percent
3 of residents were able to report on their
4 pain, and resident pain has been shown to be
5 significantly more accurate than staff
6 assessment in determining the pain.
7 In regards to the pressure ulcers,
8 the purpose of the proposed measures is to
9 report the percentage of stage 2 to 3 ulcers
10 in nursing facilities.
11 DR. MEIER: Can we not do ulcers
12 right now?
13 MS. CONSTANTINE: Oh, okay.
14 DR. MEIER: Because we are doing
15 pain.
16 MS. CONSTANTINE: Oh, sure.
17 DR. MEIER: So, I think this may
18 be more content than we should have while we
19 are talking about pain.
20 MS. CONSTANTINE: Oh, okay.
21 DR. MEIER: Is that okay?
22 MS. CONSTANTINE: Yes.

1 CO-CHAIR GIFFORD: Yes, we're just
2 doing the pain, 9, 10, and 11. Yes, we will
3 come back to do the pressure ulcers.
4 MS. CONSTANTINE: Oh, that is
5 fine.
6 CO-CHAIR MUELLER: Okay, so our
7 primary reviewers?
8 CO-CHAIR GIFFORD: Actually, you
9 guys flipflop on the different ones. So, you
10 are primary in some. Diane, I think you are
11 primary on 10, or no, on 9, and you are
12 secondary on 10, and you are primary on 11.
13 DR. MEIER: So, just to frame
14 this, there's three measures. One looks at,
15 basically, short-stay patients, meaning the
16 rehab, the subacute rehab population, and
17 assesses whether there has been improvement or
18 a reduction in either frequency or severity of
19 pain from a baseline measure.
20 The other two look at an absolute
21 measure percentage with certain level of
22 severity or a certain frequency. So, it is

1 numerator, under all residents eligible,
2 numerator with pain that exceeds a certain
3 threshold, either in terms of severity or
4 frequency. So, it is not a change measure.
5 It is an absolute measure.
6 Then, one of those two absolute
7 measures is in a short-stay resident
8 population, and the other is in a long-stay,
9 long-term care, non-rehab, resident
10 population.
11 Would that be accurate?
12 MS. CONSTANTINE: That is correct.
13 DR. MEIER: Okay. So, the one we
14 are talking about now is the short-stay
15 effective pain management. So, this is
16 actually put in a positive, in response to
17 Bill's comments of earlier. And "effective"
18 means that there's been an improvement from a
19 baseline.
20 If we could go to the denominator
21 and numerator statement, okay, so there's
22 limitations by power. In other words, if

1 there are fewer than 20 eligible residents in
2 the facility, this measure is not publicly
3 reported. The reasons for that were discussed
4 earlier, and that makes sense.
5 So, you are up at numerator. So,
6 the numerator is the number of short-stay
7 residents with a 14-day assessment or
8 discharge assessment who can self-report --
9 so, this is MDS 3.0 -- and who are on a
10 scheduled pain medication, reporting a
11 predefined reduction in pain when compared to
12 the prior assessment.
13 Okay. So, first of all, it
14 excludes people who are not on a scheduled
15 analgesic, who may well have significant pain.
16 So, I don't understand that particular
17 criterion.
18 And secondly, it is MDS 3.0 self-
19 report, where we don't have correlations or a
20 clear comparison in terms of the correlation
21 between 2.0 and 3.0. Because it is self-
22 report and because these are residents with,

1 if not dementia, other reasons for cognitive
2 impairment, such as pain, such as exhaustion,
3 such as delirium, such as transfer trauma, we
4 really don't know.
5 What we are given here, we have no
6 assessment of level of cognition in the
7 validation sample. It just says, you know,
8 900 or "X" thousand nursing home residents
9 with no way to know what their cognition was.
10 So, given that this is nursing
11 home residents we are talking about, who by
12 definition are very frail and vulnerable,
13 whether they are short-stay or long-stay, not
14 knowing the cognitive status of the subjects
15 in whom this measure was tested is a major
16 flaw in my view in the validation data for
17 this.
18 So, it is both the issue of lack
19 of comparative data between 2.0 and 3.0, not
20 having a sense of either the tests or the
21 validation sample, their cognitive levels and
22 stratification by cognition and performance of

1 this measure.

2 Then, my third major concern from

3 the reliability standpoint is the measure

4 developers point out that research shows that

5 prevalence of pain in nursing home populations

6 ranges anywhere from 40 to 60 percent to

7 higher of moderate to severe chronic pain.

8 Yet, the level that we are finding on this

9 measure averages 20 percent, and the range is

10 3 percent to 40 percent, suggesting that we're

11 teaching to the test.

12 When people know they are going to

13 be publicly reported, for some reason, they

14 find less pain, and I am very, very concerned

15 that we are not measuring what we think we are

16 measuring. The fact that the gold standard

17 nurse to gold standard nurse has a high

18 correlation is not surprising. The fact that

19 the gold standard nurse to a nurse trained by

20 the gold standard nurse has a high correlation

21 is not surprising.

22 There is no validation data on the

1 use of these measures in the standard
2 environment, usual environment, with no extra
3 training, no oversight from the gold standard
4 nurse as compared to the gold standard nurse.
5 So, there is no gold standard comparison.
6 So, I am pretty worried that we
7 are saying to the public these are accurate
8 measures of pain levels in nursing facilities,
9 when, in fact, they are very likely not to be
10 because of the public reporting and the
11 pressure on facilities to underreport, which
12 is overwhelming. And we have no way of
13 measuring that.
14 One of the things those of us who
15 live in New York, there was full-time ads that
16 Nursing Home Compare took out in The New York
17 Times comparing quality of nursing homes, and
18 one of the things was pain levels. It was
19 very clear to those of us who work there that
20 the best quality nursing homes had the highest
21 pain scores, and the nursing homes you
22 wouldn't send anybody to had the best pain

1 scores.
2 This is the opposite of what we
3 should be doing. You know, it is an
4 unintended consequence, but a predictable
5 consequence of public reporting of this stuff.
6 I think it is having the reverse effect. That
7 is, it is more likely that pain is not going
8 to be identified and addressed rather than
9 less likely.
10 I think we have a responsibility
11 to at least test that hypothesis before we put
12 forward these measures. So, those are my
13 three primary concerns, the MDS 2.0 to 3.0,
14 assuming that because we have variability on
15 2.0, we will on 3.0. Self-report versus staff
16 identification are really different measures,
17 particularly in such a cognitively-vulnerable
18 population. The lack of stratification of
19 risk adjustment by cognitive status and
20 facility type, and the impact of public
21 reporting on gaming are a concern with this as
22 well as the other two measures.

1 MEMBER NAIERMAN: This is Naomi
2 Naierman.
3 Diane and I have collaborated on
4 this, and I fully concur.
5 The other thing that I would like
6 to point out is that there is no crosswalk
7 between satisfaction and pain. So, people
8 with moderate pain may feel comfortable with
9 it. It is a very subjective kind of measure,
10 and if they are satisfied, then being
11 medicated any further just to show
12 improvement, as it were, or difference in
13 score, may be more harmful than not.
14 So, I think some crosswalking
15 between self-reporting and observation, and
16 also with satisfaction, which of course is
17 part of what palliative care is about, is
18 fulfilling the patient's own goals, makes this
19 is a very narrow, if not risky, kind of
20 measure to really assess whether pain is there
21 or not.
22 DR. MEIER: And obviously, I am

1 speaking both for Naomi and myself when I say
2 that there could be nothing more important
3 than the appropriate relief of suffering in
4 this particular part of the human population.
5 Obviously, this is what I do for a living, is
6 palliative care. So, it is distressing to say
7 that I don't think the technology has caught
8 up, the measurement technology has caught up
9 to the reality of improving care in the
10 nursing home.
11 But my biggest concern is not that
12 these measures are neutral, but that they are
13 actually having the reverse effect, that they
14 may actually be worsening quality of care
15 because there is such a strong incentive not
16 to identify pain.
17 MR. BOISSONNAULT: I have --
18 MEMBER NAIERMAN: I have one more
19 thing I just want to say. It was startling to
20 me that there was no mention here of
21 observational approach to pain management,
22 given the size of the population in nursing

1 homes with dementia, notwithstanding the 89
2 percent validity test of self-reporting among
3 dementia patients in pain. That is very
4 difficult to believe, quite frankly. I would
5 like to see more studies on that, people with
6 dementia reporting on pain.
7 I would imagine that at least in
8 some cases, in certain dementia levels, there
9 will be some crosswalking with observational
10 approach, and there was no mention of an
11 observational approach, and by the way, with
12 the folks, the nursing home staff that
13 actually spend time with the patients, not
14 just the nurses, but the LPNs and the CNAs.
15 So, the crosswalking, the self-
16 reporting, and the fact that these measures
17 just do not really apply to people with
18 dementia, which, of course, is most of the
19 patients in nursing homes, most of the
20 residents, I should say.
21 CO-CHAIR MUELLER: I just want to
22 clarify this is a time-limited measure. So,

1 you took that into account also?
2 DR. MEIER: Yes, I could go on
3 with critiques, but it assumes that there is
4 a baseline measure, and there's nothing
5 provided here that says what's the prevalence
6 that somebody comes to a subacute rehab
7 facility with a discharge from the hospital
8 baseline measure. We don't know. My guess is
9 not that many (a), and (b) that the nursing
10 home has zero control over whether it gets a
11 baseline measure from the institution from
12 which the resident is transferred.
13 So, that is a big concern because
14 it is a change measure. What are you starting
15 with? But that was a lower level.
16 MR. BOISSONNAULT: Fundamentally,
17 from a consumer perspective, I thought that
18 the move in 2.0 to 3.0 from essentially staff
19 assessment of pain on the part of the patient
20 to the patient's assessment of pain, on the
21 part of the patient, was very positive.
22 I will, without going point-for-

1 point to your comments, pain management
2 perception is reality, notwithstanding that it
3 is not more pain management or less pain
4 management, but the right pain management that
5 you want, which I think was, in essence, one
6 of your points.
7 I am sort of concerned about the
8 unintended consequences of not moving forward
9 with this, knowing that there's going to be
10 real problems in the beginning. And I will
11 give you my example.
12 When we first started publishing
13 safety measures, error measures, at hospitals,
14 it was some of the hospitals with the very
15 best reputations that had the worst results.
16 And after several years, we determined that
17 that was correct.
18 But we never would have done the
19 evaluation to find out if that was correct,
20 had the measures not been published. So,
21 notwithstanding that I think everything you
22 said is accurate, I am inclined to opt in

1 favor of not having the perverse consequences
2 of not moving forward, period.
3 DR. MEIER: Can somebody tell me
4 what are the consequences? I don't understand
5 that. What are the consequences of not moving
6 forward? What's the tradeoff of accepting
7 what we consider not really to be a
8 scientifically-valid and reliable measure at
9 this point? What happens?
10 MR. BOISSONNAULT: I am going to
11 answer, again, from a consumer's perspective,
12 and then defer to the Co-Chairs and the staff.
13 We are sort of early adopters on
14 the public reporting scene, and we have never
15 been sensational. We do hospitals, but we do
16 some nursing homes. We do some insurance
17 measures. But our thing is hospitals.
18 But my point is we have heard for
19 years that the data isn't good enough and the
20 methodology needs to evolve somewhat. And on
21 some fundamental measures, it has been our
22 experience that the measures don't get there

1 until you start using the data for that type
2 of measurement.
3 So, if you're in The New York
4 Times and it is real easy for me to say, "You
5 know what? We're going to have to work
6 through the kinks," but I just think pain
7 management is one of the things that nursing
8 homes are supposed to do. They are one of the
9 results we are supposed to get.
10 I didn't have the same sort of
11 visceral reaction to the fundamental flaws,
12 but I only saw the definition of numerator and
13 denominator here. So, I will stop and just
14 explain why I will vote how I will vote with
15 what I have said.
16 CO-CHAIR GIFFORD: To answer your
17 question, what I have seen previously in work
18 I did with nursing home quality and the
19 measures is the same issue you talked about,
20 which is studying to the test and sort of
21 doing the loopholes of that. It is the same
22 issues, that those measures that get reported

1 is what they focus on.
2 So, whatever the measures are that
3 are being -- any provider, whether they are
4 important or not, that is what they will focus
5 on. So, you will see some improvement.
6 Those who want to game the system
7 will game the system and find loopholes to
8 game the system, no matter what, whether it is
9 chart abstraction data, whenever reporting
10 data. I mean all of us have an experience
11 where we go to buy something and someone hands
12 us the stuff and says, "This is how you should
13 vote because you're going to get called a week
14 from now from our survey people, and if you
15 answer bad, I'm not going to get paid."
16 (Laughter.)
17 So, I mean, I think all of us had
18 had that at some point in purchasing
19 something.
20 So, really, what it comes down to
21 is, if you don't have any measures at all, it
22 just doesn't get the same level of focus and

1 attention. So, that is the flip side to what
2 you said.
3 But just because it is important,
4 we all said it is important. If we use that
5 as the metric, then just put all the measures
6 through and say go with them because they're
7 all important.
8 Bruce's comment earlier, though,
9 too, is waiting for the data to be perfect
10 means that most of the measures we will never
11 do, and that's a good way to kill the measures
12 in moving forward. So, we have to balance the
13 practicality and balance everything as we go
14 forward on it. I think that is why NQF set up
15 the different areas to talk about that and
16 figure that out.
17 I have seen measures -- this is my
18 third different panel I have been on, nursing
19 homes and others. I have seen some measures
20 that have gone through that the group just
21 held their nose, but said it's so important,
22 we need to get the measure out there.

1 Again, as we have said, there is a
2 review process, and it goes up through. One
3 of the things that Christine and I have to do
4 is we have to take it to the full panel and we
5 will present all those issues. Just because
6 we have approved or not approved doesn't mean
7 that it may not still get through the process.
8 I have seen measures that the
9 Committees have put forward, they get turned
10 down. I have seen measures that we have voted
11 down that end up getting approved by NQF.
12 DR. MEIER: So, here's an even
13 more drilled-down question: these questions
14 are part of MDS 3.0, and they are rolling out
15 in October with or without NQF endorsement.
16 Is that correct?
17 MS. PACE: The MDS items are, yes,
18 but not the measures.
19 MR. BOISSONNAULT: Not the mass,
20 but the items.
21 CO-CHAIR GIFFORD: Yes, the items
22 on the MDS are rolling out in October.

1 DR. MEIER: Right.
2 CO-CHAIR GIFFORD: Whether we
3 endorse or not endorse, there will be other
4 people that can take the MDS data and create
5 their own measures and do anything else. They
6 just can't call them an NQF measure.
7 DR. MEIER: So, tell me what the
8 salience of being able to call it an NQF
9 measure is, as opposed to everything else that
10 is going on out there.
11 CO-CHAIR GIFFORD: I will defer to
12 CMS, whether CMS would report. I mean CMS has
13 a large cadre of MDS measures that are used
14 for different issues. They have MDS measures
15 that are used in the survey process. They
16 have MDS measures that are in testing for
17 payment-type reform. They have MDS measures
18 that they publicly report, and they have MDS
19 measures they use for research purposes.
20 I believe -- and correct me if I'm
21 wrong -- will CMS use a publicly-reported
22 measure that is not NQF-endorsed?

1 MS. PACE: Can I answer one thing,
2 and then let CMS respond? One thing about NQF
3 endorsement, we are considered a voluntary
4 consensus standard-setting organization.
5 Under the NTTA rule, the federal government is
6 supposed to use voluntary consensus standard
7 in lieu of newly-developed standards if they
8 meet their needs. So, to a certain extent,
9 CMS generally uses NQF-endorsed measures
10 versus those that aren't, but there are
11 reasons that they may go forward, and we can
12 have CMS address that as well.
13 MS. CONSTANTINE: I just want to
14 bring a point up about the measures, not
15 answer for CMS in regards to endorsement. But
16 for the pain management measure, and we
17 probably didn't make it clear enough in the
18 numerator statement, but we assumed that
19 there's a prior admission assessment. So, we
20 were looking at the admission assessment
21 compared to either the 14-day PPS or the
22 discharge assessment.

1 Then, I guess, secondly, we would
2 be looking for time-limited endorsement with
3 all three of the measures, knowing that even
4 with the development testing that we need to
5 take a look and see what the responses are
6 coming in from validation. But our hope was
7 that this measure was an improvement in
8 regards to eliciting the patient's voice,
9 which for the majority of the time can be
10 elicited in regards to response to pain.
11 DR. MEIER: Again, everyone agrees
12 this is a critically-important outcome,
13 suffering, among the residents. There's no
14 argument about that.
15 Everyone also agrees that it is
16 much better and more valid if the report comes
17 from the resident for those who are able to
18 report. There's no debate about that.
19 The question is, are those two
20 factors sufficient for NQF endorsement?
21 MS. THOMPSON: This is Darlene
22 Thompson. I just have a couple of comments.

1 And I agree how important this is,
2 but, first of all, it is making the assumption
3 that pain medication is the only thing you're
4 going to count for effective pain management
5 because that is one of your key questions. I
6 am a firm believer and personally use non-pain
7 medication interventions for my chronic pain,
8 and it does work. So, I think that is a flaw
9 in and of itself.
10 The second thing is it is looking
11 at, yes, there will be a baseline because the
12 baseline will either be the resident's OBRA
13 admission assessment or their Medicare five-
14 day PPS assessment. Then, you are looking at
15 either their discharge assessment or their 14-
16 day.
17 What that means is that any short-
18 stay patient, which we have earlier recognized
19 as anybody who lives in a building under 100
20 days, after day 14 you're on your own; we
21 don't care because you're not being covered in
22 the short-stay measure and you're not being

1 covered in the long-stay measure. So, you
2 just drop that big group of residents whose
3 pain management improvement may occur after
4 day 14.
5 If you have a resident come into
6 the facility, they may not be starting therapy
7 by the time you do your five-day PPS MDS
8 assessment. But once they start therapy,
9 depending upon what they are having therapy
10 on, you are going to see either the intensity
11 of that pain go up or the frequency go up.
12 And there's no allocation in that.
13 When you look at the second
14 measure, short-stay measure, of going from
15 moderate to severe, what I don't understand is
16 why someone didn't sit there and look at, for
17 your short-stay resident, is there effective
18 pain management, from looking at their pain
19 scale from their most current short-stay
20 assessment, whatever that might be, to their
21 prior one? And look at it throughout the
22 continuum of that person's short stay, and not

1 just look at their 14-day, not just look at
2 whether they are on a pain medication
3 management system, but look at, has there been
4 an improvement in the intensity or frequency
5 of their pain during their short stay,
6 comparing their most current short-stay
7 assessment, whatever that might be, or
8 discharge assessment, to the prior one.
9 That is just my comment.
10 CO-CHAIR GIFFORD: Is CMS ready to
11 answer the question? I just don't want that
12 to slip through the cracks.
13 DR. LING: Well, I will answer a
14 question; I don't know if it is the question.
15 And it speaks to this issue of
16 patients and residents who have cognitive
17 impairment. When the measure was constructed,
18 and I have to admit that this is an
19 assumption, that by relying on J200, should
20 the pain assessment be conducted, that we
21 would, by definition, restrict pathway A,
22 which is the self-reported assessment, to

1 those who could respond. For those people who
2 could not reliably respond, the objective
3 nursing assessment would come into play.
4 So, having said that, we still are
5 in the position of having to rely on the data
6 that will be forthcoming, and not on the data
7 -- because we are still talking about 3.0
8 implementation starting October 1. So, we
9 acknowledge those.
10 DR. MEIER: So, I guess one
11 question is, should NQF endorse a measure that
12 actually isn't in practice yet, that we have
13 very little on-the-ground opportunities to
14 validate it? Is that true for all of these
15 measures?
16 CO-CHAIR GIFFORD: Well, actually,
17 for all the RTI measures that are coming forth
18 that are paid for, the funding was paid to RTI
19 by CMS, they are all, I believe they are all
20 coming in as time-limited, right, the MDS 3.0
21 measures? Is that correct?
22 So, unless we thought they were so

1 great, we could up it, but the request from
2 the measure developers that they be time-
3 limited is mainly because they test it with
4 the 3.0 coming forward.
5 DR. MEIER: Then, the other
6 question for CMS was the likelihood that you
7 will continue with public reporting of
8 measures that are not NQF-endorsed.
9 MS. TOBIN: As far as the ones
10 that are going to be tested with 3.0, those
11 aren't intended to be publicly reported until
12 they have actually gone through the full
13 testing and we have those test results. And
14 then, we would be submitting them for full
15 endorsement. So, we are talking public
16 reporting of those really after that stage,
17 correct.
18 What will happen is we will
19 continue to report the 2.0 for a certain
20 period of time. We will implement MDS 3.0,
21 collect the data, test the data, and there
22 will be a pause in terms of public reporting.

1 Then, when there is sufficient data that has
2 gone through that testing, we will resume in
3 publicly reporting --
4 CO-CHAIR GIFFORD: Will you report
5 a measure that has not been NQF-endorsed? I
6 mean unless it has some other consensus. A
7 measure that doesn't have consensus -- let me
8 rephrase it -- a measure that doesn't have
9 consensus development support, would you
10 publicly report those measures under Nursing
11 Home Compare?
12 MS. TOBIN: We would bring it back
13 to CMS and have an internal discussion of
14 where we would want to go with that --
15 CO-CHAIR GIFFORD: Okay.
16 MS. TOBIN: -- if that were the
17 case, and for what purpose we might use it,
18 whether it is for the research. I can't say
19 definitely yes or no.
20 CO-CHAIR GIFFORD: Okay. Yes, I
21 know in Rhode Island and several other states
22 you are seeing more and more in the statutes

1 for public reporting that they have to be NQF
2 or consensus or similar to just the language
3 CMS has.
4 We are a small, little State, so
5 it doesn't really matter a great deal. But if
6 we don't have an NQF-endorsed measure, we
7 can't report it. That is sort of the position
8 we have taken in the State.
9 MS. SCOTT: Dave, may I make a
10 follow-up comment? I want to make a comment
11 specifically about the staffing measures.
12 You know, we are being
13 legislatively mandated to report certain
14 staffing measures. They are going to go
15 without NQF endorsement, if they have to,
16 because we've got a timeline and a legislative
17 mandate.
18 I guess I also wanted to say, and
19 this is not publicly reported, but we will
20 continue to use in the survey process the
21 measures that will be useful for the survey
22 process, which are very different than the

1 kinds of measures you would publicly report.

2 MEMBER NAIERMAN: I have a

3 clarification question. If we endorse this

4 today, and the testing is going to go on and

5 will not be reported until it is tested,

6 doesn't that seem a little bit in the reverse?

7 Doesn't it seem like we ought to be reviewing

8 this after the testing goes on between 2.0 and

9 3.0?

10 CO-CHAIR GIFFORD: Yes, time-

11 limited approval means it will be NQF-

12 endorsed. So, you could go forward and

13 publicly report it, but it is time-limited,

14 and come back.

15 So, if you happen to be an

16 organization that is bound by needing to have

17 a consensus-development process, like I won't

18 pick on CMS -- I'll pick on the State of Rhode

19 Island -- we would report it. Then, when the

20 time limit expires, we wouldn't be able to

21 report it anymore. We would stop reporting it

22 until it got NQF endorsement again.

1 MEMBER NAIERMAN: Okay, but what I
2 am hearing is that CMS is not going to report
3 it publicly until it has been tested.
4 CO-CHAIR GIFFORD: Right, but they
5 can still -- the question really is whether --
6 they could test it and find it, and then
7 decide to report it without NQF endorsement or
8 not.
9 MEMBER NAIERMAN: Well, if we have
10 a time-limited, I am a little confused about
11 the sequence. If they are not going to report
12 it until they test it --
13 CO-CHAIR GIFFORD: Well, just
14 because it is time -- there are thousands of
15 NQF-endorsed measures that are not being
16 publicly reported by anyone out there. So,
17 just because we endorse it as an organization
18 doesn't mean that CMS or the State of Rhode
19 Island, or anyone else, is bound to have to
20 publicly report it.
21 MEMBER NAIERMAN: Yes, I'm asking
22 the reverse question. I'm asking, if, indeed,

1 it is not going to be reported until it is
2 tested, and we endorse it today, then it is
3 not going to be reported anyway until it is
4 tested. And why can't we look at the testing
5 once it is done?
6 DR. MEIER: What is the salience
7 of NQF endorsement or not?
8 MR. BOISSONNAULT: Does it allow
9 them to move from the 2.0 data that we know
10 has the fundamental flaw to the test 2003
11 data? Is that why you submitted it? Because
12 I have a totally different question, but I
13 didn't understand why you said what you said.
14 Do you want this approved?
15 MS. GAGE: Yes. And, in fact, the
16 concern about the prior testing, this has
17 been --
18 MR. BOISSONNAULT: Hold it. CMS
19 should answer that question, not RTI, right?
20 (Laughter.)
21 DR. LING: Yes, it would be ideal
22 if we could at least get the time-limited

1 endorsement. But at the same time, we are
2 very interested in your feedback and your
3 input. So, that was part of the reason,
4 although maybe interpreted as premature, to
5 start the process.
6 DR. MEIER: But could you say why
7 you want NQF endorsement at this stage? What
8 difference will it make for you, for CMS?
9 Could you explain that to me?
10 DR. LING: That's a really good
11 question.
12 (Laughter.)
13 DR. MEIER: Because NQF does have
14 a reputation to protect --
15 DR. LING: Yes.
16 DR. MEIER: -- in terms of the
17 validity and reliability of the measures that
18 we endorse, I would think. And therefore, I
19 think that it is clear that MDS 3.0 is going
20 to roll out, and CMS will report, frankly,
21 what it decides to report.
22 But if NQF leans too far in the

1 other direction of saying this is very
2 important, we want to hold their feet to the
3 fire, so we are going to endorse the measure,
4 despite all of the lack of validation and
5 reliability studies that everyone would agree
6 scientifically really ought to be required, I
7 think there is a serious risk of losing that
8 bully pulpit in terms of the rigor and quality
9 of the measures.
10 That is not to say these are not
11 important things to address. We all agree
12 they are all really important to address. But
13 is that really our role, is to highlight
14 things that are important to address or is it
15 to really assess the validity of the measures?
16 MR. BOISSONNAULT: Diane, I don't
17 think everyone agrees that it isn't ready
18 enough for a 12-month endorsement. I think
19 that is premature.
20 I have a question, though, of the
21 technical person. Is that you?
22 And I apologize I'm not looking at

1 the full definitions. "Percent of short-stay
2 residents" -- this is 009 -- "who are on a
3 scheduled pain medication regimen at admission
4 and" -- all in caps -- "who report lower
5 levels of pain."
6 So, I think if this is done one
7 way, what that would mean is we have given you
8 a script, and has it helped? Is that what
9 this measures? Because if it does, then I am
10 all for it. But if it doesn't, then I don't
11 know what it means.
12 In other words, there was a
13 comment before that sometimes what we try to
14 do is deliver pain management without
15 medicine. I think that is irrelevant to this
16 measure. I think this is, hey, we're giving
17 out the scripts. Are they doing any good or
18 are we just passing out pills for the fun of
19 it?
20 Is that what you are trying to get
21 at here?
22 MS. CONSTANTINE: The focus of the

1 measure, when we discussed it at the last
2 Technical Expert Panel, was looking at this
3 particular population, the short-stay
4 population, and taking a look at, on
5 admission, their pain level. As you said,
6 they are giving a script. Then, at either the
7 14-day or at discharge, being able to say that
8 their pain has been reduced since, as you
9 mentioned, being on a prescribed pain
10 medication.
11 MR. BOISSONNAULT: Well, if not,
12 take them off. But my question is, does the
13 numerator require that the center, that the
14 provider will have given the script or in some
15 way is that a change? Because if you are just
16 saying, hey, how many people are on pain
17 medication, and it went down even though we
18 didn't change anything, is that noise in
19 there?
20 In other words, do you have some
21 patients who have been on a pain medication
22 for a year come in, you say, "Yes, you're on

1 a pain medication," and 14 days later you do
2 the assessment and nothing has changed? Well,
3 of course, nothing has changed because nothing
4 has changed. They are on the same medication.
5 Is that noise going through this
6 measure? I should ask you, Diane.
7 DR. MEIER: The issue here is that
8 there are many things that cause pain to go
9 down 14 days or a month after admission to a
10 subacute rehab. Most importantly, it is
11 healing of whatever the acute injury was; it
12 is time. That has much more salience than
13 Tylenol or morphine or anything else you give,
14 as well as things like them starting to feel
15 safe in the environment and feeling well-
16 cared-for and having the appropriate type of
17 wheelchair and cushioning devices.
18 So, you can't separate those
19 things out. That is the problem. That is why
20 I have concerns about the denominator
21 requirement.
22 MR. BOISSONNAULT: Right, but this

1 seems to be -- is this the reverse of that?
2 Because is this, hey, we gave them pain
3 medication and two weeks later nothing got
4 better, so maybe we should get them off of the
5 pain medication?
6 MS. CONSTANTINE: Yes.
7 MR. BOISSONNAULT: I mean, is this
8 is an overuse measure? Because that would
9 imply that the only people in the numerator
10 and denominator are people for whom the
11 medication is new. If this is people for whom
12 the medication is -- I don't mean new at an
13 admission, but new at cause. So, if it is a
14 fall or something like that, that the primary
15 care doctor gave them the script three days
16 before they got there or something. Is that
17 what you are trying to measure, is essentially
18 some measure of, gee, we're giving these out
19 and it's not working?
20 MS. CONSTANTINE: Yes.
21 MR. BOISSONNAULT: See, actually,
22 what's the issue with that?

1 DR. MEIER: You asked a good
2 question, but it is certainly not clear in the
3 specifications that that is what it is about.
4 MR. BOISSONNAULT: All I am
5 looking at is the little summary thing. But
6 if that is it, I'm still a believer.
7 DR. MODAWAL: The issue was really
8 subreporting of pain, you know, the person
9 seeking medications, you know. I think we all
10 agree that pain is important and medication
11 needs to be used. But the issue is whether
12 they should go away from the professional
13 assessment to the patient satisfaction and
14 patients seeking the medication.
15 Isn't that the main of your
16 question? I thought the first question, the
17 description, is this is the one? You know,
18 that is the main issue really, that we are
19 empowering the patients to be reporting the
20 pain and asking for medications.
21 Then, if that is so, the two
22 issues are safety because of the professional

1 judgment, how much to give. I know certain
2 populations really, no matter what you do,
3 will be asking for medication or will
4 overreport their pain as well. There is
5 variation in the nursing homes as well in
6 terms of the mix of the patient populations.
7 So, if that is the consideration,
8 then, certainly, it can be tested and then
9 assessed later on, that this is a new measure
10 which is basically empowering the patient
11 population to really report their pain and
12 ask. Otherwise, we are doing everything
13 professionally.
14 You know, every time these are all
15 mandated, it is a vital sign, the first vital
16 signs. They say the pain is reported, and now
17 the measure is that five hours after the pain
18 tablets are given gain is reported. All that
19 is there. It is just removal of the emphasis
20 from professionals to the patient. Is that
21 the intention of this thing?
22 MS. CONSTANTINE: The intent of

1 the measure, when we discussed it during the
2 TEP, we wanted to focus on a positive measure
3 for the short stay. And given that they come
4 from post-acute with a lot of the quality
5 measures, your concern is, oh, is it something
6 that, for lack of a better word, you are being
7 dinged for that is actually something that the
8 patient has come with, say an infection or
9 something like that from the acute care
10 facility?
11 This was an attempt in discussions
12 during the TEP to say, well, if the patient
13 comes in -- and for the short stay, many of
14 the patients come from an acute care facility.
15 They come in, they have an assessment. They
16 have a pain assessment, are prescribed a
17 medication, and then that pain has improved
18 before they are either discharged or the 14-
19 day assessment.
20 The reason for the focus, there
21 was a lot of discussion about one assessment
22 versus another. Why can't you go further out?

1 In looking at the short-stay population and
2 their general length of stay, it was to give
3 the facility credit that the pain was
4 assessed, it was addressed, and there was
5 improvement in the patient's pain.
6 MS. BERNARD: Can I add something
7 to that from the RTI?
8 MS. CONSTANTINE: Sure.
9 MS. BERNARD: Given this
10 discussion, I think it is very clear, as you
11 said earlier, that this is a very important
12 measure. The intent of this particular
13 measure is not to address all effectiveness of
14 pain. It is a very conservative measure in
15 saying we know this is a very important issue.
16 We can't measure everything that is related to
17 this, but let's take a small subset of
18 residents who, at the time of admission, were
19 able to say that they had pain, and to look at
20 14 days later or a discharge to say, has the
21 pain decreased?
22 If they said they had pain and

1 were started on pain medicine, was that
2 effective? Is this enough to assess
3 effectiveness of pain management? No. Is
4 this a start to begin to address issues of
5 effective pain management in long-term care
6 facilities? Yes.
7 So, think of it that way, as a
8 conservative measure to begin to address a
9 problem that we all know is there. This is on
10 the road towards evaluating the effectiveness
11 of pain management, but it is not sufficient
12 in terms of addressing all effectiveness of
13 pain management.
14 CO-CHAIR GIFFORD: All right.
15 DR. ZOROWITZ: I'm going to talk.
16 CO-CHAIR GIFFORD: Yes.
17 DR. ZOROWITZ: Several points.
18 First of all, I think we all recognize this is
19 somewhat of a departure for a quality measure,
20 and it is a first attempt at actually showing
21 improvement on an individual basis.
22 Most of the quality measures are

1 cross-sectional measures which show how the
2 population is doing at a given point of time.
3 This is an early attempt to show some change
4 and to show effectiveness on an individual
5 basis, which I think is a good thing and I
6 think is an important thing.
7 But, as we can see, there are
8 potential flaws to it, and it has not been
9 well-tested, which gets back to the meaning of
10 the term "endorsement". I'm not sure that
11 endorsement is really the proper term.
12 Probably, if we asked, "Do you
13 think we should go ahead and test this, not
14 publicly report it, but test it first, and see
15 how it works and see if it has validity and
16 reliability," probably we would all agree. It
17 may not be a perfect measure, but it is a
18 start at getting to what we really want to be
19 measuring with appropriate pain management.
20 But I think the term "endorsement"
21 is sort of throwing us off because we are not
22 ready, I don't think anybody here is ready to

1 endorse it as a publicly-reported measure that
2 we feel confident really means something
3 because we don't know yet.
4 If I were asked, would I vote to
5 go ahead and say NQF says it's okay to go
6 start testing this, I would probably say yes.
7 If I were asked, do you endorse it as a
8 measure that should be reported to the public,
9 I would say no, because I don't know how it is
10 going to work yet.
11 MEMBER NAIERMAN: What's the
12 question?
13 CO-CHAIR GIFFORD: So, actually,
14 let me rephrase it, then, because we have to
15 make some stuff up as we go along here.
16 (Laughter.)
17 A small thing. NQF doesn't
18 develop or test measures. So, it wouldn't be
19 that we're testing it forward.
20 But I think what I hear is a
21 motion on the table that we vote to approve
22 the measure time-limited with the caveat, the

1 condition attached to that time-limited that
2 it not be publicly reported until such time as
3 sufficient reliability and validity testing is
4 done and it comes back to NQF.
5 If I could summarize what you
6 said, Bob, that would be a motion to put on
7 the table. I mean we don't need to vote it,
8 but I am going to put a motion on the table
9 for a discussion. Yes, they are going to say,
10 no, you can't do that, but I don't care.
11 (Laughter.)
12 MEMBER NAIERMAN: But may I add
13 one more thing?
14 CO-CHAIR GIFFORD: That's why they
15 picked me.
16 MEMBER NAIERMAN: What I want to
17 ask is something related to another caveat
18 that I would like to consider. Is there a way
19 that we can know -- this isn't mentioned here
20 -- that the self-reporting is going to be
21 done, that we are going to stratify between
22 those who can self-report and those who

1 cannot? In other words, can we add some kind
2 of a risk or stratification aspect to it, so
3 we are not assuming that all of the patients,
4 residents, that are going to be included in
5 this testing --
6 CO-CHAIR GIFFORD: How about if
7 you add it in that we are recommending an
8 endorsement of time-limited with sufficient
9 validity and reliability testing, including
10 the information on the cognitively-intact and
11 not intact, people who can report and not
12 report, understanding that?
13 So, rather than saying it has to
14 be stratified and bucket them in there, we
15 just want information understanding that.
16 Yes, Dede, do you want to add a
17 third condition?
18 DR. ORDIN: Well, I think there's
19 several conditions. I always find this a
20 problem when people put the numerator before
21 the denominator. Because when I look at the
22 denominator, the numerator, you have to have

1 had a medication, right? But the denominator
2 is everybody.
3 DR. MEIER: No, I don't think so.
4 They're the same denominator. The denominator
5 is everyone who has been on the pain medicine.
6 DR. ORDIN: Okay, got it.
7 MR. BOISSONNAULT: That would be a
8 real problem though.
9 DR. ORDIN: There's another
10 problem. I'm glad that's not a problem
11 because that would be a huge problem. There's
12 a small problem that I think is applicable to
13 a lot of measures of what to do when you have
14 missing data. My feeling is always the
15 missing data people should fail. I mean not
16 the people --
17 DR. MEIER: The facility.
18 DR. ORDIN: Yes.
19 CO-CHAIR GIFFORD: So, I heard a
20 couple of conditions to modification before we
21 vote. One is it is time-limited without
22 reporting; that reliability and validity

1 testing come back, which includes the issue of
2 being able to self-report and not self-report;
3 what to do with missing data.
4 And let me add something Bruce
5 said early on. Understanding the information
6 of when, since this is a change measure, to
7 Bob's point, when the measure doesn't change,
8 but it is 1/1, some understanding because the
9 self-report is on a 0-to-10 scale. So, if you
10 stay at 1/1, you don't get counted in the
11 numerator; you don't look like you improved.
12 I think all of us might say, well, I'm 1 out
13 of 10, 1 out of 10, and I'm on analgesia; I'm
14 okay with that.
15 So, understanding that the range
16 of 0 to 10 is not necessarily linear as we go
17 forward in that part of the reliability
18 testing --
19 DR. MEIER: I have to add to that.
20 CO-CHAIR GIFFORD: Yes.
21 DR. MEIER: And I think Mary Jane
22 mentioned this before, as did Naomi. There

1 are people who would rather have their pain at
2 a 4 or a 5 than be on an opioid, and we don't
3 allow for that. And we don't allow for that.
4 This whole issue of measures that
5 start with what the resident chooses or wants
6 and go from there is completely lacking in
7 this whole measure set. But it is
8 particularly important in pain management
9 because a facility will get dinged for someone
10 whose pain goes from a 3 to a 5, even though
11 the resident may have said, "I tried that
12 stuff. I don't want it. I would rather live
13 with this level of pain." That is good
14 quality care, but the facility will be
15 punished for it. And that is a big problem
16 with these measures.
17 MR. BOISSONNAULT: Actually, if it
18 goes from a 3 to a 5, or just stays a 3 to a
19 3, I think they get equally dinged. The point
20 is they have said, "We want the drugs."
21 They've had the consult with the doctor, who
22 has said, "Okay, give them the morphine," and

1 it hasn't helped. Their pain score hasn't
2 improved. That is the moving part here: did
3 the pain score improve or not as a result of
4 the intervention?
5 I think the only thing that needs
6 to be really thought through is, when is the
7 intervention? Again, if treatment is started
8 before the patient arrives at the door, it
9 seems to me those are the folks who should be
10 complaining about being dinged.
11 To make sure I understood your
12 point, what was the amendment that you just
13 made? Because it was real important.
14 DR. ORDIN: What to do with
15 missing data.
16 MR. BOISSONNAULT: And the
17 assumption is, if there's a reward for gaming,
18 you should try as much as you can to not have
19 the bad news simply be eliminated by leaving
20 it blank. I completely agree.
21 CO-CHAIR GIFFORD: Bob, and then
22 Gil.

1 DR. ZOROWITZ: I was just going to
2 say I think we have to be careful. There's a
3 lot of different individual resident stories,
4 that we talk about whether someone is going to
5 get dinged or not, but we are not looking at
6 individuals here. We are looking at a
7 population.
8 While there are residents who
9 prefer not to be on opioids or to be on
10 minimal opioids and to have more pain, we
11 don't know yet how this is going to look as an
12 overall measure until it is tested.
13 Likewise, remember that to put
14 this in context, we are looking at three
15 measures here. We are not only looking at
16 this measure, which is a measure of change,
17 but we are also looking at the two prevalence
18 measures of moderate to severe pain in short-
19 and long-term patients, which could be high or
20 low, depending on the facility and also
21 depending on how well the facility manages its
22 pain. And you have to look at the first

1 measure in context with those measures which
2 actually have been recorded now for several
3 years.
4 I think, in all candidness, this
5 is an experimental measure, and it should be
6 recognized as such until it is tested. The
7 other two measures I think have a little bit
8 more history to them. But whether it can be
9 gamed, whether an individual patient's choice
10 might ding a facility, I am not so much
11 worried about that.
12 If you document in the chart they
13 don't want this, this is why, they have had
14 informed consent, on an individual basis, the
15 state is not going to come in and say, "You're
16 not treating pain appropriately" because I
17 have documented that this is patient choice.
18 But I am more concerned about the
19 validity of the measure for a population. I
20 think it is experimental at this point.
21 CO-CHAIR GIFFORD: All right,
22 Heidi, and then we will take a vote on this

1 measure.
2 MS. GIL: Yes, just some mixed
3 thoughts about this. Diana, when you said the
4 great organizations, the five-star program
5 being affected and it's not being reality, and
6 then Bruce saying that those strong
7 organizations were sort of pushed to dig
8 deeper and to do better, I have seen
9 particularly the high-end, short-term rehab
10 organizations that are doing an exceptional
11 job on the long-term and short-term side
12 really struggling.
13 Pain is, obviously, as you all
14 know, one of the biggest hot buttons, which is
15 a good thing, which is good for those we
16 serve. I think the gaming is going to go on,
17 but I do think that we need to make certain
18 that we look at, like you said, the timeframe.
19 We are seeing part of the biggest problem is
20 that patients are coming in before they come
21 into the door, as you mentioned, Bruce, in
22 pain because they are not being pre-medicated

1 before they are leaving the hospital, as just
2 a simple solution.
3 So, there is a lot of complexity,
4 as we know, in all of this. But I do think
5 that the public reporting, as much as it pains
6 me to see good organizations not come out
7 strong, is doing its magic. It is creating
8 the best of organizations to go deeper with
9 their innovation.
10 CO-CHAIR GIFFORD: All right,
11 Darlene, 10 words or less. You said it was
12 short.
13 MS. THOMPSON: It's short, but
14 it's more than 10 words. I'm sorry.
15 I just want to make sure everybody
16 understands that the way that measure is
17 written is that it is either the frequency or
18 the intensity could go down, equates to
19 effective pain management. So, my frequency
20 could go down to rarely, but my intensity
21 could go up to horrible, and that is
22 considered effective pain management.

1 CO-CHAIR GIFFORD: Okay. Make
2 sure that's in the notes, Suzanne, in feedback
3 to RTI.
4 Okay, so we will vote on it.
5 DR. ORDIN: May I --
6 CO-CHAIR GIFFORD: No, vote on the
7 table. No. Vote on the table because we are
8 going to get through the day.
9 DR. ORDIN: This is just a
10 question for everybody and for all the
11 measures. How are we going to explain this to
12 the public? Because I mean I think it is
13 something to see it because of usability. The
14 usability issue is something that should be
15 addressed in the testing.
16 CO-CHAIR GIFFORD: So, the caveat
17 there, so the vote on the table is time-
18 limited without public reporting, because it
19 is not ready for public reporting. We want to
20 see reliability/validity testing, usability
21 testing, understand the cognitive testing,
22 missing data; this issue of the Darlene/Bruce

1 issue of the intensity, frequency, the actual
2 amount on it.
3 Then, if all those are met, we
4 still reserve the right to ask for additional
5 validity testing. That doesn't mean you meet
6 all those and then it gets NQF endorsement.
7 MEMBER NAIERMAN: So, the bottom
8 line is we are not voting for endorsement?
9 CO-CHAIR GIFFORD: No, we're
10 voting for a time-limited endorsement that is
11 not allowed to go forward on public reporting.
12 These guys are going to say you are creating
13 a new category. That's fine. It may get
14 modified as it goes up through.
15 I have a good feeling on how we
16 are going to present this to whatever --
17 what's the Committee? -- CSAC. It seems like
18 they're going to drop the bomb any day, but
19 CSAC, as we go forward on the pain measures
20 out there.
21 I mean you can vote against this.
22 The current motion that I am putting before

1 the group is that, if you don't support that
2 motion, and you want another motion, you can
3 vote against it. Then, it would be
4 actually -- not everybody wants it to go up;
5 it would probably go down to vote no at that
6 point.
7 MS. PACE: One thing, usually with
8 conditions, we first go back to the measure
9 developer to see if they agree to the
10 conditions or give a response to the
11 Committee. Then, you can say, again, you have
12 that option.
13 So, we would tell them what your
14 conditions are, and they would give a response
15 that you would then say yea or nay.
16 CO-CHAIR GIFFORD: And some
17 withdraw after they see the conditions, say,
18 no, we can't do that; it's not feasible or
19 anything else.
20 Okay. Do I need to restate the
21 motion on the table?
22 (No response.)

1 Okay. All in favor of the motion
2 on the table?
3 (Show of hands.)
4 MR. BOISSONNAULT: Which is the
5 time-limited --
6 CO-CHAIR GIFFORD: Time-limited,
7 not reporting -- Bruce, you are the one who
8 said I didn't have to mention it again.
9 (Laughter.)
10 MR. BOISSONNAULT: With the
11 applicable conditions.
12 CO-CHAIR GIFFORD: Yes. Okay.
13 Any opposed?
14 (Show of hands.)
15 One, two, three, four. Four
16 opposed.
17 Any abstaining?
18 Okay, do the opposing people want
19 to, just for the record, dissenting opinion?
20 DR. MEIER: Just to say my name?
21 CO-CHAIR GIFFORD: No, why you
22 have dissenting opinion. You would vote to

1 say not even --

2 DR. MEIER: Not ready for

3 endorsement.

4 CO-CHAIR GIFFORD: Not ready for

5 primetime.

6 DR. MEIER: Yes.

7 CO-CHAIR GIFFORD: So, the four

8 people are not ready for primetime. Okay.

9 That is helpful to know.

10 The other two measures, can we

11 knock those off quickly, so people can get a

12 quick bathroom break, or do we need to take a

13 bathroom break?

14 All right, the other two measures.

15 MEMBER NAIERMAN: This is Naomi

16 Naierman.

17 I really think the issues are very

18 similar. They are not identical, but they are

19 very similar.

20 So, all those conditions I would

21 apply to it, and I would make it, if I can

22 call it a provisional endorsement, I am

1 willing to go that way. But I don't know what
2 you can call it by your rules.
3 MR. BOISSONNAULT: It's limited.
4 MEMBER NAIERMAN: Limited.
5 CO-CHAIR GIFFORD: It is a time-
6 limited that can't be publicly reported --
7 MEMBER NAIERMAN: Yes.
8 CO-CHAIR GIFFORD: -- is the
9 closest thing to a provisional endorsement.
10 MEMBER NAIERMAN: And my interest
11 is to move it along. I really buy into the
12 whole public reporting part.
13 The notion that the measure
14 developers will have a chance to actually
15 reexamine and even redefine this is very
16 encouraging to me. If it doesn't go to the
17 public, it means that it is going to move
18 along and we are going to get some benefit out
19 of it, as opposed to letting it go to sleep
20 and become dormant. So, I am encouraged by
21 that approach.
22 CO-CHAIR GIFFORD: So, the next

1 two measures, we are going to vote
2 collectively together, which is time-limited,
3 no reporting. We want to see
4 reliability/validity testing, the issue about
5 individuals who can and can't respond, missing
6 data. They are not change measures, so we are
7 not going to look at the change measures, but
8 I do think we want to know about the intensity
9 of measures because they do vary. Well, one
10 already takes in intensity concept. And we
11 reserve the right to ask for additional things
12 in the future. It is not blanket endorsement,
13 once they are all met.
14 DR. MEIER: There's just one
15 monkey wrench I want to throw into the works
16 here, and I actually put this into my written
17 comments for both of my measures. That is
18 that, if you actually look at data, and I know
19 this is like challenging an article of faith,
20 that assessment of pain has not been
21 correlated with improved pain outcomes.
22 Several systematic reviews have looked at

1 this. Pain as the fifth vital sign has had no
2 impact on pain outcomes in hospitals.
3 MR. BOISSONNAULT: What do you
4 mean by pain outcomes?
5 DR. MEIER: Levels reported by
6 patients. That is what we are looking at
7 here. That is what we are looking at, and
8 frequency or intensity, prevalence of pain.
9 My point is, why would we measure
10 it if we didn't think it was actionable,
11 right? We don't want to measure things just
12 for the sake of measuring things. We want to
13 measure things that are actionable.
14 So, that assumed link between the
15 process and the outcome, the outcome being the
16 patient-reported level of pain, has not been
17 demonstrated in the scientific literature.
18 CO-CHAIR GIFFORD: So, are you
19 saying there's nothing we can do, as a
20 clinical community, to manage pain?
21 DR. MEIER: Well, measuring it
22 with patients, while a component of it, the

1 most important thing is workforce and
2 education of workforce. That is, obviously,
3 not in our purview. But the assessment of
4 pain in rigorously-designed studies has not
5 been shown to improve pain outcomes.
6 MS. PACE: But treating pain --
7 DR. MEIER: Treating pain does,
8 but the assessment doesn't lead to treatment.
9 That's the problem.
10 MS. PACE: But this is just, what
11 is the pain level? And if it is not good,
12 then that is what you would expect facilities
13 to act on.
14 DR. MEIER: That is a rational,
15 absolutely rational assumption.
16 MR. BOISSONNAULT: But this is so
17 basic. We are paying money and putting
18 patients at risk to give them these pills.
19 And does the patient report, self-report, that
20 it is better?
21 DR. MEIER: Just trying to add
22 some of the data from the literature to the

1 discussion.

2 CO-CHAIR GIFFORD: Diane, I think

3 you are saying that the process measures

4 haven't included outcome. This is an outcome

5 measure. You could interpret it as a process

6 measure, which is an assessment; this is an

7 outcome measure. This is measuring the

8 amount, the level of pain. Now you can say it

9 is a bad outcome measure because it is not

10 well-correlated, it doesn't address it, but

11 this is an outcome measure that we have here.

12 DR. MEIER: But do we want outcome

13 measures that are not actionable?

14 MR. BOISSONNAULT: Take them off

15 the meds. That's the action. If there is not

16 improvement, give them different meds or take

17 them --

18 DR. ZOROWITZ: Well, I don't think

19 the question is whether it is actionable. I

20 think here's where I might disagree a little

21 bit.

22 I think it is an actionable

1 outcome, but I think the interventions
2 necessary to reduce pain require a level of
3 knowledge and expertise that are not widely
4 disseminated, for whatever reasons, without
5 being too critical of providers. Not
6 everybody knows how to manage pain and use
7 that information in order to reduce pain.
8 I think for those that do have the
9 expertise, and that is why we have a whole
10 field of palliative medicine, and I think
11 anybody who is a good practitioner of
12 palliative medicine will tell you that the
13 vast majority of those who have pain can be
14 successfully treated.
15 The fact that we are not doing a
16 job of it in many, if not most, of our
17 facilities doesn't mean that it can't be done,
18 nor does that mean that we shouldn't be
19 measuring it. Because certainly if we don't
20 measure it, they are going to have no
21 incentive to improve care.
22 I think that itself is not a

1 reason to not measure it. I think it is not
2 our job to figure out how to make 15,000
3 facilities in this country adequately treat
4 pain, but I do think it is our job to
5 determine whether this is a valid outcome
6 measure that should be measured.
7 CO-CHAIR GIFFORD: Okay, the
8 motion on the table is --
9 MR. BOISSONNAULT: We've already
10 voted.
11 CO-CHAIR GIFFORD: You voted on
12 these last two? No, we haven't.
13 MR. BOISSONNAULT: Oh, no, not on
14 10 and 11.
15 CO-CHAIR GIFFORD: For 10 and 11,
16 time-limited, not ready for public reporting.
17 Give us more reliability/validity data with
18 additional caveats of understanding between
19 individuals who can self-report/not report,
20 how to treat missing data, and the different
21 intensities out there.
22 All in favor of that?

1 (Show of hands.)

2 All opposed?

3 (Show of hands.)

4 Two opposed.

5 Any abstaining?

6 The two opposing, do you want to

7 give your dissenting, just for the record, so

8 we understand it?

9 DR. MEIER: Not adequate

10 reliability and validity testing for the

11 measure.

12 CO-CHAIR GIFFORD: Okay, we will

13 take a 10-minute break, and we'll come back

14 and we will do pressure ulcers.

15 (Whereupon, the foregoing matter

16 went off the record at 1:46 p.m. and went back

17 on the record at 2:03 p.m.)

18 CO-CHAIR MUELLER: All right,

19 thank you, everyone, for taking your seats.

20 We are going to get started.

21 We are two measures behind time

22 schedule. So, we do need to move along.

1 The measures that we are going to
2 be discussing right now have to do with
3 pressure ulcers, both with short stay and long
4 stay.
5 We will begin with an overview of
6 the measures by the stewards. Then, we will
7 go to the reviewers.
8 MS. CONSTANTINE: Okay, thank you
9 very much. Yes, my microphone is on.
10 In regards to the pressure ulcer
11 measures, the proposed measures report the
12 percentage of stage 2 to 4 pressure ulcers in
13 nursing facilities in both the short-stay and
14 long-stay residents, but they do it in two
15 different ways.
16 The short-stay measure reports on
17 the percentage of pressure ulcers that are new
18 or have not improved, and the long-stay
19 measure reports the prevalence of pressure
20 ulcers in the high-risk population. That is
21 defined by patients with impaired mobility,
22 transfers, or comatose.

1 Pressure ulcers, as we know, are a
2 very serious medical condition. They are one
3 of the most important measures in the quality
4 of care in nursing facilities. They are high-
5 volume and can be high-cost events across the
6 spectrum of healthcare settings from acute
7 hospitals to home health.
8 They may cause a patient
9 discomfort and can lead to serious life-
10 threatening infections, which substantially
11 alter the resident's quality of life and
12 increases the total cost of care.
13 Indicative of the importance of
14 this on a national level is numerous
15 healthcare organizations that have ongoing
16 guideline and educational efforts. This is
17 not an exhaustive listing, but the Joint
18 Commission on the Accreditation of Healthcare
19 Organizations, the Institute of Healthcare
20 Improvement's 5 Million Lives Campaign, CDC's
21 National Center for Health Statistics and
22 National Nursing Home Survey, On-Time Quality

1 Improvement for Long-Term Care Program from
2 AHRQ.
3 Also, NQF is sponsoring the
4 National Voluntary Consensus Standards for
5 developing a framework for measuring quality
6 for prevention and management of pressure
7 ulcers, and the Advancing Excellence Campaign,
8 again, for nursing homes has this as one of
9 the top goals.
10 So, obviously, this is important
11 on a national basis as a clinical issue.
12 Again, the proposed items from the
13 MDS 2.0 to 3.0 have changed significantly.
14 Specifically, the MDS 3.0 items have utilized
15 the definitions of the National Pressure Ulcer
16 Advisory Board and also has the input of the
17 Wound, Ostomy and Continence Nurses Society.
18 Essentially, the MDS 3.0
19 eliminates reverse staging, which doesn't
20 reflect the true pathophysiology of healing of
21 a pressure ulcer. It is based on the deepest
22 anatomical stage. Unstageable pressure ulcers

1 are now a separate item.
2 The number of pressure ulcers that
3 were present on admission is now collected for
4 each stage. And again, probably most
5 important, the definitions are now based on
6 best practices and in accordance with the
7 National Pressure Ulcer Advisory Board.
8 We heard very anecdotally that a
9 lot of nursing facilities were actually
10 reporting or assessing the patient based on
11 2.0, but then, also, utilizing the National
12 Pressure Ulcer Advisory Panel's definition,
13 and sort of assessing two different ways for
14 pressure ulcers.
15 In regards to validity, with the
16 development testing, the kappas were high,
17 .92. And in terms of usability, certainly,
18 this is one of the most important clinical
19 issues for facilities to monitor and,
20 hopefully, improve in terms of their rates.
21 Then, in regards to feasibility,
22 again, this is a CMS-mandated data collection.

1 So, it is very feasible for facilities to
2 collect this data.
3 CO-CHAIR MUELLER: Thank you very
4 much.
5 The primary reviewer for this is
6 Dr. Koren.
7 DR. KOREN: I think that this was
8 probably one of the most comprehensively-
9 documented of the measures that probably came
10 before any of you. It was like really
11 impressive to see the amount of evidence that
12 has been accumulated over many years in
13 support of this as a measure.
14 I think that we all agreed that we
15 were going to accept the importance of it, and
16 I think that you really highlighted that, both
17 from a quality perspective and a cost
18 perspective.
19 Looking at it, and I will just
20 sort of reiterate a little bit what I think
21 Roberta, if that's your name, Roberta said.
22 MS. CONSTANTINE: Yes.

1 DR. KOREN: You know, this is a
2 very clear measure. I think that moving from
3 MDS 2 to MDS 3 will even further clarify it
4 because it is very difficult and there's a lot
5 of sort of subjectivity in stage 1. So, this
6 is now saying stage 2 to 4.
7 It also is something that the data
8 shows that there's huge room for improvement.
9 There is a huge spread in terms of performance
10 between some facilities and others, sort of
11 between 8 percent and 18 percent for pressure
12 ulcers. So, there is a lot of room for
13 improvement.
14 As was also mentioned, MDS 3
15 finally acknowledges the fact that there is no
16 physiologic basis in reverse staging, which is
17 a real relief. And also, one of the things
18 they did in their sort of background lit
19 review was there is no contradictory evidence
20 to this. So, there is nobody out there that
21 sort of says this is questionable or we
22 shouldn't be looking at this.

1 In terms of the weakness of this
2 particular measure, though, I should notice
3 that at this point it is not yet harmonized
4 with the way pressure ulcers are mentioned in
5 other settings, although it was noted that Deb
6 Saliba and others who developed this measure
7 really have taken this under advisement; they
8 are working on it. To the extent that they
9 were able, they have started to try to utilize
10 the same terminology and the same measurement
11 mechanisms.
12 The other thing that was noted was
13 that the pressure ulcer rate does fluctuate in
14 a manner that appears to be independent of
15 care. So, if you look at pressure ulcer
16 rates, you will see seasonal variation. This
17 also occurs with other things, such as weight
18 loss and a couple of other clinical measures.
19 Usually, it is worsening in the
20 winter months. So, one can speculate perhaps
21 that it is related to sort of the burden of
22 respiratory disease, or whatever. Maybe the

1 denominator is changing relative to the
2 denominator of the acuity of the population
3 during those periods.
4 And another question that I had,
5 and maybe somebody can explain this, is if one
6 comes in with the expectation that you are a
7 short-stay resident and you develop a pressure
8 ulcer, let's say, 50 days into your stay, and
9 you end up staying more than 100 days, are you
10 still counted as a short-stay person who has,
11 in fact, developed a pressure ulcer?
12 So, that was something that I was
13 wondering about from sort of an accounting
14 perspective, because you could well be tipped
15 over into, oh, now they're a long stay, so we
16 don't count that, but, in fact, they are
17 short-stays who have developed something. So,
18 I think that that is something to be looked at
19 a little bit.
20 They also noted that pressure
21 ulcers are not well-correlated with other
22 quality measures, but that is not a new

1 finding. We know that. Many researchers have
2 kind of looked into that and tried to do
3 aggregations, but it has been very difficult.
4 There was also a question that I
5 had which appeared on page 15, and maybe,
6 Roberta, you can answer this. It says, "While
7 the variation in rate among states makes it
8 difficult to compare facilities between
9 states, the measure remains a valuable guide
10 between facilities within the same state."
11 And I didn't understand that at all. So, that
12 would be very helpful, if you could explain
13 that. That is on the bottom of page 15.
14 MS. CONSTANTINE: Fifteen? And is
15 that the short stay or the long stay?
16 DR. KOREN: That is on the short
17 stay.
18 MS. CONSTANTINE: Okay.
19 DR. KOREN: And you don't have to
20 answer it now, but, anyway, it was something
21 that kind of jumped out at me.
22 So, if I briefly went through sort

1 of my voting on this, by and large, obviously,
2 as I said, I thought it completely answered
3 the question about opportunity for
4 improvement, that there is huge amounts of
5 evidence for this particular thing. What
6 else?
7 Obviously, it focuses on an
8 outcome, not a process measure. And let's
9 see, others? Maybe it would be just easier to
10 say that, except for that one area, that there
11 are a couple of not applicables. Comparable
12 or multiple data sources was felt to be not
13 applicable. I don't disagree with that.
14 So, generally speaking, I think
15 that this really, except for the harmonization
16 issue, I think that this pretty completely
17 meets the kind of criteria that you would want
18 to see in a measure.
19 I did talk briefly with Lisa, but
20 I will let her speak for herself on this one.
21 MS. TRIPP: Yes, Mary Jane and I
22 did speak about this. I agree with really

1 everything that she said.
2 This is an unusual situation
3 because we know we have a better method for
4 doing something. We know the staging method
5 is better. And we also had, I think, a
6 clearer issue that we are testing by
7 eliminating stage 1.
8 So, we are lucky that we got this
9 one -- because I think it is a clear winner,
10 so to speak. I gave it completes on all four
11 criteria, and I believe Mary Jane did as well.
12 CO-CHAIR MUELLER: Great. Thank
13 you very much.
14 Do you want to answer some of the
15 questions she posed before we open it up to
16 the group?
17 MS. CONSTANTINE: Sure. One of
18 your questions had to do with seasonal
19 variation. We did discuss that in our initial
20 TEP, but it didn't seem like there was such
21 substantial seasonal variation. With other
22 measures, what we have done is actually report

1 on the quarter and take six months of data,
2 but that is certainly something that we could
3 take back and consider.
4 DR. KOREN: We've been tracking
5 pressure ulcer rates for Advancing Excellence.
6 While the trendline has been going down, we do
7 see that seasonal variation because we now
8 have three years of data, and we see it there,
9 too.
10 MS. CONSTANTINE: Sure, we could
11 certainly do that.
12 And in regards to harmonization, I
13 think everybody who has had to address
14 pressure ulcers and has worked on assessment
15 improvement, it is ongoing; it is almost as
16 soon as you write something, something else
17 might be happening in terms of a measure.
18 We look at what NQF had in regards
19 to a paper coming out, and we would expect
20 that going forward we would attempt to
21 harmonize with anything for NQF.
22 DR. KOREN: One other comment I

1 would make is that, having been working with
2 this particular measure on Advancing
3 Excellence, as well as several other things,
4 this has been an area that has been
5 particularly resistant to improvement. So,
6 while it is useful and helpful to count the
7 numbers, we really have to start focusing on
8 why it is not going down.
9 You know, there's been sort of
10 marginal improvements, and it has improved a
11 little bit in some places. But even in some
12 states where it appeared to be improving, it
13 has gone back up again.
14 Part of that, we have also tried
15 to look at the denominator. If you track the
16 denominator over three years, the overall
17 denominator for acuity of nursing home
18 residents is rising. So, part of the
19 resistance to change may well be that we are
20 seeing a different population than we had
21 three years ago. As I said, we have been
22 tracking that. But, nevertheless, it really

1 hasn't gone down to the extent that we know it
2 probably could go down.
3 MEMBER NAIERMAN: Can I just ask a
4 quick question to follow up to that? Is it
5 related to anything like staffing mix or
6 staffing patterns?
7 DR. KOREN: I don't have the
8 answer to that. I don't know.
9 CO-CHAIR MUELLER: Okay. There is
10 a study, though, by Susan Horn that looked at
11 the relationship between pressure ulcers and
12 staffing, and there was a relationship between
13 RN staffing, and better RN staffing is fewer
14 pressure ulcers.
15 Other comments from the Committee
16 or questions, issues?
17 (No response.)
18 Really?
19 (Laughter.)
20 DR. MODAWAL: Did I hear stage 2
21 and 4? Why not the first stage?
22 MS. CONSTANTINE: Oh, what about

1 the first stage?
2 DR. MODAWAL: Yes.
3 MS. CONSTANTINE: When we
4 initially had our Technical Expert Panel, we
5 asked specifically about that because there's
6 a lot in the literature in regards to whether
7 stage 1 is really reliable, especially
8 assessing in darker-skinned patients. And
9 also, we found that, in a sense, you are sort
10 of, for lack of a better word, dinging
11 facilities for recognizing stage 1 ulcers.
12 Also, some of the literature, like, for
13 example, Dr. Joanne Lynn, who has done
14 research with pressure ulcers, has mentioned
15 that you could almost look at a stage 1 as
16 high-risk.
17 So, as we brought this to the TEP,
18 and after discussion, it was thought the
19 important thing was to focus on the stage 2 to
20 4 and let the stage 1 go in terms of
21 reporting.
22 DR. MODAWAL: Well, you know, as a

1 quality measure, if you are looking at the
2 impact, and we are not making much progress
3 unless we have some NASA technology and become
4 rate-free, the pressure ulcers will always
5 happen. They are preventable up to a certain
6 extent.
7 But I think if you are really
8 thinking of prevention and improvement in the
9 care overall, all stages should be included
10 because everything starts with stage 1. And
11 if you miss it, then it may be too late. This
12 is similar to what happens with falls. It
13 doesn't matter whether it is minor or major;
14 you have to have all the processes in place.
15 CO-CHAIR MUELLER: Any other
16 comments?
17 DR. ZOROWITZ: I would just like
18 to add to that. I think part of the problem
19 with stage 1's is that they can be
20 overdiagnosed sometimes. I think there is a
21 lot of confusion between stage 1 ulcers and
22 candidal rashes and minor bruises. So, I

1 think the reliability is in question.
2 I think this should be sufficient.
3 If a stage 1 is found and it is quickly
4 treated, they are usually pretty easily
5 reversible, if it is really a stage 1. If it
6 becomes a stage 2, then it is going to be
7 counted, and I think a quality measure is
8 going to be a lot more accurate, excluding
9 stage 1's, and I don't think including stage
10 1's would improve the measure that much. I
11 think it would hurt it. So, I would agree
12 with the way the measure is written.
13 DR. SCHUMACHER: And just a
14 comment. I am not sure the question that Dr.
15 Koren posed about state variability was
16 addressed. I think it related to validity.
17 I think the point that was made in there was
18 that there is a lot of variability from state
19 to state. So, that when you are trying to
20 compare a facility in one state to a facility
21 in another state, that there might be some
22 difficulty there, but that within the same

1 state it has high validity.

2 CO-CHAIR MUELLER: Mary Jane, has

3 Advancing Excellence seen any variation in

4 states?

5 DR. KOREN: We do. I mean,

6 obviously, there are very high pressure ulcer

7 states and there are very low pressure ulcer

8 states. Some of what we are finding is that

9 the impact of sort of a coalition of

10 stakeholders kind of really focusing on this

11 problem and really working on it really does

12 seem to have an effect, but it is a very hard

13 effect to continue and to sustain.

14 We saw this problem in New Jersey,

15 for example. They had sort of come together

16 and decided that pressure ulcers was not

17 solely a problem of a single setting. So,

18 they got the hospital people and the ER people

19 and the ambulance people and home care people,

20 and everybody together to kind of help

21 together solve the problem, and the numbers

22 went down. Then, the thing fell apart, and

1 now the numbers are going up again. So, it is
2 one of those things that you have to
3 constantly stay on top of.
4 MS. CONSTANTINE: I was going to
5 mention one thing that we saw time and time
6 again in the literature, is that it is the
7 ongoing monitoring and surveillance and the
8 constant sort of day-in and day-out and the
9 focus, an ongoing focus, which is difficult
10 for the facilities for sure, but so important.
11 CO-CHAIR MUELLER: Okay, are we
12 ready for --
13 DR. KOREN: One other comment to
14 make is that we assume that it is all about
15 pressure, but it is as much about management
16 of skin moisture, hydration, nutrition, a
17 number of other factors, even use of lift
18 devices in facilities. In places that are
19 using mechanical lifts, there's less because
20 they are not dragging people on sheets.
21 So, there are a lot of things that
22 we really need to start to think about that

1 could prevent these things that we are
2 ignoring because we think it is all about
3 pressure.
4 CO-CHAIR MUELLER: Very good
5 point.
6 Are we ready for a vote?
7 This is a vote for endorsing a
8 time-limited measure, which means it has not
9 been tested because it is based on the 3.0,
10 and that it satisfies most of the evaluation
11 criteria. I think our reviewers have
12 essentially said it satisfies all the
13 criteria, except for the harmonization.
14 So, given that, all those in favor
15 of supporting this as a time-limited
16 endorsement, please raise your hand.
17 (Show of hands.)
18 All those no?
19 Abstain?
20 Great.
21 So, we'll go to the second
22 measure. That is for the long-stay residents,

1 and I believe, Dr. Zorowitz, you are the lead
2 on that.
3 You are okay? You've said
4 everything you needed to say?
5 MS. CONSTANTINE: Yes.
6 CO-CHAIR MUELLER: Okay. Okay, go
7 ahead.
8 DR. ZOROWITZ: I'm very fortunate
9 because Dr. Koren has prefaced hers with many
10 of the same remarks I would make myself.
11 So, this is percent of high-risk
12 residents with pressure ulcers, long stay
13 defined as 100 days or greater. It is already
14 being measured in the current set of quality
15 measures based on MDS 2.0, but has many of the
16 problems which I think Mary Jane mentioned,
17 such as addition of stage 1, reverse staging,
18 et cetera, which have now been eliminated.
19 I think the nice thing about the
20 MDS 3.0 is that it is consistent with NPUAP
21 standards and with the way that most
22 reasonable nursing homes are staging their

1 ulcers and identifying them. So, I do think
2 that it is ready for primetime.
3 Importance, I think I don't need
4 to say very much about. I think we would all
5 agree that it is an extremely important
6 measure of quality.
7 I do want to point out the
8 evidence for interventions is, while
9 accumulating, and there's a fairly extensive
10 literature on prevention and treatment of
11 pressure ulcers, it is not completely
12 persuasive. There are facilities that do
13 better jobs and there are facilities that do
14 worst jobs, but there's still plenty of
15 studies that show that, even with
16 comprehensive programs to prevent and treat
17 pressure ulcers, that they are not 100 percent
18 preventable and they are not 100 percent
19 curable.
20 But that notwithstanding, I think
21 we would probably all agree that there is
22 tremendous potential, based on current

1 literature, for improvement in treatment and
2 management of pressure ulcers.
3 The guidelines that are out there,
4 one of the more current guidelines is AMDA's
5 guideline, are quite extensive, and there have
6 been guidelines for many years. They are
7 technically clinical guidelines.
8 I know the AMDA guideline, which
9 is excellent, doesn't really rate the evidence
10 that it uses for its guideline. It is based
11 more on clinical expertise and consensus than
12 it is on the strength of evidence. But I
13 think that if you actually look at the
14 literature backing it up, it is fairly strong
15 qualitatively.
16 Scientific acceptability,
17 therefore, I said was partial, but I think it
18 is more positive than negative. Complete I
19 think would require that there really be
20 rigorous, double-blind randomized studies that
21 we could point to that say, yes, this is
22 preventable and this is treatable 100 percent,

1 but we don't quite have that yet.

2 One question I had was that the

3 high-risk population, now I guess we are doing

4 away with the percent of low-risk residents

5 because of a variety of issues. This is high-

6 risk residents, which are defined as those who

7 are comatose, impaired in-bed mobility, or

8 transfer or suffering from malnutrition. That

9 has been fairly well validated in MDS 2.0.

10 But I don't know whether that has been

11 correlated with the Braden or the Norton

12 scales or other commonly-used scales of risk.

13 And the issue that both Kathleen

14 and I had when we looked at this is that

15 malnutrition is not defined in this except to

16 say that if it is listed as a diagnosis on the

17 MDS, and to the best of our knowledge, it is

18 rarely used as a definition. It is rarely

19 listed as a diagnosis. So, I don't know how

20 good that is going to be as an indicator of a

21 high-risk population.

22 I should point out, also, that

1 there is an item on the MDS 3.0 asking whether
2 a risk assessment has been done, yes or no.
3 That doesn't come into play at all with
4 identifying patients at risk, which I found a
5 little bit surprising. Well, maybe not
6 surprising because it hasn't been tested, but
7 that is something that probably ought to be
8 tested going forward.
9 So far as usability, I think we
10 agreed that this met the criteria completely.
11 I think this meets the standard of
12 identification and classification of pressure
13 ulcers. There's nothing in the MDS 3.0 that
14 shouldn't be consistent with the way most
15 facilities should be identifying pressure
16 ulcers now. And feasibility we also felt was
17 complete.
18 We did have one concern, and this
19 I think is also true of the current system,
20 that residents who are admitted with very
21 large, very bad stage 4 ulcers, which may not
22 be expected to heal within 100 days, are going

1 to end up counted in this number. So, I think
2 that is a weakness of this. How much that is
3 going to impact, I don't know, but that is a
4 weakness. I didn't see a mechanism for
5 excluding such ulcers on admission. That is
6 not in the exclusion criteria.
7 All that having been said, though,
8 let me go to my other comments. I think I
9 pretty much covered everything.
10 Strengths, we said that the data
11 is fairly easy to collect since it is part of
12 the usual assessment of patients. Weaknesses,
13 MDS 3.0 hasn't been rolled out yet. It is
14 still unclear whether there will be
15 discrepancies in completion of the skin care
16 items, but that is common with all of these
17 measures that are going to be based on 3.0.
18 Having said all that, we decided
19 that we would recommend the measure for
20 endorsement.
21 CO-CHAIR MUELLER: Kathleen,
22 anything to add?

1 DR. NIEDERT: No, I think our main
2 concern is those people that are on end-of-
3 life process that come in that have come in
4 with stage 4's and, yet, we are going to get
5 dinged on that, even though there's probably
6 nothing that we are going to do about it.
7 Obviously, being a dietician
8 originally in my career, the malnutrition
9 issue was extremely a high impact because of
10 anemia and all of the things. You know,
11 people always assume malnutrition means
12 essentially sarcopenia, when really obesity
13 can be malnutrition. I think a lot of times
14 we think of that person that is anorexic,
15 cachectic, not the person that is a bariatric-
16 type situation, where we really need to be
17 watching because part of the time we can't
18 even find the open areas, I mean sadly.
19 DR. ZOROWITZ: I hope in the
20 future that there will be further study on the
21 MDS 3.0. There are probably a number of items
22 on the MDS 3.0 that cumulatively will give a

1 better indication of high risk. I think this
2 is a fairy simplistic definition of high-risk
3 patients, but I think it is what we have now,
4 and I would not stop the measure for that.
5 But I do hope that in the future perhaps it
6 can be a little bit more precise.
7 DR. NIEDERT: We expand the
8 definition.
9 DR. ZOROWITZ: Yes.
10 DR. NIEDERT: The description.
11 CO-CHAIR MUELLER: Thank you for
12 the nice overview.
13 Any comments from the Committee or
14 questions?
15 DR. ORDIN: Yes, I have a
16 question. Would you recommend that an element
17 be added to 3.0 to actually have a risk score
18 or to say whatever scaling score used, you
19 know, is there a way to add whether the person
20 is at high risk, scores at high risk? Would
21 that be helpful?
22 DR. ZOROWITZ: Well, right now

1 there's an element yes or no whether a risk
2 assessment has been done, and that is really
3 it. I think if you took -- and I'm just doing
4 this off the top of my head -- I suspect that
5 if you took an established, a validated risk
6 instrument such as Braden and looked at MDS
7 3.0, you would probably be able to test out
8 some of the items to see if there were
9 correlation. But that is just off the top of
10 my head.
11 That is the kind of research I
12 would recommend going forward. But would I
13 like to see a full risk assessment on the MDS
14 3.0?
15 DR. ORDIN: No, I wasn't
16 suggesting that. Was the risk assessment
17 done, yes/no? What did it show? High risk --
18 DR. ZOROWITZ: It doesn't. It
19 doesn't say --
20 DR. ORDIN: No, but I'm saying, I
21 mean --
22 DR. ZOROWITZ: Well, the question

1 was, was the patient at risk or not? The
2 question is, was the patient at risk or not?
3 And it is not stratified as to low risk,
4 medium risk, high risk. It is just, are they
5 at risk or not, is the way the question is
6 worded, I believe. I don't have the MDS in
7 front of me.
8 CO-CHAIR MUELLER: We'll let our
9 comment from --
10 DR. NIEDERT: Well, the other
11 issue is probably, as an administrator in a
12 nursing home for several years, I don't know
13 of any nursing home that is not doing a risk
14 assessment for pressure ulcers when they first
15 come in, whether it is the Briggs form, you
16 know, something. We are doing something to
17 say that that person is at risk, and using the
18 overlays or air relief mattresses, or
19 whatever. I'm not a nurse, so I can't tell
20 you all the things that nursing uses, but I
21 know that it is done.
22 DR. LING: So, your memory is

1 intact because item MO150, is the resident at
2 risk of developing pressure ulcers? It is a
3 yes or no. And the instructional guidance
4 includes the recommendation to determine if
5 the resident is at risk for developing a
6 pressure ulcer.
7 If the medical record reveals that
8 there's currently a stage 1 or greater
9 pressure ulcer, scar, or bony prominence, et
10 cetera, and review formal risk assessment tool
11 to determine if the resident, what their risk
12 score is, and review the components of the
13 clinical assessment conducted for the evidence
14 of pressure ulcer risk. So, all that is kind
15 of rolled into and lumped into yes or no.
16 CO-CHAIR MUELLER: Thank you,
17 Shari.
18 DR. ZOROWITZ: But I don't know
19 how helpful that is because, as I said, it is
20 not stratified. So, we are talking about high
21 risk, and high risk is not identified in that
22 question. It is just, are they at risk, yes

1 or no?
2 MR. BOISSONNAULT: As it relates
3 to CMS, some nursing homes probably are going
4 to have populations that are tougher. I'm
5 really not actually interested in recommending
6 personally a risk-adjusted rate for this,
7 because if you know you have a patient that
8 you need to do more for to keep them from
9 getting a pressure ulcer, we actually would
10 kind of hope you wouldn't say, well, they are
11 not going to count against us anyway because
12 we risk-adjusted them out.
13 If at some point we can identify
14 who is absolutely going to get them or who has
15 a 90 percent chance, I would love to say, you
16 know, this person is over 400 pounds or their
17 BMI is 72, or something, and therefore, we are
18 going to throw them out of the sample. But I
19 think risk adjustment of this measure might be
20 risk adjusting away something we would
21 actually like the staffs to do.
22 DR. ZOROWITZ: And I don't think

1 it is possible. I think there are places that
2 have very high-risk residents that don't get
3 pressure ulcers. Even within a facility,
4 there are high-risk residents that are free of
5 pressure ulcers and high-risk residents that
6 get them, and there are so many factors, as
7 Mary Jane pointed out.
8 We don't always know why the one
9 that got them got them, other than: did you
10 turn and position them? Were they on a
11 pressure-reducing mattress? How's their
12 nutrition, hydration? We could look at all
13 that, but sometimes we just don't know. I
14 don't think the science is at the point where
15 we can predict with any accuracy someone is
16 definitely going to get them or someone is
17 definitely not going to get them.
18 CO-CHAIR MUELLER: I remember at
19 the end of our agenda tomorrow there is a
20 place where we can talk about recommendations
21 for future research. So, we would want to
22 hold that thought.

1 Any other comments?
2 SISTER HEERY: I think those
3 comments, you know, those questions, are they
4 at risk, or just to stop and point out that
5 you should be care planning at that point. I
6 don't think it is to pull it all together. It
7 is just a pointer that you need to stop as a
8 clinician and look deeper. So, I think that
9 is what the MDS 3 is intending on those
10 questions.
11 CO-CHAIR MUELLER: Lisa?
12 MS. TRIPP: Yes, I was just
13 wondering, what is the rationale for limiting
14 this to high-risk residents only?
15 MS. CONSTANTINE: Well, initially,
16 there were two reported measures, both the
17 high- and the low-risk. When we addressed it
18 with the TEP, the low-risk, the mean was 2.3
19 percent. I think it was based on 2007 data,
20 and the standard deviation was 2.8 percent.
21 At the 50th percentile, it was like 1.9
22 percent was the triggering rate, and for

1 facilities that had zero percent, it was like
2 about 40 percent.
3 MS. TRIPP: If you had to
4 translate that into a different type of speak,
5 what would you be saying?
6 (Laughter.)
7 MS. CONSTANTINE: I'm sorry.
8 MS. TRIPP: That's okay.
9 MS. CONSTANTINE: Essentially, in
10 regards to the reportability of the measure
11 and how usable it would be, for low-risk
12 patients it was, you know, really in terms of
13 measurement, not enough facilities could even
14 report their low risk. So, henceforth, the
15 focus on the high-risk patients.
16 MS. TRIPP: Okay, thank you.
17 DR. ZOROWITZ: I believe it will
18 still remain a sentinel event if a low-risk
19 patient gets a pressure ulcer. So, the
20 facilities aren't off the hook altogether just
21 because the measure has gone away.
22 MS. CONSTANTINE: Right, but not

1 publicly reported.
2 CO-CHAIR MUELLER: Is the group
3 ready for a vote?
4 Okay. Again, I would remind you,
5 first of all, our two reviewers have indicated
6 complete on all four criteria.
7 DR. ZOROWITZ: Well, partial on
8 scientific acceptability.
9 CO-CHAIR MUELLER: Partial on
10 scientific acceptability, which is one of the
11 reasons it is recommended for time-limited
12 endorsement. So, we would be voting on time-
13 limited endorsement for pressure ulcers in a
14 long-stay population.
15 All those in favor, please raise
16 your hand.
17 (Show of hands.)
18 No, raise your hand.
19 Abstaining?
20 Okay, we have two. Yes.
21 We are supposed to take a break,
22 but I think we did that. So, we are going to

1 be moving on to the immunization measures.
2 And just let me get my act together here. So,
3 that would be another representative from CMS.
4 And our first one is 14-10,
5 percent of residents who were assessed and
6 given seasonal influenza vaccination during
7 the flu season. This is for short stay.
8 Are you going to speak to all of
9 the immunization?
10 CO-CHAIR GIFFORD: Well, actually,
11 let's just do the influenza --
12 CO-CHAIR MUELLER: Oh, okay.
13 CO-CHAIR GIFFORD: -- short and
14 long stay together.
15 CO-CHAIR MUELLER: Okay.
16 CO-CHAIR GIFFORD: Then, we will
17 do pneumococcal short and long stay together.
18 Some of the timing issues may be the same, but
19 I think some of the other stuff is different.
20 MS. BERNARD: Yes. Some of my
21 comments will be very similar, but I will
22 begin with the influenza vaccines.

1 So, I'm Shula Bernard from RTI.
2 Good afternoon.
3 The two influenza vaccines, the
4 first one is for short stay; the second one is
5 for long stay. I think short stay and long
6 stay has been defined extensively all
7 throughout the day. So, I won't belabor that.
8 In deference to the time and Dr.
9 Gifford's request that we not go over and over
10 about the high impact, suffice it to say that
11 frail elders are particularly vulnerable to
12 complications of influenza. According to CDC,
13 more than 200,000 people in the United States
14 each year are hospitalized as the result of
15 complications. Among the adults 65 and older,
16 about 72 percent were vaccinated during the
17 2006-2007 influenza season, which is below the
18 Healthy People 2010 target of 90 percent for
19 this age group.
20 The MDS 2.0 data used to publicly
21 report on influenza vaccination, the quality
22 measure, shows that the first quarter of 2007

1 statewide averages for the short-stay
2 population ranged from 57 percent to 85
3 percent with a 73 percent national average.
4 So, there is variability in performance on
5 this measure. The Nursing Home Compare, the
6 national average for the percent of short-stay
7 residents given influenza vaccine has
8 increased to 82 percent.
9 Among the long-stay population,
10 the range is from 76 percent to 96 percent.
11 So, there is a difference between the short-
12 stay and the long-stay proportions, which is
13 an argument for us having two different
14 measures, one for each population.
15 And also, the current information
16 of the Nursing Home Compare shows the national
17 average for the percent of long-stay residents
18 given the influenza vaccine increasing to 90
19 percent. So, the public reporting of this
20 measure, whether it is causal or not, has been
21 associated with an increase in the adherence
22 to vaccination.

1 What I would like to emphasize
2 about this is that this measure is essentially
3 unchanged from the MDS 2.0 going to 3.0 with
4 an exception. The exception is that there are
5 additions to the numerator and denominator
6 that were done in order to harmonize the
7 measure to the NQF vaccine measure.
8 So, as a result, the 3.0 will be
9 harmonized with the MDS. So, this is a
10 previously-endorsed measure that we think as
11 a result of going to the 3.0 will make it more
12 consistent with the NQF measure.
13 The other areas of importance, or
14 not importance, but to consideration for this
15 panel is the usability. These measures have
16 a history of being used. Obviously, some of
17 the percentages that I quoted to you showed
18 some association with an increase in
19 vaccination, perhaps as a result of the
20 measure and the reporting of the measure.
21 The feasibility, data for the
22 measure have been collected and will continue

1 to be collected in the same manner in the MDS
2 2.0 and MDS 3.0.
3 So, I will now leave you to
4 discussion.
5 MS. PACE: Just one point of
6 clarification. On the numerator component,
7 the standard specifications indicate that
8 those are supposed to be computed and reported
9 separately. It looks as if, at least the way
10 this is written up, that it is all combined
11 into one total numerator.
12 MS. BERNARD: Combined for the --
13 MS. PACE: For the different
14 categories. The standard specifications are
15 that you report on those who actually received
16 the vaccine, those who were offered and
17 declined, and those who had medical
18 contraindications.
19 But the way it looks, the way you
20 have written up the specifications is that you
21 are adding those all up to get one rate. That
22 is not consistent with our standards.

1 MS. BERNARD: With NQF, yes.
2 Thank you. We will need to clarify that, to
3 indicate that, what the harmonization is to be
4 consistent with the NQF.
5 MS. PACE: Right. So that is
6 still going to be possible. I just want to
7 make sure because the prior nursing home
8 measure actually did kind of lay it out that
9 way.
10 CO-CHAIR GIFFORD: What we have
11 before us in writing is not what you are going
12 to propose then?
13 MS. BERNARD: No.
14 CO-CHAIR GIFFORD: I'm confused.
15 MS. BERNARD: Let me just revisit
16 that a second while we look at it. Let me
17 look at the definition with you and just see
18 what your question is.
19 MS. PACE: Right. Okay. So, if
20 we look at the numerator statement --
21 CO-CHAIR GIFFORD: That's in
22 writing.

1 MS. PACE: Right. Okay.
2 MS. BERNARD: Okay.
3 CO-CHAIR GIFFORD: That is not
4 harmonized with NQF? Is that what you are
5 saying?
6 MS. PACE: Right. So, the
7 elements are. So, those are received during
8 the most recent, either the facility or
9 outside the facility, the number who were
10 offered and declined and the number who were
11 ineligible. The only distinction is in the
12 standard specifications we want each of those
13 computed and reported separately.
14 MR. BOISSONNAULT: So, one is a
15 separate measure, two is a separate measure,
16 and three is a separate measure, all with the
17 same denominator?
18 MS. PACE: Correct.
19 MR. BOISSONNAULT: Which I think
20 is a clarification, not a change.
21 CO-CHAIR GIFFORD: It's like the
22 staffing measure.

1 MR. BOISSONNAULT: The commas did
2 not mean -- yes.
3 MS. BERNARD: Yes, that is the way
4 that it -- so, we would need to clarify that,
5 but it is consistent with the NQF. So, if the
6 commas are not in the right place, they will
7 be.
8 MS. PACE: Right. Let me just
9 give you a little history about it.
10 MS. BERNARD: Okay.
11 MS. PACE: There was a lot of
12 discussion. You know, we had lots of
13 different immunization measures and a lot of
14 different ways that people handled patient
15 refusal. Some were excluding it from the
16 denominator. Some were counting it in the
17 numerator.
18 And the Steering Committee on that
19 project said that we need to be very
20 transparent about how these are -- and,
21 ultimately, the thing that we are most
22 interested in are those who are actually

1 getting vaccinated.
2 So, in order to kind of address
3 all of the issues, so this is a harmonization
4 and a compromise kind of thing, but to
5 actually have those all in the numerator, but
6 separate components. So that you could very
7 clearly see that facilities differ on actual
8 vaccination rates. So, you could actually see
9 those.
10 MS. BERNARD: Yes, and 2 percent
11 declined.
12 MS. PACE: Right. Right.
13 MS. BERNARD: And that's the way
14 this is constructed.
15 MR. BOISSONNAULT: Just a
16 question. In the NQF specification that we
17 want to harmonize or that I believe CMS wants
18 to harmonize to, is there also a total of one
19 plus two plus three, the overall? Okay. So,
20 it is not one and two and three and the sum.
21 It is just one and two and three with the
22 exclusions and definitions tied tightly to the

1 NQF definition that already exists.
2 MS. PACE: Right.
3 MR. BOISSONNAULT: Okay.
4 MS. BERNARD: And there's a
5 separate ratio relative to the denominator,
6 which is everyone in a facility, one
7 denominator.
8 DR. ORDIN: So, I have a question
9 about the NQF consensus recommendations. I
10 mean I know it says you need the three, but is
11 it wrong to add them up? Because, in the end,
12 you really want to know -- I mean, first of
13 all, I always want to shine a light on
14 refusals because we look at this in the VA,
15 and if you don't, the number of refusals go up
16 and they get hidden when they are subtracted
17 from the denominator. So, I think it is
18 really important to have those three.
19 But for looking at the website and
20 understanding this for the public, I think it
21 is very helpful to have what proportion of the
22 time was the right thing done, whether that is

1 appropriately not giving it or appropriately
2 giving it.
3 So, are you not allowed to report
4 it?
5 MS. PACE: The standard
6 specifications actually do say computed and
7 reported separately and not to be totaled.
8 Because once you total, you start obscuring
9 those things. Discussion at the Steering
10 Committee for that project was that the whole
11 category of patient refusal is a very fuzzy
12 area and practices around that are quite fuzzy
13 on what's counted as a refusal versus -- you
14 know.
15 So, anyway, they really felt
16 pretty strongly that they needed to be
17 computed and reported separately. This gets
18 into the area of what control NQF has over
19 once measures get out there, but that is how
20 the specifications are, that that is the
21 recommendation.
22 And if you can't do all of those,

1 because, for example, claims-based measures
2 don't know the refusals, then the main thing
3 is that that element of patient vaccination
4 actually is consistent. So, at least you can
5 report that component. That was the thinking
6 of that Committee.
7 CO-CHAIR MUELLER: Bruce, you are
8 the primary reviewer on this. So, would you
9 like to proceed?
10 MR. BOISSONNAULT: I gave the
11 measure all completes. I have just a couple
12 of remarks.
13 By the way, I would modify it with
14 the proviso that was just described, that it
15 actually be reported in a way that is in
16 harmony with existing NQF measures, but I
17 think that is a clarification, not a change.
18 So, that is sort of for the record.
19 Interestingly, Diana said
20 something that I am going to say here. In my
21 notes, I said there's an opportunity for
22 gaming. Why exclude the case if it is blank?

1 I like what we concluded before, which is, in
2 the absence of any underlying, overriding
3 reason rewarding someone for leaving an
4 information cell blank, it seems to me
5 counterproductive. So, whatever mechanism
6 that the Co-Chairs think is reasonable, I
7 would have added that proviso.
8 CO-CHAIR MUELLER: Don't the
9 guidelines say that?
10 MS. PACE: It is not part of the
11 standard specification.
12 MR. BOISSONNAULT: In this, it
13 says blank; it gets excluded.
14 MS. PACE: No, I understand. I'm
15 just saying the NQF --
16 MR. BOISSONNAULT: Right, and I
17 think where there's no a reason to do that, I
18 had the same note.
19 I do have one question, having
20 said all complete. I like the measure. This
21 is a process measure that approaches being an
22 outcomes measure just because of the strength

1 of the science. And I'm not one to say that
2 often.
3 But it looks to me like the
4 measure is going to be based on deciles or
5 quartiles as opposed to some sort of
6 significance testing. In my world, sometimes
7 that leads to highlighting differences or
8 distinctions without a difference. That is
9 why we never rank hospitals, because hospital
10 No. 9 is never actually statistically-
11 significantly better than hospital No. 10.
12 So, we always compare to the mean.
13 So, I don't know if as the
14 measures developer you could talk to why you
15 explicitly sort of excluded the notion of
16 significance testing. That is my report.
17 CO-CHAIR MUELLER: Patricia, did
18 you have anything to also add?
19 MS. ROSENBAUM: No, I don't think
20 so. I agree. I agree with that, pretty much
21 what he verbalized about that.
22 CO-CHAIR MUELLER: Go ahead, Bill.

1 MR. KUBAT: Yes, just a comment.
2 Bill Kubat.
3 Maybe Bruce or Trish can help me
4 with this one. I am supportive of it as well,
5 but it always struck me, even when it came
6 around the first time, and what I see in the
7 documentation seems to bear this out. They
8 talk about guarded validity. It is almost as
9 much more of a public health interest measure
10 than it is a quality improvement measure. It
11 has always been a struggle in terms of
12 facilities and for the public.
13 The extent to which the measure
14 differentiates good and poor facilities, good
15 and poor care processes, and so forth, and how
16 that reflects in terms of the scientific
17 methodology and the usefulness, because one of
18 the things that we do also with the usefulness
19 is, well, it is already out there. I mean it
20 is already on the Compare website now. CMS
21 wants us to use it for quality improvement.
22 So, therefore, it is useful. Well, I mean it

1 is grandfathered.

2 MR. BOISSONNAULT: Could you,

3 because I remember seeing guarded validity,

4 too, and I don't remember what my notes say.

5 Do you have it in front of you by any chance,

6 where it is? Or can you do a quick word

7 search on "guarded"?

8 MR. KUBAT: It is on page 11.

9 MR. BOISSONNAULT: I thought

10 "guarded" was referencing a limited piece.

11 MS. ROSENBAUM: It's the

12 University of Colorado consistently gave

13 "guarded" for a lot of these immunizations,

14 which was a problem for me. I couldn't

15 understand what they meant by that "guarded

16 validity".

17 MR. KUBAT: It's in 2(b).

18 MR. BOISSONNAULT: Yes. Or "not

19 to be"; that is the question.

20 (Laughter.)

21 MR. KUBAT: "Influenza measure for

22 short-stay residents received a rate of

1 guarded for validity testing."

2 MR. BOISSONNAULT: The word

3 "guarded" is circled.

4 MS. GAGE: It had a level of

5 statistical significance that was a

6 borderline. So, they didn't want to go so far

7 as to say always consistent was statistically-

8 significant, but it was within the area that

9 it was considered strong. But that is why it

10 was identified as guarded.

11 CO-CHAIR GIFFORD: What metric are

12 they using? It is not U.S. Preventive Task

13 Force. I mean somehow they have "guarded" in

14 quotes. It is some metric of --

15 MS. GAGE: They had tested the --

16 CO-CHAIR GIFFORD: No, I'm saying,

17 what metric they used?

18 MS. BERNARD: They didn't use U.S.

19 Prevention Task Force.

20 CO-CHAIR GIFFORD: They just

21 created their own rating metric? "Guarded" is

22 their own rating metric?

1 MS. GAGE: Yes, it is.

2 CO-CHAIR GIFFORD: Do we know what
3 that metric range is? Is "guarded" at the
4 bottom? Is it at the top? Is it in the
5 middle?

6 CO-CHAIR MUELLER: Be sure you are
7 using a microphone.

8 MS. GAGE: Oh, sorry.

9 CO-CHAIR GIFFORD: Yes, can you
10 guys use a microphone?

11 MS. GAGE: The expectation was --

12 CO-CHAIR GIFFORD: The microphone.

13 MR. KUBAT: And while she is
14 getting to the microphone, just from a
15 simplistic standpoint, the issue or the
16 question to me is, what is this supposed to
17 mean? Or what kind of useful information is
18 it to provide the consumer that helps to
19 differentiate? That's the whole question, not
20 to say that it doesn't, but when I see the
21 word "guarded", and so forth, public health
22 interest is legitimate, but it is different

1 than --

2 CO-CHAIR GIFFORD: Before we get

3 attached to this word, it is in quotes.

4 Colorado made up some metric, like the U.S.

5 Preventive grading of A, B, C, D. I just

6 don't know what "guarded" is. "Guarded" could

7 be like the second from the top and the best

8 thing or it could be at the bottom and it

9 could be the worse thing. I just want to know

10 what Colorado says for "guarded" before we

11 jump all over "guarded". We are jumping over

12 a word. We are interpreting a word that is in

13 quotes, and I just want to know what

14 Colorado's metric is; that's all.

15 MR. BOISSONNAULT: And what

16 aspects of validity and reliability were

17 guarded because it is not the whole topic.

18 CO-CHAIR GIFFORD: I mean, if it

19 is guarded because it was .049 -- if they

20 wanted to be under .05, then who cares? If it

21 was because it was .9 --

22 MS. GALLAGHER: The issue was the

1 variability across the country. So, in the
2 analysis they did of the influenza
3 immunization measure for short-stay residents,
4 the measure was well-correlated with other
5 immunization QMs. So, they were looking at
6 how highly correlated it was to other
7 acceptable immunization QMs. But it was not
8 related to any other measure of nursing home
9 quality.
10 In addition, the measure showed
11 substantial geographic variation, which may
12 suggest that the performance was influenced by
13 factors other than facility quality. So, they
14 weren't ready to go out and say, yes,
15 definitely, this is a good measure, but it did
16 appear to suggest that it was a good measure.
17 DR. ORDIN: And since we are doing
18 these two together, I assume that it is the
19 same for the long stay, right, because it has
20 the same guarded --
21 MR. BOISSONNAULT: It says for
22 short-stay patients.

1 DR. ORDIN: But for the long stay,
2 it says the same thing, "guarded".
3 CO-CHAIR GIFFORD: So, it sounds
4 like this is the first measure that actually
5 someone tested to see whether it was
6 correlated with quality of all the measures we
7 have done.
8 DR. ORDIN: Or at least correlated
9 with the other measures.
10 CO-CHAIR GIFFORD: Yes, that's
11 what I mean. Yes. That's what I mean. So,
12 actually, it is some sort of criterion
13 validity test that no one else has actually
14 even done on any of the measures we have
15 talked about so far.
16 MS. BERNARD: Or correlated with
17 other nursing home measures. There was a time
18 when the availability of the vaccine was in
19 short supply. So, facilities may have tried
20 to get the vaccine, but couldn't get the full
21 amount of vaccine.
22 So, that is, I think, what he is

1 referring to here, is that there may be other
2 external factors to specific facility
3 performance that may impact on the proportion
4 of residents receiving the vaccine that may
5 not have to do necessarily with quality.
6 MS. PACE: And I will just make a
7 comment about this because the Measure Testing
8 Task Force is addressing some of the -- you
9 know, we haven't given real explicit direction
10 on what reliability and validity testing. I
11 think, as David said, the fact that they
12 actually have addressed this, and the
13 correlations with other quality measures is
14 one way of looking at it.
15 The fact that this is strongly
16 related to outcomes gives it quite a bit of
17 face validity.
18 The reliability statistics seem to
19 be quite high, so I am not sure why they even
20 mention "guarded" in relation to reliability.
21 MS. BERNARD: Well, the kappa
22 statistics for actually being able to measure

1 this that was done by Saliba and Buchanan were
2 .989.
3 MS. PACE: Right.
4 MS. BERNARD: It's reliability.
5 I'm sorry.
6 MS. PACE: That's reliability.
7 That's what I meant. The reliability, you
8 know, the comment about "guarded" is made for
9 both, but --
10 MS. BERNARD: Well, the comment
11 about guarded, yes, I think he is referring
12 more to validity than reliability.
13 DR. SCHUMACHER: Can I raise a
14 question about the numerator as it pertains to
15 usability? My question is I completely
16 understand why each of those three items needs
17 to be part of the numerator, but what I am
18 wondering is, Nos. 2 and 3, if we are really
19 trying to get at immunity and protection from
20 infection, what value do Nos. 2 and 3 have on
21 their own in terms of the way we report those
22 to the public? Are those going to have any

1 meaning to people?
2 MS. PACE: Well, I will answer for
3 the Committee that came up with these. Again,
4 it is to put things in context. They really
5 are most interested in the vaccination rate,
6 and should someone decide to report only that
7 component, I don't think anyone would have a
8 complaint. But they really wanted to have
9 those other elements done in a standardized
10 way and to be very transparent.
11 So, their idea was that it
12 provides, you know, for those that are
13 assessing immunization status and offering,
14 that is appropriate care. And it is a
15 different category than actually receiving
16 vaccination. They thought it provides useful
17 information for people to look at where are
18 the differences and what that relates to.
19 But I understand you point. All I
20 can say is that they are most interested in
21 the actual vaccination rate but thought those
22 other two components provided more useful

1 information.

2 DR. ORDIN: You know, the same

3 issue -- I'm a reviewer on the long stay. One

4 of my recommendations to CMS is that they

5 explore this. I mean I think they need to

6 explore what is the best way to display and

7 explain these data to the public.

8 I think that they are very useful

9 to a facility to look at themselves in

10 comparison to everyone else. I mean, you

11 know, if their proportion of refusals is much

12 higher than everyone else, everyone should be

13 pointing their finger. I personally think

14 everyone should be pointing their finger at

15 them.

16 But I agree with you. I mean I

17 think that should be something that we

18 recommend to CMS, is that they look into that.

19 MS. ROSENBAUM: Yes, I think so,

20 too, because that tells you something entirely

21 different. When I looked at the numerator, my

22 guess was they were really trying to find out

1 about assessment of the condition as opposed
2 to if you have immunization or not.
3 But when I looked at the sample
4 for the 3.0 MDS, it does pull that out, and
5 you could pull that number out, if you wanted
6 to. So, that made me happy, and I think this
7 other makes them happy.
8 (Laughter.)
9 But I think that you are right,
10 though, because this information can be useful
11 for so many other things aside from just
12 getting the immunization, as far as education,
13 as far as family members. I know in long-term
14 care facilities we sometimes include the
15 families because of their resident family
16 programs and immunize family members as well
17 as residents.
18 MS. THOMPSON: Darlene Thompson.
19 I agree. I think all three need
20 to be reflected, so that when somebody looks
21 at that, they are not just looking at the
22 number that was given without knowing the

1 other two. The only suggestion I have to the
2 reviewers, not the reviewers but the
3 developer, is that, under 2(a)(2), where it
4 talks about the numerator timeframe, with the
5 MDS 3.0, right now it is still that October
6 1st through June 30th. However, CMS has
7 indicated that they have left that open
8 because CDC may change the timeframe of the
9 influenza. So, they probably want to make
10 sure that they keep that a little bit more
11 flexible.
12 They have now removed that as a
13 hard stop and a skip pattern in the MDS 3.0.
14 So, there is a slight indication that there
15 might be some errors in data coming in because
16 right now it is a hard stop. You can't answer
17 it if you are outside those boundaries. Now
18 they will, unless the people have software
19 that will automatically turn it on and off,
20 depending upon what that influenza season is
21 defined by CDC.
22 MS. PACE: And the standard

1 specifications actually say it could be given
2 prior to October 1 if the supply is available.
3 So, in the measure, you know, the
4 specifications that were developed by this
5 Committee were to acknowledge that patients
6 may have received it prior to October 1, and
7 that would count and be very appropriate.
8 MS. BERNARD: However, there is
9 some concern about giving elderly the vaccine
10 too soon because of how long their
11 immunization would cover them through the flu
12 season.
13 CO-CHAIR GIFFORD: CDC changed
14 that recommendation this year. Their experts
15 did. I mean that is why we gave out the
16 vaccine in August and September to the
17 elderly. The seasonal this year, they said
18 was a theoretical thing that everyone sort of
19 talked about, and actually, when push came to
20 shove, they said, no, the evidence doesn't
21 support it.
22 MS. ROSENBAUM: I think part of

1 that is that it takes a couple of weeks to
2 build the immunization. Of course, with all
3 that was going on in the past year with the
4 H1N1, and so forth, they felt getting that
5 seasonal immunity in quickly would help. I
6 think that it lasts about a year or so. Plus,
7 the next year's strains are going to be
8 different from this year's strains.
9 CO-CHAIR MUELLER: This year they
10 were dealing with two different vaccine
11 issues.
12 MS. ROSENBAUM: Right.
13 CO-CHAIR GIFFORD: Dede, you did
14 the long term. Do you want to add anything?
15 Is anything different for the long term?
16 DR. ORDIN: Yes, I would say
17 there's one thing, and it is the issue that I
18 brought up before.
19 CO-CHAIR GIFFORD: Your
20 microphone.
21 DR. ORDIN: Sorry.
22 The denominator includes,

1 potentially includes people who could be there
2 less than 100 days. So, that just has to be
3 fixed.
4 The second and third parts of the
5 denominator, which are so painful to go into,
6 I will not go into any details, but of people
7 who were discharged during the flu season, but
8 came in before the flu season, and the other
9 way around. Because you are dealing with
10 admission and discharge, it could be less than
11 100 days. So, that 100-day specification
12 should be in the denominators. It has the
13 same problem that you mentioned, Bruce, about
14 that should be fixed, about people who have
15 data missing should be both, should be in the
16 denominator and the numerator.
17 MS. BERNARD: Would they be
18 captured in the short stay or are you
19 concerned they will fall through the cracks
20 completely?
21 MR. BOISSONNAULT: If all you have
22 to do to eliminate all your bad patients is

1 leave a field blank, then I know what I will
2 figure out how to do.
3 CO-CHAIR GIFFORD: So, when it is
4 on the table, summarizing it, it would be a
5 motion to approve the measure with
6 modifications. This is not a time-limited
7 measure.
8 DR. ORDIN: Can I ask one
9 clarification?
10 CO-CHAIR GIFFORD: Yes.
11 DR. ORDIN: Because I didn't read
12 the short-term measure. When you say,
13 "falling through the cracks," we just want to
14 make sure that everybody is covered, as
15 opposed to being covered twice. So, I mean,
16 it has to be defined as anyone less than 100
17 days needs to be in that short stay.
18 MR. BOISSONNAULT: That, too, yes.
19 Yes, okay.
20 MS. PACE: The prior Steering
21 Committee, and maybe you could address this,
22 asked why there needs to be two measures.

1 Because the recommendations for immunization
2 don't vary depending on whether you're short
3 stay or long stay.
4 MS. BERNARD: Part of it is that
5 you are dealing with two distinct populations
6 within a nursing facility. There is
7 variability in the percent that are being
8 vaccinated in those two populations, as I
9 indicated earlier. So, you are bringing
10 together a performance on two populations and
11 averaging them.
12 In this way, you can understand
13 whether or not the problem is that the people
14 who are coming in during the flu season or
15 something may not be assessed adequately
16 versus the long-stayers in a facility.
17 MS. PACE: So, the measure that we
18 most recently endorsed was one measure, but
19 could be stratified by those populations. I
20 mean it ends up to be the same difference.
21 MS. BERNARD: It's the same
22 difference, yes, whether you call it one

1 measure stratified or one measure for short
2 stay and another for long stay.
3 DR. ZOROWITZ: I can also tell you
4 that, based on my experience, the process to
5 vaccinate long-term residents versus short-
6 term residents tends to be different. Long-
7 term residents tend to be vaccinated within a
8 very short time on a regular schedule every
9 year. Short-term residents really require a
10 different mindset to make sure that there's a
11 standing order, an order written, and that it
12 is done on a regular basis. So, it can
13 fluctuate over the flu season, whereas the
14 long-term residents, there really should be no
15 fluctuation. So, I think it would be
16 problematic to try to keep them together.
17 CO-CHAIR GIFFORD: All right. So,
18 to summarize the discussion, what has been
19 thrown out in the pit would be a vote on
20 accepting the measure with three minor
21 modifications.
22 One would be that the long-

1 term/short-term definition be modified to make
2 sure it captures everyone and there's no
3 loophole in the 100-day.
4 No. 2 would be, and maybe this is
5 more guidance, actually, to CMS on the MDS,
6 which is the ability to expand or contract the
7 timeframe, depending on what the public health
8 recommendations are for administering the
9 seasonal influenza. Because right now it says
10 October, but, as we saw this last year, we all
11 said give it earlier.
12 And the last would be looking at,
13 if their data is missing, that it be counted
14 as not being administered.
15 DR. ORDIN: I would say there is
16 one more that --
17 CO-CHAIR GIFFORD: Okay.
18 DR. ORDIN: -- I think it might
19 help CMS to have officially added. That is
20 the usability to the public of how you portray
21 these measures needs to be explored.
22 MS. BERNARD: So, and public

1 reporting.
2 CO-CHAIR GIFFORD: Helen? Within
3 NQF, we don't have conditions or statements on
4 how the measures can be used, do we? Because
5 it is not just the CMS.
6 DR. ORDIN: Oh, no, it is through
7 the developers.
8 CO-CHAIR GIFFORD: Yes, it is
9 through developers. I mean it is some
10 guidance, but I don't think it is a condition
11 on the measure. I think it is in the notes
12 and everything else.
13 But I would say, no, it is not a
14 condition for voting because the whole science
15 about how you compare is -- yes, I know where
16 you are trying to go. I would love to go
17 there, too, but --
18 DR. ORDIN: But if we include it
19 in the recommendation --
20 CO-CHAIR GIFFORD: It is beyond
21 our scope. So, I would say not accept with
22 minor modifications that I just listed:

1 missing data, flexibility in timeframe, and
2 make sure of the denominator for the
3 timeframe, and harmonizing it with NQF
4 standards for reporting the measure, the three
5 new measures. Thank you.
6 Anyone else like to add conditions
7 on while we're at it?
8 MR. BOISSONNAULT: Did you keep in
9 there the second time, the thing about unless
10 there's some reason not to, the blank fields?
11 CO-CHAIR GIFFORD: Yes, blank
12 fields, yes, missing data.
13 MR. BOISSONNAULT: Should not be
14 excluded.
15 CO-CHAIR GIFFORD: Correct.
16 MR. BOISSONNAULT: They should be
17 a problem.
18 CO-CHAIR GIFFORD: Bank fields or
19 missing data, timeframe expanded beyond
20 October, the denominator definition,
21 short/long term, and the harmonization with
22 NQF. Those are the four conditions, except

1 with those four conditions. Okay?
2 All in favor?
3 (Show of hands.)
4 All opposed?
5 (No response.)
6 Abstaining?
7 (No response.)
8 Beautiful.
9 CO-CHAIR MUELLER: And we just
10 voted on two?
11 CO-CHAIR GIFFORD: We voted no,
12 both of them together, knocked off two at
13 once.
14 CO-CHAIR MUELLER: Okay.
15 SISTER HEERY: Pneumococcal, short
16 and long term.
17 MS. BERNARD: Pneumococcal. The
18 proposed measure is, again, the same as the
19 MDS 2.0 with the addition of harmonization
20 with the NQF pneumococcal vaccine measure.
21 So, using the MDS 3.0, the numerator -- and,
22 hopefully, it is correct this time -- measures

1 the number of short-stay residents whose
2 pneumococcal vaccine is up-to-date or who were
3 offered but declined the vaccine or who were
4 ineligible because of medical
5 contraindications. It is the same issue of
6 separating it. Otherwise, it is the same
7 measure as the current endorsed measure from
8 the MDS 2.0.
9 CO-CHAIR MUELLER: Patricia, I
10 believe you were the main reviewer on that.
11 MS. ROSENBAUM: Right. I am the
12 primary reviewer. Alice Bell and Ron
13 Schumacher are secondary.
14 The summary, the same issues. I
15 am not going to go into that because we will
16 apply the same to that.
17 I went through this, and I felt
18 that it was complete for everything, except I
19 had some questions about the scientific
20 acceptability, but we have kind of gone over
21 that because some of the same things that
22 occurred -- I went over the flu, too, and some

1 of the same things that are in the influenza
2 are in the pneumococcal with the "guarded",
3 and so forth.
4 Plus, I feel like a lot of this
5 information was from 2006, and so forth, and
6 we have come a long way since then in this
7 respect: there's been more education, more
8 promotion of immunizations, and, plus, now
9 we're seeing hospitals and the other
10 healthcare systems all becoming aware and
11 participating. So, that is going, to me, to
12 create a different environment now than
13 existed in 2006. I don't know whether you
14 feel that way, but I think that 3.0 is
15 probably going to reflect all that.
16 MS. BERNARD: Among the short stay
17 or long stay?
18 MS. ROSENBAUM: I think for both.
19 I think for both. People are more aware now,
20 and they are probably documenting better. I
21 know in hospitals now this is included in
22 their admission, standardized admission orders

1 for pneumococcal and for influenza.
2 I think there was a harmonized
3 approach as much as I can understand how that
4 worked. I think that that has been done.
5 The only weakness that I was a
6 little concerned about was the statement on
7 getting the second vaccination. In other
8 words, if the person did not meet the criteria
9 coming in, if they were under 65, or whatever,
10 that was not addressed. I have been trying to
11 remember where I underlined that.
12 NQF said that they did not want to
13 pursue that. I will just try to find the page
14 for you.
15 MS. PACE: I think this was an
16 issue of how easily you could implement that
17 into a quality measure. So, certainly, if
18 there's some way that it can be done, that
19 would be fine. But in the standard
20 specifications, the Committee at that time
21 said that's great; we recognize that that's
22 the guideline, but how would you actually

1 operationalize that in a measure for which we
2 have data across a lot of different settings?
3 I mean that is from that Committee.
4 MS. ROSENBAUM: But the
5 expectation would be that that would be
6 pursued by the facility still, right?
7 MS. PACE: The need for --
8 MS. ROSENBAUM: For the second
9 vaccination.
10 MS. PACE: -- the second vaccine?
11 MS. ROSENBAUM: Because I think
12 that's an important issue with some people.
13 MS. PACE: I don't believe that
14 that's necessarily addressed by this --
15 MS. ROSENBAUM: Oh, okay.
16 MS. PACE: -- measure, but it will
17 be something that we will take a look at.
18 MS. ROSENBAUM: Yes, I think it
19 should be looked at in light of the fact that
20 pneumococcal pneumonia is responsible for so
21 many deaths and illnesses. Now there is a
22 resistant pneumococcal out there. So that you

1 want to make sure people are fully immunized
2 against this. So, I think that should be
3 looked at.
4 And of course, importance, I think
5 it is very important. I'm a big proponent of
6 immunizations. It decreases the pneumococcal
7 pneumonia. It decreases severity of
8 pneumonia. It decreases hospitalizations, and
9 it contributes to the large population
10 immunizations. And it decreases missed
11 opportunities for giving vaccination.
12 The scientific acceptability, I
13 just told you what my own problems were with
14 some of that validity and testing. I wasn't
15 quite sure I understood how they did it. I
16 wonder about the quality of the information
17 they had at that time to work with.
18 And the usability I think is
19 wonderful because you can use this in
20 facilities for educational purposes and to
21 decrease and help with investigations like
22 that.

1 And I think it can be understood
2 by consumers, but I agree with Diana; I think
3 there has to be a way to make it palatable to
4 consumers, so they understand what the
5 importance is and why they should know about
6 that, if they are taking someone to a
7 facility.
8 And the feasibility, I think that
9 you can implement this easily and get the
10 information you need easily.
11 DR. SCHUMACHER: So, I was the
12 secondary reviewer on pneumococcal vaccination
13 for short stay.
14 There was one piece that I picked
15 up on that I thought was a little bit weaker,
16 although overall I thought it was a good
17 measure that met all the criteria. That was
18 around susceptibility to inaccuracies. There
19 were some comments here that the reliability
20 may be stronger for the chronic care measure
21 than the acute care measure, that there was 13
22 percent of the time the current pneumococcal

1 immunization measure was assessed differently
2 by different assessors. So, I think there
3 were some issues there with accuracy on the
4 short-term vaccination.
5 I don't know if anyone has any
6 comments on that.
7 MS. BELL: Alice Bell.
8 If I just might ask, because in
9 the description of the measure it speaks to
10 measuring up-to-date status, which would
11 address the second vaccination as well as
12 particularly the short-stay residents, those
13 who might have gotten the vaccine before they
14 were admitted to the center, so who are up-to-
15 date, but don't have the vaccine administered
16 in the center.
17 So, is the measure up-to-date
18 status or is it administration in the
19 facility?
20 MS. BERNARD: It is not
21 administration in the facility. It is up-to-
22 date because they are assessing. But I think

1 the key term here is assessing the residents
2 for the need for the vaccine. And if there is
3 a need for the vaccine, then they provide the
4 vaccine.
5 But among the short-stay
6 residents, there is, and especially if they
7 are coming from an acute cure setting, there
8 is a high likelihood that they would have had
9 the vaccine, especially when you are talking
10 about the pneumococcal vaccine in the acute
11 care setting.
12 So, obviously, you can't expect
13 the nursing facility to provide a vaccine for
14 someone who is already -- but if the
15 assessment, and if there is a determination of
16 need, be it because they have exceeded the
17 time since the prior one or because they have
18 never had one, that is part of the assessment
19 of what the residents need.
20 So, I am sorry if I misspoke
21 earlier.
22 MS. BELL: Thank you.

1 MS. PACE: So, in this particular
2 data item, it probably already takes into
3 account the need for a second vaccine as well.
4 MS. BERNARD: Yes, and I'm sorry I
5 misspoke before, because it does. The
6 assessment, the expectation is that the
7 resident will be assessed, and if there is a
8 need, the patient, the resident has been given
9 the vaccine.
10 MS. THOMPSON: Darlene Thompson.
11 The facilities are going to
12 determine if the residents' vaccine is up-to-
13 date based on that definition in the RAI
14 manual as to what does up-to-date mean. So,
15 I think it is real important that CMS, they
16 are continuing to refine their manual. They
17 had an excellent seminar last week on the MDS
18 3.0. I think make that clear.
19 Also, not all short-stay patients
20 coming from a hospital to a nursing center are
21 even going to be eligible to get the
22 pneumococcal vaccine because it is not

1 something you give to everybody "just
2 because".
3 And also, in the manual it needs
4 to say that, if the resident -- we get 19-
5 year-old, 20-year-old kids coming into our
6 facility. So, would they be considered not
7 eligible because it is a medical contradiction
8 or, no, because they are not old enough to get
9 it? But "no" would make it sound like they
10 should have had it when they shouldn't have.
11 So, really, that falls into that "not
12 offered". So, I think as long as the manual
13 is clear as to what to do in those instances,
14 that that would be helpful in making sure that
15 this measure is clear as well.
16 MS. BERNARD: Okay, that is a good
17 point. You are talking about refining the
18 eligibility determination
19 DR. SCHUMACHER: And I think you
20 brought up 3.0. So, it does say in here that
21 there's more clarity around this in 3.0. And
22 I notice that this one, at least on the short

1 stay -- I didn't look at long stay -- but
2 short stay is a time-limited. So, is that
3 because it is changed with 3.0 from 2.0 in
4 terms of how the questions are asked? It says
5 the changes are minor.
6 MS. BERNARD: They are minor
7 changes to the questions to clarify the way
8 that they are being asked. Now I don't have
9 the copy of the MDS 3.0 here.
10 MS. THOMPSON: The changes are
11 more on the influenza one. There are more
12 selections on when it is not offered. I don't
13 really see anything big in the pneumococcal
14 one, but it is going to be in the definitions.
15 That will be in the manual.
16 DR. SCHUMACHER: So, why is this
17 one marked as time-limited?
18 CO-CHAIR GIFFORD: Yes, actually,
19 I was going to suggest we override the vendors
20 potentially, depending on how the dialog goes.
21 I was going to see how the dialog goes, but,
22 yes, it is a reasonable request.

1 I was the secondary reviewer on
2 the long-term one. I would say the only thing
3 I would add, and I didn't pick up on it, but
4 it was a good pickup, which is the issue of
5 falling through the cracks that we talked
6 about before.
7 The only other thing there was
8 that I would say that they really didn't
9 present any, other than content validity, they
10 didn't do any criterion or construct validity-
11 type testing on the measure out there. But
12 most of the stuff we have had hasn't had that
13 out there as a quality measure overall, but,
14 really, there is a lot of good validity
15 testing on the link between the two. So, I
16 wasn't too concerned about that.
17 And to your question, it is all
18 residents because, generally, when somebody
19 goes into a nursing home, it probably meets
20 the definition of needing to get the
21 pneumococcal vaccine. And if they don't, you
22 know, they still benefit from getting the

1 vaccine anyway. So, it is so few people, it
2 is probably not worth the squeeze to try to
3 exclude them out of the measure.
4 MR. BOISSONNAULT: To the Co-
5 Chairs, as we try to harmonize, would it be
6 worth -- because I think all of the one, two,
7 three issues that we dealt with in the last
8 one, do they not apply here, Karen? You know,
9 the one, two, three issues.
10 MS. PACE: Yes.
11 MR. BOISSONNAULT: So, you are
12 going to rewrite them, essentially, identical,
13 so that the clarity that it is category 1 and
14 category 2 and category 3 for three different
15 measures with I believe the same denominator.
16 In other words, whatever you do on the other
17 one, I think you cut and paste on this one,
18 right?
19 MS. BERNARD: Yes.
20 MR. BOISSONNAULT: There's no
21 reason not to have exactly the same. Okay.
22 MS. BERNARD: And we will run it

1 by Karen to make sure that it harmonizes with
2 the NQF, which is the intent of this.
3 CO-CHAIR GIFFORD: So, on the
4 table, then, would be to approve the measure
5 with conditions. The vendor asked for time-
6 limited.
7 I guess, before we do that, why
8 were you asking for time-limited, not just ask
9 like for influenza that we just go with this
10 measure?
11 MS. BERNARD: We hadn't had the
12 MDS 3.0 --
13 MS. GAGE: Typo.
14 CO-CHAIR GIFFORD: Typo?
15 MS. GAGE: Typo.
16 MS. BERNARD: Yes, typo.
17 CO-CHAIR GIFFORD: Good answer.
18 Typo.
19 (Laughter.)
20 Okay. So, that the group --
21 MS. BERNARD: Absolutely a typo --
22 CO-CHAIR GIFFORD: Stop talking.

1 Stop talking. A typo.
2 (Laughter.)
3 So, on the table is to approve the
4 measure with three minor conditions of
5 modification, harmonize with NQF standards for
6 the numerator definition, close the loophole
7 for the short-term/long-term stay, and I am
8 going to add in, Bruce, you may have the same
9 thing with treating blanks is not given. The
10 timeframe we don't have to do that, but that
11 would be it. So, there's three conditions.
12 Approve with those three minor
13 modifications. All in favor?
14 (Show of hands.)
15 All opposed?
16 (No response.)
17 Any abstaining?
18 (No response.)
19 Wonderful.
20 You would like to do falls? Or
21 would you like a 10-minute break?
22 MEMBER NAIERMAN: Can we get an

1 idea of where we are in the process right now?
2 CO-CHAIR GIFFORD: We are 10
3 minutes behind schedule. We should have a
4 break at 3:15, and it is 3:30. So, we're
5 pretty darn close.
6 Do you guys want to keep going?
7 We'll do the falls and then we will do the
8 break? Okay, yes.
9 That was both 16 and 17. We
10 knocked off two again.
11 Okay, who from RTI is doing falls?
12 Let me ask you all, let me ask the
13 primary, are any of these under the fall
14 measures section? That's what I call it, the
15 falls measures section. Are there any of
16 these that need to be bundled together, like
17 we are going to vote and group them together,
18 like we just had the dialog here? Or should
19 we sort of break them all out?
20 DR. MODAWAL: The two I'm primary
21 on, No. 8 and No. 5, they can belong together
22 and be voted together.

1 CO-CHAIR GIFFORD: No. 8 and No.
2 5?
3 DR. MODAWAL: Yes.
4 MS. CONSTANTINE: Oh, but they are
5 two separate organizations.
6 CO-CHAIR GIFFORD: They are two
7 different organizations. Oh, so we've got to
8 do them separate, yes. Yes, we have to pick
9 which baby we like better.
10 (Laughter.)
11 There's three organizations? We
12 don't like the third. We're just going to
13 pick between the two. Okay.
14 (Laughter.)
15 RTI, do you want to start with --
16 which? You pick. Which one do you want to go
17 first here?
18 MS. CONSTANTINE: How about falls
19 with major injury?
20 CO-CHAIR GIFFORD: Falls with
21 major injury.
22 MS. CONSTANTINE: Hello again.

1 CO-CHAIR GIFFORD: Number what?
2 MS. CONSTANTINE: Falls with major
3 injury is NH-008.
4 CO-CHAIR GIFFORD: No. 8.
5 MS. CONSTANTINE: No. 8. Okay.
6 This is a new measure that we are
7 proposing. The purpose of the measure, it is
8 intended to help to monitor the falls, rate of
9 falls, with major injury. That consists of
10 either bone fracture, joint dislocation,
11 closed head injuries with altered
12 consciousness, or subdural hematomas among
13 long-stay residents occurring in nursing
14 facilities.
15 It is estimated that 75 percent of
16 nursing facility residents fall at least once
17 a year, at twice the rate of their community
18 counterparts.
19 Saliba and Buchanan tested the
20 proposed MDS 3.0 items, assessing the
21 prevalence of any falls or falls with major
22 injury. Basically, the study sample included

1 over 4500 residents. They found that during
2 this six-month data collection period
3 approximately 24 percent of patients reported
4 at least one fall since the prior assessment.
5 And among the 24 percent who experienced a
6 fall, 9 percent at least had one fall with
7 major injury.
8 Research has shown also that falls
9 can lead up to 50 to 65 percent of residents
10 with fear that impacts both their social and
11 functional activities.
12 The proposed measure is based on
13 the MDS 3.0 item J19C, number of falls with
14 major injury.
15 RAND examined the agreement
16 between the facility assessors and the gold
17 standard nurses as well as they compared the
18 responses between the peers of gold standard
19 nurses. The reliability of the MDS 3.0 item
20 was substantially better than that of the
21 analogous MDS 2.0 item, which is fell in the
22 past 30 days.

1 The MDS 3.0 item, the gold
2 standard versus facility nurse kappa, was
3 0.945, and the gold standard versus gold
4 standard kappa, 0.967 for the MDS, and there
5 was a report in 2001 by Abt. The kappa was
6 .66. Oh, I'm sorry. The kappa was a report
7 of .66 by John Morris and a kappa of .638
8 reported by Abt in 2001.
9 So, essentially, with the MDS 2.0
10 items, they had a checkoff list, check all
11 that applies. It was fell in the past 30
12 days, fell in the past 31 to 181 days. The
13 3.0 measure has a checkoff that says, well, it
14 addressed falls since prior assessment, and
15 then the categories of no injury, minor
16 injury, and then falls with major injury.
17 So, this is a proposed new measure
18 to track the long-stay residents, falls with
19 major injury.
20 CO-CHAIR MUELLER: Our reviewer on
21 this?
22 DR. MODAWAL: Yes. I was the

1 primary reviewer on this.

2 Certainly, of course, we agree
3 with the importance of the thing. In terms of
4 the scientific validity and reliability, I
5 gave it a partial. And also, the same for the
6 usability and feasibility.

7 My secondary also agrees that,
8 basically, this can be recommended for
9 adoption, though I hope there's another typo.
10 It is a time-tested recommendation from the
11 vendor.

12 However, there are a few issues
13 which need to be looked at. In terms of the
14 title itself, my personal feeling is that it
15 should be both minor and major because the MDS
16 3 actually now is categorizing injury into no
17 injury, minor and major. So, rather than just
18 major alone, it should be both minor and
19 major. So, that is one thing.

20 The other thing is the duration of
21 looking back. I think it says like 12 months,
22 but I think some of the new guidelines,

1 including some of the Ackrill guidelines,
2 memory for falls is short. So, I think it
3 will be better if it is just the last six
4 months, would be a good timeframe to assess,
5 particularly if you are looking for long stay
6 because of the nature of the problem, and this
7 fact, there's no easy answers in terms of
8 interventions.
9 Now one other thing I felt was in
10 terms of the scientific validity, that one
11 should look at most recent guidelines coming
12 out, the consensus guidelines from the
13 American Geriatric Society or the British
14 Geriatric Society and the American Academy of
15 Orthopedic Surgeons.
16 One other key things, actually,
17 they are trying to separate is the typical
18 geriatrics and normal falls, as we know. And
19 in the definition, they actually are very
20 specific. Because I was at a meeting a couple
21 of years ago in England, and they are talking
22 about deleting these falls which have a

1 history, which have a known or witnessed loss
2 of consciousness. Because your whole line of
3 thinking for a geriatric fall is very
4 different if there's a loss of consciousness.
5 So, that needs to be looked at
6 before we sort of recommend it fully, because
7 the whole line of assessment and interventions
8 is very different because of the other typical
9 medical causes which are associated with loss
10 of consciousness, like syncope and seizure
11 disorders and others, which are not in the
12 typical syndrome of geriatric fall.
13 So, I would say that, if those
14 things are addressed, it will be like a
15 category 2 recommendation with these
16 modifications and clarifications and refining.
17 Darlene would like to comment, who
18 is the second reviewer.
19 MS. THOMPSON: Thank you.
20 Under the scientific availability
21 of the measure properties, this is one of the
22 first ones where apparently it is going to be

1 looking for, according to the numerator, 12
2 months' worth of MDSes. So, for each
3 resident, it is going to be able to go over
4 anywhere from three to five to six different
5 MDSes to look for that particular injury or
6 major injury, which is a little bit different
7 than what we currently usually are doing when
8 looking at current to prior, or something, but
9 not sitting there saying for every resident
10 there's four to six chances that they might
11 actually have had this injury in the last 12
12 months.
13 Secondly, just a definition of
14 major injury, CMS did a good job last week in
15 the training to indicate that the definition
16 you have described is "includes", which means
17 it is not an all-inclusive list. I don't
18 think anybody could write down an all-
19 inclusive list of major injuries.
20 So, you run into the validity of
21 what I consider to be a major injury for a
22 resident and what somebody else might consider

1 to be a major injury for a resident. So, the
2 coding could have some issues in and of its
3 own right.
4 The issue under the stratification
5 where long-stay resident facilities with fewer
6 than 30 residents are excluded because of the
7 small sample size, if we are going back a
8 year, in which case we are also including
9 discharge assessments, we need to look and see
10 if over the period of an entire year would a
11 facility not have 30 long-stay residents.
12 Because, currently, when we look at them, we
13 are not looking over the course of an entire
14 year and gathering a year's worth of
15 discharges. That is where that added that in,
16 adding those discharges.
17 I'm still in 2. One of the
18 biggest issues falls under this summary of
19 evidence supporting the exclusion where the
20 TEP indicated that, because a comatose
21 patient, due to their physiological stage,
22 cannot actually fall, they recommend to

1 exclude that population of comatose patients.
2 If you look at the definition of a
3 fall, according to how we answer the MDS, it
4 is an unintentional change in position coming
5 to rest on the ground floor or onto the next
6 lower surface. If I am transferring a
7 comatose patient and the lift is going to die,
8 and I am going to put them on the floor, that
9 is a fall. It is a fall for a non-comatose
10 patient. An assisted fall is a fall.
11 So, therefore, why if I drop a
12 comatose patient, it is not a fall, but if I
13 drop a cognitively-impaired patient who is not
14 comatose, it is a fall? So, there is a big
15 flaw in the elimination of comatose patients
16 just because they cannot fall on their own.
17 So, I agree that the scientific
18 specifications are partially met.
19 As it relates to usability, again,
20 I think because of the issues and the
21 definitions, and the fact that it hasn't been
22 tested because this is new, that I also

1 consider that to be partially met.

2 With regard to feasibility, we do

3 have the electronic transmission of the MDS.

4 So, again, the only issue is going to be if

5 the data is going to be accurate, due to the

6 fact that it is not a concrete definition.

7 So, you could have a wide swing.

8 You are also going to find in

9 nursing centers that, should a facility

10 receive a citation from a state survey because

11 they failed to identify something as a major

12 injury in the eyes of the surveyors, you are

13 going to see that pendulum swing where they

14 are going to err on the side of calling more

15 stuff major injuries than they are or others

16 will swing the other way. So, I feel there is

17 an issue with that as well.

18 MS. PACE: And feasibility --

19 MS. THOMPSON: Partial, yes.

20 DR. ORDIN: I get the feeling that

21 you were recommending that minor injuries also

22 be included?

1 DR. MODAWAL: Yes. I mean I think
2 it should be both, one or more falls with both
3 minor and major injury because this is a new
4 categorization in the MDS 3, and the process
5 was not there. Really, it makes sense, you
6 know, in terms of delineating the two, but
7 that doesn't mean that we should not look at
8 the fall overall.
9 The minor includes abrasions and
10 bruises and some of the soft tissue injuries,
11 and the major is --
12 DR. ORDIN: Wait. But there is
13 another, "and/or any fall-related injury that
14 causes the resident to complain of pain."
15 DR. MODAWAL: The pain is not
16 there.
17 DR. ORDIN: Yes, it is.
18 MS. THOMPSON: Yes, that is in the
19 definition. It is in the manual.
20 DR. MODAWAL: It should be, then,
21 we should have some more, we should then
22 specify minor and major.

1 DR. ZOROWITZ: But Measure 005 is
2 all documented patient falls with an injury
3 level of minor or greater. So, that would be
4 exactly what you are -- that is another
5 measure.
6 DR. MODAWAL: That is why I wanted
7 to --
8 DR. ZOROWITZ: So, you are asking
9 that you eliminate this measure.
10 DR. MODAWAL: No, no. That is why
11 we wanted to discuss it together, the
12 different organizations, you know, who have
13 actually proposed this. That is why we are
14 discussing it separately.
15 CO-CHAIR GIFFORD: Yes. Just so
16 you know, the process is we are going to vote,
17 since there's two roughly competing measures,
18 we are going to vote each measure up or down,
19 not talking about the two measures. If they
20 both pass, then we have discussion about
21 voting between the two measures.
22 So, let's just vote right now, if

1 you can. Think of it that we only have one
2 measure before us, and we are going to set
3 this aside. Then, we are going to take, as if
4 we have not talked about the falls before, and
5 do another measure. So, the voting is
6 independent of the fact that we have another
7 measure out there.
8 CO-CHAIR MUELLER: So, some
9 clarification about why the measure steward
10 did not include minor?
11 MS. CONSTANTINE: Yes. During our
12 TEP, in looking at the development of this
13 being the new measure, again, they decided to
14 take a more conservative approach. So,
15 certainly falls with major injury was a step
16 in the right direction; however, to hold off
17 on reporting all falls with minor injuries.
18 So, it was the thought that, with the
19 implementation of the MDS 3.0 and gathering
20 more data, perhaps that we would revisit it.
21 The reason for the 12 months, even
22 though we would look back on the quarter, was

1 again given the statistics, to make sure that
2 we would have enough to be able to actually
3 report the measure at a facility level.
4 DR. ZOROWITZ: Let me just throw a
5 little monkey wrench into this. This is very
6 interesting, but when you look at the
7 literature of falls prevention, there's
8 nothing in the literature to suggest that it
9 is possible to differentiate between an
10 injurious and a non-injurious fall.
11 The goal of falls prevention is to
12 prevent, therefore, all falls. We cannot
13 focus on preventing injurious falls. So, in
14 essence, whether you are counting all falls,
15 whether you are counting minor or greater
16 injury falls, or whether you are counting
17 major injury falls, your intervention is not
18 going to change. Your intervention is still
19 going to be to prevent as many falls as you
20 can.
21 So, as we are discussing the
22 differences between these two, I think that is

1 something to keep in mind. I am not quite
2 sure what was the point of measuring only
3 falls with major injuries.
4 MR. BOISSONNAULT: I have just a
5 question. Actually, it might be to you,
6 Robert.
7 Does it seem like the data for
8 major injury falls are going to have a
9 different reliability perhaps than falls where
10 no one was hurt?
11 DR. ZOROWITZ: Well, falls with
12 major injury, first of all, I would expect it
13 to be fairly small.
14 MR. BOISSONNAULT: I understand
15 that.
16 DR. ZOROWITZ: And I don't know
17 how that varies from state to state, from
18 institution to institution. But I would
19 assume it is very small. But, more
20 importantly than that, I don't know how you
21 affect that without preventing all falls in
22 general anyway.

1 MR. BOISSONNAULT: Agreed. I am
2 actually just wondering if the reason that the
3 MDS 3 and this measure seemed to make a
4 distinction is because it is kind of hard to
5 hide a broken bone. I mean it is actually in
6 version 3. It's there as three different
7 categories. I hypothesize it is because the
8 data is more reliable. When you have a broken
9 bone, it is hard to hide that.
10 DR. MODAWAL: I think what Robert
11 mentioned before was this may be the number
12 issue because certainly the numbers of
13 fracture and hip injury would be a lot
14 smaller. I think that may be the reason that
15 they thought of a 12-month period as well. If
16 that was the thinking behind it, then really,
17 you know, it has to be tested and it will make
18 sense.
19 But I just want to say both 8 and
20 5 are really talking about, as you are saying,
21 it is risk factor assessment and intervention.
22 However, maybe 4, which is patient fall rate,

1 may deal with the prevention aspects. You
2 know, there are two parts to it as well. So,
3 I think both 8 and -- basically, 8 leads with
4 a risk assessment and intervention, I suppose,
5 as a measure.
6 MS. BELL: Alice Bell.
7 There is one component still,
8 though, where data is being collected in terms
9 of injurious falls as it relates to hip
10 fractures and things like hip protectors and
11 calcium and vitamin D. So, potentially,
12 although we don't have all that information
13 yet, there is potentially a distinction
14 between major injury specifically as it
15 relates to fracture and minor injury. So,
16 that is just one point.
17 MS. GAGE: That is what I was
18 going to add, is that, again, as you have seen
19 throughout the measures that we have
20 presented, we are trying to take a
21 conservative approach where there is good,
22 systematic information rather than subjective

1 definitions of things. And for a major
2 injury, that can be defined based on the ICD-9
3 code. So, there is a good, solid,
4 scientifically-based definition of that.
5 DR. ZOROWITZ: I am trying to
6 think of how this is going to assist
7 facilities in improvement efforts and what is
8 this going to mean when publicly reported. I
9 mean, obviously, a facility that has a higher
10 number of major injuries is going to be looked
11 at unfavorably by the public. No doubt about
12 that. But I am trying to understand what
13 these measures will actually mean to the
14 institution and how actionable are they.
15 And I understand so far as the
16 specificity of the definitions make it easier
17 to look at major injuries versus minor
18 injuries, and certainly looking at all
19 injuries rather than all falls, especially if
20 you have the low bed to floormat falls, which
21 are still falls but planned falls. But I am
22 trying to figure out exactly what is the point

1 of this measure; what will we do with it, and
2 how will facilities respond to it, other than
3 looking at facilities that are outliers, which
4 are problematic.
5 And is there any research looking
6 at variability among institutions with major
7 falls, with major injuries, and how that
8 relates to their total numbers of falls or
9 other measures?
10 DR. MODAWAL: There is some
11 evidence that the number of falls doesn't
12 matter. It is just ultimately it is the major
13 injury. I think that information on falls
14 will be captured in the denominator. So, even
15 if we are only looking at major injury, we do
16 have the number of falls for the facility.
17 So, that has to be seen in relation to the
18 total falls, which is creating a new specific
19 quality measure.
20 Because, as you know, there may be
21 underreporting or overreporting of falls in
22 nursing homes. Overreporting is not always

1 bad, as long as there's a process and plan in
2 place. The bottom line may be just a major
3 injury.
4 So, that will be a reflection.
5 You know, if you can look at a denominator and
6 the major injuries, you get a fair idea of
7 what is happening in a nursing facility.
8 CO-CHAIR MUELLER: We just want to
9 clarify the denominator is all patients?
10 DR. MODAWAL: All falls.
11 CO-CHAIR MUELLER: No, all
12 patients.
13 DR. MODAWAL: It is all patients.
14 Oh, I beg your pardon. But it should be all
15 falls really, you know. That would be a
16 better measure of quality as compared to all
17 patients.
18 DR. NIEDERT: I agree with that
19 because, when you are looking at falls meaning
20 lower to the floor or any lower surface, which
21 really to me isn't a fall, but it is a fall by
22 definition, and the ones where you have the

1 low bed and they roll out of bed, and there's
2 absolutely no injury, but yet we have to count
3 that.
4 And then you have facilities that
5 don't use any of those mechanisms that many of
6 us use. Yet, because they do roll out of bed
7 and we don't have them restrained with
8 siderails, it seems like we get dinged
9 because, if we have them restrained and they
10 don't fall, then that's okay. But if we have
11 them in a low bed without a restraint with a
12 mat, and they roll out of bed, then we get
13 dinged.
14 CO-CHAIR GIFFORD: So, I'm
15 starting to hear a number of discussions like
16 we are a fall TEP expert group trying to
17 design our own fall measure. That, to me, is
18 a sign that we have some concerns about the
19 measure, since that at least the information
20 has been presented to us about the measure.
21 So, we may want to start thinking about how we
22 want to formulate some vote or recommendation

1 on it.

2 I mean we are not talking about

3 just minor modifications here. We are talking

4 about major changes in this measure. And when

5 we talk about major changes, then we are into

6 the measure development process, and we

7 weren't hired, and your bonuses won't be tied

8 to -- designing new measures out of this

9 group.

10 DR. ORDIN: I don't think this is

11 the be-all and end-all of fall measures. I

12 mean it probably isn't the only fall measure

13 we need, but I think that it is a very

14 interesting and relevant measure. If I were

15 a facility, I would want to know if I were an

16 outlier. If I were looking for a facility for

17 myself, I would want to know what the falls

18 were.

19 So, I think while there could be

20 different measures, I think that there's

21 nothing wrong with this measure.

22 DR. NIEDERT: But is that the

1 information you are really going to get? Is
2 that the information the public is going to
3 get from this measure? Or is it going to get
4 the number of all those low bed rollouts, all
5 those lowered to a lower surface?
6 DR. ORDIN: This is a major
7 injury.
8 MR. BOISSONNAULT: This is only a
9 major injury one. We talked about maybe we
10 should add others in, but is there ambiguity
11 about this measure or is there ambiguity when
12 we start adding things into the numerator that
13 aren't in this measure? Notwithstanding that
14 some people think we should do that, is there
15 ambiguity about this measure, which measures
16 the percentage, essentially, a rough
17 percentage of people who fall and are badly
18 harmed in ways that are easily documented?
19 Sorry.
20 MR. KUBAT: There was ambiguity
21 for me until, Giff, you made the qualifier in
22 terms of process, that you just consider this

1 on a standalone. At the beginning, I was
2 thinking about, well, considering this vis-a-
3 vis the other three that we've got. Well,
4 that is not what we are supposed to do. That
5 removed the ambiguity.
6 CO-CHAIR GIFFORD: Actually, not
7 the other three measures. I am talking about
8 the other fall injury measure. So, this is
9 No. 8 and No. 5, yes.
10 MS. GIL: I just want to add that
11 I worry from a quality-of-life standpoint with
12 this one in terms of I think about the
13 residents who you are trying to grant wishes,
14 who really want to be live in their own room
15 and have that ability, but also have a tragic
16 fall because of that wish.
17 Knowing that at times, like
18 Kathleen said, what would happen is
19 organizations might go to that restraint for
20 some reason or alarm because of that just
21 makes me cringe a bit. So, one of my thoughts
22 is whether or not we move to test this, but

1 not do the public reporting.

2 MR. BOISSONNAULT: I recommend we

3 move post-haste to get a restraint measure.

4 It's later in the agenda.

5 DR. MODAWAL: Yes, I concur with

6 that. I think it can be tested as long as it

7 is not public because it will skew the data

8 and it may speak, as we heard before, on some

9 very good facilities, but very bad just

10 because they had a few fractures, you know.

11 CO-CHAIR GIFFORD: All right. So,

12 what I am hearing is a wide range of opinions.

13 The vendor has asked for, because it is a new

14 measure and it is based on MDS with some

15 additional reliability testing, hopefully, to

16 come from it, that this be a measure that is

17 time-limited.

18 What I heard was two things that

19 we would like maybe some conditions on the

20 time-limited, would be at least exploring the

21 issue of redefining the numerator to include

22 minor in there as well as the issue of what it

1 means if you excluded comatose, and how many
2 comatose are in there. Is it meaningful?
3 Maybe the comatose is so small it is
4 insignificant exclusion.
5 MS. THOMPSON: It is not so much
6 the comatose patient.
7 CO-CHAIR GIFFORD: Yes, right.
8 MS. THOMPSON: It is the
9 definition you can drop a comatose patient and
10 it doesn't count.
11 CO-CHAIR GIFFORD: Right. Okay.
12 MS. THOMPSON: If you drop anybody
13 else, it does.
14 CO-CHAIR GIFFORD: Yes. So, I
15 think those would be the two conditions that
16 I have heard so far with this. I have a
17 feeling we are going to come back and take a
18 bite at this apple with the two different
19 measures out there.
20 Yes?
21 MS. TOBIN: Judy Tobin from CMS.
22 I just wanted to offer one other

1 reason why we would want to separate out major
2 injury from minor injury. One, with a rehab
3 population, where you may have falls and non-
4 injurious, but with major injury as well, as
5 CMS, we would want to be able to look at those
6 because there is a whole sequelae that can
7 occur afterwards. You have a major fall. You
8 have a fracture. Now somebody is
9 catheterized, UTI. I mean there's a whole
10 sequelae that can occur, and you can be
11 talking about very different scenarios.
12 So, we would make the case that we
13 would not include the minor injuries in this
14 fall.
15 CO-CHAIR GIFFORD: So, I think the
16 condition is not that we are saying they have
17 to be combined. We just wanted the vendor to
18 look at the data and give us more data on why
19 you would or wouldn't combine it, and what it
20 would look like with the two combined. I
21 think that is the condition we are looking at.
22 So, again, it is a time-limited

1 approval with feedback and to address the
2 question about should minor and major be
3 combined together, why they should or
4 shouldn't, and the removing of the comatose as
5 an exclusion of that. That would be what our
6 recommendation would be like. That is what we
7 are sort of voting on. There's a lot of
8 differing opinions out there.
9 Do people want to comment on that
10 before we vote?
11 DR. ORDIN: Yes, I'm not clear
12 what we are voting on. Are we voting --
13 CO-CHAIR GIFFORD: You're voting
14 to --
15 DR. ORDIN: What does it address?
16 What does it address? You're saying address
17 the implications of adding minor injury.
18 I personally am against asking
19 them to do anything about minor injuries. I
20 think we should take this measure as is.
21 CO-CHAIR GIFFORD: As is. Okay.
22 DR. ZOROWITZ: If I can add

1 something, I am reading this for the first
2 time and trying to figure out. Again, we
3 mentioned it before. Having not read this
4 before, it is hard to become familiar with it
5 very quickly.
6 But, according to the summary of
7 evidence, it says, "1800 people living in
8 nursing homes die each year from falls. About
9 10 to 20 percent of nursing falls cause
10 serious injury; 2 to 6 percent cause
11 fractures."
12 So, that percentage, I mean if it
13 is 10 to 20 percent, that is a significant
14 enough number that it should show up fairly
15 consistently if data is gathered. And I
16 suspect that the reason that this measure is
17 being considered is because there is variation
18 in the way falls are defined from institution
19 to institution, even though there is a CMS
20 definition of what a fall is. To measure all
21 falls, which I think would be the best way to
22 go, is logistically difficult because of that

1 fact.
2 So, this is sort of a proxy
3 measure meant to indicate the quality of an
4 institution's falls prevention program.
5 Whether or not it works, I don't know because
6 I don't know whether it has been correlated as
7 such. But if that's the case, then it may
8 make sense to restrict it to major injuries.
9 But I have to defer to the developers to see
10 whether that is correct or not.
11 MS. CONSTANTINE: Yes, again, this
12 was something that was debated at the TEP, and
13 the thought was, given it is a new measure, to
14 take a conservative approach and examine the
15 falls with major injury.
16 Also, in regards to the usability,
17 based on the literature, although there's a
18 little bit of mixed results, the thought was
19 that many patients actually come into a
20 nursing facility because they have been
21 falling at home and they can't live
22 independently. There is sort of a multi-

1 interventional approach that you can utilize
2 to take a look, for example, at their
3 cardiovascular medications, their history of
4 falling, think about physical therapy,
5 occupational therapy to help them improve
6 their balance and their gait to prevent falls.
7 So, that is what we had in mind in developing
8 the measure.
9 CO-CHAIR GIFFORD: Go ahead,
10 Darlene.
11 MS. THOMPSON: One thing I think
12 that some people are forgetting, this is a
13 long-stay measure. It is only total residents
14 who have been in the building for 100 days.
15 They are not going to be counted in -- and
16 you're absolutely right; you do get residents
17 that come to the facility because they fall a
18 lot at home. But, hopefully, within those
19 first 100 days, we might be able to handle
20 that, although it does make you go back and
21 look in time.
22 So, I think some of the short-stay

1 people aren't going to show up in this measure
2 anyway, and that 100 days does give us some
3 time to work on the residents that come in
4 that will eventually be long-stay residents.
5 CO-CHAIR GIFFORD: So, let me
6 clarify to Dede's comment, that we are not
7 asking them to change this. It is to ask to
8 go back to their TEP or give us some more
9 information as to the pros and cons of why
10 they may or may not merge the two together.
11 That would be it.
12 So, it is a time-limited approval
13 or as defined with the question to them: what
14 would it look like or why, because we are not
15 all fall experts around the table? They have
16 a TEP and they have a process to come back and
17 say that we had questions about why they
18 shouldn't combine the two. They may come back
19 and say we want two separate measures that
20 complement each other. I don't know. But it
21 will give them an opportunity to come back;
22 plus, the issue with the comatose, and ask

1 them to go back and revisit understanding the
2 definition of MDS and the logic behind it.
3 So, that is really what we are asking them to
4 do.
5 Are you okay with that? Yes.
6 So, voting in favor of that issue?
7 (Show of hands.)
8 Okay. Opposed?
9 I want to say, "restrained". I
10 mean, abstaining?
11 (Laughter.)
12 Okay. So, can we have ANA up to
13 hear about your measure?
14 MS. MONTALVO: Good afternoon.
15 I'm Isis Montalvo, the Director of
16 the National Center for Nursing Quality.
17 The question that I have for
18 clarification, are we doing falls and then
19 falls with injury or just falls with injury
20 initially?
21 CO-CHAIR GIFFORD: I'm sorry. I
22 wasn't listening.

1 MS. MONTALVO: That's okay.
2 CO-CHAIR GIFFORD: I wasn't
3 listening. I was having a sidebar
4 conversation.
5 MS. MONTALVO: We have two
6 measures proposed, falls and then falls with
7 injury. Should we do one and then the other
8 sequentially?
9 CO-CHAIR GIFFORD: Let's do falls
10 with injury --
11 MS. MONTALVO: Okay.
12 CO-CHAIR GIFFORD: -- and then I
13 have a feeling we are going to take a break.
14 Then, we will come back.
15 MS. MONTALVO: Okay. And I also
16 have Dr. Nancy Dunton on the phone, who is our
17 technical expert with our measures.
18 This particular measure --
19 MS. PACE: Can we just clarify?
20 We are talking about 005?
21 CO-CHAIR GIFFORD: Yes, we are
22 talking about 005.

1 MS. MONTALVO: This particular
2 measure is not a new measure.
3 CO-CHAIR GIFFORD: Just a second.
4 What?
5 MR. BOISSONNAULT: Somebody is
6 talking on the phone.
7 CO-CHAIR GIFFORD: It's God.
8 (Laughter.)
9 You're hallucinating, Bruce. We
10 need a break.
11 (Laughter.)
12 MR. BOISSONNAULT: Dementia.
13 MS. TRIPP: There is somebody who
14 is trying, I think, to communicate with us
15 right now, but they are not speaking very
16 loudly or we can't hear them.
17 MS. MONTALVO: Nancy, are you on
18 the phone?
19 MS. TRIPP: Someone from RAND is
20 on the phone as well.
21 MR. WENGER: Right. We've been
22 holding.

1 MS. TRIPP: Okay. Could you
2 identify yourself, whoever is on the phone?
3 MR. WENGER: Neil Wenger and also
4 Carol Roth.
5 CO-CHAIR GIFFORD: Neil, you're on
6 a different measure, not 005, are you?
7 MR. WENGER: No, we were 003.
8 CO-CHAIR GIFFORD: So, you have to
9 wait a little bit, Neil. Is that okay?
10 You're three hours behind us, so you can wait.
11 Are you guys stuck? Are you stuck? You are
12 able to wait or do we need to take you out of
13 schedule?
14 MR. WENGER: When do you think you
15 might take us, so that we can rearrange?
16 CO-CHAIR GIFFORD: We will take
17 you -- what's your measure on?
18 MR. WENGER: 003.
19 CO-CHAIR GIFFORD: Physiotherapy?
20 We want to do this 005 right now because it
21 links in with the previous discussion. Then,
22 we can take your measure. I don't know if we

1 are going to take a break after this, either.
2 But if you're time-pressed, we can slide you
3 in now.
4 MR. WENGER: Well, no, if you tell
5 us when, we can try to get back on.
6 CO-CHAIR GIFFORD: 4:45 our time.
7 So, it will be 1:45 your time.
8 MR. WENGER: Okay. I don't know,
9 Carol, is that possible for you?
10 MS. ROTH: Yes, it's okay.
11 MR. WENGER: Okay. Very good.
12 Thank you.
13 CO-CHAIR GIFFORD: Sorry, Neil.
14 MR. WENGER: No, no problem.
15 Thank you.
16 CO-CHAIR GIFFORD: Okay. Bye.
17 MS. MONTALVO: Nancy, you're still
18 on the phone?
19 DR. DUNTON: I am, yes. Thank
20 you.
21 MS. MONTALVO: Okay. This
22 particular measure is not a new NQF-endorsed

1 measure, falls with injury. In fact, this was
2 well-tested in the acute care setting and
3 actually went before the Mental Health
4 Steering Committee, who recommended that it be
5 considered for other settings due to the
6 harmonization focus for NQF measures, and to
7 provide consistency across settings related to
8 definitions.
9 So, with that, I will turn it over
10 to Nancy related to our criterion.
11 DR. DUNTON: Thank you.
12 The falls with injury measure, the
13 definition is the number of falls with
14 injuries of minor or greater per thousand
15 resident days. It meets the importance
16 criteria because falls is a National
17 Priorities Partnership priority. It affects
18 large numbers of residents in home care
19 settings with some studies showing as many as
20 2.5 falls per person per year, of which 10 to
21 20 percent result in injury, functional
22 decline, and other sequelae.

1 There's variation across studies
2 in the rate of falls, and there's been
3 established in the research literature a
4 relationship to nurse staffing.
5 In terms of scientific
6 acceptability, the measure is well-specified
7 with a precise definition of the numerator and
8 the denominator and inclusion and exclusion
9 criteria, and it is risk-stratified by
10 setting.
11 We have not conducted validity or
12 reliability studies in the long-term care
13 arena, but we have done so in the acute care
14 setting with criterion validity as measured by
15 sensitivity and specificity around 90 percent.
16 It is the case, as has been
17 discussed, not all fall situations are clear.
18 The measure specification is that, to
19 determine the actual injury level, residents
20 should be followed for 24 hours to determine
21 injury level, if it is not immediately
22 apparent.

1 Falls are being publicly reported
2 for acute care settings at the state and
3 federal level. They are used by many care
4 settings for quality improvement programs.
5 The data come from incident
6 reports, which are supplemented with training
7 on data collection guidelines on falls,
8 include both assisted and non-assisted falls.
9 MS. MONTALVO: Nancy, can you
10 repeat that? There was a breakup, and we are
11 having a hard time hearing you.
12 DR. DUNTON: In terms of
13 feasibility, the data are captured by incident
14 reports and will be in a new common format.
15 The reliability of the data is supported by
16 specific data collection guidelines and
17 training, and we collect in falls and
18 injurious falls both falls that are assisted
19 and those that are not assisted.
20 And that is sort of the summary of
21 the scientific acceptability as well as
22 importance from the documentation that was

1 submitted to the National Quality Forum.
2 CO-CHAIR MUELLER: Dr. Modawal,
3 you were the primary reviewer?
4 DR. MODAWAL: Yes, thank you.
5 Yes, I think just like the
6 previous case with injury, of course, the
7 importance and the description includes minor
8 and major. I think for scientific validity
9 and reliability for the issues we heard, in
10 terms of lack of data, my assessment was
11 partial. The same for the usability and
12 feasibility. There are many unknown answers
13 there.
14 The few things, you know, which I
15 had questions were the calculation, you know,
16 the numerator and the denominator, as we heard
17 that they were tested in different settings,
18 you know, just not the nursing home, and how
19 that needs to be modified at home or in
20 assisted living facilities or some other
21 place.
22 So, those were the main questions.

1 Of course, some of the data has been
2 extrapolated from hospital settings and
3 applied to the nursing home and other
4 settings.
5 So, I think the vendor sort of
6 recommends time-limited endorsement, and I
7 would agree with that with some, of course,
8 clarifications and modifications and
9 refinements.
10 And, Robert, do you want to
11 comment?
12 DR. ZOROWITZ: Yes. You know, I
13 don't think it is feasible for nursing homes
14 to gather data and report from incident
15 reports. That is No. 1. I think we really
16 have to rely on the MDS for any information,
17 and the numerator and the exclusions I think
18 are problematic. The numerator is falls with
19 fall injury level of 2 minor or greater, but
20 on the MDS J1900, it is B or C. So, I am not
21 sure whether this really jibes with how it is
22 worded on the MDS.

1 Excluded populations, I understand
2 excluding visitors and students. I haven't
3 done an MDS lately on a visitor or a student,
4 although I am asked to do it.
5 But an excluded population also is
6 falls by patients from eligible reporting
7 unit; however, patient was not on the unit at
8 the time of the fall. Now that may make sense
9 in a hospital, but that makes no sense in a
10 nursing home in which a fall, no matter where
11 they fall, it is a fall because we encourage
12 them to be throughout the facility. So, the
13 numerator I think is problematic.
14 The denominator is fine, patient
15 days during the calendar month. But I think
16 right off the bat, the fact that this is
17 supposed to be gathered from incident reports
18 and the way the numerator is defined, I don't
19 think this is something that I would recommend
20 go forward unless it were redefined.
21 DR. GRIEBLING: This is Tomas
22 Griebling.

1 We were discussing there are some
2 issues with the denominator. It appears this
3 actually is based more on the inpatient acute
4 hospital settings rather than long-term care
5 or nursing homes.
6 CO-CHAIR MUELLER: I also have
7 some concern about measuring it by units
8 because I don't believe we have the capability
9 right now with the MDS to determine where
10 things are happening. We just know it is
11 happening in the nursing home.
12 DR. GRIEBLING: In terms of on-
13 the-unit versus off-the-unit, was the
14 intention for the developer, is it in the
15 facility versus, say, they are going out of
16 the facility with family or something like
17 that, and they have a fall, to exclude those
18 types of falls?
19 DR. DUNTON: Yes, it would be, if
20 a patient were being transferred to a
21 community setting, a doctor's appointment,
22 something like that, those would be treated

1 according to the definition. I agree that
2 falls in the therapy room, in the dining area,
3 et cetera, those would be included.
4 CO-CHAIR MUELLER: I was wondering
5 if the developer would have any comments on
6 the fact that we have the MDS 3.0 with fall
7 measures or fall items, and then what's being
8 proposed as incident reports. Was that just
9 an oversight or could you see that it could be
10 harmonized using a different measure?
11 DR. DUNTON: Certainly, I think
12 using MDS is an option. This measure was
13 submitted to be in harmony with measures in
14 the acute care setting as opposed to other
15 indicators in the long-term care setting. So,
16 if it were to be measured through the MDS, you
17 are correct that sections would have to change
18 to reflect that source.
19 CO-CHAIR MUELLER: Any other
20 questions or comments? Or are we ready for a
21 vote?
22 DR. ORDIN: I just have a

1 question. I mean, is there a movement among
2 nursing homes to have a standardized incident
3 report?
4 DR. ZOROWITZ: Every nursing home
5 has a different format for the incident
6 report. My own opinion is that we should be,
7 for nursing home measures, we should use data
8 sources which are currently collecting data.
9 I'm sure I know we and many facilities do
10 collect data from incident reports and report
11 them internally, but if we are going to be
12 reporting nationally, I think we ought to use
13 data sources which we all use uniformly.
14 CO-CHAIR MUELLER: I will just ask
15 one more clarification of the developer
16 because it sounded like you had been to the
17 group with mental health, who seemed to think
18 this measure worked well for them. Do they
19 also use incident reports or what was their
20 reaction to that?
21 DR. DUNTON: Could you just repeat
22 that?

1 CO-CHAIR MUELLER: We do have, for
2 example, the definition of psych units. So,
3 we represented this is a mental health unit.
4 The Steering Committee, they thought it was a
5 good measure that could be applicable to other
6 settings.
7 For example, within the database
8 that we manage, we also do have like long-term
9 care units as an option within that setting.
10 So, it is, again, taking a look at different
11 settings that could use that measure for
12 harmonization, so there is consistency.
13 And perhaps the NQF staff might
14 have something else to add.
15 DR. DUNTON: The one thought that
16 I had was I don't know what the current status
17 of the format is for incident reports, but it
18 could lead to the standardization of reporting
19 across home care settings. So, that seems to
20 be a long time, but the elements that are in
21 the common format would support this.
22 CO-CHAIR MUELLER: I don't know; I

1 wasn't at that meeting, but I assume the
2 context was inpatient mental health
3 facilities?
4 MS. PACE: Psych units.
5 CO-CHAIR MUELLER: Psych units
6 within hospitals? So, you are talking still
7 about acute care hospitals. So, that it is
8 more consistent with how you are using it for
9 the non-psychiatric units.
10 So, in terms of our approach on
11 harmonization or our interest in
12 harmonization, it is definitely to have
13 measures that are consistent across settings.
14 We recognize that different data sources may
15 require some differences, but what we would
16 like to see, and we would need to look at in
17 terms of, if you are using MDS and the items
18 on MDS, and the measure in the hospital, how
19 close can they get, so that you can have the
20 same interpretation?
21 Not that at this stage that people
22 have to change data sources. You know, the

1 future with electronic health records, we may
2 get closer to having one measure that works
3 across all settings in terms of the data
4 items.
5 But having said that, we are still
6 very interested in having measures that have
7 some consistency of interpretation across
8 settings. So, is a fall in this setting the
9 same as a fall in another setting, and are we
10 reporting on it in the same way?
11 MR. KUBAT: Maybe on a related
12 point -- this is Bill -- and too simplistic,
13 but I think in terms of the harmonization
14 issue, what is almost more compelling here is
15 within the venue, not across venues. I think
16 it would be problematic if we had multiple
17 falls measures related to long-term care, but
18 different data sources.
19 CO-CHAIR GIFFORD: Do you guys
20 have any reliability testing between
21 facilities on incident reports? And also,
22 what is the reliability if the incident report

1 is in MDS? What do you gain by adding
2 incident reports over the MDS?
3 MS. MONTALVO: We don't have the
4 data related to comparing MDS and incident
5 reporting, but we certainly have done validity
6 and reliability studies related to incident
7 reports across facilities.
8 Nancy, can you speak to that?
9 DR. DUNTON: Yes. We are just
10 completing a study, a validity study on the
11 rating of incidents to either a fall or not a
12 fall, across 600 units in acute care settings.
13 We looked at a group of experts as well as
14 clinicians and identified their ability to
15 identify a fall or an incident as a fall with
16 the sensitivity and specificity above 90
17 percent. So, there is some reliability around
18 the definition of most fall areas.
19 CO-CHAIR GIFFORD: Nancy, did you
20 say that was in the acute care setting?
21 DR. DUNTON: It is.
22 CO-CHAIR GIFFORD: Have you done

1 it in a long-term care setting?

2 DR. DUNTON: We have not. In the

3 acute care setting, versus what we get to

4 long-term care, in the acute care setting, we

5 also capture rehabilitation units, the

6 facilities.

7 MS. TRIPP: I have a question

8 about the measure we looked at a moment ago

9 only included falls with serious injuries.

10 Your measure includes falls with minor

11 injuries as well. So, I was hoping you could

12 speak to why you chose to use minor and major

13 injuries.

14 I also want to point out, I think

15 in the beginning of this meeting we were told

16 that this might be the last site-specific-type

17 meeting. And if we are going to try to

18 transcend location and preserve our interest

19 in harmonization, if other measures, you know,

20 exist right now that cover minor and major

21 injuries, if we pick one that only covers

22 major injuries, we are going to be in

1 disharmony in a sense with how these issues
2 are being looked at in other settings. So, I
3 just want to throw that out there for
4 something for us to think about. Let us know
5 why you included minor and serious injuries.
6 MS. MONTALVO: Nancy can speak to
7 the differences between the two.
8 DR. DUNTON: Sure. We collect
9 injury level of all falls, so that we report
10 them back to the hospitals for quality
11 improvement purposes as none, minor, moderate,
12 major, or death. Actually, we combine major
13 and death because they are rare in acute care
14 settings.
15 So, of course, it would be overly
16 complicated to report all of those levels
17 using public reporting. So, minor
18 distinguishes something happened
19 physiologically which could also had
20 psychological sequelae, but other people think
21 of major and moderate as cutpoints. So, we
22 concentrated on something happened to the

1 patient that incurred extra cost. CMS is now
2 not reimbursing hospitals for treatment of
3 injuries or those with some disabilities.
4 So, I can understand why there
5 would be discussion around which injury level
6 to report, but we capture whatever the injury
7 level is. And of course, the major injury and
8 death rates are, even in hospitals are
9 extremely low. So, the measure is somewhat
10 more stable for care settings that have 20 or
11 30 patients in them as in them being a long-
12 term facility, if you include all injuries.
13 CO-CHAIR GIFFORD: All right.
14 Maybe I was confused and maybe I did some
15 assumptions.
16 When I read the numerator, it
17 talks about minor injuries at a level 2. I'm
18 just assuming that was off the MDS. It is off
19 the NCI. Okay.
20 MS. PACE: They have a scale.
21 CO-CHAIR GIFFORD: I got you. So,
22 that would be minor and major then. Okay.

1 DR. ZOROWITZ: No, and it would
2 require that facilities develop incident
3 reports that have a level 2, 3, or whatever.
4 I mean I don't even recognize this. That's
5 why I think the feasibility is low.
6 MR. BOISSONNAULT: Due to harmony,
7 right? I mean there's a certain disharmony
8 with the sort of hospital-based report that
9 this is sourced off of from the MDS, is my
10 understanding of what's --
11 DR. ZOROWITZ: Apparently.
12 MR. BOISSONNAULT: Yes.
13 DR. ZOROWITZ: But I don't know
14 how hospitals report, but evidently they
15 don't, I know they don't use the MDS, and I
16 know what's on the MDS, and I know what's
17 going to be on the MDS 3.0. And I don't even
18 know whether CMS is going to want us to be
19 submitting data from another source in order
20 to report it.
21 So, I think there are a variety of
22 reasons that this isn't going to work. To me,

1 it brings up the whole issue of whether we
2 just need to go back and rethink the best way
3 of finding a measure that reflects the quality
4 of attempts to reduce falls in facilities. I
5 think we are identifying some gaps in
6 scientific knowledge and validity of these
7 measures that I am not sure we are able to
8 answer today.
9 But I don't think this measure as
10 written is going to work at all. I understand
11 the motivation behind it and the rationale.
12 But given the way nursing homes collect and
13 report information on falls and injuries, I
14 think this is logistically impossible. That
15 doesn't mean it's not a very important
16 measure, but I don't think we have really come
17 up with an ideal way of reporting a quality
18 measure on falls, based on the two proposed
19 measures so far.
20 MS. GIL: I was just going to say
21 I think this is an important lesson in terms
22 of harmonizing with acute care. I am

1 constantly working with acute and long-term
2 care to bring them together. Language is just
3 so key in everything we do. The next one that
4 Alice and I will be going over, just getting
5 through the language of it was a challenge
6 because it didn't sort of fit in my head.
7 So, I think that the process of
8 getting nursing homes and acute care together
9 from the beginning is real important in terms
10 of really looking at a solid proposal. I
11 appreciate the effort.
12 DR. MODAWAL: Yes, I think the
13 intentions are good, and I think it is an
14 important topic, we all agree.
15 I think this as a measure as it is
16 written is too broad because they have
17 hospice, long-term acute care, hospital, and
18 nursing homes, skilled nursing facility,
19 rehabilitation facility.
20 As we are hearing, the
21 transportability of these measures, the tools
22 from one side to another may not work. That

1 is the difficulty we face right now.
2 CO-CHAIR MUELLER: So, it sounds
3 like on the face of it, when you just read the
4 title of the measure, it sounds great. But
5 when you actually look at how it is measured
6 and what the data sources are to measure it,
7 it doesn't fit to long-term care. It is a
8 square peg going in a round hole, or vice
9 versa.
10 So, on that alone, it doesn't
11 sound like there's a lot of enthusiasm for
12 this measure. Are we ready to vote on the
13 measure as proposed?
14 MR. BOISSONNAULT: Do we need to
15 get the "C's" and the "N's" and all that stuff
16 from the folks? Or are they already on the
17 record?
18 CO-CHAIR GIFFORD: Did you guys
19 submit? Did the reviewers submit?
20 CO-CHAIR MUELLER: No, I don't
21 think they did.
22 CO-CHAIR GIFFORD: Turn off their

1 microphones, someone.

2 Did the reviewers already turn in

3 their stuff to NQF with their ratings?

4 DR. MODAWAL: Yes, we have.

5 CO-CHAIR GIFFORD: Then, we have

6 them on record. So, we don't have to go

7 through them, unless anyone would like to go

8 through them. Would you like to go through

9 them and vote on them all?

10 DR. MODAWAL: Well, you know, for

11 the scientific -- I think it's all partial and

12 minimal for the research and scientific and

13 minimal for the usability, and also for

14 feasibility it was partial.

15 CO-CHAIR MUELLER: Thank you.

16 DR. ZOROWITZ: I think he's being

17 polite.

18 (Laughter.)

19 The importance, I think it is

20 completely.

21 Scientific acceptability, I think

22 it's partial because it hasn't been tested in

1 long-term care facilities.

2 But usability and feasibility, I

3 am debating between minimally and not at all.

4 CO-CHAIR MUELLER: Okay.

5 DR. ZOROWITZ: But I'm leaning

6 towards not at all, just because of the data

7 sources.

8 CO-CHAIR MUELLER: Thank you.

9 So, we have now heard the

10 reviewers' recommendations. I think we are

11 probably ready for a vote right now.

12 And this is a time-limited

13 measure. So, based on its being a time-

14 limited measure, we would be voting to --

15 let's see, how do we do this?

16 You can kill it in time-limited,

17 too.

18 Okay. So, all those in favor of

19 the measure raise your hand.

20 (No response.)

21 All those not, raise your hand?

22 (Show of hands.)

1 All those abstaining?
2 (No response.)
3 Okay. So, this measure does not
4 pass our muster.
5 CO-CHAIR GIFFORD: It doesn't pass
6 muster at this time. We encourage the
7 developers to work and figure out how to
8 harmonize it with MDS and come back because
9 there clearly is an interest in looking at
10 that.
11 CO-CHAIR MUELLER: Thank you.
12 CO-CHAIR MUELLER: We have RAND
13 calling back in at 4:45. It is 4:32. Do you
14 want to do the other fall, the other
15 restraint? Do we want to do that? But when
16 RAND calls back in, we are going to have to
17 take them. We already kicked them out once.
18 CO-CHAIR MUELLER: Well, we have
19 004, which the ANA is also proposing that one,
20 the patient fall rate.
21 MS. BELL: And I would say, as
22 primary on that one, the issues are identical

1 to the previous measure. So, we might be able
2 to move through it rather quickly.
3 CO-CHAIR GIFFORD: Okay.
4 CO-CHAIR MUELLER: That's what I
5 was thinking, yes.
6 CO-CHAIR GIFFORD: Then, let's do
7 004. You guys have a hungry appetite.
8 (Laughter.)
9 MS. MONTALVO: Well, a lot of the
10 information that was said previously related
11 to the introduction and the importance has
12 already been stated.
13 Nancy, is there anything else that
14 you want to add related to the importance of
15 measuring overall patient falls?
16 DR. DUNTON: No, other than I
17 think that capturing through the MDS or
18 wherever, capturing the total fall rate is
19 important, not just the injury fall rate.
20 MS. BELL: Alice Bell.
21 And as the primary reviewer, I
22 would agree that it is important, but we

1 struggle with the same issues in terms of
2 definition, data capture, the tools that would
3 be used, and the fact that they are
4 incompatible with long-term care at this
5 point.
6 And also, we kind of went back and
7 forth a little bit in this measure between
8 looking at fall rate and also some reference
9 to looking at fall risk assessment and
10 intervention. And it wasn't clear to me
11 exactly, although fall rate was the focus,
12 some of the assessment was based on other
13 criteria.
14 But, most pointedly, the issue is
15 in and around feasibility and usability with
16 different tools to measure the data.
17 CO-CHAIR MUELLER: Any other
18 comments? Go ahead.
19 MS. GIL: As a secondary reviewer,
20 I concur with Alice. I don't think anything
21 more needs to be said.
22 I think, obviously, this

1 information across settings has incredible
2 value. I encourage you to keep on plugging
3 away to harmonize this.
4 And in terms of, obviously, its
5 usability, to bring together your performance
6 improvement strategies that you laid out, I
7 thought that was nicely done and, again, could
8 bring such strong value.
9 I guess the other thing that I
10 would mention is that, through the
11 feasibility, it spoke to the electronic
12 medical record. Certainly, acute care is far
13 more advanced in that vein as well. So, I
14 would hope you would consider that as well.
15 CO-CHAIR MUELLER: Any other
16 comments about this measure?
17 (No response.)
18 Okay. Are we ready for a vote?
19 Okay. So, all those in favor of
20 endorsing this time-limited measure 004?
21 (No response.)
22 All those not, raise your hand.

1 (Show of hands.)
2 Abstain?
3 (No response.)
4 Okay, thank you. Thank you so
5 much.
6 Now it's a break, right?
7 CO-CHAIR GIFFORD: Yes, why don't
8 we take a 10-minute break? At 4:45, be back
9 promptly; 10 minutes.
10 (Whereupon, the foregoing matter
11 went off the record at 4:37 p.m. and went back
12 on the record at 4:46 p.m.)
13 CO-CHAIR GIFFORD: All right.
14 Neil, 003, on physical therapy/assistive
15 device for new balance. You've got 20 people
16 around the table here eager to hear why we
17 should approve this measure.
18 MR. WENGER: Wonderful. Thank
19 you.
20 So, this is a process-of-care
21 measure, which I think is sort of different
22 than most of the measures that you have been

1 looking at today.
2 It is predicated upon a large body
3 of evidence that shows that people at risk of
4 falling can have that risk minimized through
5 intervention. The body of evidence on this
6 usually looks at multimodal interventions,
7 which are not measurable through most means of
8 collecting data. This focuses on two of the
9 most common components of those interventions
10 that are physical therapy and exercise and use
11 of assistive devices.
12 This is a composite measure that
13 uses data from MDS together with
14 administrative data, both of which are
15 generally available and can be combined.
16 The demonstration that someone
17 should be in the denominator for this measure
18 is that they have a new or worsening balance
19 problem based on serial MDS measures.
20 Therefore, one needs at least two quarterly
21 serial MDS measures to qualify for this
22 measure.

1 The numerator is based on either
2 MDS or claims data demonstrating that there
3 was physical therapy ordered or that a new
4 assistive device was initiated.
5 We have demonstrated that this
6 measure can be implemented in a large cohort
7 of about half of the high-risk eligibles in
8 California. The published data show that the
9 combination of MDS with administrative data is
10 feasible, and, indeed, the pass rate is
11 relatively low, with about a third passing.
12 This measure itself has not been
13 directly linked to clinical outcomes of
14 decreased falls or deceased injuries.
15 However, this measure, when measured by chart
16 review, combined with a series of other
17 companion measures that aimed at falls, does
18 demonstrate that improved quality in the
19 outpatient setting is directly related to a
20 decrease in the Tinetti fear-of-falling scale
21 over a one-year study period.
22 I think I will stop there and

1 listen for conversation.

2 CO-CHAIR GIFFORD: Okay. Who is

3 the primary reviewer? Yes, Alice?

4 MS. BELL: Alice Bell.

5 I had a couple of issues. First

6 of all, I think it is very important, and

7 there's a lot of excellent things in this

8 measure.

9 My concerns relate to treating

10 physical therapy intervention and the issuance

11 of an assistive device as being equal

12 interventions because, in reality, the

13 issuance of an assistive device without proper

14 training, fitting, and assuring that it is the

15 appropriate device, actually creates increased

16 risk for falls. So, they are not like

17 interventions. That is one issue.

18 So, I would look to look at

19 perhaps just the provision of physical therapy

20 services and not the provision of an assistive

21 device as a separate and equal intervention

22 strategy.

1 The second issue that I had was
2 the exclusion of patients with severe
3 dementia, given that dementia is a risk factor
4 for falls, and that I believe intervention
5 strategies are demonstrated through the
6 evidence that patients even with severe
7 dementia can have their fall risk managed, and
8 particularly when we are looking at a new or
9 worsening balance problem, and you are looking
10 at consecutive MDS quarterly assessments, even
11 though patients with severe dementia who
12 present now with a new or worsening balance
13 problem, I think it is indicated to provide
14 the intervention and attempt to remediate that
15 worsening condition, which may or may not be
16 related to their dementia.
17 So, those are the two issues. I
18 would say that, in terms of importance, as I
19 said, I rate it as complete. In the other
20 areas, I rated it as partial, simply because
21 of that treating an assistive device as the
22 same value as therapy intervention and the

1 exclusion of patients with dementia, with
2 severe dementia.
3 CO-CHAIR GIFFORD: And usability
4 and feasibility?
5 MS. BELL: Partial also, for those
6 same reasons.
7 CO-CHAIR GIFFORD: Okay.
8 MS. BELL: Actually, no, let me
9 change that. Usability, complete, because I
10 do think access to the data elements is fine.
11 I think it is easy to capture what we are
12 looking to capture here.
13 But feasibility, based on the
14 equal measure of an assistive device, I think
15 is problematic, partial.
16 CO-CHAIR GIFFORD: Before I turn
17 to Neil to comment on that, the secondary
18 reviewer?
19 DR. MODAWAL: Yes, Arvind Modawal.
20 Yes, I agree with what Alice has
21 said. There are basically two things, and it
22 is too broad, and combining them may not be

1 the right way because issues of compliance
2 with the assistive devices. Also, it may be
3 part of nursing interventions as well, if they
4 have had the physical therapy intervention
5 already in place.
6 So, I think half of it really
7 looks good, you know, as a physical therapy,
8 if it can be modified. Physical therapy for
9 any balance problem makes sense.
10 So, otherwise, in terms of
11 scientific validity and usability/feasibility,
12 it will be all partial for me.
13 CO-CHAIR GIFFORD: So, Neil, do
14 you want to comment on why you guys thought PT
15 and assistive devices should be together in
16 the numerator?
17 MR. WENGER: I think that those
18 are good points, but I had a difficult time
19 hearing the second speaker. But let me
20 address the first two points.
21 I don't think that we have good
22 evidence at this point how to allocate or

1 apportion which intervention works best for
2 patients with falls. In fact, the real way to
3 do this, which I think is beyond the current
4 scope of measurement, is to identify different
5 types of patients with different types of
6 lesions and to direct the interventions
7 specifically to the type of patient. But
8 given that we are attempting to develop a
9 measure, such specificity, at least in today's
10 world, I think is beyond us.
11 I think it is a good point that
12 not everyone will benefit from assistive
13 devices. I think the same is true for
14 physical therapy. It wouldn't be impossible
15 to actually report this measure dividing up
16 the numerator into assistive device or
17 physical therapy or both, if the panel felt
18 that that would be more valuable. Certainly,
19 these are separate components that can be
20 easily constructed.
21 When we developed this measure
22 with our expert panel, they included both

1 physical therapy and assistive devices for
2 different types of falls problems.
3 To address the second issue, we
4 recently convened a panel to consider advanced
5 dementia with specific quality measures. Let
6 me note that this is only advanced dementia
7 that we are excluding here, not all dementia.
8 It doesn't mean that undertaking these
9 interventions would be a mistake with someone
10 with advanced dementia, but it does mean that
11 there are many patients with advanced
12 dementia, at least in the view of our expert
13 panel, that would not be able to adequately
14 benefit from either an assistive device or
15 physical therapy. And therefore, they didn't
16 feel that it stood as a quality measure to
17 require using these interventions for a
18 patient with advanced dementia.
19 CO-CHAIR GIFFORD: Neil, how do
20 you define advanced dementia?
21 MR. WENGER: It is defined based
22 on the algorithm that we listed, which is

1 taken from several variables within MDS. This
2 is a validated algorithm developed by others.
3 I can look it up for you here.
4 CO-CHAIR GIFFORD: It's a CPS?
5 MS. BELL: It is based on a number
6 of different MDS criteria combined.
7 CO-CHAIR GIFFORD: Okay.
8 MS. BELL: Combined results.
9 MS. PACE: On the tool?
10 MS. BELL: Yes.
11 CO-CHAIR GIFFORD: Okay. So,
12 Alice, go ahead. A question?
13 MS. BELL: Sure. I think two
14 points. One is the distinction I am making is
15 I think if you combined, if you said physical
16 therapy and an assistive device or physical
17 therapy with or without the use of an
18 assistive device, that would be one thing.
19 But when you look at simply the provision of
20 an assistive device to a patient, not knowing
21 who provided the device, what criteria was
22 used for determining what device, whether any

1 training in the use of the device was
2 provided, and whether the device was even
3 fitted to the patient, that is a much lesser
4 level of intervention.
5 So, that is the issue I have, is
6 to say physical therapy or an assistive device
7 being equal interventions. If you wanted to
8 compare those two, you could look at physical
9 therapy with or without the issuance of an
10 assistive device and the issuance of an
11 assistive device independent of therapy. I
12 think that would be interesting to see, but
13 combining them I don't think makes the measure
14 meaningful.
15 I understand your statement about
16 the distinction of severe or advanced
17 dementia, but, again, I would say the
18 literature does indicate that even patients
19 with advanced or severe dementia, depending on
20 the presenting problem that has resulted in
21 their balance deficits, one of which might be
22 the issuance of an inappropriate assistive

1 device, may, in fact, benefit from therapy
2 intervention and may, in fact, see a reduction
3 in fall risk.
4 CO-CHAIR GIFFORD: Neil?
5 MR. WENGER: I certainly
6 understand what is being said. I guess I
7 don't have the literature at my fingertips
8 concerning what proportion of patients with
9 advanced dementia would not benefit and,
10 therefore, the measure would be inappropriate
11 for them.
12 When we posed this exact question
13 to our group of experts, they felt that the
14 patients with advanced dementia should be
15 excluded. Perhaps someone can shed some light
16 by presenting some literature to show that a
17 preponderance of patients with advanced
18 dementia would benefit from these
19 interventions, and we can also search for
20 that.
21 DR. ZOROWITZ: This is Bob
22 Zorowitz.

1 I am just wondering, the elements
2 to define advanced dementia or poor prognosis
3 are based on MDS 2.0, is that correct?
4 MR. WENGER: They are currently.
5 We developed based on 3.0.
6 DR. ZOROWITZ: So, this is just a
7 procedural question. I guess if we were to
8 decide to endorse this measure, would that be
9 conditional on its being changed to reflect
10 MDS 3.0?
11 CO-CHAIR GIFFORD: Yes.
12 MS. PACE: Right, and, actually,
13 your conditional recommendations, we want to
14 have the measure developer take care of before
15 it goes farther for even voting. So, from
16 what I'm understanding, 3.0 is advanced enough
17 that they could identify the elements now. Is
18 that correct?
19 DR. ZOROWITZ: I believe so. I
20 mean it is in a final enough form that it
21 could, but I don't know how well-validated the
22 data elements together are, because 2.0 has

1 been worked over pretty well over the years.
2 So, I don't know about 3.0.
3 CO-CHAIR GIFFORD: Yes, but many
4 of the items from 2.0 are just carrying over
5 into 3.0 with some changes.
6 DR. ZOROWITZ: But there's the
7 brief interview of mental state in the 3.0.
8 CO-CHAIR GIFFORD: Right.
9 MR. WENGER: We have already
10 looked at the elements in 3.0 to correspond to
11 the basic elements within this measure, but we
12 have not yet looked at that specific scale,
13 which was actually developed elsewhere. We
14 can do that.
15 MS. ROTH: Now I actually have
16 looked at the elements, and many of them are
17 unchanged. There's I think one where there's
18 a very minor change, and probably it is in the
19 physical functioning item where there are more
20 response categories that would have to be
21 taken into consideration. I think the poor
22 prognosis item actually has been improved from

1 what it was in 2.0. So, some of it is
2 unchanged, and some of it there are some
3 changes.
4 DR. ZOROWITZ: Getting back to the
5 issue with the assistive device, I mean in my
6 facility, in my experience, an assistive
7 device is rarely given out without
8 accompanying physical therapy anyway.
9 When you developed this, was there
10 a discussion of any data on how often an
11 assistive device such as a cane or a walker is
12 distributed without some sort of instruction?
13 I mean, in other words, are these always --
14 obviously, physical therapy often includes
15 giving an assistive device, but I don't know
16 how often giving an assistive device excludes
17 physical therapy.
18 MR. WENGER: Right. We measured
19 those two things separately. The expert panel
20 that included assistive device as satisfying
21 the measure did have a discussion concerning
22 advice that was required along with the

1 administration of the device, but recognize
2 that there is no way to know how well-done
3 that was.
4 CO-CHAIR GIFFORD: No, I think,
5 Neil, the question is, if you measured this
6 with PT only and then you add in PT or
7 assistive device, how many new residents get
8 counted into the numerator?
9 MR. WENGER: That is a good
10 question that I don't know the answer to off
11 the top of my head.
12 Carol, do you know?
13 MS. ROTH: No, I don't.
14 CO-CHAIR GIFFORD: Because if it
15 is not significant, then you don't need -- you
16 know, if the PT and assistive device, if PT is
17 highly, highly correlated with the assistive
18 device, then it doesn't add much. If they are
19 very different, then I think some of the
20 questions come up here.
21 DR. ZOROWITZ: And my concern is
22 that a facility, especially since physical

1 therapy, although it can be Medicare Part B
2 reimbursed in some facilities, depending on
3 how their reimbursement is, it may be more of
4 a cost to them. They may be tempted to just
5 give an assistive device to somebody rather
6 than provide the service, and they would get
7 their little chit on the quality indicator.
8 MS. BELL: And I think that is
9 one. The other, I agree that I don't think it
10 is a significant number or shouldn't be. And
11 again, the reality is that a device issued
12 without training, without proper fit, actually
13 increases risk for falls. So, even if it was
14 a small number, it could negatively impact
15 measuring the impact of the intervention.
16 I don't believe the issuance of an
17 assistive device independent of anything else
18 is actually an intervention to address fall
19 risk.
20 MR. BOISSONNAULT: And that was
21 actually to my point, which is one dimension
22 of validity. And maybe it was in the lit

1 review. I was wondering if anyone could
2 mention it from either RAND, who I have found
3 does very fine work, but one of the things
4 that I look for in terms of dimension of
5 validity is, if this happens, is there any
6 evidence that it actually improves what you
7 are trying to improve, which is falls
8 reduction? Was that correlation made well in
9 either the submission or do the folks from
10 RAND have any evidence that doing this the way
11 you are measuring it actually reduces falls?
12 MR. WENGER: So, this measure
13 itself as measured in a nursing home, we do
14 not have any link to outcome. The same
15 measure, based on chart review, within an
16 intervention study among community-based
17 patients is related to a decrease in fear of
18 falling. And when combined with several other
19 falls-based measures, because this is, of
20 course, the treatment part of measures that
21 include history and exam-taking, together
22 those are very much related to improvement in

1 fear of falling, but we have not linked it to
2 falls or injury.
3 MR. BOISSONNAULT: Did you say
4 "fear of falling" or actual falling?
5 MR. WENGER: Yes, we are using the
6 Tinetti's fear-of-falling scale.
7 DR. ORDIN: I'm sorry, I might
8 have missed this. This is Dede Ordin.
9 This uses both administrative and
10 MDS data. I assume that is the rationale for
11 restricting it to the over 65, because it
12 would seem like under 65, you know, the same
13 issues would apply. I am having trouble
14 understanding how the production of that
15 measure would happen and whether the
16 administrative data truly are needed, given
17 data elements in 3.0.
18 I looked real quickly. Obviously,
19 the G(5)(a) must be for 2.0. I don't know
20 what 3.0 has about assistive device, but I am
21 sure it has something.
22 MS. THOMPSON: Darlene Thompson.

1 I've got a couple of questions. I
2 am assuming since we are going 65 or older,
3 you are taking it from the birthdate from
4 somewhere, either from the MDS, the birthdate
5 that is on there, or from the administrative
6 claim.
7 The second part, I need you to
8 scroll it back down. I'm sorry. Thank you.
9 But I am confused. I'm trying to
10 figure out what this is actually measuring
11 because the numerator is -- now I lost it.
12 Numerator details is residents who have a new
13 balance problem which would be identified in
14 the last seven days off the ARD date who
15 received a new assistive device or physical
16 therapy in the prior four months.
17 I am trying to figure out, if a
18 resident had therapy four months before the
19 ARD date, and on this new assessment I say
20 they have an increase in their balance
21 problem, I am trying to figure out what we are
22 trying to measure here because the therapy was

1 four months before we identified they had a
2 new balance problem.
3 MR. WENGER: The denominator is a
4 comparison between two quarterly reports.
5 Therefore, it is possible that the decrement
6 in either balance or gait could have occurred
7 anytime during that interval. Therefore, a
8 physical therapy that occurred -- let's say,
9 for instance, that the balance change occurred
10 two-and-a-half months ago, two weeks after the
11 prior MDS report. Therefore, physical therapy
12 initiated at that time would be two-and-a-half
13 months prior to current MDS, but would have,
14 indeed, been the appropriate clinical
15 maneuver.
16 MS. BELL: And I think a bit of
17 the struggle is the four-month, and what they
18 do is they give a 30-day window prior to the
19 previous MDS.
20 MR. WENGER: Right, and the reason
21 for that is that in our experience balance
22 problems don't occur all of a sudden. If

1 physical therapy is being initiated, the
2 thought is that they are identifying an
3 abnormality, and therefore, they are
4 interacting clinically to attempt to
5 ameliorate it.
6 The thinking is that we are
7 attempting to include all reasonable clinical
8 intervention for a worsening gait or balance
9 problem.
10 CO-CHAIR GIFFORD: So, let me
11 throw something into the pit here for this
12 discussion. I would put forth to the group,
13 given the dialog, that we vote on any time-
14 limited approval, ask for a crosswalk to the
15 MDS 3.0, that comes back with a little bit of
16 the data literature that Neil said they would
17 look at both ends: why severe dementia was
18 excluded or any data that would suggest severe
19 dementia actually is helpful in this group,
20 and some data on whether the assistive
21 devices, how much it actually adds to the
22 measure and whether you need to actually split

1 it or not with some recommendation back to the
2 group. But a time-limited approval based on
3 that.
4 That sort of summarizes the
5 comments. Do you want to discuss that at all?
6 Bill?
7 MR. KUBAT: Well, just a comment.
8 I mean somewhat my reaction is, are the
9 qualifiers so substantive as to make it
10 problematic, hard to support?
11 MS. BELL: And I would just, to
12 that point, say that I think it would be
13 difficult to support with the alternative of
14 therapy or an assistive device as being
15 treated as equal interventions.
16 MS. THOMPSON: I've got one other
17 question. Is there an exclusion for if a
18 resident refuses therapy?
19 MS. BELL: I apologize. The
20 criteria was they actually received therapy
21 through CPT code.
22 MS. THOMPSON: All right. So, if

1 they refused therapy --
2 MS. BELL: They wouldn't --
3 MS. THOMPSON: -- they wouldn't be
4 counted.
5 MS. BELL: That is correct.
6 MS. THOMPSON: So, then, that
7 measure would show that you potentially --
8 because I am assuming this would be the higher
9 the number, the better, supposedly, the
10 measure is.
11 MS. BELL: Right.
12 MS. THOMPSON: So, you could have
13 a low measure because you have a lot of
14 residents that are refusing to take the
15 therapy.
16 MS. BELL: Now what I don't know
17 is number of days, duration of therapy
18 intervention. There's nothing to indicate
19 that. It is basically, if therapy is billed,
20 they qualify as having received therapy.
21 MR. WENGER: Correct.
22 CO-CHAIR GIFFORD: So, based on

1 those comments, let me modify the time-limited
2 approval. The time-limited approval as PT
3 only with them coming back with data as to
4 really justifying why assistive devices need
5 to be added in.
6 Then, the stuff we talked about
7 before, the MDS 3.0 crosswalk and the
8 information on exclusions of dementia, see
9 where they need to modify that.
10 Is that a reasonable approach? Or
11 you guys still don't feel comfortable with it?
12 We are suggesting a modifying,
13 dropping the assistive device, with them to
14 come back with data to see whether they should
15 include it or not. Because what I am hearing
16 from them is their concerns with leaving
17 assistive devices is, if it doesn't add much
18 to the measure, you would drop it anyway. But
19 if it adds a lot, then they have to figure out
20 how to justify to us why they would want to
21 put it in with better reliability, but that
22 the PT alone would be sufficient with all the

1 data that was suggested and presented to us.
2 That is the way I am summarizing it, but I
3 could be summarizing it wrong.
4 I am seeing head nods.
5 DR. ZOROWITZ: Yes, I think that
6 sounds reasonable. I mean, for the most part,
7 the standard of care for a new balance problem
8 is to have a physical therapy assessment. So,
9 I mean, my gut feeling is that a physical
10 therapy assessment alone should be adequate,
11 but I didn't do the research, and I would
12 trust that the Technical Expert Panel did, but
13 perhaps they just don't have that data on
14 hand.
15 So, I would agree. I think,
16 otherwise, it is a fairly sound measure.
17 CO-CHAIR GIFFORD: All right. All
18 in favor of time-limited approval with PT,
19 excluding assistive device; ask the developers
20 to come back with information about assistive
21 device; see the literature review on
22 exclusions for dementia -- but right now it

1 excludes severe dementia -- and the crosswalk
2 with MDS 3.0? All in favor?
3 (Show of hands.)
4 All opposed?
5 (Show of hands.)
6 Three opposed.
7 Any abstaining?
8 (Show of hand.)
9 One abstaining.
10 Can I just ask -- never mind. You
11 can abstain for any reason. You don't have to
12 give a reason.
13 MS. TRIPP: Well, I would like to.
14 CO-CHAIR GIFFORD: Okay.
15 MS. TRIPP: I just would like, I
16 think I've said this a few times, but more
17 time to review this would be helpful. I am
18 sure that is clear, but that is what I am
19 saying.
20 CO-CHAIR GIFFORD: And the three
21 dissenting votes, dissenting opinion?
22 MR. BOISSONNAULT: I would like to

1 see evidence that the process actually links
2 to the desired outcome, which is fewer falls
3 and not fear of falls.
4 CO-CHAIR GIFFORD: Bill?
5 MR. KUBAT: The same point.
6 CO-CHAIR GIFFORD: Darlene? And
7 exclusion for refusals is why you -- good.
8 Now you got all that? You got all
9 this feedback?
10 MR. WENGER: Yes.
11 CO-CHAIR GIFFORD: Okay. Thank
12 you, guys.
13 MR. WENGER: Okay. Thank you.
14 CO-CHAIR GIFFORD: The next
15 measure, 021, RTI.
16 MS. CONSTANTINE: Hi. This is the
17 last time I will be at the table this
18 afternoon.
19 Okay. The last measure that we
20 will be discussing is physical restraints.
21 The purpose of the proposed measure is to
22 report on the percent of long-stay residents

1 who were physically restrained daily during
2 the seven days prior to the resident
3 assessment. Again, I will sort of summarize
4 and highlight just the pertinent, important
5 points.
6 Physical restraints may be used in
7 nursing homes to control people whose
8 behaviors are judged to be disruptive,
9 aggressive, or dangerous, including patients
10 with cognitive impairment. It also poses
11 serious risk for nursing home residents,
12 including pressure sores, decreased mobility,
13 depression, agitation, and social isolation.
14 Also, residents who experience greater use of
15 restraints also experience an increased risk
16 in hospitalization.
17 Restraints reduce the residents'
18 autonomy and their dignity. According to the
19 OBRA act of 1987, it specifically grants
20 residents the right to freedom from undue
21 physical restraints.
22 The associated guideline from CMS

1 states, "The resident has the right to be free
2 from any physical or chemical restraints
3 imposed for the purpose of discipline or
4 convenience and are not required by the
5 resident's medical symptoms."
6 Concerns in regard to restraint
7 use have been voiced by various organizations,
8 such as the National Citizens Coalition for
9 Nursing Home Reform, the Alzheimer's
10 Association, the American Physical Therapy
11 Association. And the Advancing Excellence
12 Campaign in America's Nursing Homes has made
13 the reduction of physical restraints one of
14 their major goals.
15 Essentially, there's very little
16 difference between the MDS 2.0 and 3.0 items.
17 The difference is in MDS 2.0 it indicates
18 whether trunk restraint, limb restraint, or
19 chair prevents rising was utilized daily
20 during the seven days prior to the assessment.
21 However, for the proposed measure, it makes a
22 clarification and eliminates a little bit of

1 the confusion regarding whether it was used in
2 bed or whether the restraint was also used in
3 a chair or out of bed. So, that is the
4 additional categories.
5 They were designed to eliminate
6 some confusion about the definition of
7 restraint and enhance, including accuracy.
8 Essentially, the kappas during
9 development testing with the MDS 3.0 from gold
10 standard to gold standard nurses ranged from
11 .86 to .93; in gold standard to facility
12 nurses, .66 to .87.
13 And looking at the variability
14 that still remains across for this measure,
15 again, using 2.0 data and looking at July
16 through September of 2009, the national
17 average for daily physical restraint use was
18 3.3 percent with the range going from a
19 minimum of 0.2 percent to a high of 6.7
20 percent.
21 MS. TRIPP: Actually, I think I am
22 the primary on this. Yes. Okay, great. It

1 is late in the day.

2 Yes, I think this is a fairly

3 simple issue. So, clearly, this is of high

4 importance. It is responsive to a core public

5 policy goal, as expressed in OBRA '87 and CMS

6 regulations implementing OBRA.

7 Reducing restraints I think is a

8 principle that is agreed to by almost all the

9 stakeholders involved in this process. So, it

10 is clearly of high importance.

11 I will just tell you what the

12 numerator and denominator are for this. The

13 numerator is all long-stay residents who are

14 physically restrained daily during the seven

15 days prior to an annual or quarterly

16 significant change or a significant correction

17 in MDS 3.0 assessment during the selected time

18 window.

19 The denominator is all long-term-

20 stay residents who have had an annual or

21 quarterly significant change or significant

22 correction in MDS 3.0 assessment during the

1 selected quarter and haven't been excluded.
2 A resident is excluded if the
3 selected MDS 3.0 assessment was conducted
4 within 14 days of admission or if there is
5 missing data in relevant questions in the MDS.
6 So, those are the exclusions.
7 The reliability appears to be very
8 high for this. There were a couple of studies
9 that were referenced in the material. There
10 was no discrepancy in the day two study using
11 MDS 2.0.
12 There was a national pilot test
13 for the proposed MDS 3.0 measures that showed
14 good reliability with a little evidence of
15 confusion. Okay?
16 Validity, there wasn't a whole lot
17 of data presented on the validity of the
18 measure. So, I don't know if you could speak
19 to that just briefly.
20 MS. CONSTANTINE: Sure. The
21 University of Colorado evaluated validity of
22 the current measure, and they did it in a

1 couple of different ways.
2 First, they examined the expected
3 positive influence of public reporting on the
4 quality of care by assessing the degree to
5 which the quality measure was triggered and
6 whether it has been improved over time. They
7 also, again, looked at convergent validity,
8 where you examine how the quality measure
9 compared and it correlates to the other
10 quality measures.
11 They also wanted to see whether
12 the quality measure triggering rate was
13 influenced by factors unrelated to the
14 facility, such as seasonal variation in the
15 triggering rates across. They looked at 13
16 quarters of data in 2006, and also looked at
17 the amount of variance in the triggering rates
18 explained by the state where the facility was
19 located.
20 So, essentially, for public
21 reporting, it seems that the measure is having
22 some effect, as evidenced by the decline in

1 the triggering rate from 8 percent in the
2 third quarter of 2003 to 3.5 percent in the
3 second quarter of 2009.
4 And in regards to the convergent
5 validity, the correlations with other clinical
6 measures are weak, which might reflect more
7 the limited clinical relationship of physical
8 restraints to the other measures.
9 There's little evidence of
10 seasonal variation, and 19.6 percent, though,
11 of the variance in the reported rate for this
12 measure was explained by the state in which
13 the facility existed. So, there is definitely
14 a difference between states. However, it also
15 does allow a facility within that particular
16 state to examine how they perform versus other
17 facilities within the state.
18 MS. TRIPP: Okay. All right,
19 thank you.
20 So, in terms of the usability, it
21 seems like this is a highly usable measure.
22 CMS is expecting nursing homes to utilize the

1 measure as a tool to decrease the use of
2 restraints. And the Advancing Excellence in
3 America's Nursing Home Campaign supports the
4 measure.
5 And real progress in reducing the
6 use of restraints has been made since the
7 measure has been used since 2002. So, it
8 seems highly usable.
9 The feasibility seems to be quite
10 easy as well, since it comes from MDS data,
11 3.0, and there's very little difference
12 between 2.0 and 3.0 with respect to this. So,
13 because of this, I gave it -- I mean there
14 wasn't a whole lot of validity data to rely
15 on, but I found that the items were completely
16 met.
17 Ron Schumacher is the secondary
18 reviewer.
19 DR. SCHUMACHER: Yes, as the
20 secondary reviewer, I would concur with all of
21 that. I thought this one was also relative
22 straightforward. I really couldn't find a

1 significant weakness in this one. So, I would
2 recommend that we go forward with it.
3 CO-CHAIR MUELLER: Any comments or
4 questions?
5 DR. MODAWAL: Yes, I just have a
6 comment in terms of how in the new MDS 3
7 physical restraints are defined. How is it
8 categorized?
9 MS. TRIPP: It is categorized by
10 either you could have a trunk restraint, a
11 limb restraint, or chair prevents rising. It
12 could be used while in a bed or out of bed in
13 a chair. So, they refined the categories to
14 clean up the definition a little bit and make
15 it more understandable.
16 DR. MODAWAL: What is the
17 rationale for the seven days before the MDS?
18 Why was the seven-day cutoff chosen?
19 MS. TRIPP: Oh, that is basically
20 a standard look-back period. There's a couple
21 of items or quality measures that use a little
22 bit different, but a standard seven-day look-

1 back period is what is utilized in many of the
2 quality measures, taking a look seven days to
3 see how often the restraint was used, and it
4 was used with other measures.
5 MS. PACE: I was just going to ask
6 to make sure I am understanding this right, in
7 the seven days the restraints had to be used
8 every day of the prior seven days in order for
9 it to trigger?
10 MS. TRIPP: Yes.
11 MS. PACE: So, someone who is in
12 restraints five out of the seven previous
13 days --
14 CO-CHAIR GIFFORD: They're okay.
15 MS. PACE: Okay. And what was the
16 rationale for that decision?
17 MS. CONSTANTINE: Well, I think
18 that the focus was that it had to be something
19 that happened daily, and then how would you be
20 able to track, although I guess you could make
21 differences in one to two days, two to three
22 days, you know, four to five days, but --

1 MS. PACE: So, it was because the
2 MDS item only asked if it was done daily in
3 the past seven days or?
4 CO-CHAIR MUELLER: Section (P).
5 Not used, used less than daily, and used
6 daily.
7 MR. BOISSONNAULT: Karen and I
8 were more or less on the same wave length. My
9 question has to do with the research finding
10 that you put out there that I found
11 interesting.
12 You said, since '92, we have seen
13 that measurement has had an impact. So, when
14 you looked at the data, you saw that the folks
15 who are restrained every day for the past
16 seven days went down. Did they just move into
17 the six-or-fewer-day category or did we find
18 ways to get some people completely off
19 restraints? Did you look at that?
20 Is there any thought, so that you
21 don't squeeze the balloon from here to here,
22 is there any thought about looking at all

1 three buckets?

2 MS. CONSTANTINE: That is a good

3 question, and, no, not to my understanding did

4 we look at other than daily to sort of

5 stratify and look at it, but that is something

6 we could definitely consider.

7 CO-CHAIR GIFFORD: Yes, Mary Jane.

8 DR. KOREN: We have been working,

9 as you know, with Advancing Excellence on

10 reducing restraints and really have gotten the

11 national rate down quite a bit. At this

12 point, CMS I think is sort of thinking, should

13 we be on to bigger and better things? We've

14 gotten them really down pretty far.

15 But it does raise the question, I

16 think Bruce raised it, which is maybe now is

17 the time to really change the criteria and

18 say, not more than two or three days or

19 something like that, or whatever. I don't

20 know the exact buckets for the MDS. But maybe

21 this is an opportunity to take the next step.

22 MS. CONSTANTINE: And push it

1 further.

2 DR. KOREN: Yes.

3 MS. GIL: I would like to see it

4 look at the reduction in alarms.

5 (Laughter.)

6 CO-CHAIR GIFFORD: Yes, I would

7 like CMS to actually define alarms as a

8 restraint.

9 (Laughter.)

10 DR. MODAWAL: I had just a

11 question in terms of adjustment. You know,

12 restraints are used for a reason, and I think

13 the most common reason being delirium and

14 confusion and agitation, which sometimes is

15 hard.

16 We haven't reached a point where,

17 other than a person sitting with a patient, we

18 can make the person safe in terms of falls and

19 things like that. So, I wonder if some

20 adjustment is needed, raising the same

21 question, seven days and every day, a few

22 days, to sort of factor in what is acceptable

1 and what is not in terms of adjustment for the
2 behaviors and other difficult agitation or
3 delirium.
4 I mean, as you know, once delirium
5 starts, it is 30 days the person will need
6 some kind of help. It may not be physical
7 restraints, but maybe some alternative ways
8 other than alarms, of course, of helping the
9 person.
10 DR. SCHUMACHER: Well, doesn't
11 that raise another question about when you
12 talk about where did the people go who are
13 using the restraints? Are we shifting, as an
14 unintended consequence, to chemical restraints
15 as opposed to physical restraints?
16 CO-CHAIR GIFFORD: My question is,
17 why also the 14-day exclusion?
18 MS. CONSTANTINE: The 14-day
19 exclusion?
20 CO-CHAIR GIFFORD: Yes. The 14-
21 day, I mean, why? This is restraints for any
22 period. I mean the literature is pretty clear

1 on the harm restraints cause overall and the
2 fact that they induce delirium when used
3 early. I am not sure why this isn't just a
4 flat-out measure straight across the board.
5 MS. CONSTANTINE: If I could just
6 take a look at that --
7 MS. GAGE: Roberta, was this the
8 population that the short-stay patient would
9 have lines and things, and so patients are
10 sometimes restrained post-surgical in order to
11 protect them from pulling out their lines,
12 whereas that is not true with the long-stay
13 population?
14 MS. CONSTANTINE: Okay,
15 "assessment indicating it is an overadmission
16 conducted" --
17 CO-CHAIR GIFFORD: I guess I'm
18 questioning, why make this a long-stay
19 measure? Why is this just a nursing home
20 stay? Frankly, the hospitals would benefit
21 from doing what the nursing homes do out
22 there.

1 MS. CONSTANTINE: Well, yes, there
2 was some concern during the TEP about, again,
3 a patient coming straight from an acute care
4 facility, and when in doubt, you know, if the
5 patient had been restrained, until you assess
6 the patients and figure out maybe what an
7 underlying condition might be, that maybe a
8 med reduction or meds given could help the
9 patient or a change in their going from an
10 acute care facility to a nursing facility.
11 Just sort of acclimation might make a
12 difference.
13 So, they didn't want to focus on
14 the short-stay population, but I can certainly
15 take your point.
16 CO-CHAIR GIFFORD: So, I'm hearing
17 approve the measure actually as is, but the
18 concern of the group is that they would like
19 to see this measure, other measures, go
20 further and expand to why it is short term.
21 Why not go beyond daily? Add noise alarms as
22 a form of restraint, and you almost need to

1 complement this with medication as a
2 restraint.
3 But, as it is structured, I think
4 it would be approval as is with no conditions
5 other than we would really, I think, strongly
6 word something for CMS to do more than just
7 this. Give RTI some more money to do some
8 more measures.
9 (Laughter.)
10 It's my taxpayer dollars.
11 (Laughter.)
12 MS. PACE: David, this one also
13 has an exclusion for missing information. I
14 just want to see if that is a concern for this
15 measure as well. That was brought up in --
16 CO-CHAIR GIFFORD: Oh, sorry, yes.
17 MR. BOISSONNAULT: It is the issue
18 that we have talked about where, if you leave
19 any of the key things blank, they throw it out
20 instead of assuming against you. So it is an
21 incentive to leave it blank.
22 CO-CHAIR GIFFORD: So, we have to

1 amend the motion that we actually include
2 those as counting, count them in the
3 numerator?
4 MR. BOISSONNAULT: We have with
5 the last, with the caveat that unless there's
6 some compelling research, argument to go
7 otherwise, excluded data should mean that we
8 assume that they were restrained, not that
9 they weren't.
10 CO-CHAIR GIFFORD: So, it is
11 approved with that condition, and then the
12 other recommendation we had. Okay.
13 All in favor?
14 (Show of hands.)
15 Any opposed?
16 (No response.)
17 Abstaining?
18 (No response.)
19 Wonderful.
20 All right, we are through our
21 schedule to public comment and NQF member
22 comment.

1 Sandy? You don't have to say
2 anything if you don't want to, Sandy.
3 (Laughter.)
4 MS. FITZLER: I am, and maybe this
5 is something that you already have, but it is
6 just a few comments on the pressure ulcer
7 measure. That is because there wasn't much
8 discussion on it, and I don't have access to
9 the information that you have. So, you
10 already might have it in your information.
11 CO-CHAIR GIFFORD: We don't have
12 access to the information we have, either.
13 (Laughter.)
14 MS. FITZLER: Well, the issue is
15 it was identified that there's a lot of new
16 things to pressure ulcer assessment in MDS 3,
17 but one of the things that I did not hear
18 mentioned was we, for the first time, will be
19 looking at ways to code DTIs and unstageable
20 ulcers.
21 So, given that, when it comes to
22 the short-stay ulcer, or the short-stay

1 measure, if that individual has an unstageable
2 and we recognize it on admission, and then you
3 are looking at the measure, the assessment on
4 discharge, and by that time we can code it, is
5 that being considered a new measure or is this
6 an exclusion? So, that is No. 1.
7 And then, secondly, on that short
8 stay, where we are looking at the admission
9 assessment and then the discharge, currently,
10 the average length of stay is 29 days. Some
11 of those folks will be discharged much sooner
12 than that. We have a short period and we may
13 not always see healing in an ulcer in some of
14 those individuals. So, I can see that that
15 would be problematic, too.
16 MS. EDELMAN: I'm Toby Edelman
17 with the Center for Medicare Advocacy. I
18 would like to make a few brief comments.
19 First, I have been somewhat
20 troubled by what I have heard today. It seems
21 to me that a very significant portion of the
22 Steering Committee represents the nursing home

1 industry and there's very limited
2 representation of consumer or beneficiary
3 interest. I think that is an inappropriate
4 balance on this Committee.
5 And the result I think is that a
6 lot of the discussion, or a significant amount
7 of discussion today has been how facilities
8 will look when a measure is publicly reported.
9 We heard a lot of discussion about not wanting
10 facilities to be dinged. God forbid they look
11 worse than they should.
12 Not a lot of discussion about
13 whether the measure would be useful to nursing
14 homes for quality improvement purposes, and
15 certainly not discussion about whether
16 consumers really want to hear about this
17 information that is useful to them.
18 I know from working with residents
19 and their families and advocates for residents
20 that what people really care about is
21 staffing. The literature we know indicates
22 that the most important predictor of high

1 quality of care is the staff, the nursing
2 staff in the nursing home, particularly
3 registered nurses, but also the
4 paraprofessional staff. And consumers
5 understand that and, yet, the Committee voted
6 down the two measures that were considered for
7 staffing.
8 At least we are going to get that
9 from Congress. Who would have thought it's
10 easier to get something like that through
11 Congress than through a committee?
12 My final points: I was on the
13 TEP, and I think we had a very significant
14 amount of enthusiasm for the chemical
15 restraint issue that a couple of people raised
16 just now here at the end.
17 We know that there's an enormous
18 amount of anti-psychotic drug use in nursing
19 homes. The MDS for the fourth quarter 2009
20 indicated 26 percent of residents are
21 receiving anti-psychotic drugs. The general
22 numbers, like 25 to 30 percent of residents

1 get anti-psychotic drugs. As many as half
2 don't have a diagnosis that would justify the
3 use of the drug. So, theirs is a lot of off-
4 label use.
5 Since 2005, the Food and Drug
6 Administration has had black box warnings,
7 first, for the atypical anti-psychotics, then
8 for the conventional anti-psychotics, talking
9 about an increase in morbidity for residents
10 with dementia.
11 And there was testimony by the
12 Food and Drug Administration in Congress in
13 2007 that approximately 15,000 residents are
14 dying from the inappropriate use of anti-
15 psychotic drugs.
16 Our TEP was interested in this,
17 and maybe RTI could get more money to look
18 into this because I think it is a very
19 important issue. I think people that
20 understand that physical restraints are a
21 problem, but the chemical restraints I think
22 are really replacing the physical, and it is

1 killing a lot of people.

2 Thank you.

3 MS. MONTALVO: Isis Montalvo from

4 the American Nurses Association.

5 I just want to reiterate, I think,

6 some of the key points that were made earlier.

7 When we think about patients across settings,

8 patients moving from the acute care setting to

9 the long-term care setting, and we are looking

10 at measures that are going to evaluate the

11 care across settings, that it would really

12 benefit us as providers, as consumers, to have

13 those measures harmonized.

14 So, that way, you can follow that

15 patient from the acute care setting to the

16 long-term care setting, regardless of whether

17 it is a fall, whether it is a pressure ulcer,

18 regardless of staffing. Certainly

19 accommodating what needs to be accommodated

20 for that specific setting, but realizing the

21 value in being able to measure that care

22 across settings.

1 CO-CHAIR GIFFORD: So, CMS, can
2 you put the MDS into the hospital setting? It
3 would be helpful.
4 Any other comments?
5 (No response.)
6 We are ahead of schedule. So, I
7 am going to take a quick moment.
8 MS. THOMPSON: I don't want to
9 throw a monkey wrench in, but did I miss --
10 did we do 4?
11 CO-CHAIR GIFFORD: Did I miss
12 something?
13 MR. BOISSONNAULT: I think what
14 happened --
15 MS. THOMPSON: Did we do 004-10?
16 We did the 5.
17 CO-CHAIR GIFFORD: Oh, you're
18 right, we didn't do fall rate. I apologize.
19 Yes, we did. That's right, we did do it.
20 Yes.
21 MS. THOMPSON: Okay, I am sorry.
22 CO-CHAIR GIFFORD: Alice did it.

1 That's right, yes.
2 So, you're going to take us to
3 dinner somewhere, right? So, there's a
4 shuttle outside at six o'clock to take us to
5 dinner. Those who are staying there at the
6 hotel, at the Sheraton, can't get back to the
7 hotel unless you come to dinner with us. So,
8 those who are not staying at the hotel and
9 drove here, I guess you don't have to come to
10 dinner with us, if you don't want, but they're
11 welcome to come, right? Yes. Okay.
12 I want to take a quick moment. We
13 have time on the agenda tomorrow at lunch, but
14 I know some of you will probably be bolting
15 out of here. I just want to take a moment
16 just to go around the room, and each of you
17 can just sort of mention -- we are talking
18 about functional measures tomorrow. So, I
19 don't want to get into tomorrow's measures,
20 and we can talk about it afterwards.
21 But particularly in some of the
22 areas that we looked at today, which were

1 pain, pressure ulcers, prevention, staffing,
2 and the mental health area, and others, just
3 to comment on some areas that you would like
4 to see some measures developed, because we are
5 constrained by what actually gets submitted by
6 the vendors out there, and also constrained by
7 what they have actually decided to do.
8 As I say, we are not a measurement
9 group, but we do have an opportunity to at
10 least give some guidance to where we would
11 like to see some additional measures. So,
12 just I would like to go around the room, and
13 since we only have 20 minutes, and there's 20
14 of us, you've got to keep your comments pretty
15 short. We will have time to talk about it a
16 bit tomorrow.
17 Mary Rose?
18 SISTER HEERY: I think
19 psychotropic medication would be an excellent
20 measure to look at. I think that impacts
21 probably, that would be a domino effect on
22 most of the measures we talked about today,

1 and we see negative outcome from the extended
2 use of that. So, I would be a proponent of
3 that.
4 I also think another measure I
5 would like to see -- well, it is on tomorrow
6 with the ADLs and things, but that would be my
7 primary measure.
8 Thank you.
9 DR. ORDIN: I would say the CAHPS
10 measures.
11 MR. KUBAT: I think I would echo
12 that comment about CAHPS or at least about
13 satisfaction or experience of care, and so
14 forth.
15 From the first time serving on the
16 first Steering Committee, it was identified
17 then. It has been an absolute frustration to
18 me to see what the experience has been since
19 then because I saw the development of nursing
20 home CAHPS.
21 I had conversation with AHRQ and
22 whatnot about that. They developed the tool

1 to put it up in the public domain for
2 everybody to ignore. And yet, at the same
3 time, you have hospital CAHPS, home health
4 CAHPS. Home health CAHPS did go through the
5 NQF process, and so forth.
6 And the only thing I ever really
7 wanted or hoped that CMS would do is to do
8 with CAHPS or with satisfaction or experiences
9 of care what they have done with MDS, which is
10 just define the specs and let existing vendors
11 embed it within their processes.
12 MEMBER NAIERMAN: I would like to
13 echo the CAHPS idea, but I would like to add
14 a couple of nuances to it.
15 First of all, given how many
16 patients/residents there are with dementia, I
17 would like to see someone do some research on
18 surrogate reporting, where it is the
19 professional or the family caregiver.
20 I would also like to ask we
21 consider looking at end-stage dementia as a
22 possible life-limiting illness with the

1 possibility that that might lead to more
2 palliative care and less aggressive care.
3 There has been some recent literature about
4 that that has to do with, I think,
5 appropriateness of care, waste, and a lot of
6 related kinds of things.
7 So, end-stage dementia, can we
8 consider it a life-limiting illness? In that
9 case, is hospice and palliative care more
10 appropriate than life-prolonging care or
11 aggressive kinds of treatments?
12 MS. BELL: And I would agree with
13 everything that has been stated and add a
14 couple.
15 One, beyond just like psychotropic
16 meds, but looking at management of
17 polypharmacy as a whole and, additionally,
18 looking back to the fall issue, looking at
19 identification of fall risk factors and care
20 planning to address individualized risk
21 factors.
22 MS. FRANDSEN: I know we are

1 talking about it tomorrow, but incontinence;
2 there's so much prevalence in nursing homes.
3 So, that is important.
4 I would also like to see something
5 about person-directed or surrogate-directed
6 care.
7 DR. NIEDERT: And along the same
8 lines as patient satisfaction, I would like to
9 see something about texture-modified diets,
10 including the use of thickened liquids. They
11 lead to dehydration. Most of the time none of
12 us in this room would drink them, either, but
13 yet we expect our residents to do it. It is
14 a quality-of-life issue.
15 And many physicians will not
16 change the order because they are concerned
17 about lawsuits and litigation, and all of
18 that. Yet, our residents are suffering
19 terribly because they are cupping their hands;
20 they are doing all kinds of behaviors. Then
21 what do we do when they do behaviors? Then we
22 put them on meds, and it is just a vicious

1 circle.

2 So, I would like to see something

3 about dysphasia, swallowing.

4 CO-CHAIR GIFFORD: Meds that are

5 anticholinergic and dry out their mouths, so

6 they need to drink more.

7 DR. NIEDERT: That's right.

8 DR. ZOROWITZ: I'm still worried

9 about the staffing issue. I am sorry we were

10 not able to get a measure that was workable,

11 but I think that we need to somehow figure out

12 how to appropriately and accurately measure

13 staffing, given that there is diversity in how

14 staff are allocated at various nursing homes.

15 It is a difficult issue, but I don't think it

16 is one that is going to go away.

17 DR. MODAWAL: Yes, I think I agree

18 with some of the measures sort of mentioned

19 before which would make a difference. My

20 interest would be to see something on

21 delirium. I think the problem is prevention

22 is important and management is important, but

1 we don't understand the mechanism of delirium.
2 That is why we can't have concrete
3 interventions or management approaches to it.
4 We brought up the polypharmacy and
5 dementia and falls. So, I think it is a major
6 area which needs to be studied in nursing
7 homes because that is where the future studies
8 will be done. The time for studying delirium
9 in hospitals is over or at least it will be.
10 In terms of understanding the life history of
11 delirium, I think the future studies of
12 delirium will be in nursing homes. Some
13 approaches should be made as quality
14 indicators in this area.
15 MS. TRIPP: Yes, I also want to
16 talk about anti-psychotic drugs in the long-
17 term care setting. If it is okay, and I hope
18 you don't mind the intrusion, but I am going
19 to email a white paper to everyone on this
20 Committee tonight. Tomorrow I will bring a
21 basically one-page kind of talking points that
22 summarizes some of the data. So, I will bring

1 that in tomorrow. But I share that concern.
2 DR. KOREN: We have touched on
3 person-centered care, but we really have done
4 nothing around culture change. And it is
5 really too bad. I think that one of the
6 things that has inhibited the field is that we
7 haven't had metrics, but we are starting to
8 get metrics. Now we need to get them tested.
9 One of the things that we have
10 done, I think, in Advancing Excellence that
11 speaks to person-centeredness is we are
12 looking at the issue of consistent assignment
13 because we know from focus groups with
14 residents that the thing they value the most
15 highly are relationships with their nurses'
16 aides. So, figuring out ways to measure this,
17 and I think we finally have a way to
18 objectively measure it from the resident's
19 perspective.
20 We also have started to try to
21 collect some data about including residents in
22 setting goals for their care and participating

1 in care planning. Questions about how do you
2 give life meaning in a nursing home, and we
3 are very focused on you can get up anytime you
4 want, but if there is nothing to get up for,
5 what are we doing?
6 So, I think that there are things
7 that we should be starting to look for
8 metrics. We may have to be pretty creative
9 about it, and then start to test them, if we
10 are really going to start to measure quality
11 in nursing homes beyond just physical care.
12 MS. GIL: I absolutely ditto what
13 Mary Jane is saying. I think it is such an
14 important issue for us to tackle and not an
15 easy one whatsoever in terms of looking at
16 quality of life and truly looking at how we
17 are able to really fulfill lifestyle
18 preference and choice.
19 I also like the idea of CAHPS. I
20 think there's a lot of quagmires that they are
21 experiencing in other settings that we can
22 learn from, but I think it is a real important

1 piece as well.

2 And again, on all the alarms, I do

3 think it really is a restraint in a horrific

4 way. We have seen really great studies going

5 on with decreasing alarms without any increase

6 in falls. So, I will make that a plug for the

7 alarms.

8 MS. ROSENBAUM: Well, infection

9 control and prevention is where I'm at. So,

10 I would like to see more done with especially

11 communication between healthcare facilities

12 about multi-drug-resistant organisms and the

13 residents that ping-pong back and forth

14 between the hospital and the nursing home, and

15 also more judicious use of antibiotics because

16 we all know that the multi-drug-resistant

17 organisms are just continuing to appear and

18 appear. We have to look at how we treat our

19 residents in the nursing home.

20 DR. SCHUMACHER: So, I would echo

21 the thoughts about polypharmacy and anti-

22 psychotic use. I will throw out a couple of

1 others.
2 One that people kind of touch on,
3 advanced care planning. Is there a way that
4 we can measure at least attempts to have
5 discussions around advanced care planning with
6 residents?
7 Then, the last one would be
8 inappropriate hospital admissions. I think
9 that is something we need to look closely at.
10 MR. BOISSONNAULT: Yes, I think it
11 was Chuck Darby, the late Chuck Darby's dream
12 to have a unified way of measuring patient
13 experiences of care, and CAHPS was it. So, I
14 am glad you brought that up.
15 By the way, in the process of
16 getting that passed, there was a sort of
17 political deal to drop all the coordination-
18 of-care questions, which are the only ones
19 that actually have a tie to clinical outcomes.
20 So, I would love to see that go back in.
21 And there may be things that we
22 measure on a CAHPS for this population that

1 aren't relevant in the hospital, sort of a
2 well-being scale, a usefulness scale or
3 something, a happiness scale. I don't know.
4 I love the idea of, you know the
5 infection control people said it, the reason
6 MRSA is not going down is because we are
7 trying to fix it the same way we fixed heart
8 attacks, which is one hospital, one unit at a
9 time, when, in fact, infection control is no
10 stronger in any community than the weakest
11 link. Our data is real clear on that.
12 So, MRSA would be something I
13 would go after, but I would go after it not
14 only in a harmonized way, but actually in a
15 coordinated way with one set of measures over
16 different settings, which is more than
17 harmonization.
18 Then, on polypharmacy, I kind of
19 like how it intersects with chemical
20 restraints. There is one other factor that
21 folks developing a measure could consider,
22 which is the P450 pathway, overwhelming that.

1 I actually think it would be sort of a risk-
2 adjuster as to how many is too many that would
3 be easy to deal with. Certain drugs need
4 that.
5 But we talked about advanced
6 directives, and I think I'm there.
7 MS. THOMPSON: I keep crossing
8 things off my list here, but I think one that
9 would be nice to look at is return-to-
10 community and transition planning.
11 DR. GRIEBLING: As a surgical
12 specialist, I have a couple of thoughts on how
13 our care interacts with people in nursing home
14 care.
15 So, I would support things related
16 to nutrition, not just weight loss but
17 nutrition, because it impacts wound healing
18 and a number of other things.
19 Certainly polypharmacy and
20 delirium.
21 I think the issue about advanced
22 directives is critical in terms of, as Naomi

1 said, you know, utilization of care and
2 resources, especially at end of life and
3 things like that.
4 And then another area, and Lisa
5 may have some comments on this, but one of the
6 things I don't think we have touched on are
7 sort of the legal and financial aspects of
8 care, and how that influences families, family
9 caregivers. I mean I know from my own
10 practice in nursing homes I have seen couples
11 have to divorce and things in order to reach
12 spend-downs and things, and how those kinds of
13 outcomes, which I think are going to be hard
14 to capture, but how that impacts families in
15 their interactions, their spiritual needs,
16 those types of things.
17 CO-CHAIR MUELLER: I am just going
18 to amplify two. One has to do with measures
19 related to culture change. So, ways to
20 measure organizational practices that promote
21 person-directed care.
22 And then, the other one I want to

1 amplify is the nurse staffing measure or
2 measures, particularly a measure, measures of
3 turnover and stability, and also,
4 specifically, turnover and stability of the
5 director of nursing and the administrator.
6 CO-CHAIR GIFFORD: I would like to
7 see more non-MDS measures. I think we have
8 let the tail wag the dog long enough.
9 So, I will re-amplify quality of
10 life. You know we focus on the clinical. We
11 need to do quality of life. So, whether it is
12 CAHPS, whether it is culture change,
13 structural measures -- you know, if you give
14 me a medication at 4:00 in the morning and
15 stick a needle in me to draw blood at 5:00 in
16 the morning, I am going to swat you and then
17 be restrained and put on chemicals.
18 (Laughter.)
19 But I also think things like
20 flexibility in when people eat, when they
21 bathe, noising in there. It is at the
22 infancy. I thank the Commonwealth for funding

1 that type of work. If you can fund more of it
2 to get measures out there, Mary Jane, it would
3 be great, but I think we need to move in that
4 direction.
5 The other would be
6 rehospitalization, the ping-ponging. The
7 hospitalization rate is just staggering. If
8 not just for the cost control, we know that
9 the hospitals are dangerous for our patients
10 when they go there, if we can keep them out of
11 the hospital, and a lot of it goes to the end-
12 of-life discussion. So, it is not just the
13 PDA.
14 So, if we can really look at
15 rehospitalization rates, I mean it is just --
16 you know, the fact that one out of four go
17 back within 14 days is just such a bad sign of
18 their healthcare system.
19 DR. KOREN: Giff, just one thing.
20 You stimulated a thought, as did the other
21 lady who talked about transitions.
22 You know, there is an NQF

1 transitional care measure, the CTM-3. There
2 is no reason that that could not be used for
3 the discharges of the post-acute care
4 patients/residents.
5 Because at least then you would
6 see whether or not there was some value in the
7 post-acute care and whether or not, once they
8 got into the community, they stayed there.
9 CO-CHAIR GIFFORD: Yes, excellent
10 point.
11 Then, I just want to re-emphasize
12 staffing. You know, I, too, am sad that we
13 couldn't get something on staffing, but, to
14 me, I am more interested in and I think the
15 greater impact is not necessarily the staffing
16 levels and everything else. While there is
17 good data on it, it is consistent assignment
18 and turnover. If we can get those, that would
19 be very valuable.
20 DR. BURSTIN: That was a
21 spectacular list. Obviously, there is lots
22 more work to do.

1 I think the idea of the CTM-3 is a
2 great idea. We will try to make sure we bring
3 those specs for you to take a look at
4 tomorrow. That would be a relatively easy one
5 for us to go to Eric Holman and have him look
6 at it -- he is a geriatrician as well -- to
7 see whether it is easily applicable. It
8 wouldn't require any other work other than the
9 fact that it is already endorsed and in use in
10 multiple states as well.
11 DR. KOREN: We are actually
12 piloting its use in home care as for discharge
13 from home healthcare into the community.
14 I was talking to Alice Bonner, who
15 is in Massachusetts with the Department of
16 Health. They are willing to test it in a
17 couple of nursing homes.
18 CO-CHAIR GIFFORD: Yes, I would
19 just go back to the beginning comments. While
20 a lot of work in CMS really shapes the
21 direction, NQF-endorsed measures can be and
22 will be used by many groups outside of CMS.

1 So, it doesn't have to be MDS-based. You
2 know, there are states that are hungry to try
3 to do some of that.
4 CMS wants to make a comment.
5 DR. LING: Hi. I'm Shari Ling.
6 CO-CHAIR GIFFORD: You are CMS,
7 yes.
8 (Laughter.)
9 DR. LING: I'm intimidated.
10 Just thank you so much for your
11 comments and suggestions. They are
12 extraordinarily helpful. We have an open ear
13 and a collective open mind.
14 I think it is important for you to
15 know that we are just getting started. These
16 measures that you have been presented today
17 are from the MDS 3.0. There are other
18 measures still that could be built from the
19 MDS 3.0, taking full advantage of the
20 enhancements of the instrument.
21 But we are also interested in
22 facilitating the development of measures that

1 are not necessarily originating in the MDS 3.0
2 So, speaking to the intent of taking a
3 systemwide approach, the coordination of care,
4 the transfer of information and of that care,
5 I think those are important concepts that they
6 are on our radar screen. The concepts of
7 healthcare-associated infections and how to
8 look at things from a system point of view,
9 not just within facilities or a setting, that,
10 too, is on our radar screen.
11 So, I am very encouraged by your
12 comments and suggestions. I really sincerely
13 thank you.
14 DR. BURSTIN: Certainly, based on
15 the comments of the Steering Committee, we
16 will try one more time to go back to AHRQ and
17 CMS on the CAHPS issue because we really were
18 hoping to have it submitted to this project.
19 CO-CHAIR GIFFORD: So, a couple of
20 housekeeping comments.
21 I lied before. Yes, the magic bus
22 is not out there at six o'clock. It is out

1 there at 6:20. So, you have 20 minutes to do
2 whatever.
3 What is the address of the
4 restaurant? I don't know. The restaurant?
5 MS. THEBERGE: The shuttle is
6 leaving at 6:20, is what I believe the
7 schedule says.
8 It is Clyde's restaurant in Chevy
9 Chase.
10 CO-CHAIR GIFFORD: And there is a
11 change for tomorrow. The shuttle, despite
12 what was the confusing stuff slid under our
13 doors, those staying at the Sheraton, and we
14 were trying to keep you from coming; that's
15 why.
16 (Laughter.)
17 And despite the different agendas,
18 the shuttle is leaving at 8:10 tomorrow.
19 Right?
20 MS. THEBERGE: That is what my
21 schedule says, 8:10.
22 CO-CHAIR GIFFORD: At 8:10

1 tomorrow from the Sheraton. So, be down by
2 8:05 or we will leave you out.
3 The meeting starts at --
4 MS. THEBERGE: 8:45.
5 CO-CHAIR GIFFORD: -- 8:45.
6 MS. THEBERGE: With a working
7 breakfast.
8 CO-CHAIR GIFFORD: We will start
9 at 8:45, not 8:46 or 8:47, but 8:45 tomorrow
10 morning.
11 Thank you all very much.
12 MS. THEBERGE: Thank you,
13 everyone.
14 (Whereupon, at 6:01 p.m., the
15 proceedings in the above-entitled matter were
16 adjourned for the day, to reconvene the
17 following day, Thursday, April 22, 2010, at
18 8:45 a.m.)
19
20
21
22

A

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