THE NATIONAL QUALITY FORUM

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MEETING OF THE HEALTHCARE ACQUIRED

CONDITIONS AND SERIOUS REPORTABLE EVENTS
IN HEALTHCARE STEERING COMMITTEE

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Thursday, November 19, 2009

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The Steering Committee convened at 8:00 a.m. in Salon A of the Park Ballroom of the Park Hyatt Washington, located at 1201 24th Street, N.W., Gregg Meyer and Sally Tyler, Co-Chairs, presiding.

PRESENT:

GREGG MEYER, MD, MSc, CO-CHAIR (via telephone)

SALLY TYLER, MPA, CO-CHAIR

LEAH BINDER, MEMBER

PATRICK BRENNAN, MD, MEMBER (via telephone)

TEJAL GANDHI, MD, MPH (via telephone)

CHRISTINE GOESCHEL, RN, MPA, MEMBER

CYNTHIA HOEN, ESQ., MPH, FACHE, MEMBER

HELEN LAU, RN, MHROD, BSN, BMus, MEMBER (via telephone)
KATHRYN McDONAGH, PhD, MEMBER
JOHN MORLEY, MD, MEMBER
DEBORAH NADZAM, PhD, RN, FAAN, MEMBER
MARTHA RADFORD, MD, FACC, FAHA, MEMBER (via telephone)

STANCEL RILEY, MD, MPA, MPH, MEMBER
DIANE RYDRYCH, MA, MEMBER
DORON SCHNEIDER, MD, MEMBER
PHILIP SCHNEIDER, FASHP, MS, MEMBER
ERIC TANGALOS, MD, FACP, AGSF, CMD, MEMBER
MICHAEL VICTOROFF, MD, MEMBER
PETER ANGOOD, MD, FACS, STAFF

HELEN BURSTIN, MD, STAFF JENNIFER HURST, MHS, STAFF LINDSEY TIGHE, STAFF

ALSO PRESENT:

EDDIE GARCIA, CMS

NOT PRESENT:

SUSAN GENTILLI, MBA, RHIA, CPHQ, MEMBER

A-G-E-N-D-A

SELECTING OTHER ENVIRONMENTS OF CARE: EXPANSION BEYOND HOSPITALS
Peter Angood, MD Senior Advisor Patient Safety
ROLE OF TECHNICAL ADVISORY PANELS
SREs/HACS: INPATIENT HOSPITAL FACILITIES Greg Meyer, MD, MS Sally Tyler, MPA
BREAK
SREs/HACs: NURSING, REHABILITATION AND
LONG-TERM CARE FACILITIES
SREs/HACs: AMBULATORY CARE AND HOME HEALTH SETTINGS
Gregg Meyer, MD, MSc Sally Tyler, MPA
PUBLIC COMMENT
SUMMATION AND NEXT STEPS

ADJOURN

- 1 PROCEEDINGS
- 2 (8:08 a.m.)
- 3 CO-CHAIR TYLER: I'm just going to
- 4 ask folks here, just for the record to go
- 5 around and say who you are, just say your
- 6 name, so that everybody on the phone hears,
- 7 and then we'll go through and see who's on the
- 8 phone.
- 9 MEMBER GOESCHEL: Chris Goeschel.
- 10 MEMBER NADZAM: Debbie Nadzam.
- 11 MEMBER VICTOROFF: Michael
- 12 Victoroff.
- 13 MEMBER RYDRYCH: Diane Rydrych.
- 14 MEMBER HOEN: Cynthia Hoen.
- 15 MEMBER TANGALOS: Eric Tangalos.
- 16 MEMBER RADFORD: Martha Radford.
- 17 MEMBER RILEY: Stancel Riley.
- 18 MEMBER McDONAGH: Kathy McDonagh.
- 19 MEMBER DORON SCHNEIDER: Doron
- 20 Schneider.
- 21 MEMBER PHILIP SCHNEIDER: Phil
- 22 Schneider.

- 1 MEMBER MORLEY: John Morley.
- DR. ANGOOD: Peter Angood, and we
- 3 have Lindsey Tighe, and Jennifer Hurst as NQF
- 4 Staff here.
- DR. BURSTIN: And Helen Burstin.
- 6 CO-CHAIR TYLER: And Sally Tyler,
- 7 I'm here. And who do we have on the phone?
- 8 MEMBER LAU: Helen Lau.
- 9 CO-CHAIR TYLER: Okay, Helen, and
- 10 Gregg. Anybody else?
- 11 MEMBER BRENNAN: P. J. Brennan.
- 12 CO-CHAIR TYLER: P.J. Great.
- 13 Anybody else?
- DR. GANDHI: Tejal Gandhi.
- DR. ANGOOD: Gregg, are you on?
- 16 MR. GARCIA: There's also Eddie
- 17 Garcia here from CMS.
- 18 DR. ANGOOD: And Eddie, thank you.
- MR. GARCIA: Sure.
- 20 CO-CHAIR TYLER: Anybody else on
- 21 the phone? Well, I wanted to thank you all on
- 22 the phone, especially those -- I know Tejal

- 1 and Helen, this is your second day with us on
- 2 the phone, and I know it's kind of a
- 3 challenging environment to do these meetings,
- 4 especially when they're day long meetings on
- 5 the phone, but we appreciate your hanging in
- 6 there with us, and look forward to see you in
- 7 person at the next Steering Meeting. So,
- 8 thank you.
- 9 MEMBER GANDHI: Sure, thank you.
- 10 MEMBER LAU: Definitely.
- 11 CO-CHAIR TYLER: And I think now
- 12 Peter and Helen are going to review what we
- 13 did yesterday, as far as updating the
- 14 definitions.
- DR. ANGOOD: Yes, I will. And,
- 16 first off, just in terms of the day's agenda,
- 17 we're going to do this review just to make
- 18 sure we're still on the same page we thought
- 19 we were by the end of yesterday. Ideas do
- 20 change in 24 hours, as we know.
- Then we'll jump back in to finish
- 22 reviewing the existing list of SREs. We'll do

- 1 a very collapsed discussion on what's supposed
- 2 to be part of Day 2 here regarding the
- 3 Environments of Care and the Role of Technical
- 4 Expert Panels, or Advisory Panels. And then
- 5 we'll see how well we can get into some of
- 6 these other environments. We probably won't
- 7 need to spend much time at all, on the
- 8 inpatient hospital setting, but certainly want
- 9 to at least begin the discussion on the
- 10 nursing, rehab, long-term care in the
- 11 ambulatory settings, get some discussion going
- 12 on those.
- 13 While we want to get as much work
- 14 done today as possible, I don't think we are
- 15 feeling like we have to get everything tied up
- 16 and wrapped into a nice little tight bow by
- 17 the end of the day. We have an ongoing
- 18 process here.
- 19 So, in terms of where we thought we
- 20 came out yesterday, we made that significant
- 21 change to the one word in this definition of
- 22 Serious Reportable Events. I've forgotten,

- 1 Donald, I forgot to mention to the operator,
- 2 we're formally open for the meeting. I forgot
- 3 that part. Thank you.
- 4 So, the significant change being
- 5 that the definition now says "defined as
- 6 preventable, serious, unambiguous, adverse
- 7 events that should not occur." Are we all
- 8 comfortable with that? Leah is not
- 9 comfortable, for the record. Yes? Not a
- 10 problem. Michael?
- 11 MEMBER VICTOROFF: I have
- 12 dismissible discomfort because I don't think
- 13 the last phrase is needed, because I can't
- 14 think of the other list we have of serious
- 15 reportable events that should occur.
- 16 DR. ANGOOD: I think, however,
- 17 though, to get back to some of Diane's point
- 18 yesterday, we have to be able to imprint a
- 19 sense of need or urgency on that. And that's
- 20 part of that purpose. Leah?
- 21 MEMBER BINDER: All right. So, let
- 22 me give you my two seconds on why I think the

- 1 word "never" is still appropriate. First of
- 2 all, not does not differentiate these events.
- 3 The word "not" does not differentiate these
- 4 events as special. The fact that we say they
- 5 should never occur does not mean that they, in
- 6 fact, never occur, any more than when we say
- 7 an airline crash is a never event.
- 8 We know it actually does occur,
- 9 sometimes. It's just something that is such
- 10 an awful outcome that we set a very high
- 11 standard for how much we want to prevent it,
- 12 which means we say never, never, never. And
- 13 except that, unfortunately, it might happen.
- 14 So, setting the standard at never has captured
- 15 the imagination of the public. I mean, there
- 16 is nothing that I can -- I've said it before
- 17 yesterday. It is something that people really
- 18 respond to, and understand, that the
- 19 healthcare community is setting a very high
- 20 standard around certain events that are so
- 21 catastrophic, and so awful to families and
- 22 patients that they're really going to make

- 1 sure there's zero tolerance.
- 2 "Never" is the word that has
- 3 captured the imagination. "Not" does not
- 4 differentiate these SREs from anything else,
- 5 and it shies away from a high standard that we
- 6 had already set. So, in doing so, it will,
- 7 itself, be newsworthy to no longer really put
- 8 that word "never" on the table.
- 9 DR. ANGOOD: Thank you, Leah. Any
- 10 comments?
- 11 CO-CHAIR MEYER: This is Gregg. I
- 12 guess my counter to that would be that
- 13 although it has captured the imagination, it's
- 14 also created equal anxiety on the other side,
- 15 and confusion. And I think, in the end, my
- 16 sense is, is that these are differentiated,
- 17 because the National Quality Forum, and
- 18 through its authority through the National
- 19 Technology Transfer and Advancement Act, is
- 20 telling states that these ought to be reported
- 21 publicly. And I think that that's incredibly
- 22 powerful. And, at the end of the day, whether

- 1 or not we say "not" or "never", doesn't matter
- 2 a whole lot.
- I think the downside of the
- 4 confusion of "never" makes me think that
- 5 abandoning it is the right thing to do at this
- 6 point in time. Yet, the overall importance of
- 7 this, and the public imagination is that
- 8 they're going to see this information, and
- 9 that this body is recommending that it be
- 10 publicly reported by states. And, to me,
- 11 there is no stronger statement of urgency and
- 12 importance than that.
- DR. ANGOOD: Thanks, Gregg.
- 14 CO-CHAIR TYLER: I think Leah
- 15 wanted to follow-up.
- 16 MEMBER BINDER: Just one more
- 17 statement about that. Most people in the
- 18 public do not know that it is not a reportable
- 19 event in some places for some of the wrong
- 20 side surgery, and so that is not going to gain
- 21 us a huge amount of enthusiasm from
- 22 purchasers, or from the public, if we say oh,

- 1 the big drama is that it's now going to be
- 2 reportable. I think for them, of course, it's
- 3 reportable. Most people can't imagine why it
- 4 wouldn't be, so that's not capturing anybody's
- 5 imagination, to be quite frank.
- 6 The word "never" did, and the word
- 7 "never" set the kind of standard I think that
- 8 we should all set as a healthcare system. I
- 9 don't think it's confusing. I think it says
- 10 we think these events are so bad that we're
- 11 going to put the word "never" to them. And
- 12 understand that mistakes happen, and maybe it
- isn't going to be never, just like an airline
- 14 crash, just like any other catastrophic event,
- 15 but we do see them at that level.
- DR. ANGOOD: Martha.
- 17 MEMBER RADFORD: I took away from
- 18 the discussion yesterday, and please correct
- 19 me if I'm wrong, that part of the role of this
- 20 group is to, in a sense, broaden the scope of
- 21 reportable events to get beyond the serious
- 22 catastrophes, and into near misses and things

- 1 like that, that do occur, and we know they
- 2 occur. And that, in fact, reporting near
- 3 misses can prevent the serious catastrophe.
- 4 So, I think that it's accurate, and there is
- 5 something to be said for accuracy, to say
- 6 these things, to use "not" instead of "never".
- 7 DR. ANGOOD: Diane, you had a
- 8 comment?
- 9 MEMBER RYDRYCH: Yes, I just wanted
- 10 to say, you know, I was one of the people who
- 11 didn't want to take out the phrase entirely,
- 12 because I was worried that we would lose some
- of that sense of urgency, if we got rid of
- 14 "never". The reason that we, as a group, came
- 15 up with "not" as a compromise, and maybe it's
- 16 not the right word, and maybe there are others
- 17 that are better, is because I think we all
- 18 would have felt more comfortable with "never",
- 19 if the list didn't include things like
- 20 pressure ulcers, and falls, that are kind of
- 21 in a different class of events in some ways,
- 22 than some of the others.

- In my state, when we talk about
- these, we don't usually use the term "never
- 3 events." For some, we do, because wrong side
- 4 surgery shouldn't ever happen, and some of
- 5 these other events are definitely in that
- 6 category. But we felt uncomfortable saying
- 7 even one of these events is too many when it
- 8 came to things like pressure ulcers, so that
- 9 was just kind of what was behind some of the
- 10 discussion, and the decision to move it to
- 11 "not" yesterday. I don't know if "not" is the
- 12 absolutely right word to use, but we were
- 13 trying to acknowledge that there are some of
- 14 these that are a little bit different than
- 15 some of the others.
- 16 DR. GANDHI: This is Tejal Gandhi.
- 17 I just wanted to confer with that. I think
- 18 that's definitely where my level of concern
- 19 comes from around "never", as well, is around
- 20 the falls and pressure ulcers, because it
- 21 would lead to the most discussion for us, as
- 22 well. I just wanted to agree with that

- 1 comment.
- DR. ANGOOD: Thanks, Tejal. John,
- 3 and then Leah.
- 4 MEMBER MORLEY: I certainly do
- 5 appreciate the emotion attached to that
- 6 "never" term, but that emotion is something
- 7 that can be used in a positive mechanism for
- 8 drawing additional resources, additional
- 9 attention, additional focus, all sorts of very
- 10 positive things.
- 11 On the other side, unfortunately,
- 12 in the area that we live, and the time that we
- 13 live today, that "never events" also brings
- 14 with it the concept that if it never should
- 15 happen, then somebody, obviously, didn't
- 16 create a human error, they did something that
- 17 was either malicious, or demonstrated total
- 18 incompetence. And I think we can accept that
- 19 those can certainly lead to those events we
- 20 have on our list, but there are many other
- 21 mechanisms by which those things can occur,
- that don't, necessarily, imply incompetence,

- 1 or maliciousness.
- DR. ANGOOD: And Leah, again.
- 3 MEMBER BINDER: Well, we've been
- 4 using the term "never events" at Leapfrog, and
- 5 have the policy, and it's been wildly
- 6 replicated. We've never ever accused anyone
- 7 of incompetence, nor has it been interpreted
- 8 that way, frankly. I don't think that has
- 9 ever been the consequence of the term "never",
- 10 and why "never" matters.
- 11 And in terms of your point about
- 12 pressure ulcers, absolutely, pressure ulcers
- 13 are not never events, but I don't think that
- 14 we've defined, at least in the policies that
- 15 I've seen in NQF before this, we haven't
- 16 defined it as all pressure ulcers. We've
- 17 isolated the specific kinds of pressure ulcers
- 18 that really should never occur. I don't think
- 19 a Stage Four pressure ulcer -- I mean, we
- 20 should set that as a standard that that should
- 21 never occur. We should be able to prevent
- 22 that.

- 1 The word "never" does have some
- 2 emotional resonance, but, frankly, we're
- 3 talking about things that are emotional to
- 4 people, that wrong side surgery, removing the
- 5 wrong limb, I'm sorry, that's a catastrophic
- 6 event. That's a very emotional event, and I
- 7 think that the healthcare system by responding
- 8 and saying yes, it is a catastrophic event.
- 9 There is emotion attached to that. It's
- 10 important to us, too. The word "never" gets
- 11 to that point the way nothing else can, or
- 12 maybe there's another word, but "never" has,
- in my mind, been very effective as a strategy,
- 14 at least from a purchaser's point of view, it
- 15 has been a very effective way to describe what
- 16 these events really are. And to address them,
- 17 I think, in very effective ways.
- DR. ANGOOD: Michael, and then
- 19 Cynthia.
- 20 MEMBER VICTOROFF: Just to
- 21 interject the dilemma of the malpractice
- 22 defense, because we live in a litigious

- 1 environment, as well. And what our experience
- 2 is beginning to be, as this list gets
- 3 propagated and understood by plaintiffs, is
- 4 that this is a kind of get into jail free card
- 5 for a plaintiff, that the phrase, which I
- 6 object to for logical reasons, not because it
- 7 doesn't emotionally emphasize how horrified we
- 8 are about things, but because it emotionally
- 9 trivializes how horrified we ought to be.
- 10 Because I really can't come up with the
- 11 alternative list of the errors that should
- 12 happen, or that ought to happen in your
- institution at a certain rate, or that you
- 14 should encourage people to commit.
- So, in a way, no matter how minor
- 16 an error is, it shouldn't occur. "Never" is
- 17 the goal for errors, but when we get into
- 18 court, it's a whole other discussion. It's
- 19 not rhetoric, at all. There is a legal
- 20 mousetrap here that we're experiencing, and is
- 21 causing consternation among people who have to
- 22 make logical arguments in front of juries,

- 1 that if some authoritative body published a
- 2 list that simply said the following items are
- 3 indefensible under any condition, which is how
- 4 it's been presented, that it puts us in a very
- 5 difficult position when, actually, there is a
- 6 defense.
- So, for that reason, there's a very
- 8 strong sentiment among the people that have to
- 9 deal with administrative accountability, and
- 10 litigation that this is a terribly prejudicial
- 11 term. They could live with "not", but the
- 12 folks I work with couldn't live with "never"
- 13 any longer.
- 14 MEMBER HOEN: I would agree with
- 15 Michael, and we have, in fact, seen a
- 16 significant increase in the number of lawsuits
- 17 associated with pressure ulcers, which were
- 18 not preventable, because the family believed
- 19 based upon the wording in these particular
- 20 guidelines that they were never events.
- 21 We just recently tried one twice,
- 22 both to defense verdicts, but to a tune of

- 1 probably a million dollars in attorneys fees.
- 2 And we've had many others arise in those
- 3 events, which should not have occurred, and it
- 4 was unfortunate the expectations of the
- 5 families and the patients were furthered by
- 6 the "never" concept. And, thus, became very
- 7 angry, and uncontrollable.
- 8 I agree that we don't want these
- 9 things to happen, but some of them are not
- 10 preventable, and "not", therefore, is a little
- 11 bit of a softer and less accusatory term in
- 12 those instances.
- 13 CO-CHAIR TYLER: Philip.
- 14 MEMBER PHILIP SCHNEIDER: I'm
- 15 wondering when we get to the discussion of
- 16 alternate healthcare settings, where the
- 17 control over the healthcare that's delivered
- is less rigorous, whether we would be hemmed
- in by having a term like "never", because in
- 20 a home care environment, for example, there
- 21 may be some things that are egregious, and
- 22 should not happen, but maybe less easy to

- 1 assure that they never happen, because the
- 2 care is less carefully overseen than it is in
- 3 a hospital setting. So, this definition may
- 4 well have made sense in a highly organized
- 5 healthcare delivery setting, like a hospital,
- 6 that may be less easy to conceive of in other
- 7 healthcare settings.
- 8 CO-CHAIR TYLER: Eric.
- 9 MEMBER TANGALOS: I'm actually
- 10 worried about the extended environment, as
- 11 well, not so much -- we've already heard about
- 12 the threat of the "never" piece, but on the
- 13 opposite side, if we just blow it off, because
- 14 "never" makes no sense, then we lost the
- 15 middle ground, where we really want to do
- 16 something about it. And one of the biggest
- 17 abuses we have right now with pressure sores,
- 18 which are bad, and should not occur in almost
- 19 all situations, is you get a free pass when
- 20 you convert the patient to hospice. So,
- 21 you've thrown in the towel, so to speak, and
- 22 I don't want to see that part happening,

- 1 either.
- 2 CO-CHAIR TYLER: Leah.
- 3 MEMBER BINDER: I can't speak to
- 4 the legal ramifications, except that, as you
- 5 all know, there are studies that show that if
- 6 you apologize to the patient, you will reduce
- 7 the rate of -- the likelihood of malpractice
- 8 by whatever it is, 55 percent I think was the
- 9 latest.
- 10 That's the extent of my knowledge
- 11 on that, so I defer to your knowledge that
- 12 there's -- that "never" is somehow triggering
- 13 lawsuits. But, again, I think saying
- 14 something should never occur does not
- 15 prescribe that this thing -- who is at fault,
- 16 or why. There can be reasons why it still
- 17 does occur, or it doesn't occur, but it
- 18 doesn't prescribe who's at fault. It simply
- 19 says that this is the standard we've set for
- 20 this particular condition that we name, and
- 21 that's why it's considered an extreme case, a
- 22 serious reportable event. So, "never" says

- 1 that like other things don't.
- Now, having said that, I'm not -
- 3 I'm very strongly, as you know, in favor of
- 4 keeping "never" in there, but if the
- 5 alternative that this group is going to vote
- 6 on is not occur, I particularly don't like
- 7 that, because that implies that there's some -
- 8 in that Venn diagram that we did, that
- 9 there's some other things that maybe should
- 10 occur. I mean, the opposite is true, or
- 11 something. I think it would be better just to
- 12 leave it at serious, ambiguous adverse events,
- 13 period. That would be my second choice, but
- 14 I'm just -- but I'm extremely strongly in
- 15 favor of keeping "never".
- 16 MEMBER TANGALOS: Well, if you were
- 17 here yesterday for that vote, I think it
- 18 occurred beforehand, that was almost a split
- 19 vote yesterday. That piece was very close to
- 20 leaving it all out, versus putting "not" in.
- 21 CO-CHAIR TYLER: Philip.
- 22 MEMBER PHILIP SCHNEIDER: On the

- 1 other side, I'm kind of going back and forth
- 2 on this in my own mind. I'm concerned about
- 3 hemming ourselves in for the alternate care
- 4 settings, but I also -- I'd be interested in
- 5 the opinions of the rest of the group as to
- 6 whether or not it's important to either
- 7 retain, or recommit ourselves to a sense of
- 8 urgency when it comes to the safety agenda.
- 9 It's my feeling that it's not as
- 10 urgent as it has been, when To Err Is Human
- 11 was published. And I think that the momentum
- is, I don't want to say lost, but I just get
- 13 a sense that in setting standards for patient
- 14 safety we do need to be, I don't know if the
- 15 term "dramatic" is the right word, but we need
- 16 to be forceful. And I -- Leah's comments are
- 17 really striking a responsive chord with me.
- 18 I know when we talked about this at
- 19 an international meeting, and one of my
- 20 colleagues talked about never events, it
- 21 really got people's attention, that in the
- 22 U.S. we're talking about things that we really

- 1 shouldn't allow to happen in the healthcare
- 2 system. And that really raised a lot of
- 3 eyebrows, and that kind of sound byte really
- 4 was powerful in our discussion. And I'm
- 5 resonant to the idea of maintaining a sense of
- 6 urgency, or recommitting. Maybe that's the
- 7 way I'd say it. And I'd be interested in
- 8 whether other people feel that that's true, or
- 9 not. Maybe I'm being too pessimistic.
- 10 CO-CHAIR TYLER: Stan, I think was
- 11 next.
- 12 MEMBER RILEY: I guess the word
- "never", to me, means that there's a solution,
- 14 that we have a way to make these things be
- 15 okay. So, if you say "never", that means --
- 16 that implies that you have the fix for
- 17 whatever it is, wrong side surgery, for any of
- 18 those other things.
- 19 I think the thing that would really
- 20 help the sense of urgency is to come up with
- 21 a fix, say this is what works for this. That
- 22 would make a headline, I think, just as well

- 1 as saying "never".
- DR. ANGOOD: And that's probably
- 3 where in the opening comments trying to weave
- 4 the SREs, practices, and measures all sort of
- 5 together over time, because they have their
- 6 individual purposes, but we need to get them
- 7 closer together to help reinforce one another
- 8 along the point you were just making.
- 9 CO-CHAIR MEYER: This is Gregg. I
- 10 can I just make a comment along those lines.
- 11 CO-CHAIR TYLER: I'm sorry. Is
- 12 someone on the line?
- 13 CO-CHAIR MEYER: Yes, it's Gregg.
- 14 I agree with this need to re-establish
- 15 urgency. I disagree that the right way to do
- 16 that is to keep the word "never". I think
- 17 that the way to do that has to do with I think
- 18 the way that the Quality Forum is trying to
- 19 repackage, and reinvigorate its safety
- 20 portfolio. And, in particular, I think that
- 21 when this new list of SREs, along with the
- 22 next version of Safe Practices comes out, I

- 1 think that there's a great opportunity for the
- 2 Quality Forum to really take the bully pulpit
- 3 and push very hard to say we took a fragmented
- 4 approach in the past, we're trying to pull
- 5 these things together to the extent they make
- 6 sense to pull together, and doesn't -- a
- 7 completely tight coupling. But that will be,
- 8 I think, very, very powerful.
- 9 And, in the end, you know, my
- 10 vision is, is that we ought to have the
- 11 accountability out there with a list of
- 12 serious reportable events that states are
- 13 reporting publicly, and creating a sense of
- 14 urgency through that mechanism. But, at the
- 15 same time, I believe we ought to have public
- 16 reporting on who's implementing the safe
- 17 practices, taking the systems approach. And
- 18 I think the Quality Forum would be positioned
- in a way that it's never been before through
- 20 that, to create that sense of urgency.
- 21 CO-CHAIR TYLER: Okay. Thanks,
- 22 Gregg. We have Kathryn, and then Diane.

- 1 MEMBER McDONAGH: I think these
- 2 points are excellent, as well. And I do feel
- 3 strongly that we need to make some strong
- 4 statements. I agree with Gregg, that when we
- 5 look at the totality of the work when we're
- 6 done, we've got to have a balance of really
- 7 creating a safety of culture, because we have
- 8 an issue with that in terms of just cultures,
- 9 and creating an openness in organizations.
- But, yet, we want to really hold
- 11 people accountable, and increase that sense of
- 12 urgency, so I do that the way we've worded it
- is fine, but then we've got to add some other
- 14 statements, and frame it very aggressively,
- 15 what we think needs to be required to be
- 16 reported, and really, I think, putting the
- 17 whole package together, so that it's a very
- 18 strong statement of accountability; but, yet,
- 19 it's balanced with, if we're really trying to
- 20 move healthcare to a high reliability
- 21 organization, it can't be done in a punitive
- 22 environment. It needs to be done in a culture

- 1 of safety. So, I think what we're trying to
- 2 balance there is, there's a natural dynamic
- 3 tension, but I think we can come out with very
- 4 strong statements.
- 5 MEMBER RYDRYCH: I agree on the
- 6 sense of urgency. And I think I talked a
- 7 little bit yesterday about the experience
- 8 we've had in Minnesota, and it's challenging
- 9 sometimes to balance, talking about the fact
- 10 that some of these things may not be
- 11 preventable, but still wanting to make sure
- 12 that they're kind of held above other types of
- 13 events, and taken seriously. And that can be
- 14 difficult to do.
- I appreciate Gregg's point, but I
- 16 don't entirely agree that the consolidation
- 17 and updating of measures is going to create
- 18 that sense of urgency, because out in the
- 19 field, I think people -- we've talked about
- 20 this. There is Leapfrog, and there's NQF, and
- 21 there's CMS, and there are all these other
- 22 things. And when these measures get updated,

- 1 people notice that, but that, in and of
- 2 itself, doesn't really create a sense of
- 3 urgency. And I don't think the consolidation
- 4 will, either, in the absence of other action.
- 5 And it does feel like we need to focus on
- 6 those corrective actions.
- 7 What are -- we've got 27 states
- 8 that are -- that have implemented part, or
- 9 all, of the NQF list, and are doing public
- 10 reporting, and are collecting data. And, in
- 11 many cases, they're not sharing any of that,
- 12 and they're not sharing what's working in
- 13 their states. And there aren't really good
- 14 mechanisms for that, so there's a lot of good
- 15 work that's going on in individual hospitals,
- 16 and in different states, that there's not
- 17 really a good mechanism to capture.
- There might be people who are
- 19 starting to figure out how you fix some of
- 20 these things, but it's difficult to really
- 21 know that. And it feels like that's the way
- 22 we end up energizing this, rather than dealing

- 1 just with the measurement and the reporting
- 2 side of it; although, that's important, too.
- 3 DR. GANDHI: Hi, this is Tejal on
- 4 the phone. Could I jump in?
- 5 CO-CHAIR TYLER: Sure, on the
- 6 phone, first.
- 7 DR. GANDHI: Okay. I just wanted
- 8 to make a comment about the sense of urgency,
- 9 as well. I mean, the term "never events" was
- 10 around for a long time, and at least in the
- 11 State of Massachusetts, the urgency, I think,
- 12 didn't really happen until it became a
- 13 reporting requirement.
- I don't think the term "never" got
- 15 people's attention, as much as the
- 16 reportability piece. And, certainly, at that
- 17 point, got the attention of hospitals, who
- 18 then really starting putting additional
- 19 efforts towards these things. So, at least in
- 20 Massachusetts, and Gregg can agree or
- 21 disagree, but that was, I think, the
- 22 experience I've seen.

- 1 MEMBER DORON SCHNEIDER: One of the
- 2 goals of the work effort is to lead to further
- 3 harmonization of efforts, and I wonder if we
- 4 could gain something by adding a couple of
- 5 words on, which would, essentially, go
- 6 something like "that should not occur, should
- 7 lead to disclosure, and investigation of root
- 8 cause." That's really Joint Commission
- 9 language. Leapfrog has taken that on, and it
- 10 really does put a stamp on it that is a little
- 11 bit different than well, yes, we want you to
- 12 report this. Great. Well, we want to
- 13 disclose, and we want investigation of root
- 14 cause.
- 15 CO-CHAIR TYLER: John, and then
- 16 Leah.
- 17 MEMBER MORLEY: I think you may
- 18 actually have another agenda item. I'm not
- 19 sure that it will fit for today, but perhaps
- 20 the next time. But I think there is a very
- 21 strong feeling, I have a very strong feeling
- 22 that whatever we can do, short of the "never"

- 1 word, but by other mechanisms to increase the
- 2 urgency, and to support this issue, in
- 3 general, of reporting.
- 4 Some of the things that Doron was
- 5 just describing, I mentioned at our meeting a
- 6 few weeks ago that even though we call this a
- 7 reporting system, there's a lot more to this
- 8 than reporting. I think, unfortunately, the
- 9 press hooks onto that word "reporting", and
- 10 there's a belief out there, maybe that's too
- 11 strong a word for the press, that just
- 12 reporting is going to fix the problems. And
- 13 I've commented in testimony to the state
- 14 legislature that if reporting were the answer
- 15 that was going to fix everything, just
- 16 reporting, we would have fixed things nine
- 17 years ago.
- 18 It's about a lot more than that.
- 19 So, any opportunity to increase urgency and
- 20 provide backgrounds, and support for doing
- 21 more than reporting, for PDCA, would be a
- 22 major plus for this report.

- 1 CO-CHAIR TYLER: I think Leah was
- 2 next, and then Michael.
- 3 MEMBER BINDER: I can only speak
- 4 from my experience, but I can tell you that I
- 5 have spoken to New York Times, Washington
- 6 Post, CNN, I can name major broadcasts, or
- 7 major newspapers about never events. This
- 8 captures the imagination.
- 9 This will be a major story, and I
- 10 think Gregg has brought up the point, modern
- 11 healthcare, if nothing else, will grab on to
- 12 this in a second. Where's the word "never"?
- 13 This will be the story, so you're right. We
- 14 better come up with some other language that
- 15 will clarify that oh, we're not lowering the
- 16 standard, we're just using a new word, even
- 17 though this is the word, "never events", that
- 18 has come into our language thanks to NQF in a
- 19 way that I have found to be very powerful,
- 20 very compelling, and a tribute to our health
- 21 care system, that providers are willing to say
- 22 no, we are going to go lay down the gauntlet

- 1 on certain events that should never occur.
- 2 And I want to go back for one
- 3 second to my airline analogy. An airline
- 4 crash is a never event. It should never
- 5 happen. Does that mean that it's always
- 6 preventable? No, there can be birds that fly
- 7 into your plane, and you have the best pilot
- 8 in the air, and he handled it, and the whole
- 9 crew survived, et cetera, but it's still a
- 10 never event. It's still -- and airlines still
- 11 stand up for that. That's a never event. We
- 12 will do everything in our powerful humanly to
- 13 avoid that from happening again.
- 14 The public understands that
- 15 sometimes it is preventable, but setting that
- 16 standard gives comfort to the public, that the
- 17 healthcare system, or the airline industry,
- 18 does understand that it is -- that they have
- 19 a special trust placed in them. So that word,
- 20 and that is why I think it's captured the
- 21 attention of the public.
- 22 CO-CHAIR TYLER: Michael, then

- 1 Helen.
- 2 MEMBER VICTOROFF: Well, I'm
- 3 getting more uncomfortable the longer we
- 4 discuss this. And despite my fondness for
- 5 Leapfrog, and your very good contributions, I
- 6 now envision dueling interviews with CNN,
- 7 where members of groups like our s are going
- 8 to explain in strong terms why one or the
- 9 other view about this word is absolutely
- 10 necessary, and critical. And that bothers me
- 11 a lot.
- I think the "never" word should
- 13 never have been spoken. It was a mistake from
- 14 the beginning. It was a rhetorical device.
- 15 It's scientifically silly. It's logically
- 16 impossible. And no one in the airline
- industry uses that word ever about anything.
- 18 In fact, if there's one thing you never say,
- 19 it's "never" in the safety business.
- 20 I'm particularly wanting to address
- 21 this issue about urgency. If you look at
- 22 global warming, or the rain forest depletion,

- 1 or any popular cause, there's a great deal of
- 2 hand waving possible about urgency, and the
- 3 urgency of the people in the meetings is
- 4 always dramatic, but I don't really care about
- 5 urgency. On the front line practicing
- 6 medicine, living in a hospital, going in as a
- 7 patient on a gurney, I don't care if people
- 8 are urgent about problems that can't be fixed.
- 9 I think the credibility of this
- 10 organization rests on being able to move from
- 11 hand waving and publicity, which are very nice
- 12 at Stage One. Stage Two of science, where
- 13 we're able to say and, look, we have a
- 14 vaccine. It's one thing to say, oh, my God,
- 15 we're all going to get HIV, heavens. Okay.
- 16 There was a hand waving at the time
- 17 for HIV, but now is really the time to look at
- 18 the molecules a little. And I'd love to
- 19 progress to that stage in the safety business.
- 20 And I think that this move -- I mean, my
- 21 interview with New York Times, heaven help us,
- 22 is going to say as we mature as scientists,

- 1 and strategists about remedies, we didn't find
- 2 it was necessary to use that word "never" any
- 3 more. We became more refined, and
- 4 sophisticated. That's my current
- 5 understanding.
- 6 DR. BURSTIN: I just want to make
- 7 two points, one of which is that NQF has not
- 8 supported the word "never event" since the
- 9 origination of the Serious Reportable Events.
- 10 I just want to make that clear. That's been
- 11 something that has been stricken from the
- 12 language, explicitly, because we made it clear
- 13 that we believe there are appropriate public
- 14 reporting and improvement, but never was not
- a word that was really used beyond the 2000
- 16 initial definition.
- I think the second thing is that I
- 18 think we've also tried to create a broader
- 19 corridor for more reporting. And I think the
- 20 only way to do that is, in fact, to make it a
- 21 broader definition. And that, I think, was
- 22 the basis of most of our discussion yesterday.

- 1 So, that broader corridor allows us
- 2 to get to that list John mentioned yesterday
- 3 of those 40 things that might be really
- 4 significant, but would have an incredible
- 5 amount of discomfort saying "never" associated
- 6 with, but some of them are equally bad. So,
- 7 I think that those two things together, we
- 8 would not support the term "never events",
- 9 haven't in years, so others may call it that,
- 10 but just to be clear, from NQF's perspective,
- 11 they are serious reportable events, they are
- 12 not called "never events."
- 13 And, secondly, the intention of
- 14 yesterday was to create a broader corridor to
- 15 allow us to bring in bad things that may not,
- 16 necessarily, fit a "never" designation.
- 17 CO-CHAIR TYLER: Okay. Just -- I'm
- 18 going to interject to see if you all -- if
- 19 there is any -- from what we're getting. I
- 20 mean, we're reinforcing positions, it sounds
- 21 like, but do people feel the need to take a
- 22 vote on what Doron offered, as far as adding

- 1 some modifying language? Would you offer that
- 2 again, Doron, just to make your suggestion
- 3 again?
- 4 MEMBER DORON SCHNEIDER: For the
- 5 intent of further harmonizing, it would read
- 6 defined as "preventable, serious, and
- 7 unambiguous adverse events that should not
- 8 occur, should lead to disclosure, and a search
- 9 for root cause."
- 10 CO-CHAIR TYLER: Should lead to
- 11 disclosure and search for root cause." Is that
- 12 right?
- 13 MEMBER DORON SCHNEIDER: Yes,
- 14 something like that.
- 15 CO-CHAIR TYLER: Causes.
- 16 MEMBER RADFORD: Search for and
- 17 correction of.
- 18 MEMBER DORON SCHNEIDER: I like the
- 19 correction.
- 20 CO-CHAIR TYLER: Yes.
- 21 MEMBER DORON SCHNEIDER: That's the
- 22 punch.

- 1 CO-CHAIR TYLER: Search for and
- 2 correction of.
- 3 DR. BURSTIN: The first one you
- 4 said investigation, by the way, which I think
- 5 is better.
- 6 CO-CHAIR TYLER: Yes.
- 7 MEMBER BINDER: And what about,
- 8 "should always lead to", and what about adding
- 9 an apology to the patient?
- 10 CO-CHAIR TYLER: Disclosure.
- 11 MEMBER BINDER: Should always lead
- 12 to disclosure, search for correction, apology
- 13 to the patient.
- 14 MEMBER BRENNAN: I think all this
- 15 language could be included in text, but I
- 16 would prefer to keep the definition of the
- 17 actual event crisp.
- 18 CO-CHAIR TYLER: Is that P.J.?
- 19 MEMBER BRENNAN: Yes.
- 20 CO-CHAIR TYLER: Okay.
- 21 MEMBER RYDRYCH: It feels a little
- 22 wordy, to me. It feels like we're -- I don't

- 1 like the idea of making it this broad, and I'd
- 2 prefer to keep the definition a little
- 3 cleaner. But I would like to see in the text,
- 4 or somewhere in the explanatory language, I'd
- 5 like to see more about disclosure and apology,
- 6 because I think that's something we certainly
- 7 encourage people to do, but having that be
- 8 sort of more -- getting a little more weight
- 9 from NOF around these events should be
- 10 disclosed to patients, and there should be an
- 11 apology would give more weight to that.
- 12 CO-CHAIR TYLER: Cynthia.
- 13 MEMBER HOEN: That's a great idea,
- 14 but not, necessarily, doable in every
- 15 instance. In the State of New Jersey, an
- 16 apology is admissible in the court of law.
- 17 The other problem is, in a lot of these
- 18 events, it's not clear -- I mean, you can say
- 19 I'm sorry this happened to you, and here's
- 20 what happened to you, and we do that. But to
- 21 go beyond that is not, necessarily, possible,
- 22 because you have multiple players involved.

- 1 And if you start pointing at each other before
- 2 you understand what really occurred, and what
- 3 needs to be corrected, it's very problematic.
- 4 So, I appreciate the research out
- 5 there. I've not seen a decrease in lawsuits
- 6 because we apologize. We've seen a decrease
- 7 nationally in lawsuits, because that's the
- 8 climate, so I'm not sure you can attribute it
- 9 to that. Although, I do think it's obviously
- 10 -- we do need to take care of our patients,
- 11 and be there for them when bad things happen.
- 12 CO-CHAIR TYLER: Michael.
- 13 MEMBER VICTOROFF: Unlike New
- 14 Jersey, Colorado has a robust apology statute
- 15 that allows those things to be not introduced
- 16 as evidentiary. And we have a very extensive
- 17 apology program in our malpractice environment
- 18 in Colorado. And we would never want to see
- 19 apology introduced as some sort of a
- 20 quideline, or some sort of a mandatory remedy,
- 21 or step in the management of a terrible event.
- 22 Although, we know that, at times,

- 1 it seems to be really a good idea, the problem
- 2 with sticking it in here, and I don't like
- 3 adding any of it. I mean, what you're saying
- 4 is logical, but I think it ruins the rhetoric
- 5 here. I just, for stylistic reasons, I'm
- 6 going to just say I can't support adding more
- 7 words now.
- 8 But, especially -- even adding to
- 9 the apology thing for the serious reportable
- 10 events, a different topic, the reason why we
- 11 probably wouldn't like that, is because then
- 12 it would single out serious reportable events
- 13 as the apology things. And where we're making
- 14 our great headway is in the not so serious
- 15 events, where there's a potential to preempt
- 16 litigation, and not even have it. Whereas,
- 17 most of the serious events are still ones that
- 18 are getting litigated. So, when an
- 19 anesthesiologist knocks a tooth out, we have
- 20 a chance to not even have litigation, if we
- 21 apologize, and actually offer some money,
- 22 early resolution. There are lots of things

- 1 you can do to not serious events.
- 2 So, putting apology into this
- 3 document would raise a whole bunch of
- 4 discussion, for me, in terms of whether the
- 5 unintended consequences were as good as the
- 6 intended ones. I haven't even -- I'm not even
- 7 prepared to think about that yet, so I caution
- 8 you to ponder it.
- 9 MEMBER RYDRYCH: I'm sorry, but if
- 10 apology is effective in reducing litigation
- 11 for the non-serious events, wouldn't it also
- 12 be effective -- I'm borrowing Michael's -- if
- 13 apology is effective in limiting litigation
- 14 for the non-serious events, wouldn't it also
- 15 be effective in limiting litigation for the
- 16 serious reportable events?
- 17 MEMBER VICTOROFF: We have no good
- 18 evidence about that. We'd like to think so,
- 19 sentimentally. And there's theoretical reason
- 20 to think that might be true, if we had
- 21 conducted a double blind trial. But the
- 22 problem is, I'm very nervous about putting in

- 1 too much sentiment with no evidence. You
- 2 know, if you want to put an appendix that says
- 3 gee, we should study apology, study the hell
- 4 out of apology, because, look, it might be
- 5 good. Oh, I'll subscribe to that. But this
- 6 is too much toward the front of the document.
- 7 MEMBER RYDRYCH: I agree. I don't
- 8 want it in this definition, either.
- 9 CO-CHAIR TYLER: Christine wants to
- 10 get in on this.
- 11 MEMBER BRENNAN: Peter, if I could
- 12 interject here, it seems like this is beyond
- 13 the scope of the project. I mean, it seems
- 14 like we're getting into issues of
- 15 implementation after the discovery and
- 16 reporting of an event.
- 17 CO-CHAIR MEYER: This is Gregg.
- 18 Just one of the Safe Practices is explicitly
- 19 around disclosure and apology, so there's an
- 20 existing Safe Practice on this issue.
- I think that what we may want to do
- 22 in this report is somewhere in the text note

- 1 that -- to cross-reference the serious
- 2 reportable event with saying that, and by the
- 3 way, there is this patient -- there is this
- 4 Safe Practice related to disclosure and
- 5 apology. So, I think this is a great
- 6 opportunity for linkage. I agree, it's
- 7 probably beyond the scope of this document,
- 8 but I do think it's a good way to link the
- 9 work.
- 10 MEMBER BRENNAN: Leah, would it
- 11 help your concerns about "never" to include
- 12 language in the text that speaks to the issue
- of never, rather than putting it in the
- 14 definition, and explains that never is -- we
- 15 believe these events should never happen, but
- 16 are not always preventable, and should not be
- 17 -- and to points that Michael made earlier,
- 18 goes on to make points about the effect, in
- 19 terms of litigation, and how they should be
- 20 construed.
- 21 CO-CHAIR TYLER: I think Christine
- 22 had a point, and we're going to, hopefully,

- 1 then kind of put a beat on this, wrap it up.
- 2 MEMBER GOESCHEL: My point was
- 3 exactly that. I kept going back to the
- 4 definition, and my immediate thoughts were
- 5 scope creep. This is a definition of serious
- 6 reportable event, not what we do about it, how
- 7 we do what we do about it.
- 8 So, I would be highly in favor of
- 9 the minimalist approach that we took
- 10 yesterday. And I just wanted to go on record
- 11 supporting what Michael and others have said
- 12 all along, and I believe that Gregg said the
- 13 same thing, is that we want to move the
- 14 evolution of this towards science and
- 15 evidence. And, as we go down that path, I
- 16 think clear and succinct definitions of terms
- 17 are going to be critical. So, that was it.
- 18 CO-CHAIR TYLER: Given what we've
- 19 discussed, and it sounds like that is where
- 20 the sentiment of the group is, but are people
- 21 -- can we vote for confidence in leaving it as
- 22 it originally was, after occur, and then

- 1 adding in the text of the report trying to
- 2 capture as much of this discussion, and some
- 3 of the various thoughts, particularly around
- 4 "never", and what that concept means to
- 5 people. Are people comfortable with that? Do
- 6 we want to actually vote for that?
- 7 MEMBER BINDER: I'd like to say
- 8 something.
- 9 CO-CHAIR TYLER: Okay, Leah.
- 10 MEMBER BINDER: I just want to make
- 11 a point about Michael's point, just to be
- 12 really clear. I'm not talking about calling
- 13 up the New York Times, and I can't -- I'm not
- 14 trying to do a dueling thing here. I just
- 15 want to be clear about that.
- I raised that point, because this
- 17 group should be cognizant of how the public,
- 18 consumers, and purchasers are perceiving
- 19 what's done here. And I'm just telling you
- 20 from my experience, purchasers are extremely
- 21 passionate about the issue of never events.
- 22 And we do call it that. It is our policy, and

- 1 others have replicated it. So, purchasers
- 2 have conferences on this all the time.
- 3 There's one coming up in a month that's done
- 4 by a big purchaser out in Ohio.
- 5 In fact, the Purchasers Coalition
- 6 in Ohio has dedicated their whole year to
- 7 eliminating never events, to addressing never
- 8 events in hospitals, or something. I mean,
- 9 this -- so, when this comes out, you can bet
- 10 they're going to notice the word.
- 11 So, I understand maybe "never"
- 12 should have been there to begin with. We
- 13 certainly could debate that. It was there.
- 14 It captured a lot of attention, and it set a
- 15 standard that I happen to support. But I
- 16 understand the issues, I understand that
- 17 that's a difficult -- I understand the
- 18 difficulties, but I also think that this is a
- 19 serious move, to remove that word. And I hope
- 20 that it's understood that I'm bringing this
- 21 forward in the way that I have to, to
- 22 represent my constituency, which will notice

- 1 this.
- CO-CHAIR TYLER: Okay. Let's go to
- 3 a vote. The vote would be to leave it as it
- 4 is on the screen, what we had agreed to
- 5 yesterday, but elaborate further in the text
- 6 particularly around "never", and why it's not
- 7 in the definition at this point. Okay. If
- 8 you think that's sufficient, that's what
- 9 you're voting yes for. If you think it's
- 10 insufficient, then there would be some other
- 11 remedy. But, do people vote -- is this what
- 12 people want? Yes? All those voting yes?
- 13 (Vote taken.)
- 14 CO-CHAIR TYLER: And on the phone?
- 15 CO-CHAIR MEYER: I'm sorry. That
- 16 wasn't clear to me. Could you -
- 17 CO-CHAIR TYLER: Okay. What we're
- 18 voting on is to leave the definition as we did
- 19 at the end of the day, which is defined as
- 20 "preventable serious, and unambiguous adverse
- 21 events that should not occur." And then we
- 22 would also in the text of the report really

- 1 flesh out a bit about why the term "never" was
- 2 removed, and substituted with "not".
- 3 CO-CHAIR MEYER: Okay.
- 4 CO-CHAIR TYLER: And some of the
- 5 thoughts around this debate.
- 6 CO-CHAIR MEYER: Okay.
- 7 CO-CHAIR TYLER: Okay. That's what
- 8 we're voting on. And we saw the hands of
- 9 support here in the room. On the phone, do we
- 10 have yes for that, or -
- 11 (Chorus of yes.)
- 12 CO-CHAIR TYLER: Okay. No's?
- 13 Okay. On the phone, any nos?
- DR. ANGOOD: Sorry. Diane, you had
- 15 a quick question?
- 16 MEMBER RYDRYCH: Yes, I do just
- 17 have a quick question. I know that with any
- 18 changes to the list of events that this group
- 19 makes, it goes to a membership vote of NQF.
- 20 Do changes to the definition go to a vote, as
- 21 well, so the membership will be voting on that
- 22 change?

- DR. BURSTIN: The entire document,
- 2 definitions, all of it, will go actually first
- 3 out for comment. The comment is going to be
- 4 where I think a lot of this debate will
- 5 happen, more so than the vote at the end. And
- 6 I guess one question might be, is there a need
- 7 to think about putting some of these
- 8 definitions out for comment, even in advance
- 9 of the call for SREs. We'll have to think
- 10 that through.
- 11 MEMBER BRENNAN: I do think that
- 12 would be helpful.
- DR. ANGOOD: All right. So, we
- 14 have a couple of more slides just to make
- 15 sure, similarly, on the same page, as best as
- 16 we can. So, we've all now just agreed on the
- 17 definition of SRE.
- 18 The further language on the
- 19 definition, for those on the phone, this is
- 20 the second slide that was sent out earlier
- 21 today. "Current set of SREs is not intended
- 22 to capture all events, but the events are of

- 1 concern to both the public and healthcare
- 2 professionals and providers, clearly
- 3 identifiable and measurable, thus, feasible to
- 4 include in reporting, and of a nature that's
- 5 such that the risk of occurrence is
- 6 significantly influenced by policies and
- 7 procedures of the healthcare facility."
- 8 We did not change any language in
- 9 this one, so we'll presume that everybody is
- 10 still comfortable with that. I'm not seeing
- 11 any heads nodding in the opposite, so the next
- 12 slide.
- 13 The third slide, for those on the
- 14 phone, is the SRE Criteria. And this is,
- 15 basically, where we chose to get rid of the
- 16 and/or in-between each of the three bullets.
- 17 So, "An event must be unambiguous,
- 18 preventable, serious in any of the following
- 19 adverse indicative of a problem in a
- 20 healthcare facility, safety systems, important
- 21 for public credibility, or public
- 22 accountability." Any further discussion on

- 1 that? Seeing and hearing none, so the next
- 2 one.
- 3 And then this slide is defining the
- 4 individual terms of the larger definition. We
- 5 have "event", which is unchanged, means "a
- 6 discrete, auditable, and clearly defined
- 7 occurrence." "Adverse", we got rid of the
- 8 latter part of that definition, so that it now
- 9 reads, "Adverse describes a negative
- 10 consequence of care that results in unintended
- 11 injury or illness." "Preventable" is
- 12 unchanged, describes "an event that could have
- 13 been anticipated or prepared for, but that
- 14 occurs because of an error or other system
- 15 failure." "Serious" has some changes. We
- 16 added a couple of words, and deleted half of
- 17 the definition from last time. So, it
- 18 currently now reads, "Serious describes an
- 19 event that can result in death or loss of a
- 20 body part, disability, or loss of bodily
- 21 function, or risk thereof." The added words
- 22 were "can result in death", as well as the

- 1 term "or risk thereof."
- 2 And then the final term,
- 3 "Unambiguous" was unchanged, and that refers
- 4 to, "An event that is clearly defined and
- 5 easily identified." So, I guess we'd ask for
- 6 comments, or affirmation that that's what we
- 7 all agreed to yesterday.
- 8 MEMBER BRENNAN: Peter, this is
- 9 P.J. I think these are -- I agree with these
- 10 definitions. I think I would just like to see
- 11 in the text under serious, not in the
- 12 definition, but in the accompanying text,
- 13 language related to psychological harm, as
- 14 well, so that that's clearly included.
- DR. ANGOOD: Yes, that's a good
- 16 point, P.J., and we certainly talked about
- 17 that. Thanks. Okay. Everybody still
- 18 comfortable with those sets of slides? All
- 19 right. Next slide, please.
- 20 And now we have the Venn Diagram
- 21 that was floated around in a few different
- 22 versions. We tried to clean it up, and we

- 1 already have a few shaking heads in the room.
- 2 And this is an important set of discussions,
- 3 because my sense was, as we left yesterday,
- 4 not everybody was on the same page. And does
- 5 anyone on the phone not have this? I don't
- 6 want to try to do the -- describe a Venn
- 7 Diagram to the outside world, if we don't have
- 8 to.
- 9 MEMBER BRENNAN: I think we all got
- 10 it. Thank you.
- DR. ANGOOD: Yes, so we've got -
- DR. GANDHI: I got it.
- DR. ANGOOD: We've got the larger
- 14 circle, which encompasses the so-called white
- 15 matter of all events. We, as near as we can
- 16 tell yesterday, agreed that the serious
- 17 reportable events were their own little
- 18 subgroup, HAIs, because they are an entity
- 19 that's out there, are their own subgroup. And
- 20 that there was a whole collection of these
- 21 other types of events in the broader groupings
- 22 that were not necessarily as serious, and not

- 1 necessarily reportable, but they were
- 2 certainly items that needed to be taken into
- 3 account. And then in our discussions later,
- 4 we sort of added an extra circle, sort of to
- 5 recognize that other small subgroups may or
- 6 may not show up in this realm, not to suggest
- 7 that we need to make any more of those, but
- 8 that just their existence over time may occur.
- 9 So, I'm going to turn this back to
- 10 Sally in a moment, but we've got Michael and
- 11 Diane, who are jumping on us here. So, Mike.
- 12 MEMBER VICTOROFF: Looking at this
- 13 now, it doesn't resemble what I thought I
- 14 agreed to yesterday, and I don't want to
- 15 discuss it any more.
- 16 (Laughter.)
- 17 MEMBER VICTOROFF: Apparently, I
- 18 didn't even get anything out of yesterday's
- 19 discussion. I don't see any need for this
- 20 diagram, and if a diagram like this were to
- 21 show up in the report, I couldn't explain it.
- 22 And I don't think it adds anything. That

- 1 isn't to say the discussion yesterday wasn't
- 2 useful, because it really was. I thought that
- 3 the process we went through taught me a lot.
- 4 And I think it helped me articulate stuff that
- 5 I hadn't really. But now that I look at this
- 6 version of somebody's version of what they
- 7 thought happened yesterday, I don't recognize
- 8 it, so I really think the prudent thing to do
- 9 would be to not have a Venn Diagram, because
- 10 I don't want to perfect a Venn Diagram today.
- 11 We've got too much else to do.
- DR. ANGOOD: Well, just, again -
- 13 sorry, Sally. The discussion got started
- 14 because we were struggling with this
- 15 healthcare acquired, or healthcare associated
- 16 conditions. And it kind of evolved along in
- 17 this, and this is where we had left off.
- 18 That's why we're opening it again today.
- 19 MEMBER VICTOROFF: And just for --
- I mean, you're reminding us that the problem
- 21 of the two lists was the reason for the Venn.
- 22 And we solved the problem of the two lists, in

- 1 the course of which, I think the Venn has now
- 2 become not useful. And, as it looks to me
- 3 here now, it's definitely not useful, because
- 4 I don't know what it really means.
- 5 MEMBER RYDRYCH: Yes. I think what
- 6 we had decided on -- I agree with Michael. I
- 7 don't think we should spend much time on this,
- 8 but I think what we had decided on was just
- 9 the big circle of all events, one circle for
- 10 SREs, one circle for HAIs, and that was it.
- 11 Because, otherwise, we're created new
- 12 categories that we then have to define. And
- 13 what struck me about the discussion yesterday
- 14 was that we spent a lot of time having these
- 15 important conversations, but we ended up right
- 16 back where we started, which was with the
- 17 statement in the briefing document that said
- 18 SREs are a subset of the larger set of HACs.
- 19 And then we were just showing it visually, so
- 20 I don't know that it really adds much, either.
- 21 CO-CHAIR TYLER: Philip.
- 22 MEMBER PHILIP SCHNEIDER: I agree.

- 1 I think the use of this -- the evolution of
- 2 this was derived from our attempt to clarify
- 3 the difference between HACs and SREs. And
- 4 since we're no longer discussing HACs, I don't
- 5 see any reason to have it.
- 6 CO-CHAIR TYLER: Okay. Given the
- 7 fact that we did have a good discussion, which
- 8 sounds like it did get a lot -- people got a
- 9 lot out of it, and largely did resolve the
- 10 situation with the two lists, can we take a
- 11 vote for removing the diagram from the report,
- 12 but just knowing that we -- what it stands
- 13 for. Yes, remove the -
- 14 (Vote taken.)
- 15 CO-CHAIR TYLER: Anybody on the
- 16 phone supporting removing the diagram from the
- 17 report?
- 18 CO-CHAIR MEYER: This is Gregg. I
- 19 definitely support. It was a great
- 20 conversation starter yesterday, but I think at
- 21 this point it's superfluous.
- DR. BURSTIN: This is Helen, I

- 1 support.
- 2 MEMBER BRENNAN: P.J., I agree.
- 3 CO-CHAIR TYLER: Okay. Thank you.
- 4 MEMBER DORON SCHNEIDER: Just a
- 5 quick -- Diane's last statement is where we
- 6 started, and it concerns me that you just said
- 7 that, because you just said that SREs are a
- 8 subset of all healthcare acquired conditions.
- 9 MEMBER RYDRYCH: No, a subset of a
- 10 broader group.
- 11 MEMBER DORON SCHNEIDER: Okay.
- 12 MEMBER RYDRYCH: I think we
- 13 abandoned the HAC term. Yes, the bad things
- 14 list.
- 15 MEMBER DORON SCHNEIDER: Okay. So,
- 16 maybe you misspoke, but that's -- okay, we're
- 17 clear.
- 18 CO-CHAIR TYLER: Okay. Is there
- 19 another slide?
- 20 (Laughter.)
- 21 MEMBER RYDRYCH: It was a breakdown
- 22 in the communication system. It happens.

- 1 DR. ANGOOD: I want to just make
- 2 sure that we're clear, then, that as just
- 3 articulated, we've got all events that occur.
- 4 We've got these serious reportable events, and
- 5 we've got this cluster of healthcare acquired
- 6 infections, which have their own sets of
- 7 initiatives. And there may or may not be
- 8 other types of similar things that occur over
- 9 time.
- 10 We still will need to go back to
- 11 HHS and say okay, this group does not feel
- 12 that the term "healthcare acquired", or
- 13 "healthcare associated" conditions is a term
- 14 to be used. Is that what we're still saying
- 15 now?
- 16 DR. BURSTIN: Just to be clear, the
- 17 HAC term was always a term of CMS, so we were
- 18 trying to decide if we needed -
- DR. ANGOOD: That's hospital.
- DR. BURSTIN: Right. We were
- 21 trying to decide if we needed yet another
- 22 categorization of our events, NQF's side of

- 1 this to capture those. And I think what the
- 2 group came to was the idea that we have a
- 3 broader corridor now that can encompass a
- 4 broader set of events, so that I think from
- 5 where NQF sits, the SREs, and I would
- 6 obviously welcome CMS' feedback when we put
- 7 this out for comment, but our broader
- 8 conceptualization of SREs should capture that
- 9 broader space.
- 10 CO-CHAIR TYLER: Michael.
- 11 MEMBER VICTOROFF: Again, I am
- 12 happy leaving this the way I -- I kind of
- 13 think of it as -- the reporting process at CMS
- 14 has found a way to make itself happy capturing
- 15 certain bad things. I'm not sure how you can
- 16 capture all the SREs, because there's a
- 17 capture identification, intervention. There's
- 18 a lot of things after the definition step that
- 19 you've got to do. So, there are some of them
- 20 that CMS looks like they figured out in their
- 21 own system a way to capture through their use
- 22 of ICD, and whatever they have. And we could

- 1 talk to them about that, but I think that, for
- 2 me, the lower level -- a different level than
- 3 the plane of defining events, and my confusion
- 4 yesterday that got clarified was that we're
- 5 not talking with healthcare acquired
- 6 conditions, whatever that is, but defining
- 7 certain kinds of events. We're talking about
- 8 capturing some reportable stuff that might be
- 9 good fodder for intervention. So, if that's
- 10 generally agreed, then I don't have any
- 11 trouble talking to CMS and saying we didn't
- 12 say your list is no good, but we see that it
- 13 fits in a different plug than in the
- 14 definitions of the bad things we care about.
- 15 MEMBER BRENNAN: Peter.
- DR. ANGOOD: Yes.
- 17 MEMBER BRENNAN: P.J. here. Don
- 18 Wright at HHS has been leading a Steering
- 19 Committee to coordinate activities across HHS,
- 20 and to create a national plan for the
- 21 reduction of HAIs. And I think we ought to be
- 22 in touch with him. That plan was published in

- 1 January of 2009, and has five-year goals,
- 2 incorporates the term "healthcare associated
- 3 infections". And I think to the extent that
- 4 we can align ourselves with that, it would
- 5 help reduce confusion for hospitals, and
- 6 promote that agenda.
- 7 DR. ANGOOD: Yes. No, I certainly
- 8 agree, P.J., and we actually have had several
- 9 discussions with Don, and we actually followed
- 10 up with Don after the State-Based Reporting
- 11 meeting of a couple of weeks back. And Don is
- 12 very keen to harmonize with what NQF is doing,
- 13 with what the State-Based Reporting entities
- 14 are doing. And, hopefully, in his new
- 15 position, which was just announced yesterday,
- 16 he will continue along this HAI action plan,
- 17 as it rolls itself out over the next few
- 18 years. But a very good point, thanks.
- 19 CO-CHAIR TYLER: Okay. Do you have
- 20 other to review?
- 21 DR. ANGOOD: No, I just -- I mean,
- 22 I just want to make sure we're comfortable.

- 1 CMS, it's the hospital acquired conditions.
- 2 HHS came to us with this healthcare type of
- 3 term. And I think with us redefining SREs,
- 4 we're able to back off that healthcare
- 5 acquired thing. And I just want to make sure
- 6 everybody is comfortable with that.
- 7 I think it's important, just
- 8 because the CMS term of the hospital will
- 9 continue to be a confusion generator, but
- 10 that's their business, and they can move
- 11 towards taking some of our SREs, if they so
- 12 choose to do that, but that's their business,
- 13 not our business. And adding this other
- 14 healthcare acquired/healthcare associated
- 15 would be, I think, more confusing to the
- 16 field, rather than less. So, I just wanted
- 17 to, again, reaffirm that we're comfortable
- 18 leaving that term alone. Don't even go there
- 19 any more, and we'll just convince HHS they
- 20 don't need to go there any more, either.
- 21 MR. GARCIA: Peter, this is Eddy
- 22 Garcia.

- 1 DR. ANGOOD: Yes.
- 2 MR. GARCIA: Just so it's clear,
- 3 we're probably going to be creating other
- 4 terms, such as nursing home acquired
- 5 conditions, home health acquired conditions.
- 6 So, we were looking for a term that would
- 7 encompass all of those as an umbrella. And
- 8 then my thinking was under each of those,
- 9 there are SREs, so I think that you've also
- 10 defined with your Venn Diagram, which you're
- 11 not publishing, that there is a larger term,
- 12 and SREs fits under that. HAIs also fit under
- 13 that. So, I guess my question is, what is
- 14 that larger term that you're defining?
- DR. ANGOOD: Yes, I can certainly
- 16 understand the question, Eddy, and I sense
- 17 that we'll certainly have more discussions
- 18 between your guys' groups, and ours in moving
- 19 forward, but from yesterday's discussion, the
- 20 broader full context of events is what we just
- 21 are calling the adverse events, or all events.
- 22 Within all healthcare events, there are these

- 1 SREs. And, as we go through the rest of this
- 2 Steering Committee's deliberations, we'll
- 3 begin to -- and the use of the TAPS, we'll
- 4 begin to make them more environment-specific.
- 5 But another term isn't necessarily needed at
- 6 this point in time. And it would actually
- 7 make more sense to have SREs for home health,
- 8 SREs for ambulatory, if you will. And they
- 9 may be similar in each of those environments,
- 10 but that would be another way of identifying,
- 11 or specifying, as opposed to creating new
- 12 terms all of the time.
- 13 Helen, did you want to add other
- 14 comments?
- 15 DR. BURSTIN: No, I think it's a
- 16 conversation I think that will continue. I
- don't think it's something we're going to
- 18 resolve today. I think the idea of creating
- 19 this broader corridor, our hope was, in fact,
- 20 if you look at what's on the CMS Never Events
- 21 List, at the moment, I think what we talked
- 22 about yesterday was all of those would now fit

- 1 in the broader category of SREs. So, I think
- 2 our hope is, by broadening the definition, we
- 3 have created something that works for the
- 4 purposes of what CMS is trying to get at, and
- 5 I think that's a discussion to follow, that I
- 6 think we'll continue to have, but I think that
- 7 was the hope, that we could actually -- if you
- 8 look at that list, based on the definitions we
- 9 talked about yesterday, all of those now would
- 10 fit under the broadened I'm sorry -
- 11 diagnosis. I can't help myself, sometimes.
- 12 The broader definition of SREs, and I think
- 13 that's our hope, that we can consolidate under
- 14 one term. But, again, further discussions are
- 15 certainly welcome.
- 16 CO-CHAIR TYLER: Leah.
- 17 MEMBER BINDER: I just want to say,
- 18 I appreciate Helen's comments, because I'm
- 19 vaguely uncomfortable with it. I just want to
- 20 make sure that there's harmony with CMS. I
- 21 mean, I think they've made major inroads.
- 22 There's been a lot of attempt on their part,

- 1 and on NQF's part, to create better harmony.
- 2 I think that's all of our goals, so I just
- 3 want to make sure that as we go forward, we're
- 4 mindful of that. That's a discomfort that I
- 5 have with it right now. Do we have any
- 6 opinion from CMS, or have we talked about this
- 7 to anyone at CMS to get their feedback?
- BURSTIN: Eddy Garcia, who's on
- 9 the phone, was here with us yesterday, and is
- 10 here with us today, who just made those
- 11 comments. Obviously, this is a broader
- 12 discussion, including the payment side folks,
- 13 which Eddy is not on. Eddy is on the quality
- 14 side, so we'll have those discussions. I
- think our goal is, as much as possible, with
- 16 the majority of the work we do, harmonization
- is the end game. If there's a way to make
- 18 that work for all purposes, and get at the
- 19 magical list John talked about of those 40
- 20 events, I'm in. It seems like the way to go,
- 21 but see if we can get there.
- 22 CO-CHAIR TYLER: Okay.

- DR. BURSTIN: It's going to forever
- 2 be that magic list of John's events, by the
- 3 way, in my mind. Always going to be those --
- 4 and if we don't get to 40, I'll be very sad.
- 5 (Laughter.)
- DR. ANGOOD: Yes, and the way
- 7 things are, it'll shift from Never Events to
- 8 John's 40 list.
- 9 (Laughter.)
- DR. ANGOOD: Not quite the same
- 11 sense of urgency, Leah, but -
- 12 CO-CHAIR TYLER: Okay. Peter, did
- 13 you have anything else from yesterday you
- 14 wanted to review?
- DR. ANGOOD: No, I believe that was
- 16 it.
- 17 CO-CHAIR TYLER: Okay. Good.
- 18 Before we plunge into what we had on today's
- 19 agenda, we still need to pick up from
- 20 yesterday, jump back into the list of serious
- 21 reportable events. We got, I guess, about
- 22 halfway through that list, so we're going to

- 1 plow on with that, if we can get -- we under
- 2 the care management events, 4A, if we can get
- 3 that up. I think when we last left, Eric had
- 4 updated us all that older people kill
- 5 themselves by dumping their wheelchairs into
- 6 jacuzzis. I remember that, that was our -
- 7 so we've all had a lot to think about
- 8 overnight.
- 9 (Laughter.)
- 10 CO-CHAIR TYLER: Okay. So, now
- 11 we're in Care Management Events, 4A. Patient
- 12 death or serious disability associated with a
- 13 medication error, e.g., errors involving the
- 14 wrong drug, wrong dose, wrong patients, wrong
- 15 time, wrong rate, wrong preparation, or wrong
- 16 route of administration. Okay. Let's see.
- 17 The new language excludes
- 18 "reasonable differences in clinical judgment
- 19 involving drug selection and dose, includes
- 20 administration of a medication to which a
- 21 patient has known allergy and drug
- 22 interactions, for which there is known

- 1 potential for death, or serious disability."
- Okay. What do we want to comment
- 3 on? Diane.
- 4 MEMBER RYDRYCH: One thing that's
- 5 never really been clear to me with this event
- 6 is how to deal with cases where a medication
- 7 should have been administered, but was not, as
- 8 opposed to the wrong medication being
- 9 administered. Examples that have come up, for
- 10 us, include cases where like a pre-op
- 11 antibiotic was supposed to be given, but
- 12 wasn't, and then a patient got an infection,
- or should have been DVT prophylaxis, that was
- 14 not provided. And then there ended up being
- 15 a serious disability to the patient, as a
- 16 result.
- 17 I don't know what the intent was at
- 18 the event around those types of situations.
- 19 My guess is that they're not captured. I
- 20 don't know if they were intended to be
- 21 captured, or not.
- 22 CO-CHAIR MEYER: Diane, this is

- 1 Gregg. I think that that's been an ongoing,
- 2 I think, vexing issue with this. And I think
- 3 it's one of the fundamental issues with both
- 4 this work, and to some extent, the Safe
- 5 Practice work. And that is, is that we
- 6 largely focus here on execution, meaning what
- 7 was done, rather than design, rather than was
- 8 the plan right. And that's, actually, a
- 9 limitation across much of safety right now, is
- 10 that we focus much more on you gave the wrong
- 11 antibiotic in terms of an allergy, rather than
- 12 asking the question, did the patient need the
- 13 antibiotic at all. And I would say that
- 14 that's something that, when we think about
- 15 what are the areas for future research, and
- 16 what needs to be kind of focused on in the
- 17 future, I'd like to see that highlighted here.
- 18 And, again, that cuts across both this, and
- 19 the Safe Practices.
- 20 CO-CHAIR TYLER: Philip.
- 21 MEMBER PHILIP SCHNEIDER: Wouldn't
- 22 that be covered in the second bullet point in

- 1 the middle column, "Occurrences which a
- 2 patient dies or suffers serious disability as
- 3 a result of a failure to administer prescribed
- 4 medicine"? And, secondly, but as an
- 5 additional point, though, if you think of
- 6 medication use as being comprised of a number
- 7 of steps, starting with prescribing, would
- 8 this encompass a failure to prescribe a drug
- 9 that was needed, to encompass the whole
- 10 process, as opposed to simply the
- 11 administration of the medicine?
- 12 CO-CHAIR TYLER: Michael.
- 13 MEMBER VICTOROFF: I have a problem
- 14 like that -- with that. I appreciate the
- 15 comment here, but I think we heard the
- 16 clarification, there's a difference between
- 17 commission and omission, and the commission
- ones are a lot easier to capture, and the
- 19 omission ones are actually different in kind.
- 20 When -- and this one skirts the
- 21 boundary here, when we say that it was
- 22 prescribed. There's an order. We saw it, it

- 1 was ordered. The order was not taken off, or
- 2 whatever, didn't get into the right IV. That
- 3 still is, in a way, an error of commission.
- 4 I'm opening to hearing it both ways. But
- 5 guideline adherence is not comprised by this
- 6 kind of error, this particular error.
- 7 I don't see -- you didn't realize
- 8 that people with heart disease are supposed to
- 9 get statins or something. We don't have beta
- 10 blocker, we don't see aspirin, we don't see
- 11 whenever you have a broken leg, you should put
- 12 a splint on it. There's a lot of guideline
- 13 management processes that are not in here at
- 14 all.
- 15 I'm very open to talking about
- 16 them. In fact, I want to open that up. We're
- 17 going to start talking about additions, but I
- 18 don't think that this canoe carries that
- 19 baggage. This looks, to me, more like -- and
- 20 I'm a little disturbed about that bullet you
- 21 pointed out, but this looks, to me, pretty
- 22 much more like we gave something, and it was

- 1 wrong.
- DR. GANDHI: This is Tejal from the
- 3 phone. Another, I don't know if we want to
- 4 open another can of worms, but the other issue
- 5 is monitoring. Usually, when we think about
- 6 the medication process, it goes all the way
- 7 from ordering, dispensing, prescribing,
- 8 administering, and then monitoring. So, I'm
- 9 wondering if you want to put any language --
- 10 again, it's more of an omission, but I'm
- 11 thinking of failure to appropriately monitor
- 12 an INR, for example, or a PTT, or something
- 13 like that, leading to a serious event. So,
- 14 I'm wondering if you want to put in the term
- 15 "monitoring", at all.
- 16 CO-CHAIR TYLER: Okay, thanks.
- 17 Michael, again, and then Cynthia.
- 18 MEMBER VICTOROFF: Again, good
- 19 comment, good addition. I don't want to put
- 20 it in this canoe. You hurt the category if
- 21 you put in so many things that everything to
- 22 do with -- I mean, you could have a category

- 1 that any bad thing conceivably having to do
- 2 with anything to do with a drug, but that's
- 3 too big for me. So, I'm going to be a
- 4 splitter in this case.
- 5 CO-CHAIR TYLER: Cynthia.
- 6 MEMBER HOEN: This is one of those
- 7 categories that concerns me, because we have
- 8 a lot of medication errors, but very few of
- 9 them rise to the level of the definition here.
- 10 And, I guess, that as we talk about how we
- 11 share this information going forward in an
- 12 attempt to broaden our knowledge, and put in
- 13 preventative measures, or give risk alerts, or
- 14 whatever you want to call them, to other
- organizations, that this is one where I would
- 16 like to consider whether we put in wording
- 17 that death or disability, or could have
- 18 resulted in death or disability, such that
- 19 those events which just because we caught them
- 20 before they reached the patients, have the
- 21 likelihood of occurring in other venues, or
- 22 hospitals, could then get that information out

- 1 to the state, for then sharing amongst other
- 2 facilities.
- 3 CO-CHAIR TYLER: Eric.
- 4 MEMBER TANGALOS: There's currently
- 5 a very nice way of starting to look at those
- 6 near misses in a variety of different
- 7 environments. And it's through a medication
- 8 process where you look at rescue drugs. So,
- 9 you can just do -- and Pittsburgh has done a
- 10 lot of this work, and Steve Hadler has done.
- 11 And, again, it's in the process steps, but it
- 12 starts to address a lot of those questions
- 13 that now come to the surface, because you can
- 14 look at drugs that rescue patients from
- 15 disaster.
- 16 CO-CHAIR TYLER: I don't think we
- 17 have any other -- Martha, and then Philip.
- 18 MEMBER RADFORD: I wonder if this
- 19 is -- part of this is in reporting about the
- 20 structures around medication management in an
- 21 organization, any type of organization, versus
- 22 the specific events, themselves, reporting

- 1 specific events themselves. So, I'm concerned
- 2 about where we are on the specificity,
- 3 sensitivity spectrum here, and, for this
- 4 particular one, I'm going to go with Michael
- 5 and be a splitter.
- 6 CO-CHAIR TYLER: I'm not sure I
- 7 understand what you're getting at. I mean, we
- 8 are meant to begin applying these to other
- 9 contexts. That's part of our -
- 10 MEMBER RADFORD: What I mean is
- 11 that the sins of commission are different. I
- 12 am agreeing with Michael, they are different
- 13 than the sins of omission. In addition, the
- 14 fixes around near misses are organizational
- 15 fixes. They're not, necessarily, event fixes.
- 16 And I think that if we -- we risk the
- 17 possibility of losing the potential fixes,
- 18 because there's usually more than one, in the
- 19 -- if we broaden the reporting category. You
- 20 don't have to report everything to get some
- 21 good clues about what needs to be fixed.
- 22 MEMBER PHILIP SCHNEIDER: I'd like

- 1 to ask a question of procedure, because I
- 2 don't -- I'd like to see included, a method
- 3 defined where we could include errors of
- 4 omission from prescribing, through monitoring.
- 5 Errors of omission in prescribing, dispensing,
- 6 administering, and monitoring therapy,
- 7 somehow. I'm not going to fall on a sword to
- 8 say it has to be in this, but I would like to
- 9 know how we would go about making sure that
- 10 those kinds of events are captured, because I
- 11 think they're equally important.
- 12 CO-CHAIR TYLER: Okay.
- 13 MEMBER PHILIP SCHNEIDER: I can
- 14 rest, if I know that there will be a method
- 15 developed in order to do that. I notice we've
- 16 looked at surgical complications, and diced
- 17 that up a lot of different ways. I went back
- 18 and looked at, there's probably four different
- 19 things that relate to -- events that relate to
- 20 surgical procedures, and the medication used
- 21 is no less complicated. It's less dramatic,
- 22 but I think we need to, potentially, tease

- 1 that out a little bit more than embedding
- 2 everything in one standard.
- 3 CO-CHAIR TYLER: So, do you think
- 4 it makes to have a separate event around
- 5 omission through monitoring?
- 6 MEMBER PHILIP SCHNEIDER: I'm not
- 7 sure I do, but I sense that there's enough
- 8 people that do, that that would be okay, as
- 9 long as it's captured.
- 10 CO-CHAIR TYLER: Michael.
- 11 MEMBER VICTOROFF: Since you're
- 12 asking for a possible mode, I'd like to
- 13 propose that we keep in mind that we're
- 14 allowed to add stuff. And I have a whole
- 15 shopping list to make it up to 40 of things
- 16 like this. And, for me, near miss events are
- 17 completely separate, because they're analyzed,
- 18 captured, and dealt with separately. And I
- 19 want to put them on, and make sure they get on
- 20 here, but I don't want to load these boats
- 21 with all of this diffusing stuff that actually
- 22 complicates the analysis of these fairly crisp

- 1 ones. So, what I would propose is that when
- 2 we say oh, you know, there's something else
- 3 that's kind of like this, but not the same,
- 4 what I'd encourage us to think is, do we want
- 5 to dilute, or do we want to add something at
- 6 the bottom of the list, that then needs the
- 7 same kind of scrutiny as all the rest. Are
- 8 they identifiable? Are there remedies? Are
- 9 there interventions? Can we count them? Do
- 10 they matter? Are they important? Rather than
- 11 concealing -- sneaking in some stuff in these
- 12 that I already kind of like.
- 13 CO-CHAIR TYLER: John. You're
- 14 next, John.
- 15 MEMBER MORLEY: Okay. I agree with
- 16 Mike, and in this particular case, I guess, as
- 17 I'm looking over the list and the concept of
- 18 medication errors, I'm becoming more and more
- 19 of a splitter on this. I think the world of
- 20 medication errors is the world of safety.
- 21 It's massive. It's far bigger than we can
- 22 bite off.

- 1 At the end of a year of data
- 2 collection, whether it be for a state, a
- 3 region, or the country, you're going to have
- 4 far more information than you can dissect at
- 5 one time. And the information that's related
- 6 to the pediatric issues are going to be
- 7 clearly different than the issues related to
- 8 chemotherapy, which are going to be a lot
- 9 different than heparin issues.
- 10 I'd like to see us be able to
- 11 identify a more focused area, or focuses
- 12 within medication, so that at the end of the
- 13 year when you've collected the data, the boxes
- 14 are a neater pile of information, not just
- 15 data, that can be used to drive that change.
- 16 And you're not going to get that if you have
- one report on heparin, one report on Coumadin,
- 18 one on daunorubicin, one on pediatric dosing
- 19 issues, one on Fentanyl, and so, and so on.
- 20 So, some mechanism by which you can create
- 21 more biteable, more fixable sections of
- 22 medication error would be much more useful for

- 1 people.
- 2 CO-CHAIR TYLER: I was going to
- 3 check to see if anybody on the phone want to
- 4 weigh in on that? Okay. Philip.
- 5 MEMBER PHILIP SCHNEIDER: I'd like
- 6 to hear if there's an explanation for the last
- 7 bullet point in the middle column. I read
- 8 this many times, and I don't understand it
- 9 even this morning. I just don't understand
- 10 what that means.
- 11 CO-CHAIR TYLER: The bullet point
- 12 to which he's referring, "All situations in
- 13 which two or more medications are administered
- 14 for which there are drug-drug interactions
- 15 with known potential for death, or serious
- 16 disability, only those that result in death or
- 17 serious disability." I do not know the
- 18 answer, if there is a specification
- 19 justification. Peter, can you weigh in?
- 20 MEMBER MORLEY: Would meperidine
- 21 and MAO inhibitors fall into that category?
- 22 Something with known drug interactions that

- 1 are potentially lethal. Patients that are on
- 2 MAO inhibitors shouldn't be getting
- 3 Meperidine. We're talking a very small --
- 4 that's not going to get you a lot of
- 5 interactions that I can think of.
- 6 MEMBER RYDRYCH: Isn't the
- 7 clarification there just to say that that
- 8 would only be reportable if it actually did
- 9 result in the serious disability or the death.
- 10 Right? Not just the potential, thereof.
- DR. ANGOOD: Right.
- 12 MEMBER VICTOROFF: This says events
- 13 that are not intended for capture. What I
- 14 don't understand is the drug interaction that
- 15 was known and caused a fatal event, then it
- 16 should be included, I think. It seems like a
- 17 paradoxical statement.
- 18 DR. ANGOOD: It's more along the
- 19 lines of what -- as I understand it, anyways,
- 20 I'm still relatively new to NQF, wasn't part
- 21 of the genesis of the original list, but I can
- 22 do some more homework to further clarify, but

- 1 my take on it is basically sort of what John
- 2 was saying in terms of the significant
- 3 interactions that do result in death or
- 4 significant disability.
- 5 MEMBER PHILIP SCHNEIDER: But
- 6 shouldn't those be reported, John?
- 7 MEMBER MORLEY: Yes.
- 8 MEMBER PHILIP SCHNEIDER: So why is
- 9 it under a list of things that -- the
- 10 statement above those two bullet points at the
- 11 bottom is, "This event is not intended to
- 12 capture", so it strikes me as a paradoxical
- 13 statement. It should be it's intended to
- 14 include drug interactions that can be
- 15 predicted.
- 16 MEMBER RYDRYCH: I think if you
- 17 rephrase that to say unless they result in
- 18 death or serious disability. But, you're
- 19 right, it would make more sense to kind of
- 20 move that out of the exclusions category.
- DR. ANGOOD: I agree. Got that
- 22 note.

- 1 CO-CHAIR TYLER: Okay. We have
- 2 anything else on this one? Have you all
- 3 discussed it thoroughly? All right. Move on
- 4 to 4B. "Patient death or serious disability
- 5 associated with hemolytic reaction due to the
- 6 administration of ABO, HLA, incompatible
- 7 blood, or blood products. What do we know
- 8 about this one? Anybody have anything they
- 9 want to add?
- 10 CO-CHAIR MEYER: The only thing I
- 11 would consider adding here is to consider ABO
- 12 incompatible organs, as well.
- 13 CO-CHAIR TYLER: Incompatible
- 14 organs. Okay.
- DR. ANGOOD: Gregg, this is Peter,
- 16 or was that P.J. I'm not sure, you both sound
- 17 similar on there.
- 18 CO-CHAIR MEYER: It was Gregg.
- 19 DR. ANGOOD: Thanks. That topic
- 20 that you just brought up actually has
- 21 generated a fair amount of discussion in the
- 22 Common Format Steering Committee in terms of

- 1 trying to decide and differentiate between
- 2 blood, blood products versus organ donation
- 3 types of issues. And the way this one is
- 4 sitting now, it's pretty clear it's just
- 5 blood, blood product as opposed to bringing in
- 6 that larger scale of issues. If we want to
- 7 have something -
- 8 CO-CHAIR MEYER: The organ events
- 9 are blessedly, incredibly rare, but they are
- 10 of great import, and delving into why they
- 11 happen is incredibly valuable.
- DR. ANGOOD: Oh, I certainly agree,
- 13 and I don't discount the importance of it.
- 14 It's a matter of trying to keep it clean and
- 15 crisp between where the boundaries are. You
- 16 know, if we want to have a -
- 17 CO-CHAIR MEYER: So maybe we should
- 18 put this on a list of something for the
- 19 future.
- 20 DR. ANGOOD: Yes, I was just going
- 21 to say it may become part of what we actively
- 22 seek out in terms of solicitations for other

- 1 SREs, because it's an important topic by
- 2 itself.
- 3 CO-CHAIR TYLER: Okay. So, maybe
- 4 you'll look at that in the future. If we have
- 5 no other discussion on that, then we'll move
- 6 on to the next one.
- 7 Okay, 4C. "Maternal death or
- 8 serious disability associated with labor or
- 9 delivery in a low-risk pregnancy while being
- 10 cared for in a healthcare facility." Let's
- 11 see. The added language includes "events that
- 12 occur within 42 days post delivery, excludes
- 13 deaths from pulmonary or amniotic fluid,
- 14 embolism, acute fatty liver of pregnancy, or
- 15 cardio myopathy." Okay. Michael.
- 16 MEMBER VICTOROFF: This, to me,
- 17 looks like another legacy of the blame
- 18 paranoia philosophy that I thought we were
- 19 moving away from. I don't see any reason to
- 20 exclude a reported death from any cause,
- 21 because, to me, I'm considering all of these
- 22 causes blame neutral, or blame irrelevant.

- 1 We're not doing a root cause analysis here.
- 2 I think if there's women dying from stuff, the
- 3 only issue that I have is whether there should
- 4 be dual reporting, because what we have here
- 5 is a condition that is universally, as far as
- 6 I know, reportable to State Health Departments
- 7 under some other rubric than whatever NQF's
- 8 rubric is. And we haven't even discussed
- 9 that. But I surely think that every instance
- 10 of maternal death, regardless of cause, should
- 11 be counted, and collected, and reported.
- DR. GANDHI: But the term
- 13 "preventable" is in the definition on the SRE.
- 14 CO-CHAIR TYLER: Tejal, is that
- 15 you?
- DR. GANDHI: Sorry, this is Tejal.
- 17 Yes. I agree that we need to know about all
- 18 maternal deaths, and potentially the DPH or
- 19 the Board of Registration Medicine wants to
- 20 know about them, but in terms of actually
- 21 calling it an SRE, if we're going to keep this
- 22 term "preventable" in our definition, I think

- 1 we have to be cognizant of that as we go
- 2 through defining these various categories.
- 3 CO-CHAIR TYLER: John, then Eric,
- 4 then Kathryn.
- 5 MEMBER MORLEY: I agree with Mike
- 6 100 percent. I think we would want to know all
- 7 of them. I think there is one area of
- 8 limitation or refinement, and that would be
- 9 time limitation. So, not somebody that dies
- 10 as they're walking out of the hospital, run
- 11 over by a car. But anybody that dies within
- 12 a reasonable time period, or some other
- 13 criteria, not getting into the reasons. And
- 14 I think we were talking yesterday about
- 15 potentially preventable, so I would not want
- 16 to see an institution get into an internal
- 17 discussion about whether we have to report to
- 18 somebody because it's potentially, or not
- 19 potentially, and argue that point. Just
- 20 report them all. We sort them out in the end.
- In terms of a subcategory that's
- 22 not listed there, that's becoming an

- 1 increasingly important issue, we've got this
- 2 thing called the obesity epidemic, and the
- 3 obstetricians are more cognizant of that than
- 4 the average person. We've had two maternal
- 5 mortalities. We happen to be reviewing
- 6 maternal mortalities in New York State right
- 7 now. New York State has approximately 25
- 8 maternal mortalities per year in one state.
- 9 Obviously, some of those are into that
- 10 category that we would likely say is not
- 11 preventable, but some are still hemorrhage,
- 12 and are preventable. But two of the patients
- 13 that I reviewed, one had a BMI of 60, and the
- 14 other had a BMI of 70. And we're particularly
- interested in beginning to track those cases,
- 16 and start to talk about should those cases be
- 17 referred to a center that just has the
- 18 expertise and ability to deal with those types
- 19 of issues.
- 20 CO-CHAIR TYLER: I have a question
- 21 for clarification just on the consumer end.
- 22 So, I mean, if someone is that morbidly obese,

- 1 would they still be considered in a low-risk
- 2 pregnancy, or would that put them in a high-
- 3 risk category?
- 4 MEMBER MORLEY: It would be high-
- 5 risk at 60 or 70 for sure. The obstetricians
- 6 I've spoken with suggest a cutoff of about 50
- 7 or 55. But I would -- but that just goes back
- 8 to what Mike was saying about I'd want all of
- 9 them, all maternal mortalities, I believe
- 10 should be reported. Then let's sort them out
- 11 at the end.
- 12 CO-CHAIR TYLER: I was just
- 13 clarifying. So, those deaths would not fall
- 14 into this category, anyway, because this is
- 15 for low-risk. But you're talking about
- 16 certainly reporting all. Yes. Okay.
- 17 MEMBER TANGALOS: My concern is, as
- 18 we expand our horizons again, what if a low-
- 19 risk pregnancy death occurs at the hands of a
- 20 healthcare provider in the home.
- 21 CO-CHAIR TYLER: Well, this just
- 22 refers to in a healthcare facility. Right?

- 1 MEMBER TANGALOS: Well, but that's the point.
- 2 The point is -
- 3 CO-CHAIR TYLER: Right.
- 4 MEMBER TANGALOS: I mean -
- 5 CO-CHAIR TYLER: Should it apply.
- 6 MEMBER TANGALOS: Should it apply.
- 7 And how would you measure it?
- 8 CO-CHAIR TYLER: I think Kathryn
- 9 was next, then Michael.
- 10 MEMBER McDONAGH: Actually, that
- 11 was my point, too, is that I thought
- 12 healthcare facilities should be removed,
- 13 because if we begin to think about the
- 14 continuum of care, then a home delivery would
- 15 be included here, too.
- 16 MEMBER VICTOROFF: But now we're
- into exactly what I thought was going to be
- 18 the fun part of today, which is to expand the
- 19 locus of care. I think that's an enormously
- 20 relevant question, and it gives us -- I would
- 21 defer it for now, but it's a perfect model for
- 22 asking what I've been struggling with. Okay,

- 1 when we have the same event that occurs in two
- 2 different things, two different places,
- 3 antibiotic reaction at home, tonsillectomy on
- 4 the kitchen table, whatever it is we're doing.
- 5 Is the -- don't laugh. Is the problem we have
- 6 one of defining -- are they really the same
- 7 error, or is there something about the locus
- 8 of care change the nature of the error, or
- 9 does it change the remedy, or the collection
- 10 process, or the way we're going to report it,
- 11 to whom we report? And I think all those
- 12 things are on the table, but for right now,
- 13 for the purpose of ending this list, what I
- 14 would say is yes siree, home delivery
- 15 catastrophe should be one of the things in the
- 16 40, the Morley 40. Right? But it isn't this
- one, because we're just doing facility now.
- 18 That's what all these are. If you allow me to
- 19 introduce home stuff, then I've got to go back
- 20 over the whole list again.
- 21 DR. ANGOOD: I think that's a good
- 22 clarification for us, because the focus right

- 1 now is, does the existing list still make
- 2 sense for what its original purposes were, and
- 3 with our new definition. Moving forward, then
- 4 we'll start getting into these other
- 5 environments, and the applicability of the
- 6 list to other environments. If we start doing
- 7 both processes simultaneously, we'll be here
- 8 until next week, and still looking for
- 9 clarity.
- 10 CO-CHAIR TYLER: Christine.
- 11 MEMBER GOESCHEL: Yes, I just have
- 12 one question, being new to this. So, the spec
- 13 here that says initially on the
- 14 maternal/child, in the original things it
- 15 talked about within 42 days post delivery. Do
- 16 we no longer have that time? I'm look at the
- 17 initial -
- 18 (Off mic comment.)
- 19 MEMBER GOESCHEL: Right. Exactly.
- 20 So, it includes -- so, one of my questions
- 21 that I'm sure there's a crisp answer to, I
- 22 have one of these events after a low-risk

- 1 pregnancy at day 30, and I'm home. And I
- 2 don't go to the hospital, where I delivered.
- 3 I mean, when we're talking about issues of
- 4 public reporting, one of the things we always
- 5 think about is attribution. It begins to get
- 6 at the continuum of care, but if it's going to
- 7 be publicly reported that I had 30 deaths of
- 8 low-risk women, and they occurred 15 days
- 9 after delivery, but they didn't deliver at my
- 10 hospital, I think that's just something we
- 11 need to keep in consideration when we explain
- 12 what this means, because at an institutional
- 13 level, that is highly relevant.
- 14 CO-CHAIR TYLER: Leah.
- 15 MEMBER BINDER: I'm sorry.
- 16 Christine, can -- I'm sorry, what's your -
- 17 MEMBER GOESCHEL: Chris.
- 18 MEMBER BINDER: Oh, you are Chris.
- 19 Okay. Can you just explain that? I was
- 20 confused by what you were talking about.
- 21 MEMBER GOESCHEL: Okay. So, this
- 22 says this includes women within 42 days after

- 1 delivery. And we're going to publicly report
- 2 these deaths. A woman delivers at Hospital X,
- 3 she gets sick, and goes on day 30 post
- 4 delivery and dies at my institution,
- 5 Institution Y, so it's going to be reported as
- 6 a maternal death at my hospital, but she
- 7 didn't deliver at my hospital. I tried to
- 8 save her at my -- do you know what I'm saying?
- 9 It just gets at the public -- how we use
- 10 public reporting, not only to improve, but
- 11 issues of attribution, issues of some of the
- 12 emotional responses to what the numbers mean
- 13 or don't mean.
- 14 CO-CHAIR TYLER: Okay. That
- 15 clarifies. Stan.
- 16 MEMBER RILEY: I was just going to
- 17 say as a part of that, what we usually do is
- 18 we usually run down the original hospital. I
- 19 don't know if John and Diane do that, but we
- 20 try not to attribute it to the second
- 21 hospital. We try to attribute it back to the
- 22 first one for these events.

- 1 MEMBER MORLEY: For HAIs, that's
- 2 clearly what we attempt to do. It's not
- 3 always easy, but that's what we attempt to do.
- 4 MEMBER BRENNAN: Pennsylvania does
- 5 that in the Health Care Cost Containment
- 6 Council's reporting. It's not a perfect
- 7 system, but mostly it gets it right.
- 8 CO-CHAIR TYLER: Okay. Great. Any
- 9 other discussion on this? Okay. We'll move
- 10 on to the next one, 4D. "Patient death or
- 11 serious disability associated with
- 12 hypoglycemia, the onset of which occurs while
- 13 the patient is being cared for in a healthcare
- 14 facility." Stan, what have you got?
- 15 MEMBER RILEY: I quess the
- 16 hypoglycemia part, particularly the definition
- 17 part, where you have a blood sugar of less
- 18 than 60, if you're a pediatric hospital, for
- 19 instance, lots of children have much lower
- 20 blood sugars than that, so one of the real
- 21 problems is setting the limit at 60 doesn't
- 22 work for all institutions. And for some, it's

- 1 just -- it seems sort of crazy, particularly
- 2 for children's hospitals.
- 3 CO-CHAIR TYLER: Okay. Any other
- 4 concerns, considerations on this one?
- 5 CO-CHAIR MEYER: This is Gregg. It
- 6 just strikes me that we ought to reach out to
- 7 the children's hospital community, NACHRI, or
- 8 another group to give us official kind of
- 9 feedback on that specific issue.
- 10 CO-CHAIR TYLER: Okay. All right.
- 11 Making note of that. Okay. Next, 4E. "Death
- 12 or serious disability, kernicterus associated
- 13 with failure to identify and treat
- 14 hyperbilirubinemia in neonates. Let's see.
- 15 And it has a definition, it is defined as
- 16 "bilirubin levels greater than 30 milligrams."
- 17 Neonate refers to the first 28 days of life.
- 18 Anybody have any concerns on this one?
- 19 MEMBER MORLEY: I'm not sure that
- 20 concern is the right word, but I just think
- 21 that the only ones -- I'd be curious to know
- 22 if that's happened in a hospital in the United

- 1 States in the last couple of years. It hasn't
- 2 in Colorado. I would have thought for the
- 3 home deliveries, perhaps, but I'm surprised to
- 4 -- very little surprises me about hospitals,
- 5 but I'm surprised that's a -
- 6 MEMBER VICTOROFF: It was biliary
- 7 atresia that was not diagnosed.
- 8 DR. BURSTIN: Just as quick
- 9 clarification. This came up in one of the
- 10 measures this past year. The U.S. Preventive
- 11 Services Task Force recently came out, not
- 12 quite as controversial decision as the one
- 13 they had just a couple of days ago, with an
- 14 evidence report about six months ago
- 15 indicating there was insufficient evidence to
- 16 routinely recommend testing of bilirubin prior
- 17 to discharge on all neonates. So, there may
- 18 still be some confusion in places. I know in
- 19 a lot of places, like in D.C. when I deliver,
- 20 there wasn't any choice. It was D.C. law that
- 21 you did it, but there's still, I think,
- 22 perhaps some issues around the lack of clear

- 1 evidence that, unfortunately, tracking
- 2 bilirubin at discharge is not always
- 3 necessarily going to not have kernicterus
- 4 happen.
- 5 MEMBER RADFORD: Again, for my
- 6 edification, is that something that NQF does
- 7 again track, which states do have it as law,
- 8 which don't? Do you -
- 9 DR. BURSTIN: No, we don't, but I'm
- 10 not sure who does. These are the kind of
- 11 things I think are kind of holes out there
- 12 that I think we need to better understand.
- 13 MEMBER BINDER: Leapfrog -- there
- is an NQF endorsed measure which Leapfrog uses
- on the survey, so we have data on which
- 16 hospitals are using that.
- DR. BURSTIN: Do you also have data
- 18 about state laws, which state by law?
- 19 MEMBER BINDER: No, we don't.
- DR. BURSTIN: Okay.
- 21 MEMBER BINDER: We just track it by
- 22 hospital.

- 1 DR. ANGOOD: This is one of those
- 2 topic areas, this particular one, that
- 3 generates a lot of debate in terms of the
- 4 weight of the evidence versus the need. It's
- 5 in here, it's a part of other major
- 6 initiatives out there, National Patient Safety
- 7 Goals, et cetera. And it was the point that
- 8 Helen just made, I think is still some
- 9 actually worsening confusion. It's not up to
- 10 the same level as the whole breast screening
- 11 this week, but in some circles it generates a
- 12 lot of debate, and a lot of discussion. I
- 13 think removing it would really generate a much
- 14 more hostile environment, but, you know -
- DR. BURSTIN: I wasn't making -
- DR. ANGOOD: No, no. No, I know
- 17 you weren't.
- DR. BURSTIN: I just think it's
- 19 important to understand the context that the
- 20 evidence base is not as firm as I think many
- 21 of us would have suspected. It was a very
- 22 surprising evidence report, if you haven't

- 1 seen it. You kind of leave, and you go
- 2 really?
- 3 DR. ANGOOD: Yes, I know.
- 4 CO-CHAIR MEYER: This is Gregg. I
- 5 think this is a -- this being on the list, I
- 6 think, as some folks know, it's a testimony to
- 7 a small but vociferous group trying to make
- 8 sure that something never ever happens again.
- 9 And all the more power to them. I think that
- 10 regardless of the testing strategy issues, my
- 11 sense is that these are incredibly rare, but
- 12 probably important failures when they occur.
- 13 CO-CHAIR TYLER: Doron had
- 14 something, and then Leah.
- 15 MEMBER DORON SCHNEIDER: I actually
- 16 had a comment about 4D, if we can come back,
- 17 just one comment I'd like to make about that,
- 18 after this discussion.
- 19 CO-CHAIR TYLER: Leah, you're on
- 20 4E. Right?
- 21 MEMBER BINDER: Pardon me?
- 22 CO-CHAIR TYLER: You're on the

- 1 current one. Right?
- 2 MEMBER BINDER: Yes. Just to make
- 3 -- I think we should make the distinction, I
- 4 think what Helen was referring to was the
- 5 screening protocol. This is referring to the
- 6 consequence of not detecting hyperbili, and
- 7 that's very different. So, I think we need to
- 8 be clear about -- I think it's perfectly
- 9 appropriate, regardless of how you feel about
- 10 the screening tool, perfectly appropriate to
- 11 have this as an SRE.
- DR. BURSTIN: The problem is at
- 13 times you can't tell, necessarily, by clinical
- 14 exam is what the Task Force really pointed
- 15 out. So, you may still miss people. You may
- 16 not be screening people for whom there's not,
- 17 necessarily -- again, I'm not an internist,
- 18 that is not necessarily clear evidence that
- 19 they are hyperbilirubinemiac, yellow, whatever
- 20 the case may be. So, it's a related issue,
- 21 but you're right, this is a stronger point.
- 22 CO-CHAIR TYLER: Okay. Anything

- 1 else on this rule? Okay. Then we can go back
- 2 to hypoglycemia.
- 3 MEMBER DORON SCHNEIDER: Just a
- 4 quick comment in support of what John was
- 5 saying before about the specificity of some of
- 6 these never events. You know, we have this
- 7 medication error section, and then we have a
- 8 4D, which I actually like, and hope we keep,
- 9 where we can then define hypoglycemia, usually
- 10 due to insulins or oral hypoglycemics. And if
- 11 we're going to do that, then it's sort of
- 12 inconsistent that we don't have
- 13 anticoagulants, or narcotic sedation, et
- 14 cetera, in there as separate categories. So,
- 15 I think there is lack of consistency in
- 16 breaking that out, and I just point that out.
- 17 MEMBER LAU: This is Helen. I
- 18 concur with that point.
- DR. BURSTIN: And in terms of
- 20 expanding the SRE's, it's exactly that kind of
- 21 thing that we'd want to get a sense. I mean,
- 22 we know the top three causes of ED, adverse

- 1 events are exactly the ones you listed, plus
- 2 insulin, so you just named them, and that
- 3 would be a logical approach, very evidence-
- 4 based, to add SREs.
- 5 MEMBER VICTOROFF: It's now the
- 6 Morley 80. I've been keeping track.
- 7 CO-CHAIR TYLER: The list grows.
- 8 Okay. Move on to the next rule. Let's see,
- 9 4F. "Stage Three or Four Pressure Ulcers
- 10 acquired after admission to a healthcare
- 11 facility, excludes progression to Stage Two
- 12 and Stage Three, if Stage Two was recognized
- 13 upon admission." Okay. Diane wants to start.
- 14 MEMBER RYDRYCH: I'll start with a
- 15 small comment, and then the bigger one. We've
- 16 made some changes in how we define the scope
- of this one in Minnesota, which may be
- 18 controversial or not. The little one is just
- 19 to say, if Stage Two is recognized and
- 20 documented upon admission, because that gets
- 21 at -
- 22 (Music in background.)

- 1 CO-CHAIR TYLER: Musical
- 2 accompaniment.
- 3 DR. ANGOOD: Yes, those of you who
- 4 are on the phone -
- 5 MEMBER LAU: What's that?
- 6 CO-CHAIR TYLER: Yes, someone on
- 7 the phone has music when they put us on hold,
- 8 I think.
- 9 MEMBER LAU: Oh, okay.
- 10 CO-CHAIR TYLER: It doesn't appear
- 11 to be on any more. Okay.
- 12 MEMBER RYDRYCH: It kinds of get at
- 13 the present on admission issue, that if it
- isn't actually documented, you can't,
- 15 necessarily, say whether it was recognized on
- 16 admission, so that's a change we made. But
- 17 the larger one, which people may or may not
- 18 agree with, and it had upsides and downsides,
- 19 was to expand it to include unstageable
- 20 pressure ulcers, in addition to Stage Three
- 21 and Four. Based on the fact that almost
- 22 always those unstageable pressure ulcers, when

- 1 they can be staged, are going to be staged at
- 2 Three or Four. We do allow people to remove
- 3 them if they end up being staged at Stage Two,
- 4 but that doesn't happen very often. We also
- 5 include, if something progresses from a
- 6 suspected deep tissue injury to a Stage Three
- 7 or Four.
- 8 CO-CHAIR TYLER: Doron.
- 9 MEMBER DORON SCHNEIDER: This
- 10 documentation piece is creating all kinds of
- 11 havoc in the regard of whose documentation we
- 12 will accept, and the physician documentation
- is, in many settings, the one that is
- 14 accepted, when we have physicians not really
- 15 completely understanding it, as well as
- 16 nursing, and specialists within wound care.
- 17 So, as we define the implementation guidance,
- 18 I'd love to see us be able to accept wound
- 19 care nursing and other specialists that are
- 20 not, necessarily, physicians in that
- 21 documentation present on admission, I think is
- 22 the way to go.

- 1 CO-CHAIR TYLER: Anything else on
- 2 this one? Helen.
- 3 DR. BURSTIN: Just point out that
- 4 NQF has just got out for vote a framework, an
- 5 updated framework for classifying pressure
- 6 ulcers based on the sort of latest thinking
- 7 that, in fact, the actual number stages are
- 8 very problematic. There's not a logical
- 9 progression from One, to Two, to Three, to
- 10 Four. Some people start at different stages.
- 11 You guys, again, probably know some of this
- 12 more than me, but the point they made was
- 13 really trying to look at deep tissue versus
- 14 superficial, so I'll make sure we share that
- 15 report with the group. I think this is one
- 16 we're going to have to come back to and take
- 17 a pretty serious look at in light of some of
- 18 the new evidence.
- 19 DR. ANGOOD: And we're doing the
- 20 same thing with the Safe Practices sort of
- 21 pending this report.
- 22 CO-CHAIR TYLER: I have a question

- 1 for edification on the consumer end. Somebody
- 2 give me a really quick thumbnail, why would a
- 3 pressure ulcer be unstageable?
- 4 MEMBER RYDRYCH: I'm not a wound
- 5 care expert at all, but, generally, it's
- 6 covered with -- for the lay person's term
- 7 would be sort of a scabbing. They're sort of
- 8 scabbed over, and you can't see the depth of
- 9 the wound.
- 10 CO-CHAIR TYLER: Cynthia had
- 11 something, then Michael.
- 12 MEMBER HOEN: Yes, I would have to
- 13 get back to the group with specifics, but in
- 14 New Jersey, we have changed our classification
- 15 of pressure ulcers to recognize things like
- 16 multi-system organ failure as taking pressure
- 17 ulcers outside of reportable. And I think
- 18 there are some other clinical criteria which
- 19 have been applied, which have been
- 20 demonstrated to suggest that those are not
- 21 preventable, and that's helped us tremendously
- 22 with respect to focusing in on events which we

- 1 can prevent, versus those which we are not
- 2 able to do anything about.
- 3 MEMBER RYDRYCH: And I would just
- 4 say, too, again, not being a clinical person,
- 5 I'm at a disadvantage here, but I do know that
- 6 we've had discussion about end of life ulcers,
- 7 and Kennedy ulcers, and whether those are
- 8 really pressure ulcers, as well. And that's
- 9 been a difficult conversation. I think where
- 10 we came down on that is that they're still
- 11 reportable, but that we did get a lot of push-
- 12 back from people saying if someone is
- developing a sore in the last days of life
- 14 because their system is shutting down, that's
- 15 a different situation than other pressure
- 16 ulcers.
- 17 MEMBER TANGALOS: Yes. I think
- 18 this is where you're going to have a technical
- 19 panel help you with this. As we expand into
- 20 this universe, again, I brought up the hospice
- 21 question, the near death, I'm not sure where
- 22 the right answers are.

- 1 MEMBER LAU: This is Helen. I
- 2 concur. In California, when I review death,
- 3 that pops up a lot. And I think we really
- 4 need some other experts to help.
- DR. ANGOOD: This is Peter. This
- 6 is another example of if you don't nudge the
- 7 reporting to look at all events, then you're
- 8 not going to learn what's actually out there,
- 9 and you run the risk of complacency occurring.
- 10 And the home health pressure ulcer, it's a hot
- 11 debate, but we want to be able to at least
- 12 have the discussion, whether it was
- 13 unpreventable, or actually could have been
- 14 prevented.
- 15 MEMBER TANGALOS: Again, I think we
- 16 have to be really careful, because there is a
- 17 trend with pressure ulcers to throw in the
- 18 towel, and make the claim that the patient is
- 19 terminal, and then they get put on hospice.
- 20 So, there's an untoward action that goes on
- 21 with these ulcers right now. It's a free
- 22 pass.

- 1 CO-CHAIR TYLER: Michael has wanted
- 2 to get in for a while, and then Doron.
- 3 MEMBER VICTOROFF: You know, this
- 4 is such a wonderful topic that I totally
- 5 support the idea that this is for an expert
- 6 panel. There is an enormous discussion to be
- 7 had here with pros and cons, terminal care,
- 8 what do you mean by preventable? What do you
- 9 mean by something that might be preventable,
- 10 but we elected not to, because it was
- 11 inappropriate to take the action that would
- 12 have prevented it for other reasons that were
- 13 totally good. And, therefore, what I would do
- 14 is just put a big asterisk in the discussion
- of this thing saying that, you know, to be
- 16 continued, because I don't think I'll be happy
- 17 -- as long as the word "facility", you know,
- 18 this is about healthcare facility. I'm not
- 19 quite clear I understand for this purpose what
- 20 the definition is. And when you admit a
- 21 terminal person who broke their hip, but now
- 22 they're still terminal, but they're in a

- 1 hospital. Have I illustrated why this is a
- 2 good thing to move off to somebody else?
- 3 CO-CHAIR TYLER: Well, it sounds
- 4 like we definitely need help from TAPs on this
- 5 one, and maybe developing some separate
- 6 reporting around this. But, Doron, you're
- 7 next.
- 8 MEMBER DORON SCHNEIDER: I'd want
- 9 the TAP also to come in on trach care, and
- 10 pressure ulcer definition, therein, because,
- 11 obviously, that's a very different set of
- 12 processes, care processes, that sometimes get
- 13 intermixed within this larger heading. So, we
- 14 may need to have implementation guidance on
- 15 that.
- 16 MEMBER TANGALOS: Twenty years ago
- 17 I would never see a home patient for any
- 18 reason have pressure ulcers, but we take care
- 19 of home patients now with greater and greater
- 20 frailty, and it is not -- it's just a shock to
- 21 see -- I mean, they come in with pressure
- 22 ulcers, and you just never used to see that.

- DR. BURSTIN: Again, the TAPs we're
- 2 talking about are sort of setting specific, so
- 3 long-term care, nursing home, so we can
- 4 utilize the Steering Committee from the
- 5 pressure ulcer framework to give us -- they
- 6 are the experts in measuring these things, so
- 7 we'll specifically bring whatever comes out of
- 8 that TAP to the Steering Committee for their
- 9 input.
- 10 Again, I think this one may need to
- 11 be pretty radically changed in terms of the
- 12 staging and things like that, to some of the
- 13 newer ways of thinking about partial versus
- 14 full thickness, and things like that.
- 15 CO-CHAIR TYLER: All right. We'll
- 16 move on to 4G. "Patient death or serious
- 17 disability due to spinal manipulative
- 18 therapy." Anything on this? Diane.
- 19 MEMBER RYDRYCH: Just a comment,
- 20 that I've always found this one to be kind of
- 21 odd, because -- not because we've never had
- 22 this reported, or because I don't even know

- 1 how often spinal manipulative therapy happens,
- 2 at least in a hospital setting, but because it
- 3 seems to be focused on a provider, rather than
- 4 a system. And if you're going to talk about
- 5 death or serious disability related to one
- 6 type of therapy, why wouldn't you be talking
- 7 about death or serious disability related to
- 8 other kinds of therapy? I don't know why you
- 9 would single out spinal manipulative therapy,
- 10 as opposed to any other death or serious
- 11 disability that happens due to the therapeutic
- 12 process in a hospital.
- 13 CO-CHAIR TYLER: Anyone else on
- 14 this? Mike.
- 15 MEMBER VICTOROFF: Well, you raised
- 16 a question that I've been real nervous about,
- 17 because so far I haven't found any category of
- 18 these things that I really felt like dropping.
- 19 And we're sensitive to the political potential
- 20 ramifications of our deciding oh, well, we
- 21 changed our mind, that's not so serious any
- 22 more. Go ahead and do it, to make a

- 1 burlesque. But if there were one on this that
- 2 I really think is fishy for the reasons you
- 3 said, and others, it would be this, because
- 4 the frequency is incredibly rare, and it isn't
- 5 a hospital event. There's more than one
- 6 specialty that yanks on spines, but it looks
- 7 to me as though this one -- am I misreading or
- 8 do I have the mild odor of a political agenda
- 9 here?
- 10 It's just that -- I mean, really,
- 11 this one just has a kind of a sense to it,
- 12 that it's not like the others, and I don't
- 13 know what to do about that. It's your
- 14 problem.
- 15 DR. ANGOOD: Well, it's like a lot
- 16 of things, you know, once you create
- 17 something, it's always hard to get rid of it.
- 18 And I think what we need to do on our side is
- 19 do a little bit more homework on the genesis
- 20 of why this showed up on the list to make sure
- 21 we're not running the risk of taking it off,
- 22 when there was a perfectly good reason for it

- 1 being on there. So, we'll get that feedback
- 2 on the history of the genesis to the group.
- But, to your point, all items on
- 4 the list are open for addition, deletion,
- 5 modification, and it's just a bigger step to
- 6 remove, as opposed to add.
- 7 CO-CHAIR TYLER: Chris, and then
- 8 John.
- 9 MEMBER GOESCHEL: Quick point. I
- 10 would be curious as to the background, having
- 11 lived through spinal manipulative therapy in
- 12 an osteopathic facility where there were
- 13 serious untoward effects, and it was a
- 14 clinician, I mean, different ways to deal with
- 15 that. I think understanding where it came
- 16 from, and if could go away would be
- interesting, need to raise that, and I'm not
- 18 a television person, but the new thing about
- 19 getting your massage and becoming paralyzed in
- the process, so whether people would confuse.
- 21 I mean, I think there are some other dynamics
- 22 in the general public going on about having

- 1 people mess around with pressing on your spine
- 2 and ending up incapacitated. I put that out
- 3 there as an aside, public to be aware.
- 4 CO-CHAIR TYLER: John, and then
- 5 Helen.
- 6 MEMBER MORLEY: I agree with
- 7 Diane's comments, and Mike's comments both.
- 8 I would just say that this is an example, in
- 9 my mind, of one of those things that is
- 10 already on the list relative to outside the
- 11 hospital environment. The same with 4H, for
- 12 the most part. 4G and 4H these days
- 13 frequently, if they're occurring, are outside
- 14 the hospital environment. Maybe they'll end
- 15 up being moved over to another list that says
- 16 outside hospitals.
- 17 DR. BURSTIN: And I just want to
- 18 make a point. It actually doesn't say in a
- 19 facility, which is one important
- 20 consideration, and neither does the second
- 21 one. But, also, I don't think there should be
- 22 concern of a political issue around removing,

- 1 or adding, or anything. The point here is,
- 2 does this remain true to the criteria? Could
- 3 it be incorporated into another one, I think
- 4 is a very valid point. We want to try to
- 5 minimize as much as we can harmonize these
- 6 events, make it easier on -- John's list of 40
- 7 becomes 39, I don't think he'll mind that too
- 8 much. But it needs to be justified, and
- 9 grounded in the evidence, not because of a
- 10 perception of whatever the politics may be.
- 11 CO-CHAIR TYLER: Okay. John,
- 12 again.
- 13 MEMBER MORLEY: One thing that just
- 14 strikes me just now is that, as we look at
- 15 many of the other things on the list, those
- 16 are things that I have major interest in
- 17 understanding how those things are happening,
- 18 and leading to change. Getting this report is
- 19 one that, towards the point Mike made about an
- 20 agenda that somebody may or may not have, I'm
- 21 not sure what I would do at the end of the
- 22 year with this information.

- 1 Trying to prevent this. Well, how
- 2 do you try and prevent this? Do you go to the
- 3 chiropractor or osteopathic societies and say
- 4 how do you prevent this, or do you refer
- 5 somebody for professional conduct issues, or
- 6 practice? They don't strike me as the rest of
- 7 the list as process issues, and looking for
- 8 something that we can do to create a safety
- 9 net. And one of the things that Jim Bagian,
- 10 and some other nationally recognized folks
- 11 have commented on, we would like to reduce
- 12 errors, for sure, but we're not going to
- 13 eliminate errors, so let's figure out ways to
- 14 prevent the error from reaching the patient.
- 15 And I'm not -- this is an event that occurs
- 16 between one person and another. It's a single
- 17 step. And, again, I can't see a process, or
- 18 anything that would intervene to prevent that,
- 19 if there's an error made, of having an impact,
- 20 a direct impact on the patient.
- DR. BURSTIN: That raises an
- 22 interesting issue with me about whether we

- 1 should consider our criteria for these around
- 2 this issue of provides additional information
- 3 that can be used to drive improvement. Just,
- 4 again, something -- I'd prefer to have these
- 5 things codified, rather than feeling like
- 6 we're -- so, just something to think about,
- 7 because I think that does add value to the
- 8 list in a different kind of way.
- 9 CO-CHAIR TYLER: Okay. Well, we'll
- 10 say that we can count on getting some more
- information about the genesis of this rule.
- 12 And, after that, we may think about whether it
- 13 needs to be in there, or take further action.
- 14 Okay.
- 15 Next, 4H. "Artificial insemination
- 16 with the wrong donor sperm, or wrong egg." We
- 17 already had a comment on this. Anybody else
- 18 have any others? Okay. Nothing on -- anybody
- 19 on the phone? You guys still there?
- 20 MEMBER LAU: Yes. Someone
- 21 mentioned -- this is Helen. Someone mentioned
- 22 early on this might be potential moved to

- 1 another list, not in a hospital setting. I
- 2 tend to agree with that.
- 3 MEMBER RYDRYCH: And I would
- 4 actually not move it. I think it's typically
- 5 not a hospital event, but it can be a hospital
- 6 event, so I wouldn't remove it. I'm just
- 7 saying that from the perspective of someone
- 8 who's collecting reports on all of these
- 9 events.
- 10 CO-CHAIR TYLER: Okay. All right.
- 11 Now we're in 5A. "Patient death or serious
- 12 disability associated with an electrical shock
- 13 while being cared for in a healthcare
- 14 facility." Let's see, the language.
- 15 "Excludes events involving planned treatment,
- 16 such as electric counter shock, electrocardio
- 17 version." Okay. Doron.
- 18 MEMBER DORON SCHNEIDER: I'd just
- 19 throw into deliberation, should it be patient
- 20 or staff?
- 21 CO-CHAIR MEYER: This is Gregg.
- 22 That was the addition that I would make, as

- 1 well.
- 2 CO-CHAIR TYLER: Okay.
- 3 MEMBER RYDRYCH: I'm wondering, why
- 4 do we exclude electroconvulsive therapy? I
- 5 mean, certainly -
- 6 CO-CHAIR MEYER: It's not
- 7 electroconvulsive therapy that's being
- 8 excluded. It's defibrillation, and
- 9 cardioversion that are for restarting the
- 10 heart. So, death during ECT would be --
- 11 during electroconvulsive therapy for
- 12 depression would be reportable.
- 13 CO-CHAIR TYLER: Actually, Gregg,
- in the implementation guidance it does say,
- 15 "This event is not included to capture patient
- 16 death or disability associated with emergency
- 17 defibrillation, ventricular fibrillation, or
- 18 electroconvulsive therapies." So, Diane is
- 19 right.
- 20 CO-CHAIR MEYER: Well, I don't have
- 21 that exclusion in front of me here, but I
- 22 would say we should revisit the ECT one.

- 1 MEMBER RYDRYCH: Yes. I mean,
- 2 certainly, death or serious disability during
- 3 ECT was not the intent of that therapy.
- 4 CO-CHAIR MEYER: Yes. I think
- 5 that's very different than the others.
- 6 MEMBER LAU: This is Helen. I
- 7 agree.
- 8 DR. ANGOOD: Although, I think the
- 9 original intent of this was -- again, this is
- 10 environmental issues. You shouldn't get
- 11 shocked from some environmental exposed
- 12 wiring, or faulty equipment with wiring, et
- 13 cetera, as opposed to bad outcomes from
- 14 medical treatment, which is what ECT is, or
- 15 cardioversion, et cetera. And it's a
- 16 differentiation here, I think we need to be
- 17 cognizant of.
- 18 CO-CHAIR TYLER: Okay. Philip,
- 19 then Michael.
- 20 MEMBER PHILIP SCHNEIDER: Is there
- 21 any reason -- I'm not a physician or
- 22 cardiologist, but reason to exclude elective

- 1 electrocardioversion? It seems to me that if
- 2 it's an elective procedure, if there's a
- 3 death, it's a reportable event, or does this
- 4 fall under the sitting craniotomy story, where
- 5 you've got a medical procedure that has such
- 6 a high risk, that it's just part of the
- 7 process. But it's -- and I don't know the
- 8 data. I mean, it could be that elective
- 9 cardioversion, electrocardioversion is well -
- 10 is developed to an extent where that really
- 11 shouldn't happen, a death shouldn't happen.
- 12 MEMBER RADFORD: Again, I think it
- 13 gets to the intent of this -- I'm a
- 14 cardiologist, so I'm chiming in here. I mean,
- 15 deaths associated with medical care. It's
- 16 kind of like a death after surgery. You know,
- 17 some people are ASA 5, and stuff happens.
- 18 MEMBER PHILIP SCHNEIDER: That
- 19 could be said of medication therapies, too.
- 20 And we actually did -- on some of the other
- 21 ones, do have ASA limitations, so that a low-
- 22 risk patient, so that may be applicable here.

- 1 I don't want to chase this too hard. It just
- 2 seems to me that we ought to avoid setting
- 3 safety nets that are arbitrary.
- 4 MEMBER RADFORD: I think if we want
- 5 to have death or serious disability related to
- 6 the electrical delivery of care, which is what
- 7 we're talking about with ECT, I think that's
- 8 a little bit different than getting shocked
- 9 from a light switch.
- 10 MEMBER VICTOROFF: Okay. That was
- 11 the point I was going to make. And it seems
- 12 to me there are implicitly two issues here
- 13 that should be teased apart. And one of them
- 14 has to do with using electrical machinery
- 15 therapeutically, deliberately. And that would
- 16 include -- unfortunately, that would include
- 17 Bovies, but the risk of Bovies is the not the
- 18 electricity, it's the fire, a burn. But
- 19 however we settle that, and I don't propose to
- 20 settle it in one sentence, the environmental
- 21 safety hazard thing, no one should get
- 22 electrically shocked because there's a short

- 1 in the TV in their room, or no one should get
- 2 killed, crushed to death by falling stairways,
- 3 or eaten by rats. I don't know what else
- 4 there is in institutions, so I would really be
- 5 in favor of pulling out the environmental
- 6 hazards in a facility safety thing. You know,
- 7 like there should be non-slip treads, whatever
- 8 the heck, fire extinguishers, OSHA, OSHA,
- 9 OSHA. And make sure that that doesn't
- 10 contaminate this if the intent here is
- 11 misadventures using electrotherapeutic
- 12 devices.
- 13 MEMBER MORLEY: The patients that
- 14 undergo not ECT, but cardioversion that have
- 15 an adverse outcome like death, the ones that
- 16 would interest me, that would be excluded, I
- 17 think, if we were to eliminate associated with
- 18 that, are the ones with an anesthesia issue,
- 19 an airway issue, an overdose of a drug, or
- 20 those types of things that may not have been
- 21 recognized as an overdose of a drug, may not
- 22 have been recognized, but I would like to find

- 1 out about those deaths, and then do a more
- 2 careful analysis. I would not like to see
- 3 this eliminated.
- 4 MEMBER RADFORD: I concur. I just
- 5 think it's a different category.
- 6 CO-CHAIR TYLER: Okay. Philip.
- 7 MEMBER PHILIP SCHNEIDER: Yes, I
- 8 think I would agree with that. I think it's
- 9 kind of like a medication error. It's a
- 10 treatment that results in a preventable
- 11 injury, so environmental hazards versus
- 12 treatment hazards -- I think maybe this is a
- 13 splitter category, like Michael suggested.
- DR. GANDHI: This is Tejal from the
- 15 phone. I agree, as well. I think that sounds
- 16 much more like a care management type of
- 17 issue, as opposed to environmental. And then
- 18 you can broaden it. There's a whole lot of
- 19 other categories of treatments that we give,
- 20 that you don't expect someone to die from, but
- 21 sometimes they do. So, I think it could end
- 22 up opening a lot of other options, but I think

- 1 it should be under care management, as opposed
- 2 to environmental.
- 3 MEMBER LAU: This is Helen on the
- 4 phone. I agree.
- 5 CO-CHAIR TYLER: So, potentially
- 6 move this to care management. Leave it in
- 7 tact, but potentially just move it.
- 8 CO-CHAIR MEYER: This is Gregg. I
- 9 agree, as well.
- 10 MEMBER BRENNAN: Me, too.
- 11 CO-CHAIR TYLER: Okay.
- 12 MEMBER LAU: This is Helen on the
- 13 phone. If we move it to care management, I
- 14 think someone suggested earlier, on patient
- 15 and staff, I think we need to remove the
- 16 staff.
- 17 CO-CHAIR TYLER: Remove the what?
- 18 MEMBER LAU: Someone suggested
- 19 earlier on patient or staff.
- 20 CO-CHAIR TYLER: Okay.
- 21 MEMBER LAU: So, we need to remove
- 22 the staff, focus on patients.

- DR. GANDHI: But I thought we were
- 2 potentially splitting, because, I mean, the
- 3 light switch electrical shock thing could stay
- 4 in environmental, but then the one that's more
- 5 of a treatment-related issue would go to care
- 6 management.
- 7 MEMBER LAU: Okay. Good.
- 8 MEMBER DORON SCHNEIDER: I would
- 9 hope the staff wouldn't die during those
- 10 treatments, as well. It should be reported.
- 11 CO-CHAIR TYLER: I concur.
- 12 MEMBER VICTOROFF: Okay. Just to
- 13 get even more splitty, the staff is subject to
- 14 characteristic misadventures during treatment,
- 15 the most common of which is needle sticks.
- 16 And getting zapped, I mean, I've burned myself
- 17 with a Bovie too. I shouldn't say that, but
- 18 there probably is another category for hazards
- 19 of providers in the course of care. But,
- 20 typically, we don't die, or die right away, or
- 21 die from the same cause pathway as the patient
- 22 does. So, for me, that suggests different

- 1 definitions, and different remedies, and
- 2 probably then different categories.
- 3 CO-CHAIR TYLER: But this isn't
- 4 just death, it's or serious disability. I
- 5 mean, staff certainly could incur serious
- 6 disability from -
- 7 MEMBER VICTOROFF: Yes, if I get
- 8 Hep C from a needle, that should be definitely
- 9 reported.
- 10 CO-CHAIR TYLER: Right.
- 11 MEMBER VICTOROFF: But then that's
- 12 another category, for me.
- 13 CO-CHAIR TYLER: If we have nothing
- 14 else on this, we can move on to 5B. "Any
- 15 incident in which a line designated for oxygen
- 16 or other gas to be delivered to a patient
- 17 contains the wrong gas, or is contaminated by
- 18 toxic substances." Cynthia.
- 19 MEMBER HOEN: This is one of those
- 20 areas I think is too narrow. We've seen
- 21 instances where oxygen was hooked up to IV
- 22 lines, or the potential for IVs, or oxygen to

- 1 be hooked up to trach ports meant for
- 2 suctioning. There's any number of
- 3 opportunities to misconnect lines to line in
- 4 our environment, and I think that we ought to
- 5 be cognizant of those so that those devices
- 6 get pulled from other entities, and those
- 7 things are taken care of.
- 8 CO-CHAIR TYLER: John.
- 9 MEMBER MORLEY: I agree, and I
- 10 would feel very strongly about that. We've
- 11 certainly seen and read a number of different
- 12 cases, as have been described. I think those
- things are preventable, very preventable. I
- 14 think that we used to see a lot of different
- 15 gases being hooked up, and I think the
- 16 engineers were always, always, always looking
- 17 for an engineering response. You know, it's
- 18 not a bad idea to have a meeting in a place
- 19 where you can't get a signal, that way people
- 20 don't play around on their Blackberry, or
- 21 whatever. It's an engineering solution to a
- 22 problem. And they engineered the fact that

- 1 oxygen tanks can only be hooked up because of
- 2 a pin system to certain lines.
- 3 We still hear cases of tube feeding
- 4 being hooked up to the pilot cuff of a trach,
- 5 tube feedings hooked up to IVs. There's a
- 6 number of different types of those
- 7 connections, and I'd love to see that
- 8 information, and then an engineering response
- 9 to that.
- 10 CO-CHAIR TYLER: Okay, Doron.
- 11 MEMBER DORON SCHNEIDER: So, I
- 12 concur entirely. However, I think that
- they're two separate issues, very similar to
- 14 our last discussion. This is an environment
- of care consideration that is structurally
- 16 different than process of care, so I think
- 17 that we need two categories here. You can
- 18 have this in your facility if you've
- 19 mislabeled your lines, if you have tubing
- 20 misconnections, that's more nursing or care
- 21 processes, not environmental events.
- 22 CO-CHAIR TYLER: But you would have

- 1 two rules, one under care management, and one
- 2 under environmental. Is that what you're
- 3 saying?
- 4 MEMBER DORON SCHNEIDER: Yes,
- 5 that's what we're proposing.
- 6 CO-CHAIR TYLER: Stan, did you have
- 7 something?
- 8 MEMBER RILEY: I quess for Doron's
- 9 comment, I'm not sure that I've ever seen on
- 10 that was the lines mislabeled, at least not in
- 11 the wall in terms of the facility. But in
- 12 terms of plugging things up, just like John
- 13 has said, we've seen, certainly, the oxygen
- 14 plugged into the feeding -- I mean, the
- 15 feeding tube plugged into the oxygen,
- 16 everything, every kind of combination of tube
- 17 plugged into the wrong thing that you can see,
- 18 we've seen. So, I think that's a huge thing
- 19 that needs to be captured somewhere.
- 20 DR. ANGOOD: Yes. I'm sort of
- 21 struggling with how we deal with this, because
- 22 while this existing SRE is very specific, and

- 1 it's gas lines, and all those horrendous
- 2 things that used to happen once upon a time,
- 3 those have almost pretty much gone away
- 4 because of the structural engineering
- 5 strategies. But this broader based topic of
- 6 tube misconnections is a huge topic. It's not
- 7 addressed anywhere in here, but as we go to
- 8 solicitation for SREs, it might be something
- 9 that we have language for, because it is a
- 10 huge topic, and we don't have an easy avenue
- 11 at this point in time to get them corrected.
- 12 CO-CHAIR MEYER: This is Gregg.
- 13 I'm also strongly in favor of creating a
- 14 separate -- I don't think you can lump it in
- 15 with this one, but creating a separate issue
- 16 around the kind of line mishaps that were
- 17 stated there. And I would suggest that
- 18 perhaps we can reach out to one of the
- 19 biomedical engineering societies and ask them
- 20 to help us craft this. I think that they
- 21 would actually welcome this.
- 22 MEMBER GOESCHEL: We actually have

- 1 a small Robert Wood Johnson Foundation grant,
- 2 and are working with some manufacturers and
- 3 other to do some of that initial work, so I
- 4 can pursue that and get you some baseline
- 5 information and background.
- 6 CO-CHAIR TYLER: Philip.
- 7 MEMBER PHILIP SCHNEIDER: Just for
- 8 the sake of completeness of the record, in the
- 9 first bullet point in the comment section, I
- 10 would say, "the wrong lines being connected,
- 11 i.e., enteral feeding tubes connected to an IV
- 12 line." I don't think I've ever heard of an
- 13 oxygen line being attached to an IV line,
- 14 although I guess it's technically possible.
- 15 Since we're going to -- this will probably be
- 16 part of our permanent record, I think that's
- 17 a more common, and often fatal situation.
- 18 DR. ANGOOD: We can put that under
- 19 the air embolism one.
- DR. BURSTIN: Just as a process
- 21 point, you should feel part of the role of the
- 22 Steering Committee is going to be recommending

- 1 whether some of these need to be retired. So,
- 2 I think it would be very appropriate, if you
- 3 think this is really past its time, to
- 4 recommend retirement of this SRE, and then
- 5 recommend the creation of the SRE that you
- 6 just talked about under care management.
- 7 And, again, these are not the usual
- 8 kind of classic measures that require an
- 9 external entity to develop a measure to submit
- 10 to NQF. The work of the SREs was typically
- 11 done by the Committee. The amount that's
- 12 actually submitted is minimal, so I think
- 13 we'll cast the net to say here's our new
- 14 definition. Here are the sites of care.
- 15 Please submit your ideas. But the actual work
- 16 of writing these, is actually you guys with
- 17 the TAPs. So, just to be clear, it's you, so
- 18 you've just given yourself some work on a new
- 19 SRE.
- 20 CO-CHAIR TYLER: Anything else on
- 21 this one before we move on? Okay. Hearing
- 22 nothing, move on to 5C. "Patient death or

- 1 serious disability associated with a burn
- 2 incurred from any source while being cared for
- 3 in a healthcare facility." Anything?
- 4 MEMBER DORON SCHNEIDER: Or staff,
- 5 and staff.
- 6 CO-CHAIR TYLER: Well, I'm glad at
- 7 least Doron is standing up for the staff.
- 8 MEMBER VICTOROFF: And, again, I --
- 9 when we're thinking about criteria, I think
- 10 about can we identify it as a precise -- is
- 11 there an intervention? Is it important? And
- 12 when I look at burn in its own little universe
- isolated, I say well, yes, that's important.
- 14 But there may be other injuries like burns.
- 15 You shouldn't drown, you shouldn't be scalded.
- 16 Do we mean scalding, including burns, or how
- 17 about slips and falls, and how about
- 18 lacerations?
- 19 I'm content leaving it burns,
- 20 because burns are good. Let's not lose the
- 21 burns, but do -- for future consideration, my
- 22 note here is simply, is this -- is there

- 1 evidence to expand because of importance or
- 2 intervention, the other things, to some other
- 3 injuries beside burns, specifically?
- 4 CO-CHAIR TYLER: Stan.
- 5 MEMBER RILEY: And, I guess that if
- 6 this is a burn, as in the closet is on fire
- 7 kind of burn, that's one thing. But what
- 8 about the burn that happens in the OR, where
- 9 somebody is using alcohol-based prep, and then
- 10 the Bovie is on, and somebody has a facial
- 11 burn, or something like that. So, I think
- 12 it's one of those splitter kind of things,
- 13 again.
- 14 DR. BURSTIN: We do currently have
- 15 a measure in the ambulatory surgery
- 16 environment on OR fires. It's actually,
- 17 unfortunately, not as rare as one might hope.
- 18 And I assume this would be covered under that.
- 19 But, again, the blending to care management is
- 20 going to get a little tough on some of these,
- 21 like the Bovie example earlier.
- 22 CO-CHAIR TYLER: Any other thoughts

- 1 or comments on burns?
- 2 MEMBER BRENNAN: I just wonder
- 3 about whether it should be limited to death or
- 4 serious disability. Reporting less serious
- 5 events could have a significant impact on
- 6 safety, as well. We've had burns, and they've
- 7 all been minor, but they've been pretty
- 8 alarming events that galvanize a lot of
- 9 action.
- DR. ANGOOD: Yes, I think, P.J.,
- 11 this is Peter. That's a good point, and I'll
- 12 put my old Joint Commission hat on. Huge
- 13 under-reporting of these burns, because the
- language of the SREs is well, it's not a bad
- one, so we'll send you home with your blisters
- 16 anyway, but we don't have to tell anybody.
- 17 So, I think that's a good suggestion that the
- 18 group should think about.
- 19 CO-CHAIR TYLER: Doron.
- 20 MEMBER DORON SCHNEIDER: We talked
- 21 about the selective use of the words, "or risk
- 22 thereof", and this would be an example of the

- 1 time to use it.
- 2 CO-CHAIR TYLER: Diane.
- 3 MEMBER RYDRYCH: Well, just an
- 4 observation. I think part of what's difficult
- 5 about this is that we've set the system up so
- 6 that we have death or serious disability, or
- 7 neither, which is sort of this no harm
- 8 category. I'm not suggesting that we add some
- 9 other level of harm, and then define it, but
- 10 sometimes it is difficult to figure out what's
- 11 that line between no harm and serious
- 12 disability, and is there a need for kind of a
- 13 middle ground? Because if somebody has a
- 14 teeny little burn versus something that does
- 15 require some treatment, there's a gray area
- 16 in-between there that can be difficult to
- 17 define.
- 18 CO-CHAIR TYLER: Michael.
- 19 MEMBER VICTOROFF: This is
- 20 illustrative of the difference between an end
- 21 point, which a burn can be, burn being the end
- 22 point injury, which could be serious or not,

- 1 and a pathway of harm, which is -- the word
- 2 "burn" is being used, as in this case. We have
- 3 the endpoint, which is you're dead, and the
- 4 pathway is you burned to death. And in this
- 5 case, I think it would be possible to say
- 6 because burn as a mechanism of death
- 7 illustrates almost always an important safety
- 8 issue, that if there's any burns, burns of any
- 9 degree in the pathway, that the fact that it
- 10 killed you or not is not as important as
- 11 there's something to learn from looking at the
- 12 fact that a burn event occurred to a human,
- 13 because that's almost never intentional in
- 14 this context.
- So, okay. That's a long way of
- 16 saying here's where I would invoke the
- 17 exception clause and say get rid of death or
- 18 serious disability. And I would just say any
- 19 burn to patient or staff, unintentional -- any
- 20 unintentional burn that occurs in a facility.
- 21 Then we'll deal with homes, and hospices
- 22 later.

- 1 MEMBER TANGALOS: It will be a huge
- 2 issue.
- 3 MEMBER VICTOROFF: Much larger than
- 4 it is in the hospital.
- 5 MEMBER LAU: This is Helen. For
- 6 clarification, does that also include chemical
- 7 burns?
- 8 CO-CHAIR TYLER: The question is
- 9 does it also include chemical burns. Right,
- 10 Helen?
- 11 MEMBER LAU: Yes.
- DR. ANGOOD: This is Peter. My
- 13 interpretation of it over time has been yes,
- 14 it's any kind of burn. We tend to think about
- 15 it, electrical, et cetera, but a burn is a
- 16 burn. It shouldn't happen.
- 17 CO-CHAIR TYLER: Scalding, as well.
- DR. ANGOOD: Yes, scalding would be
- 19 part of that.
- 20 CO-CHAIR TYLER: Philip.
- 21 MEMBER PHILIP SCHNEIDER: This is
- 22 probably way out of chemical burns, but

- 1 extravasation injuries, does that fall in any
- 2 of these categories, particularly ones that
- 3 require surgical -- surgery?
- DR. ANGOOD: Well, this would be my
- 5 own personal view on that. That, to me, is
- 6 more of an administration error, and kind of
- 7 in the medication management area, as opposed
- 8 to what we're talking about here. But your
- 9 point is very well taken, because those are
- 10 sometimes horrendous outcomes.
- 11 CO-CHAIR TYLER: John.
- 12 MEMBER MORLEY: I just heard Martha
- 13 make the comment about second degree burn.
- 14 But I agree, Peter said burn is a burn, is a
- 15 burn. But is there any limitation in terms of
- 16 first-degree burns, if somebody has a heating
- pad on the operating room table, and they're
- 18 on the OR table for several hours, end up with
- 19 some erythema on their skin. So, perhaps
- 20 second-degree burn. I don't know.
- DR. ANGOOD: Well, it's like a lot
- 22 of our discussions, you know, where is your

- 1 line, and do you want to have -- do you want
- 2 to promote an excess of reporting, just so
- 3 you're not missing stuff, versus do you want
- 4 to allow things to be hidden because they
- 5 don't meet your criteria. And the
- 6 subjectivity in meeting your criteria is
- 7 always the bugaboo.
- BURSTIN: I do think, though,
- 9 there is -- I think Diane and John both raised
- 10 really good points about we still have left
- 11 the definition of being serious, which at
- 12 least implies disability or risk thereof. And
- 13 we've not really kind of gone -- risk thereof
- 14 is a pretty far place away from pretty bad
- 15 injury, but maybe not disability. So, the
- 16 question might be, is there a need, if we want
- 17 this corridor of these not so bad events, but
- 18 they're reportable because they're important,
- 19 and getting back to John's point, I can learn
- 20 from them. We may need to think about -- I
- 21 was just looking at the definition of adverse,
- 22 for example. At least have a definition of

- 1 adverse, which is, "It describes a negative
- 2 consequence of care that results in unintended
- 3 injury or illness, which may or may not" -- we
- 4 got rid of the parental part. So, at least
- 5 there's an injury involved, and what some
- 6 would argue the question is, you know, is a
- 7 little redness an injury? And we may need to
- 8 actually play some of the legalistic games we
- 9 played when I was part of the Harvard Medical
- 10 Practice study. Actually, there's a real
- 11 gradation of injury, and it may not be a bad
- 12 idea to codify this, although, it would
- 13 complicate it a bit. But it would give us the
- 14 corridor for reporting in a way that sticks to
- 15 our definitions.
- 16 CO-CHAIR TYLER: Diane.
- 17 MEMBER RYDRYCH: Just a brief
- 18 comment. I was glad that we added that risk
- 19 thereof statement in one of our definitions,
- 20 but just to throw another thing out there, we
- 21 never really did talk about how we would
- 22 define risk thereof. And we are kind of

- 1 creating more ambiguity there, because it's
- 2 what -- how much risk is considered risk
- 3 thereof, and whose assessment of risk? That's
- 4 something that we probably have to circle back
- 5 to at some point.
- 6 CO-CHAIR TYLER: Doron.
- 7 MEMBER DORON SCHNEIDER: I just
- 8 want to capture radiation burns here, as well.
- 9 CO-CHAIR TYLER: Anything else on
- 10 burns before we move on? All right. Moving
- 11 on, 5D, I believe. Right? "Patient death or
- 12 serious disability associated with a fall
- 13 while being cared for in a healthcare
- 14 facility." New language, "Includes, but is
- 15 not limited to fractures, head injuries, and
- 16 intracranial hemorrhage." Any comments?
- 17 DR. BURSTIN: I'm being Deborah,
- 18 who had to leave. She handed me her notes.
- 19 This was one of them. She had concerns about
- 20 this one, specifically patient death
- 21 associated with a fall. She said she would
- 22 consider moving it into care management. I'm

- 1 speaking as her now. She thinks that
- 2 environmental -- as an environmental event, it
- 3 plays down the role of caregivers and the
- 4 assessment, and the use of strategies to
- 5 minimize harm if a patient falls. A fall may
- 6 not be preventable, but there are effective
- 7 methods for reducing harm from a fall. So, I
- 8 think just the fact that it's an environmental
- 9 here was her concern. Maybe that same issue
- 10 we've had before, is this really a care
- 11 management event, as well, or in addition.
- 12 CO-CHAIR MEYER: Yes, I would
- 13 second that. The problem here is not the
- 14 floor that the patient impacts, it's the
- 15 management process.
- 16 MEMBER BRENNAN: Agreed.
- 17 MEMBER LAU: Agree.
- 18 CO-CHAIR TYLER: Diane.
- 19 MEMBER RYDRYCH: I have one
- 20 question. Is that second -- is the exclusion
- 21 under implementation guidance from a different
- 22 event, because it's talking about

- 1 defibrillation and ECT. Yes, I'm not sure how
- 2 I feel about all this splitting, but I do
- 3 think when I look at the falls that we get
- 4 reported to us, some of them are environmental
- 5 still, and some of them are care management.
- 6 We've had cases where falls are
- 7 related to the color of the shower curtain, or
- 8 the way the door works, or the slippery floor,
- 9 or the slippery blanket on the bed. I mean,
- 10 we've had environmental, as well as care
- 11 management. It definitely mixes up both of
- 12 them.
- 13 CO-CHAIR TYLER: Do we have
- 14 implementation guidance for that that can be
- 15 plugged in, or just -- no, we're just kind of
- 16 missing it. Okay. Helen. Leah.
- 17 MEMBER BINDER: I would agree care
- 18 management approach on this one. I mean, I
- 19 really do see, even issues that are
- 20 environmental, in some of the hospitals that
- 21 we've seen, they've anticipated those
- 22 environmental issues. They found the slippery

- 1 blanket, or the shower curtain, or whatever.
- 2 They've actually looked that closely at their
- 3 systems to prevent falls, and have really seen
- 4 results. So, I think, fundamentally, this is
- 5 a care management issue.
- 6 DR. BURSTIN: Just going to make
- 7 the point that, again, to be -- I think you
- 8 should feel that this is really your
- 9 opportunity to kind of explode this list a
- 10 bit. So, I guess the question might be, and
- 11 I don't know it from the states' perspectives,
- 12 but how important is it to have them
- 13 categorized in this way, care management
- 14 versus environmental. And why not come up
- 15 with events that are logical and make sense,
- 16 that's more patient-centered.
- 17 And then, lastly, might there be a
- 18 group of these sort of more environmental
- 19 things I told you I was a lumper yesterday -
- that you might be able to lump together, to
- 21 not necessarily significantly increase the
- 22 size of the list, but just thoughts.

- 1 MEMBER RYDRYCH: I would say from
- 2 our perspective, the categorization doesn't
- 3 really matter that much, because we focus on
- 4 what works to prevent them. It's not
- 5 environmental events only -- we only focus
- 6 environmental solutions on those.
- 7 CO-CHAIR TYLER: Okay. I think we
- 8 can move on, next one, 5E. "Patient death or
- 9 serious disability associated with the use of
- 10 restraints or bed rails while being cared for
- in a healthcare facility." Does anybody have
- 12 any thoughts on this?
- DR. BURSTIN: In essence, same as
- 14 above. This is a care management event, not
- 15 environment. So, perhaps if we just exploded
- 16 that, it's okay.
- 17 CO-CHAIR TYLER: All right. John,
- 18 and Stan.
- 19 MEMBER MORLEY: The question just
- 20 comes to mind of the issue that CMS is tackled
- 21 with physical restraints versus chemical
- 22 restraints, or pharmacological restraints. I

- 1 mean, this doesn't suggest a distinction, so
- 2 I'm not sure exactly how it would be covered.
- 4 exactly. What about chemical restraints?
- 5 DR. ANGOOD: I think the original
- 6 intent obviously, the way it's worded is to
- 7 the physical piece. Whether we want to add a
- 8 second category, or put it as new, I mean,
- 9 that's -
- 10 MEMBER TANGALOS: In this regard,
- 11 again, hospitals have had the free pass on the
- 12 chemical restraints. The regulations within
- 13 the long-term care industry have been there
- 14 forever, but hospitals are left off of this
- 15 one.
- 16 CO-CHAIR TYLER: Philip.
- 17 MEMBER PHILIP SCHNEIDER: Might
- 18 that also fall in the category of medication
- 19 errors. And we've started to tease out some
- 20 things, like hypoglycemia, that relate to the
- 21 use of medicine, so this -- the chemical
- 22 restraints might fall into the category of

- 1 medication error.
- 2 MEMBER TANGALOS: Actually, there
- 3 is replete literature in long-term care
- 4 regulation. And it's very complete, and it's
- 5 very different from what you observe in the
- 6 hospital. And the physical restraints that
- 7 you see oftentimes in the hospital, you can't
- 8 get away with in long-term care at all, so the
- 9 literature, again, is very prolific with
- 10 regards to chemical restraints, and how it's
- 11 taken care of. And, again, a technical expert
- 12 panel is going to help you with that.
- 13 CO-CHAIR TYLER: Okay.
- DR. ANGOOD: Sorry, if I could.
- 15 Actually, the last five, ten minutes, for me,
- 16 is helping me understand that maybe as part of
- 17 what our group needs to do is to not just look
- 18 at our individual events, but perhaps we need
- 19 to look at the categorization of these events,
- 20 as well, and make sure we're still on the
- 21 right track. Again, what started off in `02-
- 22 03, isn't necessarily the same as right now,

- 1 but we don't want to get wild and crazy here.
- 2 But we should -- if we're going to do a deep
- 3 analysis on everything, we should.
- 4 CO-CHAIR TYLER: Okay. Anything
- 5 else? Yes, Michael.
- 6 MEMBER VICTOROFF: Well, actually,
- 7 I'm following up on that tangent. You may
- 8 want to table this for later, but I envision
- 9 a grid here that has more columns. And in my
- 10 fantasy, the categories have disappeared, and
- 11 we're just alphabetizing or something, or
- 12 arbitrarily listing the left column, but
- 13 across the right, my fantasy columns have
- 14 bullets or stars, or something indicating the
- 15 relevance and interpretation to several
- 16 different venues for care. Because the
- 17 discussion is very different of some of these
- 18 things, as soon as you move to a different
- 19 kind of care environment. So, I actually -- I
- 20 don't think that there are -- well, maybe
- 21 there are like global comments that apply to
- 22 them all, but I think the solution to the

- 1 categories is to drop them. And then capture
- 2 the value of what we used to have in
- 3 categories by looking much more precisely at
- 4 the venues.
- DR. ANGOOD: Well, Helen and I go
- 6 back and forth amongst ourselves on this, and
- 7 whether there's a matrix sort of strategy that
- 8 can be applied, not just to the SREs, but to
- 9 the practices, even to some degree the
- 10 measures, and the other side of the matrix
- 11 would be conditions, environments, even
- 12 procedures, and to some degree you could even
- 13 get down to disciplines or teams. Yes, you're
- 14 building your matrix. It gets hugely complex
- over time, but conceptually, it helps you sort
- of frame these things up, so that you're in
- 17 the home care, and it's a nurse who is looking
- 18 after a patient with this condition. You kind
- 19 of know what the issues are. That's a long-
- 20 term project to populate that type of a
- 21 framework, but, conceptually, it helps move
- 22 you along.

- 1 MEMBER LAU: This is Helen on the
- 2 phone. Something just came to my mind. I'm
- 3 not a behavioral health or a psych area expert
- 4 in that area, but I would think that a
- 5 situation, some of those psych patients may be
- 6 locked up in certain area, that will also
- 7 define as restrained in that case. So, these
- 8 examples here, I don't see those really
- 9 mentioned there. Should that be included?
- 10 CO-CHAIR TYLER: Okay. Making note
- 11 of that. Helen, can you repeat what you like
- 12 to be included specifically, just so we'll
- 13 make sure we note it.
- 14 MEMBER LAU: I would like to have
- 15 some language around the behavioral health and
- 16 psych patients being -- I don't know what the
- 17 term is, that they are in seclusion. That
- 18 might be expanding the whole restrain -
- 19 CO-CHAIR TYLER: Okay.
- 20 MEMBER LAU: I don't know.
- 21 CO-CHAIR TYLER: Okay. Well, we
- 22 had said -- one of the notes we made here is

- 1 that we need the TAP to give a lot of input on
- 2 chemical restraints, which I think would
- 3 include that. Right? The use of psych and
- 4 behavioral medications?
- 5 MEMBER LAU: Yes, and also one is
- 6 on seclusion, that got locked up.
- 7 CO-CHAIR TYLER: Okay.
- 8 MEMBER LAU: That also need to get
- 9 included.
- 10 CO-CHAIR TYLER: Okay. Got it.
- 11 Okay. Thank you. And, Cynthia.
- 12 MEMBER HOEN: Going back to what
- 13 Peter was saying, it might be helpful if the
- 14 TAP groups could take a look at what reporting
- 15 IT equipment is out there, and what buckets
- 16 they have. I mean, that may be helpful in us
- 17 determining where certain things may fall, and
- 18 not turning our systems on their head, if
- 19 there are already tools out there to capture
- 20 some of this, what they call them. Do we want
- 21 to follow that metric?
- 22 CO-CHAIR TYLER: Okay. One more

- 1 thing from Michael.
- 2 MEMBER VICTOROFF: The word
- 3 "corrections." We don't have corrections
- 4 facilities here, and there are astonishingly
- 5 interesting issues that begin to overlap
- 6 behavioral, and get acute in the corrections
- 7 environment. And let's not forget them, when
- 8 we are going to our TAPs.
- 9 DR. ANGOOD: Yes, we haven't
- 10 actually given them a lot of thought. And
- 11 having, as a trauma surgeon and background,
- 12 looked after a lot of those criminal types,
- 13 and those criminal environments. They get very
- 14 poor care, and so I think it's a sub-category
- 15 that we need to not overly profile, but
- 16 certainly not forget.
- DR. BURSTIN: Actually, the bigger
- 18 issue, from training in a public hospital, the
- 19 bigger issue is the care that we provided to
- 20 prisoners who were chained to their beds, when
- 21 you couldn't do an adequate physical exam. I
- 22 mean, there are real issues there in our

- 1 healthcare facilities, as well.
- 2 CO-CHAIR TYLER: Well, your mention
- 3 of corrections kind of gives us a nice segue
- 4 to criminal events, which is the next section,
- 5 moving into Category 6. Starting with 6A,
- 6 "Any instance of care ordered by, or provided
- 7 by someone impersonating a physician, nurse,
- 8 pharmacist, or other licensed healthcare
- 9 provider." Any comments? Anybody on the
- 10 phone want to weigh in? Okay. Hearing none,
- 11 we'll move on to 6B. "Abduction of a patient
- 12 of any age." Any concerns?
- 13 DR. BURSTIN: It seems like there
- 14 may be some harmonization concerns, our whole
- 15 code pink discussion yesterday. It sounds
- 16 overlapping, to me.
- 17 DR. ANGOOD: Yes, that's the one --
- 18 that was 3A. It was the infant discharged to
- 19 the wrong person. And we had a discussion, if
- 20 you might remember, is this just newborns, is
- 21 it the within one year, is it anybody? What's
- 22 competent, what's not competent, that whole

- 1 discussion which we had.
- 2 CO-CHAIR TYLER: Cynthia, you may
- 3 be able to shed light on this. I mean,
- 4 abduction is very -- a legal term. Right?
- 5 Abduction, it's a very specific term.
- 6 MEMBER HOEN: Yes. When you get to
- 7 this level, I mean, this is an event that
- 8 you're calling the police about, you're
- 9 reporting to the state, I think it's good to
- 10 keep track of it, but that's kind of a
- 11 secondary thought. You're going to let the
- 12 police take over that, as opposed to a
- 13 discharge to the wrong parent, or something
- 14 that's more controllable by the hospital and
- 15 its environment.
- 16 CO-CHAIR TYLER: Okay. Martha.
- 17 MEMBER RADFORD: With this one, and
- 18 the next one, I wondered about staff, as well.
- 19 CO-CHAIR TYLER: Okay. Good thing
- 20 to add. Okay. Michael.
- 21 MEMBER VICTOROFF: And also for
- 22 opening to the next one, the healthcare

- 1 facility becomes much more problematic here in
- 2 each of these. And we're going to have to do
- 3 more thinking as we spread our rows to the
- 4 other venues. So, what that means to me is
- 5 that, if we're -- you're going to have a left-
- 6 hand column sort of in my fantasy that
- 7 describes the general definition, then I'm
- 8 going to have to go back over the list a
- 9 little, and look at all those ones where we
- 10 said healthcare facility, and see if it bears
- 11 just clipping that off, because we're going to
- 12 address the facility in my right-hand columns.
- 13 So, then am I happy with calling this sexual
- 14 assault on a patient or healthcare provider,
- 15 which broadly means staff. And I think yes,
- 16 I think sexual assault on a patient or
- 17 healthcare provider, and then leave the
- 18 facilities over here on the right.
- And, in my mind, I'm beginning to
- 20 think that that might be the model I want to
- 21 use for some of these other things, where the
- 22 word "facility" is now irritating me in the

- 1 left column.
- 2 (Off mic comment.)
- 3 CO-CHAIR TYLER: P.J., do you have
- 4 a comment on the phone?
- 5 MEMBER BRENNAN: No, I'm sorry, I
- 6 don't.
- 7 CO-CHAIR TYLER: Okay. I just want
- 8 to make sure that we're done with abduction.
- 9 Right? Before moving onto sexual assault.
- 10 Everybody is okay with comments on that?
- 11 Okay. Any more comments on the sexual assault
- 12 category? Chris.
- 13 MEMBER GOESCHEL: I just have one
- 14 question, and that is, if we're taking this
- 15 from patients to providers, is there any room
- 16 in here for visitors? I mean, those things
- 17 happen, and we're getting -- we're talking
- 18 about criminal events. And there have been
- 19 times when our providers have allegedly
- 20 assaulted families or visitors. I just raise
- 21 the question.
- 22 CO-CHAIR TYLER: Doron.

- 1 MEMBER DORON SCHNEIDER: Just as a
- 2 -- for clarity for me, some of these may not
- 3 apply in some of the settings. And they just
- 4 have an N/A when you go down that column, so
- 5 I wouldn't box ourselves in to make sure that
- 6 it applies across all.
- 7 DR. ANGOOD: And this may be one of
- 8 those lumping categories, to use Helen's
- 9 favorite term, where you can just simplify
- 10 that no criminal events should occur, period.
- 11 And in our definition footnote, dot, dot,
- 12 dot, dot. And that allows you flexibility in
- 13 the individual states, et cetera.
- 14 CO-CHAIR TYLER: I certainly would
- 15 think that visitors should have an expectation
- 16 of safety when they come. Pretty basic to me.
- 17 MEMBER PHILIP SCHNEIDER: Just a
- 18 question of whether the NQF focuses on care
- 19 provided to patients or the running of an
- 20 organization, as we continue to broaden these.
- 21 I mean, they're all undesirable events, but is
- 22 it outside of the scope of the work of NQF to

- 1 talk about the quality of healthcare to begin
- 2 looking at management issues that relate to
- 3 employees and staff. And I'm not -- I'm just
- 4 asking a question. That's not an opinion.
- DR. ANGOOD: Helen may have a
- 6 different opinion than I, but we're certainly
- 7 in this evolving new era for NQF very much
- 8 focused on improving health quality, and
- 9 health safety on all fronts.
- 10 CO-CHAIR TYLER: Michael.
- 11 MEMBER VICTOROFF: And, again,
- 12 although I have some sympathy with lumping,
- 13 like any illegal act, here's an instance where
- 14 I think we might to keep the sexual assaults,
- or the sexual improprieties, or misdemeanors
- 16 separate. And the reason I will invoke is
- 17 that when I went to the Colorado Board of
- 18 Medical Examiners 25 years ago with a taxonomy
- 19 of medical errors to help sort disciplinary
- 20 actions for physicians, what they said to me
- 21 was well, look, we get one or two of these
- 22 cutting off the wrong legs things a year, but

- 1 we get eight complaints per month about sexual
- 2 impropriety, or alleged sexual something or
- 3 other, or hanky panky of some kind involving
- 4 providers. That's our big problem here at the
- 5 Board. So, in recognition of that, I kind of
- 6 think that this very sensitive issue of
- 7 inappropriate sexual behavior, which has the
- 8 full spectrum, probably deserves special
- 9 attention, if not being highlighted in some
- 10 way. So, that's where -- I wouldn't just lump
- 11 it in with other batteries, and other theft,
- 12 you know, whatever else.
- 13 CO-CHAIR TYLER: Just to be clear,
- 14 I mean, the term is sexual assault, so it's
- 15 not inappropriate sexual activity, which
- 16 there's a distinction. Obviously, you know
- 17 that.
- 18 MEMBER VICTOROFF: Well -- so, I --
- 19 this is almost a time for an expert panel for
- 20 this one, because I'll tell you that it's one
- 21 of the longer and more tedious issues that we
- 22 run physician risk management seminars about.

- 1 We have boundary seminars, we have all kinds
- 2 of discussion. And I don't know how much of
- 3 that ought to be reportable, and not. And I
- 4 don't know the difference between what a
- 5 criminal definition of sexual assault is, as
- 6 opposed to a tort. But this is so big for me,
- 7 that I think it ought -- we ought to move it
- 8 to a place where we can really focus on it.
- 9 CO-CHAIR TYLER: Cynthia.
- 10 MEMBER HOEN: From the standpoint
- 11 of the hospitals, an assault, to me, as a
- 12 lawyer, and when we report this is when the
- 13 patient or somebody else alleges that there
- 14 was an assault, or a battery. It's not the
- in-office, allegedly improper touching by a
- 16 physician with a patient, where the patient
- 17 could then go complain to the Board of Medical
- 18 Examiners. This is where it rises to a level
- 19 where I believe under the law, I'm required to
- 20 report it to the police. And that's when the
- 21 patient says I've been assaulted. I've been
- 22 improperly touched, dah, dah, dah, dah. So,

- 1 to me, there's a very clear cutoff line as to
- 2 when these are reported, and rise to a
- 3 criminal level.
- 4 DR. ANGOOD: Well, this, in my
- 5 mind, just sort of prompted up, and I really
- 6 don't think it fits into this activity here,
- 7 but there is that whole issue of providers who
- 8 are not just misbehaving in terms of sexual
- 9 confrontations, but perhaps they're engaged
- 10 with substance abuse, or all of the elements
- 11 of disruptive behavior. And that is clearly
- 12 an element that's getting a lot of attention,
- 13 and will continue to do so. How we put that
- in the SRE categories, I don't -- I'm not sure
- 15 we have a fitting for that, but it does bump
- 16 up in some instances towards the criminal
- 17 activities, and there are expectations of what
- 18 the providers are going to be providing in
- 19 terms of their interactions to the patients in
- 20 those populations.
- 21 And, as we all know, there's a
- 22 number of individuals on all disciplines that

- 1 will go and practice in different
- 2 environments, so they know where they can
- 3 hide. And how do you unmask that? Again, it
- 4 may not be the purview of this whole set of
- 5 activities, but it is an issue.
- 6 CO-CHAIR TYLER: Okay. One more
- 7 thing from Leah.
- 8 MEMBER BINDER: I really like
- 9 Michael's suggestion about an expert panel.
- 10 I actually didn't realize, you're enlightening
- 11 me that this was something that may be more
- 12 common than perhaps we might have understood.
- 13 But it is a -- and I like it as a particular
- 14 category of criminal offense, because there's
- 15 such a high level of bodily vulnerability that
- 16 a patient feels in going into a healthcare
- 17 setting, that sexual impropriety is probably
- 18 compounded, and more damaging, possibly, than
- 19 it would be otherwise. And they're more
- 20 vulnerable to it, so I think -- and that I'm
- 21 sure goes for any kind of healthcare facility.
- 22 So, I do think that it raises an important

- 1 issue. I agree.
- 2 CO-CHAIR TYLER: Okay. If we have
- 3 nothing else on this, then we've wrapped up.
- 4 It was a great job of ploughing through the
- 5 rest of these, the list of SREs. And now I
- 6 think we are going to take a break.
- 7 (Off mic comment.)
- 8 CO-CHAIR TYLER: Oh, we do have
- 9 one, one more, so close, so close. All right.
- 10 We're not done. One more, 6D. "Death or
- 11 significant injury of a patient or staff
- 12 member resulting from a physical assault,
- i.e., battery that occurs within or on the
- 14 grounds of a healthcare facility." Michael,
- 15 then Diane.
- 16 MEMBER VICTOROFF: And, again,
- 17 here, for me, the argument is, do we want to
- 18 broaden it to include any, and are we able to
- 19 define it, if we broaden it to include any?
- 20 MEMBER TANGALOS: Well, we have a
- 21 celebrated case going on in Minnesota right
- 22 now. A professional wrestler killed his

- 1 roommate. The professional wrestler is with
- 2 the Alzheimer's disease, he will not be
- 3 charged for a criminal assault. And it's yet
- 4 to see what will happen with the facility, but
- 5 it will be an important issue that has to be
- 6 addressed, because the facility does have a
- 7 fair amount of culpability with regards to the
- 8 events leading up to the death, so we'll see.
- 9 CO-CHAIR TYLER: Diane.
- 10 MEMBER RYDRYCH: Just two short
- 11 observations. Just, one, this is the only
- 12 event where we talk about significant injury,
- 13 rather than disability. So, for consistency's
- 14 sake, we might want to deal with that. The
- 15 other issue is, we have, in the past, had
- 16 physical assault events that involved only
- 17 staff members, staff members assaulting each
- 18 other, so we probably want to be clear, if
- 19 there's no patient involvement at all, whether
- 20 that -- whether this category was intended to
- 21 capture that type of event.
- 22 CO-CHAIR TYLER: Anything else on

- 1 this? Helen, you had something.
- DR. BURSTIN: I just want to
- 3 follow-up on Diane's point about significant
- 4 injury. I do think we need to go back and
- 5 think about, is that that middle category? Is
- 6 there another term that's better. But I think
- 7 that's there because they wanted, I assume, to
- 8 get broader than serious disability or death,
- 9 so I just think it might be worth -- and I'm
- 10 assuming it's not an accident, but it could
- 11 have just been. We'll find out.
- 12 CO-CHAIR TYLER: Okay. Anybody on
- 13 the phone have anything on this?
- 14 CO-CHAIR MEYER: This is Gregg.
- 15 Just responding to, I think it was Diane who
- 16 made the earlier comment, my interpretation of
- 17 this is that staff-on-staff violence would be
- 18 included here. And I'm not sure if -- we
- 19 should be hearing from the folks in the states
- 20 if that's their interpretation, as well.
- 21 MEMBER RYDRYCH: I think that was
- 22 our interpretation, but I'm somewhat

- 1 ambivalent whether it should be -- whether it
- 2 should include the brawl in the break room
- 3 between two staff members. I just think we
- 4 need to clarify it for anyone who's
- 5 implementing this, whether it does apply or
- 6 not, rather than kind of dealing with it case-
- 7 by-case, or state-by-state.
- 8 CO-CHAIR TYLER: Stan.
- 9 MEMBER RILEY: I think, for us,
- 10 that we would agree that staff-on-staff is a
- 11 huge issue, too, mostly because everybody
- 12 deserves to have a safe place to have
- 13 treatment. So, if that environment is there,
- 14 it frightens everybody.
- DR. ANGOOD: Sorry. While you were
- 16 finishing your comment, Stan, I was just
- 17 reminding ourselves that before we take our
- 18 break, we should ask if there are any members
- 19 of the public on the phones, so, operator, if
- 20 you could please check. And then if there is,
- 21 do any of those members of the public on the
- 22 phone have questions or comments around what

- 1 has been discussed so far this morning.
- 2 OPERATOR: There are only Committee
- 3 members on line.
- DR. ANGOOD: Okay. So, I think -
- 5 CO-CHAIR TYLER: Okay. So, we can
- 6 do a break then, which is good. I need one,
- 7 at least. Okay. Let's say 10:05, I mean
- 8 11:05. Will that allow people enough time to
- 9 take a break, stretch your legs? Okay, see
- 10 you back then.
- 11 (Whereupon, the proceedings went
- 12 off the record at 10:54 a.m. and resumed at
- 13 11:11 a.m.)
- 14 CO-CHAIR TYLER: Okay. Well, it
- 15 looks like we have most of our folks back in
- 16 the room, so I think we're going to go ahead
- 17 and start back. And Peter is going to pick up
- 18 on our agenda on the second day. We're going
- 19 to try to keep on schedule in terms of time,
- 20 at least, because we know everybody else has
- 21 prior commitments, including flight plans
- 22 home, so we're still going to break at the

- 1 same time, which means we're going to collapse
- 2 some of the things, and rework the agenda a
- 3 bit, and get through as much as we can in a
- 4 meaningful way today.
- 5 So, Peter is going to talk about --
- 6 are you going to do the TAPs first?
- 7 DR. ANGOOD: A bit of both.
- 8 CO-CHAIR TYLER: Okay. He's going
- 9 to talk about role of TAPs, and also about how
- 10 we're going to select other environments of
- 11 care to expand these beyond hospitals. Okay.
- 12 Peter.
- DR. ANGOOD: Thanks so much. And
- 14 a slide that we're putting up in preparation
- 15 for this is Slide 28 from the slide deck that
- 16 Helen and I had up for you yesterday.
- 17 Basically, outlines the three applicable
- 18 healthcare settings. So, just for those of
- 19 you on the phone, if you want to find that.
- Now, in terms of my comments, I was
- 21 just kind of musing that well, here we are at
- 22 11:15 on the second day, and we're just

- 1 starting the second day's morning agenda. So,
- 2 I think that's a reflection on the complexity
- 3 of this whole topic, and the robustness of the
- 4 discussion. So, I think I'm actually very
- 5 happy with where we've landed so far, and I
- 6 think you all should be, as well.
- 7 I'm obviously going to truncate my
- 8 comments, basically, to sort of give a bit of
- 9 background further on this sort of concept of
- 10 other environments, or expanding into other
- 11 environments, and then however we then agree,
- 12 and after some discussion, that will drive how
- 13 we then want to begin utilizing the TAPs, sort
- of rounding out the processes here.
- 15 As Helen made mention, the original
- 16 genesis of the SREs was a few smart people
- 17 sitting in a room generating a list, and then
- 18 it got ratified through the consensus
- 19 development process. And the Committee at the
- 20 second iteration was the main driver for
- 21 developing and reviewing the existing current
- 22 SRE list. So, there still is a fair amount of

- 1 expectation that you will be the ones to help
- 2 generate the ideas for where we take this
- 3 current version of the list and move forward.
- 4 We will, as we've said, solicit
- 5 some external, or outside inputs on this, and
- 6 that's part of what we do with the measures
- 7 consensus process. But the Safe Practices and
- 8 the SREs are different than the measures, so
- 9 we don't run it as -- in the same sort of
- 10 rigorous expectation for submissions from
- 11 externals to put into our process. So, I just
- 12 wanted to further clarify that for you.
- DR. BURSTIN: A point of
- 14 clarification. The real distinction is the
- 15 fact that the actual steward of the Safe
- 16 Practices and the SREs is NOF.
- DR. ANGOOD: Yes.
- DR. BURSTIN: So, we are
- 19 responsible for the content and the
- 20 maintenance, unlike the measures, where an
- 21 external steward is responsible. So, we
- 22 wouldn't write their measures for them, but

- 1 there is an expectation that you guys will
- 2 really be the source of the SREs.
- DR. ANGOOD: Thanks, Helen. That,
- 4 I think, is an important distinction. So, the
- 5 reason I go through all of that and lead up to
- 6 this part of the agenda is, as we were
- 7 submitting our work plan proposal to HHS on
- 8 those three deliverables, we were struggling
- 9 with this issue of what conditions are going
- 10 to be ultimately covered? Well, there's the
- 11 top 20 CMS conditions, which are sort of a
- 12 start point, but we don't have to define that
- 13 for ourselves, necessarily. The specific on
- 14 the request from HHS was, well, we need to
- 15 expand into other environments beyond the
- 16 hospital setting. So, we looked -- well,
- 17 let's still stick with CMS, and there's
- 18 basically 10 CMS environments of care. And we
- 19 realized well, that's far too many, and,
- 20 certainly, there are some overlaps for many of
- 21 these areas. And we, initially, worked towards
- 22 four of these clusters, and then because of

- 1 resources, basically, decided no, we need to
- 2 really pretty much stick with trying to work
- 3 on three clusters of environments of care.
- 4 So, those are the three that we've got labeled
- 5 up here, recognizing that this is less than
- 6 perfect, but it represents pretty good
- 7 clustering, overall. But we wanted you all to
- 8 have some input, and some deliberation on
- 9 these three.
- 10 And then, depending on how this
- 11 deliberation goes will drive the Technical
- 12 Advisory Panels that we'll put into place and
- 13 get the technical experts on those TAPs to
- 14 help us take our new definition of the SREs,
- and to sort of begin generating some of the
- 16 ideas around what are the appropriate SREs for
- 17 those different environment clusters. Okay?
- 18 Clear so far?
- 19 The use of the TAPs are expert
- 20 input, but it's still the Steering Committee
- 21 that makes the choices in the end, based upon
- 22 the input from the TAPs. And then, in terms

- 1 of process, what the Steering Committee does
- 2 is submit its final iterations after we go
- 3 through all of our process up to our Consensus
- 4 Standards Approvals Committee, the so-called
- 5 CSAC. And that's where the approval actually
- 6 occurs, and then the Board ratifies it. So,
- 7 the TAPs are experts with input, but the
- 8 Steering Committee still drives the final
- 9 document, and the final content. And then the
- 10 CSAC approves, and the Board ratifies. So,
- 11 any quick questions on that?
- DR. BURSTIN: Make one comment on
- 13 the environments of care. We did do some
- 14 lumping, as you'd imagine. And I just want to
- 15 see if what the group thinks is -
- DR. ANGOOD: That's where I was
- 17 headed.
- 18 DR. BURSTIN: Good. It is logical,
- 19 and I figured you might question home health.
- 20 So, there you go.
- DR. ANGOOD: Yes, so here's our
- 22 proposal, but it's open for deliberation. And

- 1 just before we dive in, because this group,
- 2 they like -- you guys are great, actually. I
- 3 mean, Helen and I both comment, you guys are
- 4 a great group. But in terms of, we're still
- 5 going to finish on time this morning. Don't
- 6 start changing your flight patterns around.
- 7 The final product doesn't have to be out
- 8 today. We want to do some brainstorming with
- 9 you in the last bit after we get through this
- 10 piece, as well, what other types of SREs would
- 11 be relevant or helpful in the general list,
- 12 and then that will help, between this
- 13 discussion, and initial brainstorming on other
- 14 SREs, that will drive us for our next several
- 15 weeks, which we'll continue electronically and
- 16 by some phone calls.
- 17 MEMBER TANGALOS: Well, there's
- 18 nothing wrong with the items that are there,
- 19 but they're not organized the way I usually
- 20 think about it. I mean, they're not even
- 21 close to the way I would think about them.
- 22 So, it's very -- let me -- I'm not going to

- 1 try to sort it just yet, but we think of home
- 2 and community-based services nowadays, and
- 3 that's the concept that we think about. We
- 4 think about long-term care settings. That's
- 5 the vernacular that we use. We oftentimes
- 6 leave hospice and palliative care in its own
- 7 little universe, as well. And when we think
- 8 about rehabilitation, we think about it as
- 9 being at some site, whether it's the hospital,
- 10 the home, or a long-term care facility. And
- 11 a healthcare -- a nursing healthcare setting,
- 12 I can't put anywhere. I don't know what that
- 13 means. I don't know -- nursing, as a separate
- 14 entity kind of fits in.
- DR. BURSTIN: They're called
- 16 nursing homes.
- 17 MEMBER TANGALOS: Well, we don't
- 18 call them that any more.
- DR. BURSTIN: I'm just saying, but
- 20 CMS list -- that's where that comes from.
- 21 MEMBER TANGALOS: But if that's
- 22 what it was, it -

- 1 MEMBER TANGALOS: Skilled nursing
- 2 facility is another story within long-term
- 3 care settings, and that has a very definite
- 4 definition. There's no question about it. But
- 5 that's how that would be. So, within the 10
- 6 environments that we had from the CMS, it
- 7 would be fine, but the reorg here, you know,
- 8 it's not there yet.
- 9 DR. BURSTIN: And just to be clear,
- 10 the only intention of the reorg is to try to
- 11 think about what the logical groupings of
- 12 experts might be who could think through these
- 13 issues. That's all. You guys will have a
- 14 chance to do further work on any of these.
- 15 It's just a question of who are the logical
- 16 people who would logically come together? So,
- 17 that's why I think a lot of that last group,
- 18 we'd want to make sure we've got nursing,
- 19 geriatrics, rehab, those kind of folks. For
- 20 the ambulatory care, you want to make sure you
- 21 bring the voice of primary care, and others.
- 22 So, that was the logic, but I could certainly

- 1 -- the home health was the one I thought might
- 2 be questionable.
- 3 CO-CHAIR TYLER: Michael.
- 4 MEMBER VICTOROFF: Actually, the
- 5 one that's questionable for me is dialysis.
- 6 You know, we're playing the game of which one
- 7 of these is not like the other things. And I
- 8 can see that a person could be versed in
- 9 ambulatory office outpatient hospice, as well,
- 10 because when I think of internists, and family
- 11 docs, and even pediatricians, there is an
- 12 overlapping skill set to those things.
- 13 However, very few of them monkey around with
- 14 dialysis units, and the nature of the way
- 15 dialysis is run, organized, paid for, staffed,
- 16 and administered is a different beast from
- 17 those others. So, I have to just sort of
- 18 question whether the TAP would feel confident
- 19 -- whether they would think their own skills
- 20 would need to be augmented. And my answer, if
- 21 I were on that committee, would be yes. All
- 22 the rest of them, I'm smart. Dialysis, no.

- 1 So, I would actually propose relocating
- 2 dialysis, if we only are allowed three
- 3 choices, to the one that's called inpatient
- 4 hospital, because dialysis looks more like an
- 5 ambulatory surgical center, or a radiation
- 6 treatment center, than it looks like a
- 7 doctor's office.
- 8 MEMBER LAU: This is Helen. I
- 9 concur.
- DR. ANGOOD: Okay, thanks. And
- 11 just in your pre-meeting packet, we did you
- 12 that listing of the so-called 10 environments.
- 13 But that was just a starting point.
- MEMBER RADFORD: It's on page 87.
- DR. ANGOOD: Page 87 of the packet.
- 16 Thank you, Martha. If you, as a group, want
- 17 to make up three new different ones and
- 18 cluster them, so be it. It'll take us a
- 19 little bit longer, but we're trying to stick
- 20 with ambulatory environments, the inpatient
- 21 setting, and then sort of that intermediate
- 22 zone in-between the ambulatory and the

- 1 hospital setting.
- DR. BURSTIN: And just one more
- 3 clarification. We're talking about bringing
- 4 people together in person. We've got funds to
- 5 do that. If you think there are groups that
- 6 are truly different, we'll just pull them out
- 7 and deal with them as calls. I mean, that's
- 8 fine. If you think dialysis truly is just a
- 9 different universe, we'll try to pull together
- 10 some dialysis folks on a technical panel, set
- 11 of technical advisors to advise. So, tell us
- 12 what should get pulled out, I guess.
- 13 MEMBER TANGALOS: Well, even in
- 14 long-term care, wherever that continuum is,
- 15 the dialysis piece does separate out. It's
- 16 just in its own world. Again, when you think
- 17 about rehab, that one actually crosses all of
- 18 these things, but it's not just rehab. It's
- 19 speech, occupational therapy, PM&R. And,
- 20 again, you can have them in any site, but the
- 21 discipline is more than the site-specific
- 22 stuff, as far as I'm concerned.

- 1 CO-CHAIR TYLER: That's not one of
- 2 the 10 sites, rehab.
- 3 DR. ANGOOD: That's a good
- 4 clarification. Why did we bring that one back
- 5 in? Oh, you know where that came, in part, is
- 6 that -- and I may not have the exact
- 7 knowledge, but someone was pointing out that
- 8 SNF, Skilled Nursing Facility, is very
- 9 specific on the payment side for a particular
- 10 population. So, we want -- in terms of trying
- 11 to generate broader-based discussion here, we
- 12 kind of took it back to nursing and rehab --
- 13 rehabilitation centers.
- 14 MEMBER TANGALOS: But I would put
- 15 the skilled nursing in with that other long-
- 16 term care, because those provide -- and those
- 17 patients bang around back and forth, as well.
- 18 So, that's a logical connection with that
- 19 group.
- DR. ANGOOD: So, just SNFs and
- 21 long-term care?
- 22 MEMBER TANGALOS: Actually, the

- 1 umbrella is long-term care, and within that
- 2 you've got the SNFs.
- 3 DR. ANGOOD: Okay.
- 4 MEMBER VICTOROFF: My question
- 5 would be, and I'm happy to have it either way,
- 6 hospice has probably 50-50 shared skill set
- 7 between ambulatory primary care, and long-term
- 8 care. And, often, it's different docs doing
- 9 it, but they have the same credential. I
- 10 would be happy to see hospice moved out of
- 11 that first group, into the long-term care
- 12 category, if someone felt that made more
- 13 sense.
- 14 MEMBER TANGALOS: Well, it doesn't,
- 15 and the reason it doesn't is hospice is time-
- 16 limited, presumably, six months or less.
- 17 Long-term care presumes a much different time
- 18 continuum. And we were just talking about
- 19 that. We have hospice in the hospital, we
- 20 have hospice in the nursing home as a Medicare
- 21 benefit. We have hospice in the community
- 22 that's freestanding. Hospice is kind of on

- 1 its -- it overlaps, but it's kind of its own
- 2 discipline, and it's becoming more of its own
- 3 discipline with regards to palliative care.
- 4 And the palliative care piece is what you
- 5 really want to capture as you expand this, as
- 6 well.
- 7 CO-CHAIR TYLER: Cynthia, and I
- 8 think, Stan, you also want to -- Cynthia
- 9 first.
- 10 MEMBER HOEN: Actually, this is
- 11 probably obvious, but I just need for my own
- 12 clarification. Ambulatory surgery centers
- 13 would be included in ambulatory care? And
- 14 also urgy centers, or are they out of this
- 15 grouping? Urgent care centers.
- DR. ANGOOD: Again, as I made my
- 17 opening comment, it's far from a perfect
- 18 clustering. And we chose, initially, that the
- 19 ambulatory surgery would be in the ambulatory
- 20 setting, since there's -- obviously, many of
- 21 them do occur as part of hospital settings and
- 22 systems, but there's many freestanding ones,

- 1 as well. And there's a huge accreditation
- 2 program out there for that whole set of
- 3 settings, too. As far as the urgent care
- 4 piece, we sort of felt that was basically
- 5 ambulatory, but there's debate on that, as
- 6 well. Sorry.
- 7 MEMBER RILEY: The ambulatory
- 8 surgery care was my question, as well.
- 9 DR. ANGOOD: Okay. Thanks.
- 10 MEMBER VICTOROFF: Again, it really
- 11 doesn't matter. We're going to have to do
- 12 these all -- I'm not going to want to be the
- 13 one that holds this all up. But if I was
- 14 looking at the safety issues that one
- 15 encounters, and the remedies one encounters,
- 16 and the reporting channels through which one
- 17 reports, again, the one that doesn't look like
- 18 the others in that first group is ambulatory
- 19 surgical center, because they're paid for,
- 20 administered, managed, and staffed, and
- 21 operated quite a bit differently from an
- 22 outpatient clinic.

- 1 Again, I think you're going to get
- 2 experts together that are going to be able to
- 3 handle this. So, I'm not too worried that we
- 4 have to do it perfectly, because we can't.
- 5 But if you were thinking about the experts
- 6 that are all going to feel comfortable in the
- 7 room together, the SU guys are going to be a
- 8 little bit out of place in that first group.
- 9 DR. GANDHI: This is Tejal from the
- 10 phone. Do you mind reading out what's on that
- 11 first group to me on the phone?
- DR. ANGOOD: Sure. It's
- 13 "Ambulatory Care, and Home Health" is the main
- 14 title, and that is bracketed with [including
- 15 physician offices, outpatient clinics,
- 16 dialysis facilities, and hospice settings].
- 17 For completeness, the second bullet is
- 18 inpatient hospital [including related
- inpatient services and emergency departments].
- 20 And then the third one is "Nursing,
- 21 Rehabilitation, and Long-Term Care." And it
- 22 was -- yes, the recent suggestion was just

- 1 long-term care with some sub-bullets under
- 2 there, which would be skilled nursing
- 3 facilities, and others.
- 4 MEMBER TANGALOS: Long-term care
- 5 settings.
- DR. ANGOOD: Yes.
- 7 DR. GANDHI: So, ambulatory
- 8 surgical centers is in that first bullet.
- 9 DR. ANGOOD: Yes.
- 10 DR. GANDHI: I think it's a
- 11 reasonable place to put it, because some of
- 12 the ambulatory clinics also are doing
- 13 significant procedures, and so I think a lot
- 14 of the procedural issues, even though I know
- 15 that ambulatory surgical centers are different
- in a lot of ways, but I think a lot of the
- 17 safety issues do overlap with some of the more
- 18 procedural ambulatory specialties.
- 19 CO-CHAIR TYLER: Chris.
- 20 MEMBER GOESCHEL: Could I just ask
- 21 just to clarify, so long-term care settings
- 22 would include long-term acute LTACs and rehab

- 1 hospitals, and long-term psych hospitals.
- 2 We're talking about all of those. Is that
- 3 correct? Okay.
- 4 CO-CHAIR TYLER: Martha, Leah, and
- 5 then Doron.
- 6 MEMBER RADFORD: I'm also, like
- 7 Michael, not too worried about this. I think
- 8 maybe we're trying to -- we should do this in
- 9 three waves instead of two, the first wave
- 10 being acute care that's already been
- 11 discussed. And pick the big ticket items. I
- 12 might leave hospice for a later edition. I
- 13 might leave some of these other for just a
- 14 later edition, to get the big ticket items, a
- 15 variety of others one.
- 16 DR. BURSTIN: And if I could just
- 17 add to that, we said we would expand to the
- 18 likely -- to the applicable settings. We
- 19 didn't say we'd do all ten.
- 20 MEMBER RADFORD: Right.
- 21 DR. BURSTIN: So, I think it would
- 22 also be very useful for you to prioritize

- 1 based on your thinking of our broadened
- 2 definition of SREs, what sites make the most
- 3 sense, especially for the state folks. What
- 4 are the kind of sites you don't tend to get,
- 5 that you worry about?
- 6 MEMBER RADFORD: You know, I like
- 7 Michael's idea about the grid and the columns.
- 8 And there's nothing to prevent us from having
- 9 10 columns, eventually, except for you'd have
- 10 to get 17 inch paper. Oh, well.
- 11 CO-CHAIR TYLER: Leah, Doron, and
- 12 then John.
- 13 MEMBER BINDER: By dividing these
- into three categories, I assume it's more of
- 15 a -- just for interest, as opposed to any kind
- 16 of use. The reason I'm asking that is simply
- 17 because it's odd to me that we're sort of
- 18 dividing inpatient hospital from their
- 19 outpatient clinics. So, one hospital, I
- 20 guess, is in two categories. I don't think
- 21 that matters unless, for some reason, we're
- 22 asking them to do some kind of reporting on

- 1 two different bullets. It doesn't matter, but
- 2 I just want to make sure it doesn't.
- 3 And then the second thing is, do we
- 4 want to -- we had some discussion earlier
- 5 about home birthing, or freestanding birth
- 6 clinics. Is that something we want to add to
- 7 this, as well?
- 8 MEMBER DORON SCHNEIDER: So, I
- 9 think the outpatient clinics are okay with
- 10 ambulatory care, because the events that occur
- 11 there are the same that occur in physician
- 12 offices. My issue is with the ambulatory
- 13 surgery unit, and what Tejal was saying, in
- 14 that the procedures that I'm considering
- 15 ambulatory surgery are those that require
- 16 anesthesia. And I think if I had to put them
- 17 somewhere, I would them more in inpatient
- 18 hospital, and have the outpatient clinic folks
- 19 speak very eloquently to the smaller
- 20 procedures that don't require anesthesia, and
- 21 really just require smaller time out, and
- 22 those issues.

- 1 CO-CHAIR TYLER: John, then Eric.
- 2 MEMBER MORLEY: You struck a nerve
- 3 when you asked the question about which ones
- 4 of those are we most interested in. We've
- 5 got, in New York, a law that was passed two
- 6 years ago that requires reporting for office-
- 7 based surgery, so that's an area of intense
- 8 interest and effort in the last two years.
- 9 We've had some very interesting information.
- 10 One piece of information I would like to share
- 11 with the group, and that's just simply that
- 12 more and more care is being rendered in that
- 13 setting.
- I need to say that again for my own
- benefit, more and more care is being, so we're
- 16 seeing things like renal artery stents, and
- 17 prostate surgery being done in an office
- 18 setting, and more than that. So, it's an area
- 19 that I think we have interest in for lots of
- 20 reasons, but what caused the law to be passed
- 21 was some headlines of some patients that had
- 22 office-based surgery and passed away. We now

- 1 know that we had 600 reports last year, and 30
- 2 of those reports on adverse events were
- 3 deaths. Some of those deaths were dialysis
- 4 patients after a catheter manipulation, and
- 5 those patients are high-risk mortality without
- 6 procedures. But a surprising number of
- 7 patients expired as a result of office-based
- 8 procedures, surprising just to us.
- 9 Dialysis facilities is an issue
- 10 that keep cropping up around the country
- 11 related to infection transmission. And one of
- 12 the more regulated areas by CMS, but not one
- of the areas where we know a great deal about
- 14 what happens.
- 15 Long-term care, highly regulated in
- 16 terms of the skilled nursing facilities, and
- 17 so forth. I think some of those areas offer
- 18 us the most opportunity for what I'll call
- 19 interesting information, actionable
- 20 information. Thank you.
- 21 CO-CHAIR TYLER: Eric.
- 22 MEMBER TANGALOS: Yes. I'm

- 1 thinking that you can divide up the work how
- 2 you want, but as far as the bullets, I'm
- 3 seeing five, more than three. And I really
- 4 see the ambulatory care with its DRGs, with
- 5 its payment system, relatively unique. Home
- 6 and community-based services is that catch
- 7 word, and where that jargon is right now. And
- 8 then hospice tends to be a unique piece. So,
- 9 I would pull home and community-based services
- 10 out of that first bullet, and I would make
- 11 hospice and palliative care its own bullet,
- 12 as well. So, I can only come up with five. I
- 13 can't get down to three.
- DR. BURSTIN: Just, again, point of
- 15 clarification. We're just trying to think
- 16 about the logical groupings of experts.
- 17 MEMBER TANGALOS: No, but that -
- 18 DR. BURSTIN: So just think of it
- 19 from that perspective. And, again, if there
- 20 are specific settings, if ambulatory surgery
- 21 is such a big issue, we'll just convene an
- 22 Ambulatory Surgical Technical Panel. It's not

- 1 a big deal. We'll pull five people together
- 2 and have a phone call. Just tell us -- this is
- 3 really just for you to tell us what expertise
- 4 is really important, which of these settings
- 5 you really want to focus on. Are we ready, I
- 6 think going back to Martha's point, are we
- 7 ready to do hospice and palliative, or is that
- 8 something to save for the next time, perhaps?
- 9 Should dialysis be on its own? Again, we just
- 10 here to listen to you.
- DR. ANGOOD: So, Eric, can you -
- 12 just so we can capture it on, perhaps, a fresh
- 13 slide, and let people see that, those five
- 14 categories.
- 15 MEMBER TANGALOS: Well, ambulatory
- 16 care is by itself. And I'm disappointed, but
- 17 that universe may not interface too well with
- 18 any of these other things. And it's home and
- 19 community-based services, is what it is. And
- 20 that gets the home health, that gets the rehab
- 21 that can occur at home, that gets some of the
- 22 other things that are there. But that's a lot

- 1 of community-based things there right now.
- 2 And you may find that there's no data set,
- 3 that there's no data set worth ploughing, as
- 4 there would be with the long-term care
- 5 settings. Okay? But I still think home and
- 6 community-based stands by itself. Then the
- 7 inpatient hospital, then the long-term care
- 8 settings, and then the hospice and palliative
- 9 care. Yes, that is the grouping that I kind
- 10 of see that politically works, and
- 11 organizationally works. Whether you want to
- 12 bite it all off, or pieces of it, but that's
- 13 where the expertise resides in those
- 14 individual camps.
- 15 CO-CHAIR TYLER: And just to
- 16 clarify, Eric, what you're suggesting, the
- 17 modifying language in the parens there, that
- 18 still goes with ambulatory care.
- 19 MEMBER TANGALOS: Yes.
- 20 CO-CHAIR TYLER: That "including
- 21 physicians offices". Right?
- 22 MEMBER TANGALOS: Yes.

- 1 CO-CHAIR TYLER: So, that needs to
- 2 be moved.
- 3 MEMBER TANGALOS: Yes.
- 4 CO-CHAIR TYLER: All right.
- 5 MEMBER RADFORD: And just where
- 6 does ambulatory surgery fit?
- 7 MEMBER RYDRYCH: I think part of
- 8 the issue here is we're trying to put
- 9 something into list based -- groups based on
- 10 settings, when really we're talking about
- 11 services. Right? And services that kind of
- 12 fit better together. Because, for us, we
- 13 already collect data from ambulatory surgical
- 14 centers, so, in effect, we're treating them
- 15 the same way as we do the inpatient hospitals.
- 16 And we apply the same list to them, and if a
- 17 certain event happens to not occur at an ASC,
- 18 then so be it. They just don't report those,
- 19 but we apply the same list to them. But from
- 20 a licensing perspective, they're very
- 21 different situations, and I would tend to
- 22 think of them as closer to -- I mean, just

- 1 what seems intuitive to me is to put them
- 2 closer to ambulatory care, if we're talking
- 3 just about the setting, but the services are
- 4 closer to inpatient. So, we seem to be having
- 5 that tension there, is this about a physical
- 6 type of setting, or is about the type of
- 7 services that are being provided?
- 8 CO-CHAIR TYLER: Doron.
- 9 MEMBER DORON SCHNEIDER: I would
- 10 think it's about the kind of harm that we're
- 11 trying to get -- find the reporting. So, it
- 12 really is the services, for me. And,
- 13 personally, I would think it would be more
- 14 inpatient like, because of the kind of
- 15 service, the intensity of the services that
- 16 we're talking about, as opposed to the
- 17 procedures, the smaller procedures that are
- 18 going to lead to different error types in the
- 19 ambulatory care.
- 20 MEMBER RYDRYCH: But I wonder then
- 21 if we want to change our nomenclature so we're
- 22 not talking about healthcare settings, because

- 1 it seems strange to say we're having this
- 2 technical advisory group on ambulatory, or on
- 3 inpatient hospital that includes ambulatory.
- 4 MEMBER RADFORD: So, it's really
- 5 service types.
- DR. BURSTIN: I think what they
- 7 wanted was to get us out of just thinking of
- 8 all these SREs and hospitals. So, if you can
- 9 accomplish that, go for it. Just give us -
- 10 MEMBER LAU: This is Helen. I just
- 11 want to make a comment on ambulatory care. I
- 12 think we shouldn't forget those groups that
- 13 run emergency type of ambulatory care, or the
- 14 clinic, you know, those people that pay some
- 15 money, and then go to those emergency care
- 16 settings other than a hospital. Am I making
- 17 sense?
- 18 CO-CHAIR TYLER: Emergency room
- 19 service that would not be included under
- 20 inpatient hospital, is what you're saying.
- MEMBER LAU: Yes.
- 22 CO-CHAIR TYLER: Because we have

- 1 emergency department there.
- MEMBER TANGALOS: Well, what's
- 3 emerging is -- or re-emerging, there's a
- 4 finding, again, of the urgent care centers,
- 5 which are outpatient. But, even more so, the
- 6 unregulation of the "minute clinics."
- 7 MEMBER LAU: Yes. Yes.
- 8 CO-CHAIR TYLER: I just want to
- 9 make sure that Helen's point -- Helen, does
- 10 that clarify your point? Is that correctly
- 11 stated?
- 12 MEMBER LAU: Yes, as long as that
- includes the group of people who go for those
- 14 emergency type of care, not in a hospital type
- of emergency department, or emergency room,
- 16 but in a separate like clinic type of
- 17 location. I think there are lots of error in
- 18 those areas, so I just want to make sure those
- 19 areas are being captured.
- 20 CO-CHAIR TYLER: Okay. I think we
- 21 got that. Thank you. I think, Michael, and
- 22 then -

- 1 MEMBER VICTOROFF: You know, I can
- 2 see us cutting this pizza endlessly, but at
- 3 the end of the day, if you tell me there's
- 4 only three people that get pizza, divide it
- 5 however you want, them I'm not going to
- 6 actually worry too much. And what I would
- 7 think is that any of these groups, as they're
- 8 configured, or as I could conceive
- 9 configuring, would work. You'd get useful
- 10 stuff out of them. We ought to just plough on
- 11 and starting getting the useful stuff. And
- 12 then when we go through the process of seeing
- 13 what we missed, and what we did wrong, and
- 14 criticizing it, we'll, inevitably, pick up
- 15 some stuff that we goofed on.
- 16 DR. BURSTIN: Can I just ask maybe
- 17 a question a slightly different way for the
- 18 group? Going back to the question I was
- 19 trying to ask John. So, what are those sites,
- 20 that if you said boy, SREs really need to
- 21 expand, or services, SREs really need to
- 22 expand, you think are ripe for serious

- 1 reportable events. Let's start with that,
- 2 maybe, and work backwards, rather than
- 3 starting from the list.
- 4 MEMBER VICTOROFF: Physician
- 5 offices.
- 6 MEMBER MORLEY: I just want to say
- 7 thank you. You just said exactly what I was
- 8 going to say.
- 9 DR. BURSTIN: Well, tell me the
- 10 answer.
- 11 (Laughter.)
- 12 MEMBER MORLEY: You know, one
- 13 question for the group, asking the same issue
- 14 a different way, is do you really want to
- 15 start coming up with a list for all 10 of
- 16 these at the same time? And I'm thinking if
- 17 we picked a few and start, there'd be lessons
- 18 learned from those few that you would then
- 19 apply going forward. And each one would
- 20 subsequently go a little bit smoother, in
- 21 terms of its initiation.
- 22 As I was saying before, I mean, New

- 1 York has an office-based surgery program. I
- 2 would like to see that started at a national
- 3 level. I would like to see dialysis
- 4 facilities. There's a few other things that
- 5 while I'd like to see them, maybe 2011, as
- 6 opposed to 2010, seeing dialysis and office-
- 7 based surgery, ambulatory surgery type things.
- 8 MEMBER BRENNAN: Helen, this is
- 9 P.J.
- DR. BURSTIN: Yes, go ahead.
- 11 MEMBER BRENNAN: From my
- 12 perspective, representing the ID society and
- 13 healthcare epidemiology, there is significant
- 14 interest in the ambulatory practices,
- 15 including physicians' offices, ambulatory
- 16 surgical centers in terms of infection control
- 17 hazards that are created in those areas. And
- 18 HICPAC is going to be working on culling
- 19 evidence-based guidelines, evidence-based
- 20 practices from existing guidelines, and trying
- 21 to apply them to those areas, and to pull
- 22 together some guidance. So, there have been

- 1 a number of outbreaks recently that have been
- 2 related to practices that just seem to fall
- 3 outside of regulation in these areas, either,
- 4 in part, because they're not regulated, or
- 5 because they're seldom visited by CMS
- 6 surveyors. So, I think that, from our
- 7 perspective, ambulatory surgery, dialysis, and
- 8 physician practices are important places.
- 9 DR. GANDHI: This is Tejal from the
- 10 phone. I would completely agree with those
- 11 areas, particularly, the physician offices,
- 12 and ambulatory surgery. And then the only
- other one I would probably throw in there,
- 14 just based on if we're trying to be a little
- 15 more evidence-based, I mean, there's been a
- 16 lot of stuff about the skilled nursing
- 17 facilities, and issues there with some of the
- 18 stuff that Jerry Gurwitz has done, so I think
- 19 that might -- if we were limiting it to three
- 20 or four, I might throw that one, as well.
- 21 CO-CHAIR TYLER: Stan.
- 22 MEMBER RILEY: I guess the only

- 1 thing I'd add from my wish list, besides the
- 2 things that have already been spoken about, is
- 3 infusion centers, which are sort of completely
- 4 on a different level, you know, cancer
- 5 infusion centers, primarily, that we see sort
- of the Wild Wild West. You know, there's not
- 7 any real reporting for them, and we don't know
- 8 exactly what happens there.
- 9 CO-CHAIR TYLER: Cynthia, then
- 10 Martha.
- 11 MEMBER HOEN: From a hospital
- 12 perspective, I know that we feel put upon that
- 13 we're more highly held to standards than the
- 14 ambulatory surgery centers, the urgent care
- 15 centers, and the doctor's procedural offices.
- 16 So, I would put in my vote for those things,
- 17 as well.
- 18 MEMBER RADFORD: I'd actually like
- 19 to put a vote in for weighting on dialysis
- 20 centers, because they are pretty heavily
- 21 regulated, and they do have a reporting system
- 22 around certain things that happen, not

- 1 everything. And maybe that's the next --
- 2 that's the wave after the next wave.
- 3 CO-CHAIR TYLER: Eric.
- 4 MEMBER TANGALOS: Even though I
- 5 would separate hospice and palliative care in
- 6 its own universe, I wouldn't focus there. I
- 7 know the science is almost non-existent, so
- 8 it's not -- science is very poor in hospice
- 9 and palliative care. It is not matured.
- 10 MEMBER RYDRYCH: I would agree with
- 11 that, and I would say I think we're biting off
- 12 plenty just trying to deal with a couple of
- 13 higher priority areas, and not getting into
- 14 hospice and palliative.
- DR. ANGOOD: So, sorry to jump in.
- 16 We seem to be gravitating on office-based
- 17 surgery/ambulatory surgery centers, dialysis
- 18 with Martha's caveat, physician offices, and
- 19 perhaps SNFs. Can we just sort of take a hand
- 20 poll on that one, and then -- what I'm trying
- 21 to get us towards is to actually think of a
- 22 secondary list that we would put into the

- 1 pipeline, because I'm trying to anticipate the
- 2 discussions with HHS, in terms of well, here's
- 3 our expanded term of SREs, the definition.
- 4 Here's our revised list. Here's our tiering
- 5 approach to where the priority environments
- 6 need to be, because that's kind of how they're
- 7 approaching us with this. So, the first step
- 8 is office-based surgery/ambulatory surgery
- 9 centers, dialysis, physician offices, and then
- 10 SNF.
- 11 CO-CHAIR TYLER: I thought we had
- 12 said long-term care settings, broadly, and
- 13 SNFs would be under that. So, is that -
- DR. ANGOOD: I was just reacting to
- 15 somebody's comment here a few moments ago.
- 16 CO-CHAIR TYLER: Okay. I thought
- 17 we were still focusing on -
- 18 MEMBER TANGALOS: I think the
- 19 science and the information is going to be
- 20 best in SNFs, so you can -- I don't see any
- 21 problem with still labeling it the whole
- 22 thing, and then bringing it down just to SNFs.

- 1 Representing the SNF, that universe, we are
- 2 delighted that NQF is interested in that
- 3 universe. I don't know about the other
- 4 parties, but we think it's neat that NQF is
- 5 interested.
- DR. ANGOOD: We are making a
- 7 concerted effort to be neat.
- 8 MEMBER TANGALOS: Right.
- 9 (Laughter.)
- 10 CO-CHAIR TYLER: Doron.
- 11 MEMBER DORON SCHNEIDER: So, this
- 12 may take us back to the original list, but
- there's increasing need and use for home care.
- 14 I mean, that is going to be where most of our
- 15 care is going to be occurring in the future.
- 16 The doctor's visits occur once a quarter, the
- 17 home care, the frequency of visits are going
- 18 to go up, and they're going to be a major
- 19 piece of how we're going to reduce re-
- 20 admissions. There's many error types that
- 21 occur that overlap there, everything from
- 22 mistubing, misinfusions, misadministration,

- 1 you know, of medications, et cetera. And for
- 2 us to not have that on the list, I think is an
- 3 oversight.
- 4 DR. ANGOOD: Well, it's a good
- 5 point, and I guess it'll be a matter, well,
- 6 how many do we have on our primary list, and
- 7 how many do we have on the secondary list.
- 8 And everyone is always going to have a
- 9 favorite, or a least favorite. So, if we
- 10 could, you know, you're not going to be held
- 11 accountable to it in the long-term, but why
- 12 don't we just do a little straw poll here on
- 13 those four items that we listed.
- 14 MEMBER VICTOROFF: I hate to do
- 15 this. Could I propose we vote individually
- 16 and count the votes for each one individually?
- DR. ANGOOD: That's fine, too.
- 18 MEMBER VICTOROFF: Because that
- 19 would teach me something.
- DR. BURSTIN: Let's look at this,
- 21 make sure we have the list. So, it's
- 22 ambulatory care including physician offices,

- 1 and outpatient facilities. I think that was
- 2 one of them, clearly. Then there was
- 3 ambulatory care surgery and procedure-based -
- 4 DR. ANGOOD: Office-based surgery.
- DR. BURSTIN: And office-based
- 6 surgery. Those were surgical, but more
- 7 outpatient oriented. Infusion centers was
- 8 listed. I'm not sure where that would live.
- 9 DR. ANGOOD: That was a secondary
- 10 list.
- 11 CO-CHAIR TYLER: That would be
- 12 number two.
- DR. BURSTIN: That goes on
- 14 secondary? Okay.
- DR. ANGOOD: Yes.
- 16 MEMBER VICTOROFF: Phase two.
- DR. BURSTIN: Phase two. And then
- 18 long-term care, and home health are the ones
- 19 that are currently on the table. Yes?
- DR. ANGOOD: Dialysis.
- DR. BURSTIN: We moved dialysis,
- 22 got moved to they already moved it. Yes.

- 1 I thought you guys already moved dialysis -
- DR. ANGOOD: Well, that was
- 3 Martha's comment. I'm not sure the rest of
- 4 the group was with Martha. Well, let's take
- 5 Mike's approach then. Sorry, we kind of
- 6 jumping on you here, but we're trying to
- 7 anticipate our interaction with HHS, I think,
- 8 and that is -- so, let's go one by one, and
- 9 just a straw poll. And if something falls off
- 10 the -
- 11 MEMBER RADFORD: So, we're voting
- 12 on -- this is the first tier. Is that right?
- DR. ANGOOD: First tier, yes. And
- 14 then after we finish this, we'll try to get to
- 15 a second tier.
- MEMBER RILEY: And how many votes
- 17 do we get?
- 18 (Laughter.)
- DR. ANGOOD: Each item, one time.
- 20 Okay?
- DR. BURSTIN: But I think it's okay
- 22 for us, I mean, one of the possibilities, the

- 1 question is, do we really need a technical
- 2 panel on hospitals, if that's sort of the
- 3 collective group here. So, one idea might be
- 4 to jettison the idea of a TAP on hospitals,
- 5 instead, think about technical panels in these
- 6 specialized areas where we need the expertise.
- 7 So, don't vote for hospitals.
- B DR. ANGOOD: So, office-based
- 9 surgery/ambulatory surgery centers. Who sees
- 10 that as an important one?
- 11 (Vote taken.)
- DR. ANGOOD: And on the phone?
- 13 MEMBER LAU: Yes, this is Helen.
- DR. ANGOOD: Okay. That's a strong
- 15 yes.
- DR. GANDHI: Yes from Tejal.
- 17 DR. ANGOOD: Okay. Thank you. And
- 18 then we had physician office -
- 19 MEMBER BRENNAN: Yes from P.J.
- DR. ANGOOD: Thanks, P.J.
- 21 Physician offices, and ambulatory care. We've
- 22 got a strong positive in the room. On the

- 1 phone?
- 2 MEMBER LAU: Yes from Helen.
- 3 DR. GANDHI: Yes from Tejal.
- 4 MEMBER BRENNAN: Yes from P.J.
- DR. ANGOOD: Okay. Thank you. And
- 6 then we had dialysis centers, although, Martha
- 7 made a comment that they're already pretty
- 8 well regulated. Who would like to have
- 9 dialysis on this primary list? Less popular.
- 10 Okay. Anybody on the phone want it? Hearing
- 11 none. Martha, you're a strong influence. I'm
- 12 just teasing.
- 13 All right. That takes us to a
- 14 fourth item, which would be long-term care
- 15 with focus on the SNFs. Strong positive for
- 16 that in the room. And on the phone?
- 17 MEMBER LAU: Yes from Helen.
- DR. GANDHI: Yes from Tejal.
- 19 MEMBER BRENNAN: Yes from P.J.
- DR. ANGOOD: Okay. Thanks. So,
- 21 that gives us three groups to get started on.
- 22 Office-based surgery/ambulatory surgery,

- 1 physician offices, and ambulatory outpatient
- 2 care, and then long-term, and SNFs, with a
- 3 focus.
- 4 CO-CHAIR TYLER: I have a question.
- 5 Where -- I mean, it seemed like there was a
- 6 lot of consensus around home-based care, but
- 7 that's not on your list at all now. There
- 8 seemed to be much consensus on that, I think.
- 9 DR. ANGOOD: I was just sort of -
- 10 I know there was a lot of discussion.
- 11 MEMBER TANGALOS: Well, that's a -
- I mean, it's a huge area, but, again, if
- 13 you're going to do some data mining and look
- 14 at the science, there's nothing there.
- 15 MEMBER RYDRYCH: I don't think
- 16 we're ready to go there, yet.
- 17 MEMBER TANGALOS: No.
- 18 CO-CHAIR TYLER: So that would be
- 19 parking lot, along with -
- DR. ANGOOD: Secondary, yes.
- 21 Sorry. On the phone, there's lots of
- 22 mumblings off microphone here, and basically

- 1 everyone is accepting that home health is
- 2 important, but the science isn't quite there.
- 3 And, perhaps, we should put that on our next
- 4 wave of activity. I'm seeing a lot of heads
- 5 yes in there.
- 6 CO-CHAIR TYLER: Cynthia, you had
- 7 a comment?
- 8 MEMBER HOEN: Yes. Just with
- 9 respect to the physician offices, I agree,
- 10 that's a good thing to look at, but I would
- 11 ask that the TAP group also look at the
- 12 feasibility of those physicians implementing
- anything that was recommended, because I think
- 14 that's going to be a very -- point of
- 15 contention and discussion.
- DR. ANGOOD: Yes. My sense would
- 17 be a galvanizing statement from NQF, but not
- 18 easily implementable in terms of actually
- 19 getting stuff.
- 20 MEMBER DORON SCHNEIDER: Can you
- 21 please clarify what the second tier would
- 22 bring us? Home health care, I agree, there

- 1 may not be science there, but we, I think,
- 2 have an opportunity to understand what's
- 3 occurring there, by having reportable events.
- 4 If you have somebody in the home that is
- 5 misadministering medications, or putting the
- 6 tube feed into the IV line, or these kinds of
- 7 things that we're talking about, and we're not
- 8 really asking for reporting of these serious
- 9 events, there's an opportunity lost, I think.
- 10 So, what does it mean, actually, if it goes to
- 11 tier two?
- DR. ANGOOD: Well, I think we have
- 13 to be careful about not, necessarily,
- 14 prioritizing, per se. You know, if we think
- 15 about those -- we started with a list of 10
- 16 from CMS as environments of care. We've gone
- 17 around, we've come up with three areas that
- 18 people think are good areas to get started for
- 19 a combination of concern, evidence, and
- 20 potential to try and create some important
- 21 change for improving quality.
- The second, I would rather than

- 1 tier or class, it would be more of a second
- 2 wave, saying that let's get started on this
- 3 grouping, and then look for ways, as we get
- 4 better experienced with this, to then roll out
- 5 the next wave of environments, which would be
- 6 whatever we choose, home health, et cetera, et
- 7 cetera. That's my view on where the group is
- 8 at, but there's other opinions.
- 9 MEMBER GOESCHEL: Could I ask a
- 10 question about the feasibility of NQF staff,
- 11 I'm going to say even beginning for these next
- 12 wave, to begin to do some data collection. I
- 13 mean, I'm struck by our questions earlier
- 14 today to say how many states collect a report?
- 15 I mean, even to begin to do some of the
- 16 footwork on home health, what kind of data is
- 17 collected? The regulations are very different
- 18 state-to-state. I'm just wondering if it could
- 19 be on the list with the understanding that the
- 20 work that will be done right now is going to
- 21 be background work to help us get what we need
- 22 to determine what SREs would like that.

- 1 MEMBER RYDRYCH: Well, I think we
- 2 even need some of that on the first tier
- 3 groupings that we identified, because for
- 4 physician offices, and we don't even know
- 5 where they all are in our state. Just a
- 6 question, too. I mean, we know each physician
- 7 is licensed, but we don't know what all the
- 8 clinics are. They're not licensed separately,
- 9 so we don't even know what the universe is.
- 10 And just a question. So, inpatient
- 11 hospital is kind of the status quo group that
- 12 we already have. Is there a TAP that's
- 13 getting together to talk about the expansion
- or modifications to the existing list for
- 15 hospitals, separate from these other groups
- 16 then?
- 17 DR. ANGOOD: You did that yesterday
- 18 and today.
- 19 MEMBER RYDRYCH: Right. But wasn't
- 20 there also going to be -- because we've sort
- 21 of just raised some of the issues, but we
- 22 haven't really fleshed any of them out.

- DR. ANGOOD: Right. But that will
- 2 -- we kind of ran the list yesterday, and
- 3 today, and if we can get through this part of
- 4 the discussion this morning, we were hoping to
- 5 brainstorm a little bit on other potential
- 6 ones for the SRE list, which could be mostly
- 7 on the hospital setting.
- BURSTIN: Does the group feel
- 9 like a hospital TAP would be helpful?
- 10 MEMBER RYDRYCH: I just wasn't sure
- 11 if there was additional work beyond that kind
- 12 of initial brainstorming that we had done that
- 13 needed to happen with inpatient hospital, as
- 14 well.
- DR. BURSTIN: There is, and the
- 16 question is, are you comfortable that you're
- 17 the group that will do that?
- 18 CO-CHAIR TYLER: And, Doron, I just
- 19 wanted to close the circle with you, a little
- 20 discussion about what would happen with that
- 21 secondary tier, putting home health on. Is
- 22 that satisfactory to you, or you think -

- 1 MEMBER DORON SCHNEIDER: In 2002,
- then 2006, then 2009, so if you're in second
- 3 tier, does that mean 2012 for the next
- 4 environment, or are we moving to more of a
- 5 annual review for the additional environments,
- 6 or is it going to be a three-year cycle, or is
- 7 that not determined? And maybe I feel too
- 8 strongly about the home care, and wanting to
- 9 know what's going on there. I just -- I know
- 10 that services that are rendered there are
- 11 going to just go through the roof over the
- 12 next decade, and we don't know what's going on
- 13 there. And I know, we all know that harm is
- 14 being committed there, and it's just an
- 15 opportunity.
- DR. ANGOOD: I think the short
- 17 answer is, it's not been determined, because
- 18 we wanted to see how the deliberations of this
- 19 group started, and it's up to this group to
- 20 sort of drive that future direction. We have
- 21 historically done an every three-year
- 22 maintenance update, but we have moved into an

- 1 annual update cycle for the Safe Practices.
- 2 Again, as Helen said, these SREs are NQF's, so
- 3 we can move them along in new directions, if
- 4 this group feels that's important.
- 5 CO-CHAIR TYLER: Martha.
- 6 MEMBER RADFORD: I'd like to -- we
- 7 have two definites here, the outpatient
- 8 procedure venues, and the long-term care
- 9 venue. And I did not vote for physician
- 10 office venues, because I just feel like the
- 11 feasibility issues are just too massive.
- 12 I'd like to offer that if we're
- 13 going to do a third one, it should be home
- 14 health, for the very reasons that Doron has
- outlined. It'll be a challenge, both of them
- 16 would be challenges.
- 17 CO-CHAIR TYLER: I want to offer up
- 18 something, and also maybe get some
- 19 clarification/feedback. Because we use them
- 20 as though they're interchangeable, the terms
- 21 home health, and home and community-based
- 22 services, and they're not at all, not the way

- 1 they're being used now. So, in my way of
- 2 thinking, because we have a lot of workforce
- 3 involved in this, so this is -- but, I mean,
- 4 home health, visiting nurses, they do wound
- 5 care, whatever. Home and community-based is
- 6 so much broader than that, includes a lot of
- 7 just personal care services that don't fall
- 8 into healthcare and medical, although they may
- 9 be Medicaid reimbursed. So, that blurs the
- 10 lines. Also, these terms home and community-
- 11 based setting doesn't necessarily mean someone
- 12 is in their own home. That's so much broader.
- 13 It includes group homes, it includes very,
- 14 very small ICFs, and up to 16 could be
- 15 considered community-based services. So, it's
- 16 very broad, both in the services, and in the
- 17 settings. So, if we adopt that, we need to be
- 18 clear that we're looking at a pretty big range
- 19 there. And I just want to know, is that what
- 20 people are thinking about, or are you thinking
- 21 more of home health, rather than home and
- 22 community-based services?

- 1 MEMBER TANGALOS: Well, Sally, the
- 2 same might apply, you might disagree, that
- 3 just as we've put a bigger umbrella under
- 4 long-term care settings, and we will focus on
- 5 SNFs, you could argue that home and community-
- 6 based services would have within it, home
- 7 health services, and focus only on that.
- 8 In fact, I'm not convinced the data
- 9 is there, either, but it might be a better
- 10 challenge, and it might be more worthwhile
- 11 than the ambulatory care sites.
- DR. GANDHI: This is Tejal from the
- 13 phone. I just would put in a plug for the
- 14 ambulatory practice sites. I think the vast
- 15 majority of care is given in those sites. I
- 16 think we have pretty good data, compared to
- 17 some of the other sites, in terms of what the
- 18 issues are. So, I just think that has to be
- 19 one of the things that was on this list in
- 20 terms of -- I mean, we know there's lots of
- 21 serious issues going on in those practices,
- 22 and they're a private site. Of all the sites

- 1 we've talked about, that's probably the site
- 2 with the most data to kind of back that up.
- DR. ANGOOD: Okay. That's good.
- 4 So, we'll keep going around, but I just want
- 5 to offer a comment based on what Eric was
- 6 suggesting, and that is, maybe it's sort of
- 7 ambulatory with a focus on, maybe it's home
- 8 health, or home care settings with a focus on,
- 9 home care, long-term care with a focus on,
- 10 SNFs, that kind of an approach. So, we're
- 11 getting lunch delivery here, so I'll help
- 12 Sally get re-engaged, so why don't we just go
- 13 around the table, Leah, then Cynthia, then
- 14 Diane and Mike.
- 15 MEMBER BINDER: Well, I wonder if
- 16 one criteria we should use to think about
- 17 what's in the first tier is the level of
- 18 potential harm to the patient, and their
- 19 vulnerability to that potential harm. That's
- 20 why home care sounds very compelling to me,
- 21 especially after Doron's comments. Because
- 22 that is in a setting where serious adverse

- 1 events could do a lot of harm, and there's
- 2 very little oversight between the clinician
- 3 and their direct relationship with the
- 4 patient, so the patient is particularly
- 5 vulnerable if something happens. So, it would
- 6 strike me as a stronger need for reporting,
- 7 than maybe others. And I think that might be
- 8 one thing we should at least consider in
- 9 thinking through what's the tiering.
- 10 MEMBER HOEN: Leah, I agree with
- 11 you, and I also agree with Doron, but I'm kind
- 12 of on Chris' page. We've just started
- 13 collecting data with respect to our home care
- 14 services, and whether it's for profit or not-
- 15 for-profit, and we're finding some fairly
- 16 disturbing things, sometimes. But I don't
- 17 have enough data to even begin to carve out
- 18 what we should be concerned about, so I don't
- 19 know if this Committee could make a
- 20 recommendation that those areas start
- 21 collecting data on at least A, B, C, and D,
- 22 and prepare to report on them the following

- 1 year, or something like that, so that that
- 2 could be fleshed out more, because I suspect
- 3 we don't have a lot of information. But I
- 4 think it's very, very prime for question.
- 5 MEMBER LAU: Talking about that,
- 6 this is Helen on the phone. I see one
- 7 suggestion is the home care and hospice area.
- 8 There's a lot of shortage out there in
- 9 clinician providing those care, and a lot of
- 10 time it's delay in service. And that might
- 11 even cause an unnecessary readmission to the
- 12 hospital, so if we are looking at getting more
- 13 data on that, on harm -- and I think one of
- 14 that could be even on the timeliness on
- 15 starting those services.
- 16 CO-CHAIR TYLER: Helen, what was
- 17 your last suggestion? You thought that one of
- 18 them might even be what? I didn't hear the
- 19 end. Sorry.
- 20 MEMBER LAU: The timeliness in
- 21 starting the service, so you could have a
- 22 hospice patient should go to hospice, and

- 1 because of lack of clinician, they couldn't
- 2 start the service early, and patient end up go
- 3 back to the hospital.
- 4 CO-CHAIR TYLER: Okay. Thank you.
- DR. BURSTIN: I was just going to
- 6 say, I mean, there are all kinds of ways for
- 7 us to stage this work. I think we've now heard
- 8 what's most important, but there's no reason,
- 9 for example, when we write the call for
- 10 events, we can't be very broad-based and say
- 11 these are the potential areas of interest. If
- 12 we get in 15 suggestions related to home
- 13 health, we might think differently than we do
- 14 right at this moment, so I'm not sure we need
- 15 to necessarily decide that right now.
- 16 The other thing is that you may
- 17 have some of the existing SREs that you'd
- 18 still feel comfortable that they be applicable
- 19 to a dialysis facility, even if you didn't,
- 20 necessarily, bring in dialysis facility-
- 21 specific events. So, I think there -- you can
- 22 kind of play it from both sides. And I think

- 1 we might be able to expand the sites to which
- 2 the existing SREs apply, even without,
- 3 necessarily, creating a whole new set of SREs.
- 4 And I think we could stage this to make that
- 5 work.
- 6 CO-CHAIR TYLER: Martha, then
- 7 Michael.
- 8 MEMBER RADFORD: I was just going
- 9 to put a plug in for Michael's grid. And if
- 10 we start to build that grid, then we'll know
- 11 where we need to go, I think.
- 12 MEMBER VICTOROFF: Okay. And
- 13 talking to you from the depths of the grid, I
- 14 want to reassure people who are nervous about
- 15 the potential for useful work in the office
- 16 environment, in this way, using the three Is
- 17 I've been quoting over and over again, I
- 18 believe that I can identify the top five or
- 19 ten injuries and events, and hazardous
- 20 procedures that occur in the office
- 21 environment, in terms of importance, using our
- 22 own claims data, looking just at lawsuits, and

- 1 claims that arose because there was a major
- 2 injury. Fifty-four percent of all of the
- 3 losses were outpatient in our company, and in
- 4 CRICO, and RMF, and other companies; whereas,
- 5 fewer of them were inpatient. And that's in
- 6 dollars, as well as in numbers. Our big
- 7 losses are all happening in offices, mostly.
- 8 MEMBER RADFORD: Is that office-
- 9 based procedures or offices?
- 10 MEMBER VICTOROFF: No,
- 11 unfortunately. And about 54 to 55 percent are
- 12 cognitive errors, as opposed to procedural
- 13 errors, and we can debate those. And then the
- 14 third I is intervention. I mean, is there
- 15 evidence that we know what to do, and the I
- 16 could tell you five or six things that I think
- 17 have at least tentative support in evidence as
- 18 being effective ways to remediate, mitigate,
- 19 or prevent those kinds of office-based errors.
- 20 So, I think there is science. Although, I'm
- 21 aware that not every state works the same way,
- 22 and this data is only coming from a few

- 1 pockets right now. But I think it's more than
- 2 enough to get started with.
- 3 And the one thing that I'm prepared
- 4 to defend strongly, is that the big problem is
- 5 in offices. And home health care, yes, there
- 6 will be a future quagmire, but it isn't now.
- 7 The deaths, and horrors, and miseries, and
- 8 problems that are rising to the level of
- 9 injury, harm, and urgency are happening in
- 10 offices more than homes, or even dialysis
- 11 centers, for that matter, because we insure
- 12 all those guys, and we kind of know who's
- 13 goofing up.
- DR. GANDHI: This is Tejal on the
- 15 phone. I completely agree with that.
- 16 MEMBER RILEY: I was just going to
- 17 say, even though CRICO and RMF have data, they
- 18 have their own insurance data. As a reporting
- 19 state, we don't have any data from offices in
- 20 terms of what happens there, so it's a captive
- 21 population for RMF, and we don't have any idea
- 22 of what's actually going on there.

- 1 MEMBER VICTOROFF: We'll show you.
- 2 It's not hard.
- 3 CO-CHAIR TYLER: We may have
- 4 brainstormed our list on this. There's some
- 5 discussion, huh? Pretty satisfied with where
- 6 we are? Make sense, at least, in the
- 7 beginning? Okay.
- 8 DR. ANGOOD: Are we all on the same
- 9 page up here, Helen? Helen and I have good
- 10 strong opinions, but not always the same.
- DR. BURSTIN: Yes, not always the
- 12 same ones. There you go. Although, you did
- 13 teach me that I could get monovision for my
- 14 near -- it is quite spectacular, so there you
- 15 go. Very helpful piece of information this
- 16 week.
- DR. ANGOOD: I'm mollified that you
- 18 are teachable.
- DR. BURSTIN: I am teachable.
- 20 There you go. I just find myself thinking
- 21 that it's probably time to think through some
- 22 next steps. And I think we've sort of reached

- 1 a point where maybe that would be useful. And
- I have a few, and I assume you have a few, but
- 3 if you want me to start, I'd be happy to
- 4 start. Okay.
- DR. ANGOOD: Yes, why don't we just
- 6 synopse, do this and -
- 7 DR. BURSTIN: Just one thought I
- 8 had, is I think that we're probably ready to
- 9 create the call for SREs broadly based on the
- 10 definitions you've given us, so I think one of
- 11 the next things we'll do is create a draft of
- 12 call for SREs, comments on existing SREs, as
- 13 well as call for new SREs. It will be very
- 14 broad-based in terms of environments of care.
- 15 We could potentially indicate the ones that
- 16 people -- the Committee indicated were highest
- 17 here, but not, necessarily, limit ourselves to
- 18 that.
- 19 I think we can create the Michael
- 20 grid, the SRE list, and send it to you with
- 21 the environments of care kind of listed out,
- 22 and ask you to, perhaps as a Committee

- 1 exercise, populate the ones you think
- 2 logically could be expanded to other sites of
- 3 care. And then I think we'll do the call, see
- 4 what we get in. And I think, at that point,
- 5 it might be the better time to think about
- 6 what are the expansion technical panels we
- 7 want to pull in for new SREs, and new settings
- 8 of care. I think we probably at least got two
- 9 or three of them for sure, but if there's four
- 10 or five that fit, we'll make it work.
- DR. ANGOOD: Yes, I tend to agree
- 12 with what Helen just described. You know, we
- 13 could spend the rest of the afternoon teasing
- 14 out the environments, who's got which
- 15 priorities, and why nots, and all that sort of
- 16 stuff. But I think, as outlined, that was
- 17 pretty close to where I was thinking, as well.
- 18 The group has done terrific work in this day
- 19 and a half. It's given us good, I think,
- 20 focus, more focus than I had anticipated. So,
- 21 setting up the call, whether it's a matrix or
- 22 a grid, or whatever, it suits my bias, as

- 1 well.
- We'll get that circulating
- 3 electronically for your guys' inputs and
- 4 further ideas, as you think about it further.
- 5 We'll discuss more in terms of the TAPs, and
- 6 we'll get that communicating to you, as well.
- 7 And we shall set up for some follow-up phone
- 8 call in the next month to six weeks, so that
- 9 we don't get too far past your guys' thinking.
- 10 And this is an 18-month process. We've got
- 11 built into the plan a number of phone calls,
- 12 obviously email is always there, and as we get
- the ideas firmed up, I think that'll really
- 14 drive us in terms of putting the expansion, or
- 15 the maintenance document on the SREs together.
- 16 It'll give us opportunity to set up the
- 17 messaging within that document where the field
- 18 will need to go to in all of this.
- 19 CO-CHAIR TYLER: I think Leah has
- 20 something she wants to add.
- 21 MEMBER BINDER: It is a question,
- 22 when you say call, you mean call to the

- 1 membership, or just for us? You said you were
- 2 going to put out a call -
- 3 DR. ANGOOD: It would be both. It
- 4 would be both, because this group will
- 5 generate their own ideas. And we may have -
- 6 we're fast running out of time, but maybe we
- 7 can do through it Survey Monkey, or something
- 8 like that, solicit your other ideas for the
- 9 existing SREs, see how that comes. But we had
- 10 talked about, also, doing an open solicitation
- 11 for ideas to see what comes in there.
- 12 MEMBER BINDER: Okay. If there's
- 13 an open solicitation, I would just request, as
- 14 well, that we talked earlier about having the
- 15 revised definition of SREs -
- DR. ANGOOD: That would be out
- 17 there.
- 18 MEMBER BINDER: -- put out as part
- 19 of the call to get comment.
- DR. ANGOOD: Yes.
- 21 MEMBER BINDER: Thanks.
- 22 CO-CHAIR TYLER: Doron.

- 1 MEMBER DORON SCHNEIDER: This kind
- 2 of work, in my opinion, is -- could be
- 3 accelerated if we use some virtual workspace
- 4 kind of environments, whether it's Google
- 5 Documents, or there's other methodologies to
- 6 really see changes as they occur, the thread
- 7 of discussions. I sometimes get lost in
- 8 emails where documents are sent, and then it's
- 9 not the latest version, and versioning
- 10 control. And I don't know if NQF has embedded
- 11 within your website that kind of a workspace,
- 12 but this would, ideally, happen within a
- 13 workspace that we can log into, and see the
- 14 documents, see Michael's latest revision, or
- 15 my comment, or your comment, and kind of build
- 16 off of that. It will make the phone calls all
- 17 that much more productive. I just throw that
- 18 out there.
- DR. ANGOOD: Sorry, we have moved
- 20 to a new platform, and we do utilize Google
- 21 Docs as one of the platforms. So, I certainly
- 22 agree with you that having kind of your own

- 1 little environment in space to hang out on
- 2 electronically, and go look whenever we pulse
- 3 you to go check, is the way to go. So, we'll
- 4 work on that. A combination of the electronic
- 5 forum, and the phone calls will be helpful.
- 6 Other suggestions, comments,
- 7 feedback on this day and a half? I always
- 8 think it's important to get your feedback on
- 9 how this worked for you, and to get some ideas
- 10 as to how it might work better. I think
- 11 Doron's idea is a good one, but others?
- 12 CO-CHAIR TYLER: I have a question
- 13 for the group, actually. How are you all --
- have you been thinking about, and do you have
- 15 any specific mechanisms, if you -- those of
- 16 you who do feel that you have constituencies
- 17 you have to answer to, or try to involve in
- 18 this, to go back and involve them, or are you
- 19 doing anything like that? If so, what? What
- 20 are you doing? Anybody. Michael is nodding
- 21 his head.
- 22 MEMBER VICTOROFF: Well, I end up

- 1 being, inadvertently, in a lot of professional
- 2 and social networks, so I have gossiped to
- 3 everybody about gee, we're going to go over -
- 4 you know that NQF thing, and that horrible
- 5 list of stuff, and you have now is your
- 6 chance, because they actually let me in, and
- 7 I can talk. So, I not only informally, but
- 8 formally have solicited opinions from people
- 9 I consider authoritative, and informed. And
- 10 I'll be bringing those. As soon as we have
- 11 whatever, the groupware site that helps that,
- 12 I'll be able to even give you sources and
- 13 footnotes for people that really had a message
- 14 that is valuable here.
- 15 MEMBER TANGALOS: I've already met
- 16 with the American Geriatric Society Ouality
- 17 Group, which I'm on, and we've discussed this
- 18 process, and we've had other members on other
- 19 NQF activities, as well. So, they're very
- 20 supportive. It will show up in the
- 21 newsletters for them. It'll also show up in
- 22 the newsletters for the American Medical

- 1 Directors Association. There's an extra added
- 2 benefit, because of the relationships there,
- 3 too. And if something shows up that needs
- 4 membership review, the reason I'm here is
- 5 because I'm good enough at figuring out what
- 6 they need to know about, and let them know.
- 7 DR. ANGOOD: And that's exactly why
- 8 you folks have been chosen, in part, not only
- 9 just for your expertise, but for your
- 10 secondary networks for us to get -- this is
- 11 not a bunch of smart people with their own
- 12 personal ideas. This is all about open
- 13 transparency, and full inputs, as broad-based
- 14 input as we can get. Chris?
- 15 MEMBER GOESCHEL: I have one
- 16 question, and thank you for that, obviously,
- 17 connected to lots of networks, both across the
- 18 country as part of the HAI work that we're
- 19 doing, but also internationally in terms of
- 20 some work on reportable events, and the
- 21 National Health Service, where we'll be in
- 22 December doing some of this very same kind of

- 1 conversation. But one of the things I was
- 2 going to ask as my first committee, is how
- 3 quickly will we get documents relative to the
- 4 changes that we've suggested today, because as
- 5 a newbie to this, I've taken notes, but I have
- 6 been much quieter than I typically am, to just
- 7 try to take this all in. And I want to speak
- 8 the truth about what happened, not what I
- 9 remember in my head.
- DR. ANGOOD: Yes, in general, we
- 11 are pretty good with our turnarounds. We have
- 12 fairly rigid processes in terms of all of our
- 13 meetings. We get the transcripts back. We
- 14 review the transcripts. We put meeting
- 15 summary notes usually within a week to ten
- 16 days.
- DR. BURSTIN: And the actual
- 18 transcript will be posted, as well.
- 19 DR. ANGOOD: Yes. Other comments,
- 20 other feedback, things we need to do better
- 21 for you? It looks like people are hungry, and
- 22 -- go on.

- 1 MEMBER MORLEY: I will be talking
- 2 with -- I work closely with different
- 3 associations back in New York. We'll be
- 4 talking to them, as well as hospital medical
- 5 directors. I want to thank you for getting us,
- 6 for allowing me and us to participate. This
- 7 has expanded all of our networks, and I'm
- 8 particularly happy that you've shared
- 9 addresses, and so forth, on the information
- 10 you provided. So, we've already connected in
- 11 a number of areas, and I'm sure we're going to
- 12 be connecting on a number more going forward.
- 13 Thank you.
- DR. ANGOOD: All right. I think
- 15 that about wraps it up. Any other comments
- 16 from folks on the phone before we close out?
- 17 Hearing none, thank you folks who are on the
- 18 phone for bearing with us, appreciate all your
- 19 inputs, and look forward to the ongoing
- 20 documents. And, as I said to everybody here,
- 21 thank you so much. This has been exceptional
- 22 work. This group has come together very

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     quickly, and we appreciate that. So, more to
 1
     follow, and safe travels home.
 2
 3
                 MEMBER BRENNAN:
                                   Thank you.
 4
                 MEMBER LAU:
                               Thank you.
                 DR. ANGOOD: All right, everybody.
 5
     Bye.
 6
                  (Whereupon, the proceedings went
 7
 8
     off the record at 12:16 p.m.)
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