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, CoChairs, 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

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A-G-E-N-D-A
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1
2
3

4

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

PROCEEDINGS
(8:08 a.m.)

CO-CHAIR TYLER: I'm just going to
ask folks here, just for the record to go around and say who you are, just say your

MEMBER GOESCHEL: Chris Goeschel.
MEMBER NADZAM: Debbie Nadzam.
MEMBER VICTOROFF: Michael
Victoroff.
MEMBER RYDRYCH: Diane Rydrych.
MEMBER HOEN: Cynthia Hoen.
MEMBER TANGALOS: Eric Tangalos.
MEMBER RADFORD: Martha Radford.
MEMBER RILEY: Stancel Riley.
MEMBER McDONAGH: Kathy McDonagh.
MEMBER DORON SCHNEIDER: Doron
Schneider.
MEMBER PHILIP SCHNEIDER: Phil
Schneider.

MEMBER MORLEY: John Morley.
DR. ANGOOD: Peter Angood, and we have Lindsey Tighe, and Jennifer Hurst as NQF Staff here.

DR. BURSTIN: And Helen Burstin. CO-CHAIR TYLER: And Sally Tyler, I'm here. And who do we have on the phone?

MEMBER LAU: Helen Lau.
CO-CHAIR TYLER: Okay, Helen, and
Gregg. Anybody else?
MEMBER BRENNAN: P. J. Brennan.
CO-CHAIR TYLER: P.J. Great.
Anybody else?
DR. GANDHI: Tejal Gandhi.
DR. ANGOOD: Gregg, are you on?
MR. GARCIA: There's also Eddie
Garcia here from CMS.
DR. ANGOOD: And Eddie, thank you.
MR. GARCIA: Sure.
CO-CHAIR TYLER: Anybody else on the phone? Well, I wanted to thank you all on 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.

MEMBER GANDHI: Sure, thank you.
MEMBER LAU: Definitely.
CO-CHAIR TYLER: And I think now Peter and Helen are going to review what we did yesterday, as far as updating the definitions.

DR. ANGOOD: Yes, I will. And, first off, just in terms of the day's agenda, we're going to do this review just to make sure we're still on the same page we thought we were by the end of yesterday. Ideas do change in 24 hours, as we know.

Then we'll jump back in to finish 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.

18 process here.

While we want to get as much work done today as possible, I don't think we are feeling like we have to get everything tied up and wrapped into a nice little tight bow by the end of the day. We have an ongoing

So, in terms of where we thought we came out yesterday, we made that significant change to the one word in this definition of 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

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?

So, the significant change being

MEMBER VICTOROFF: I have
dismissible discomfort because I don't think the last phrase is needed, because I can't think of the other list we have of serious reportable events that should occur.

DR. ANGOOD: I think, however, though, to get back to some of Diane's point yesterday, we have to be able to imprint a sense of need or urgency on that. And that's part of that purpose. Leah?

MEMBER BINDER: All right. So, let 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

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 patients that they're really going to make

1 sure there's zero tolerance.

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.
"Never" is the word that has

DR. ANGOOD: Thank you, Leah. Any comments?

CO-CHAIR MEYER: This is Gregg. I guess my counter to that would be that although it has captured the imagination, it's also created equal anxiety on the other side, and confusion. And I think, in the end, my sense is, is that these are differentiated, because the National Quality Forum, and through its authority through the National Technology Transfer and Advancement Act, is telling states that these ought to be reported publicly. And I think that that's incredibly powerful. And, at the end of the day, whether

1 or not we say "not" or "never", doesn't matter
2 a whole lot.

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.

I think the downside of the confusion of "never" makes me think that

DR. ANGOOD: Thanks, Gregg.
CO-CHAIR TYLER: I think Leah
wanted to follow-up.
MEMBER BINDER: Just one more statement about that. Most people in the public do not know that it is not a reportable event in some places for some of the wrong side surgery, and so that is not going to gain us a huge amount of enthusiasm from 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.

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 13 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.

MEMBER RADFORD: I took away from the discussion yesterday, and please correct me if I'm wrong, that part of the role of this group is to, in a sense, broaden the scope of reportable events to get beyond the serious 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".

21 in a different class of events in some ways,
DR. ANGOOD: Diane, you had a
comment?
MEMBER RYDRYCH: Yes, I just wanted to say, you know, I was one of the people who didn't want to take out the phrase entirely, because I was worried that we would lose some of that sense of urgency, if we got rid of "never". The reason that we, as a group, came up with "not" as a compromise, and maybe it's not the right word, and maybe there are others that are better, is because I think we all would have felt more comfortable with "never", if the list didn't include things like pressure ulcers, and falls, that are kind of than some of the others.

1
2 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
In my state, when we talk about absolutely right word to use, but we were trying to acknowledge that there are some of these that are a little bit different than some of the others.

DR. GANDHI: This is Tejal Gandhi.
I just wanted to confer with that. I think that's definitely where my level of concern comes from around "never", as well, is around the falls and pressure ulcers, because it would lead to the most discussion for us, as well. I just wanted to agree with that

1 comment.

3 and then Leah.

4

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 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

DR. ANGOOD: Thanks, Tejal. John, MEMBER MORLEY: I certainly do positive things.

On the other side, unfortunately, in the area that we live, and the time that we live today, that "never events" also brings with it the concept that if it never should happen, then somebody, obviously, didn't create a human error, they did something that was either malicious, or demonstrated total incompetence. And I think we can accept that those can certainly lead to those events we have on our list, but there are many other mechanisms by which those things can occur, that don't, necessarily, imply incompetence,

1 or maliciousness. 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. 21 never occur. We should be able to prevent

DR. ANGOOD: And Leah, again.
MEMBER BINDER: Well, we've been
using the term "never events" at Leapfrog, and have the policy, and it's been wildly ever been the consequence of the term never'

And in terms of your point about pressure ulcers, absolutely, pressure ulcers are not never events, but I don't think that we've defined, at least in the policies that I've seen in NQF before this, we haven't defined it as all pressure ulcers. We've isolated the specific kinds of pressure ulcers that really should never occur. I don't think a Stage Four pressure ulcer -- I mean, we should set that as a standard that that should that.

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,

The word "never" does have some in my mind, been very effective as a strategy, at least from a purchaser's point of view, it has been a very effective way to describe what these events really are. And to address them, I think, in very effective ways. DR. ANGOOD: Michael, and then Cynthia.

## MEMBER VICTOROFF: Just to

interject the dilemma of the malpractice 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
13 institution at a certain rate, or that you 14 should encourage people to commit.

16 an error is, it shouldn't occur. "Never" is
17 the goal for errors, but when we get into

21 causing consternation among people who have to
22
So, in a way, no matter how minor court, it's a whole other discussion. It's not rhetoric, at all. There is a legal mousetrap here that we're experiencing, and is 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 strong sentiment among the people that have to deal with administrative accountability, and litigation that this is a terribly prejudicial term. They could live with "not", but the folks I work with couldn't live with "never" any longer.

MEMBER HOEN: I would agree with Michael, and we have, in fact, seen a significant increase in the number of lawsuits associated with pressure ulcers, which were not preventable, because the family believed based upon the wording in these particular guidelines that they were never events.

We just recently tried one twice, 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.

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.

21 may be some things that are egregious, and
CO-CHAIR TYLER: Philip.
MEMBER PHILIP SCHNEIDER: I'm wondering when we get to the discussion of alternate healthcare settings, where the control over the healthcare that's delivered is less rigorous, whether we would be hemmed in by having a term like "never", because in a home care environment, for example, there 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
9
10
11 well, not so much -- we've already heard about
12 the threat of the "never" piece, but on the

21 you've thrown in the towel, so to speak, and
22 I don't want to see that part happening,

1 either. 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.

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

CO-CHAIR TYLER: Leah.
MEMBER BINDER: I can't speak to the legal ramifications, except that, as you That's the extent of my knowledge serious reportable event. So, "never" says

1 that like other things don't.

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

Now, having said that, I'm not -  leave it at serious, ambiguous adverse events, period. That would be my second choice, but I'm just -- but I'm extremely strongly in favor of keeping "never".

MEMBER TANGALOS: Well, if you were here yesterday for that vote, I think it occurred beforehand, that was almost a split vote yesterday. That piece was very close to leaving it all out, versus putting "not" in. CO-CHAIR TYLER: Philip.

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. urgent as it has been, when To Err Is Human was published. And I think that the momentum is, I don't want to say lost, but I just get a sense that in setting standards for patient safety we do need to be, I don't know if the term "dramatic" is the right word, but we need to be forceful. And I -- Leah's comments are really striking a responsive chord with me.

I know when we talked about this at an international meeting, and one of my colleagues talked about never events, it really got people's attention, that in the 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.

11 next.

MEMBER RILEY: I guess the word "never", to me, means that there's a solution, that we have a way to make these things be okay. So, if you say "never", that means -that implies that you have the fix for whatever it is, wrong side surgery, for any of those other things.

I think the thing that would really help the sense of urgency is to come up with a fix, say this is what works for this. That would make a headline, I think, just as well

1 as saying "never".

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.

21 when this new list of SREs, along with the
DR. ANGOOD: And that's probably where in the opening comments trying to weave

CO-CHAIR MEYER: This is Gregg. I
can $I$ just make a comment along those lines. CO-CHAIR TYLER: I'm sorry. Is someone on the line? CO-CHAIR MEYER: Yes, it's Gregg. I agree with this need to re-establish urgency. I disagree that the right way to do that is to keep the word "never". I think that the way to do that has to do with I think the way that the Quality Forum is trying to repackage, and reinvigorate its safety portfolio. And, in particular, I think that 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.

11 accountability out there with a list of
12 serious reportable events that states are
And, in the end, you know, my
vision is, is that we ought to have the reporting publicly, and creating a sense of urgency through that mechanism. But, at the same time, I believe we ought to have public reporting on who's implementing the safe practices, taking the systems approach. And I think the Quality Forum would be positioned in a way that it's never been before through that, to create that sense of urgency. CO-CHAIR TYLER: Okay. Thanks, Gregg. We have Kathryn, and then Diane.

21 organization, it can't be done in a punitive
MEMBER McDONAGH: I think these points are excellent, as well. And I do feel strongly that we need to make some strong statements. I agree with Gregg, that when we look at the totality of the work when we're done, we've got to have a balance of really creating a safety of culture, because we have an issue with that in terms of just cultures, and creating an openness in organizations.

But, yet, we want to really hold people accountable, and increase that sense of urgency, so I do that the way we've worded it is fine, but then we've got to add some other statements, and frame it very aggressively, what we think needs to be required to be reported, and really, I think, putting the whole package together, so that it's a very strong statement of accountability; but, yet, it's balanced with, if we're really trying to move healthcare to a high reliability 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.
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.

21 there's CMS, and there are all these other
I appreciate Gregg's point, but I don't entirely agree that the consolidation and updating of measures is going to create that sense of urgency, because out in the field, I think people -- we've talked about this. There is Leapfrog, and there's NQF, and 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.

21 know that. And it feels like that's the way
There might be people who are
starting to figure out how you fix some of these things, but it's difficult to really 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.

4 the phone. Could I jump in?

6 phone, first.

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,

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.

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 4 could gain something by adding a coupl
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
MEMBER DORON SCHNEIDER: One of the report this. Great. Well, we want to disclose, and we want investigation of root cause.
CO-CHAIR TYLER: John, and then

Leah.
MEMBER MORLEY: I think you may actually have another agenda item. I'm not sure that it will fit for today, but perhaps the next time. But I think there is a very strong feeling, $I$ have a very strong feeling 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.

21 more than reporting, for PDCA, would be a 22 major plus for this report.

It's about a lot more than that.
So, any opportunity to increase urgency and provide backgrounds, and support for doing

2 next, and then Michael.

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.

21 care system, that providers are willing to say
CO-CHAIR TYLER: I think Leah was

MEMBER BINDER: I can only speak

This will be a major story, and I think Gregg has brought up the point, modern healthcare, if nothing else, will grab on to this in a second. Where's the word "never"? This will be the story, so you're right. We better come up with some other language that will clarify that oh, we're not lowering the standard, we're just using a new word, even though this is the word, "never events", that has come into our language thanks to NQF in a way that I have found to be very powerful, very compelling, and a tribute to our health no, we are going to go lay down the gauntlet

1 on certain events that should never occur.

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 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

21 attention of the public.
And I want to go back for one will do everything in our powerful humanly to avoid that from happening again.

The public understands that sometimes it is preventable, but setting that standard gives comfort to the public, that the healthcare system, or the airline industry, does understand that it is -- that they have a special trust placed in them. So that word, and that is why I think it's captured the

CO-CHAIR TYLER: Michael, then

1 Helen.

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. 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 17 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. 21 this issue about urgency. If you look at

I think the "never" word should

I'm particularly wanting to address global warming, or the rain forest depletion,

MEMBER VICTOROFF: Well, I'm getting more uncomfortable the longer we

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.
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. 20 And I think that this move -- I mean, my

21 interview with New York Times, heaven help us,
22
There was a hand waving at the time
for HIV, but now is really the time to look at the molecules a little. And I'd love to progress to that stage in the safety business. 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

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

21 broader definition. And that, I think, was
DR. BURSTIN: I just want to make language, explicitly, because we made it clear that we believe there are appropriate public reporting and improvement, but never was not a word that was really used beyond the 2000 initial definition.

I think the second thing is that I think we've also tried to create a broader corridor for more reporting. And I think the only way to do that is, in fact, to make it a the basis of most of our discussion yesterday.

1
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

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
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."
MEMBER DORON SCHNEIDER: For the

CO-CHAIR TYLER: Should lead to disclosure and search for root cause." Is that right?

MEMBER DORON SCHNEIDER: Yes, something like that.

CO-CHAIR TYLER: Causes.
MEMBER RADFORD: Search for and correction of.

MEMBER DORON SCHNEIDER: I like the correction.

CO-CHAIR TYLER: Yes.
MEMBER DORON SCHNEIDER: That's the punch.

CO-CHAIR TYLER: Search for and correction of.

DR. BURSTIN: The first one you said investigation, by the way, which I think is better.

CO-CHAIR TYLER: Yes.
MEMBER BINDER: And what about,
"should always lead to", and what about adding an apology to the patient?

CO-CHAIR TYLER: Disclosure.
MEMBER BINDER: Should always lead to disclosure, search for correction, apology to the patient.

MEMBER BRENNAN: I think all this language could be included in text, but I would prefer to keep the definition of the actual event crisp.

CO-CHAIR TYLER: Is that P.J.?
MEMBER BRENNAN: Yes.
CO-CHAIR TYLER: Okay.
MEMBER RYDRYCH: It feels a little 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 NQF around these events should be
10 disclosed to patients, and there should be an
11 apology would give more weight to that.

CO-CHAIR TYLER: Cynthia.
MEMBER HOEN: That's a great idea,
but not, necessarily, doable in every
instance. In the State of New Jersey, an apology is admissible in the court of law.

The other problem is, in a lot of these events, it's not clear -- I mean, you can say I'm sorry this happened to you, and here's what happened to you, and we do that. But to go beyond that is not, necessarily, possible, 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.

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.

21 or step in the management of a terrible event. CO-CHAIR TYLER: Michael.

MEMBER VICTOROFF: Unlike New Jersey, Colorado has a robust apology statute that allows those things to be not introduced as evidentiary. And we have a very extensive apology program in our malpractice environment in Colorado. And we would never want to see apology introduced as some sort of a guideline, or some sort of a mandatory remedy,

Although, we know that, at times,

So, I appreciate the research out

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
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,

1 you can do to not serious events.

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.

11 for the non-serious events, wouldn't it also 12 be effective -- I'm borrowing Michael's -- if

21 conducted a double blind trial. But the
MEMBER RYDRYCH: I'm sorry, but if apology is effective in reducing litigation apology is effective in limiting litigation for the non-serious events, wouldn't it also be effective in limiting litigation for the serious reportable events?

MEMBER VICTOROFF: We have no good evidence about that. We'd like to think so, sentimentally. And there's theoretical reason to think that might be true, if we had problem is, I'm very nervous about putting in

So, putting apology into this

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.

8 want it in this definition, either.
CO-CHAIR TYLER: Christine wants to get in on this.

MEMBER BRENNAN: Peter, if I could
interject here, it seems like this is beyond the scope of the project. I mean, it seems
like we're getting into issues of
implementation after the discovery and reporting of an event.

CO-CHAIR MEYER: This is Gregg.
Just one of the Safe Practices is explicitly around disclosure and apology, so there's an existing Safe Practice on this issue.

I think that what we may want to do 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.

11 help your concerns about "never" to include 12 language in the text that speaks to the issue 13 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.

CO-CHAIR TYLER: I think Christine
had a point, and we're going to, hopefully,

1 then kind of put a beat on this, wrap it up.

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

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
So, I would be highly in favor of all along, and I believe that Gregg said the same thing, is that we want to move the evolution of this towards science and evidence. And, as we go down that path, I think clear and succinct definitions of terms are going to be critical. So, that was it. CO-CHAIR TYLER: Given what we've discussed, and it sounds like that is where the sentiment of the group is, but are people -- can we vote for confidence in leaving it as 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?

8 something.

MEMBER BINDER: I'd like to say

CO-CHAIR TYLER: Okay, Leah.
MEMBER BINDER: I just want to make
a point about Michael's point, just to be really clear. I'm not talking about calling up the New York Times, and I can't -- I'm not trying to do a dueling thing here. I just want to be clear about that.

I raised that point, because this group should be cognizant of how the public, consumers, and purchasers are perceiving what's done here. And I'm just telling you from my experience, purchasers are extremely passionate about the issue of never events. 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.

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

21 forward in the way that I have to, to
In fact, the Purchasers Coalition they're going to notice the word.

So, I understand maybe "never" should have been there to begin with. We certainly could debate that. It was there. It captured a lot of attention, and it set a standard that I happen to support. But I understand the issues, $I$ understand that that's a difficult -- I understand the difficulties, but I also think that this is a serious move, to remove that word. And I hope that it's understood that I'm bringing this represent my constituency, which will notice

1 this.

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

21 events that should not occur." And then we
CO-CHAIR TYLER: Okay. Let's go to people want? Yes? All those voting yes?
(Vote taken.)
CO-CHAIR TYLER: And on the phone?
CO-CHAIR MEYER: I'm sorry. That wasn't clear to me. Could you -

CO-CHAIR TYLER: Okay. What we're voting on is to leave the definition as we did at the end of the day, which is defined as "preventable serious, and unambiguous adverse 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".

CO-CHAIR MEYER: Okay.
CO-CHAIR TYLER: And some of the thoughts around this debate.

CO-CHAIR MEYER: Okay.
CO-CHAIR TYLER: Okay. That's what we're voting on. And we saw the hands of support here in the room. On the phone, do we have yes for that, or -
(Chorus of yes.)
CO-CHAIR TYLER: Okay. No's?
Okay. On the phone, any nos?
DR. ANGOOD: Sorry. Diane, you had a quick question?

MEMBER RYDRYCH: Yes, I do just have a quick question. I know that with any changes to the list of events that this group makes, it goes to a membership vote of NQF. Do changes to the definition go to a vote, as well, so the membership will be voting on that change?

1
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.

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
DR. BURSTIN: The entire document,

MEMBER BRENNAN: I do think that would be helpful.

DR. ANGOOD: All right. So, we have a couple of more slides just to make sure, similarly, on the same page, as best as we can. So, we've all now just agreed on the definition of SRE.

The further language on the 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
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.

21 for public credibility, or public
The third slide, for those on the phone, is the SRE Criteria. And this is, basically, where we chose to get rid of the and/or in-between each of the three bullets. So, "An event must be unambiguous, preventable, serious in any of the following adverse indicative of a problem in a healthcare facility, safety systems, important accountability." Any further discussion on

1 that? Seeing and hearing none, so the next
2 one.

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 consequence of care that results in unintended injury or illness." "Preventable" is unchanged, describes "an event that could have been anticipated or prepared for, but that occurs because of an error or other system failure." "Serious" has some changes. We added a couple of words, and deleted half of the definition from last time. So, it currently now reads, "Serious describes an event that can result in death or loss of a body part, disability, or loss of bodily function, or risk thereof." The added words were "can result in death", as well as the

1 term "or risk thereof."

5 easily identified." So, I guess we'd ask for
6 comments, or affirmation that that's what we
7 all agreed to yesterday.

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

21 that was floated around in a few different
And then the final term,
"Unambiguous" was unchanged, and that refers to, "An event that is clearly defined and MEMBER BRENNAN: Peter, this is well, so that that's clearly included.

DR. ANGOOD: Yes, that's a good point, P.J., and we certainly talked about that. Thanks. Okay. Everybody still comfortable with those sets of slides? All right. Next slide, please. And now we have the Venn Diagram 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.

21 other types of events in the broader groupings
MEMBER BRENNAN: I think we all got
it. Thank you.
DR. ANGOOD: Yes, so we've got -
DR. GANDHI: I got it.
DR. ANGOOD: We've got the larger
circle, which encompasses the so-called white matter of all events. We, as near as we can tell yesterday, agreed that the serious reportable events were their own little subgroup, HAIs, because they are an entity that's out there, are their own subgroup. And that there was a whole collection of these 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.

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. 21 of the two lists was the reason for the Venn.

DR. ANGOOD: Well, just, again sorry, Sally. The discussion got started because we were struggling with this healthcare acquired, or healthcare associated conditions. And it kind of evolved along in this, and this is where we had left off. That's why we're opening it again today. MEMBER VICTOROFF: And just for -I mean, you're reminding us that the problem 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.

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

CO-CHAIR TYLER: Philip.
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.

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 -

CO-CHAIR MEYER: This is Gregg. I definitely support. It was a great conversation starter yesterday, but I think at this point it's superfluous.

DR. BURSTIN: This is Helen, I

1 support.

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.

MEMBER BRENNAN: P.J., I agree. CO-CHAIR TYLER: Okay. Thank you.

MEMBER DORON SCHNEIDER: Just a

MEMBER RYDRYCH: No, a subset of a broader group.

MEMBER DORON SCHNEIDER: Okay.
MEMBER RYDRYCH: I think we abandoned the HAC term. Yes, the bad things list.

MEMBER DORON SCHNEIDER: Okay. So, maybe you misspoke, but that's -- okay, we're clear.

CO-CHAIR TYLER: Okay. Is there another slide?
(Laughter.)
MEMBER RYDRYCH: It was a breakdown in the communication system. It happens.

1
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.

11 HHS and say okay, this group does not feel
DR. ANGOOD: I want to just make

We still will need to go back to that the term "healthcare acquired", or "healthcare associated" conditions is a term to be used. Is that what we're still saying now?

DR. BURSTIN: Just to be clear, the HAC term was always a term of CMS, so we were trying to decide if we needed DR. ANGOOD: That's hospital. DR. BURSTIN: Right. We were trying to decide if we needed yet another 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.

CO-CHAIR TYLER: Michael.
MEMBER VICTOROFF: Again, I am happy leaving this the way I -- I kind of think of it as -- the reporting process at CMS has found a way to make itself happy capturing certain bad things. I'm not sure how you can capture all the SREs, because there's a capture identification, intervention. There's a lot of things after the definition step that you've got to do. So, there are some of them that CMS looks like they figured out in their own system a way to capture through their use 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.

21 reduction of HAIs. And I think we ought to be
MEMBER BRENNAN: Peter. DR. ANGOOD: Yes.

MEMBER BRENNAN: P.J. here. Don
Wright at HHS has been leading a Steering Committee to coordinate activities across HHS, and to create a national plan for the 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.
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.

20 other to review?

DR. ANGOOD: No, I just -- I mean,
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.

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 choose to do that, but that's their business, not our business. And adding this other healthcare acquired/healthcare associated would be, I think, more confusing to the field, rather than less. So, I just wanted to, again, reaffirm that we're comfortable leaving that term alone. Don't even go there any more, and we'll just convince HHS they don't need to go there any more, either.
MR. GARCIA: Peter, this is Eddy

Garcia.

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
DR. ANGOOD: Yes. MR. GARCIA: Just so it's clear, defined with your Venn Diagram, which you're not publishing, that there is a larger term, and SREs fits under that. HAIs also fit under that. So, I guess my question is, what is that larger term that you're defining?

DR. ANGOOD: Yes, I can certainly understand the question, Eddy, and I sense that we'll certainly have more discussions between your guys' groups, and ours in moving forward, but from yesterday's discussion, the broader full context of events is what we just are calling the adverse events, or all events. 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.

21 List, at the moment, I think what we talked
Helen, did you want to add other comments?

DR. BURSTIN: No, I think it's a conversation I think that will continue. I don't think it's something we're going to resolve today. I think the idea of creating this broader corridor, our hope was, in fact, if you look at what's on the CMS Never Events 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.

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?

8
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

15 think our goal is, as much as possible, with 16 the majority of the work we do, harmonization 17 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.
CO-CHAIR TYLER: Okay.

1
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.

7 things are, it'll shift from Never Events to 8 John's 40 list.

21 reportable events. We got, I guess, about
DR. BURSTIN: It's going to forever
(Laughter.)
DR. ANGOOD: Yes, and the way
(Laughter.)
DR. ANGOOD: Not quite the same sense of urgency, Leah, but -

CO-CHAIR TYLER: Okay. Peter, did you have anything else from yesterday you wanted to review?

DR. ANGOOD: No, I believe that was
it.
CO-CHAIR TYLER: Okay. Good.
Before we plunge into what we had on today's agenda, we still need to pick up from yesterday, jump back into the list of serious 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.
(Laughter.)
CO-CHAIR TYLER: Okay. So, now we're in Care Management Events, 4A. Patient death or serious disability associated with a medication error, e.g., errors involving the wrong drug, wrong dose, wrong patients, wrong time, wrong rate, wrong preparation, or wrong route of administration. Okay. Let's see.

The new language excludes
"reasonable differences in clinical judgment involving drug selection and dose, includes administration of a medication to which a patient has known allergy and drug interactions, for which there is known

1 potential for death, or serious disability."

3 on? Diane.

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

21 captured, or not.
Okay. What do we want to comment

MEMBER RYDRYCH: One thing that's

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.

CO-CHAIR TYLER: Philip.
MEMBER PHILIP SCHNEIDER: Wouldn't 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?

21 boundary here, when we say that it was
CO-CHAIR TYLER: Michael.
MEMBER VICTOROFF: I have a problem
like that -- with that. I appreciate the comment here, but I think we heard the clarification, there's a difference between commission and omission, and the commission ones are a lot easier to capture, and the omission ones are actually different in kind. When -- and this one skirts the 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.

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.

21 pointed out, but this looks, to me, pretty
I'm very open to talking about them. In fact, I want to open that up. We're going to start talking about additions, but I don't think that this canoe carries that baggage. This looks, to me, more like -- and I'm a little disturbed about that bullet you much more like we gave something, and it was

1 wrong.

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 -again, it's more of an omission, but I'm thinking of failure to appropriately monitor an INR, for example, or a PTT, or something like that, leading to a serious event. So, I'm wondering if you want to put in the term "monitoring", at all. CO-CHAIR TYLER: Okay, thanks. Michael, again, and then Cynthia. MEMBER VICTOROFF: Again, good comment, good addition. I don't want to put it in this canoe. You hurt the category if you put in so many things that everything to 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.

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

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.
CO-CHAIR TYLER: Eric.
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.

21 organization, any type of organization, versus
CO-CHAIR TYLER: I don't think we have any other -- Martha, and then Philip.

MEMBER RADFORD: I wonder if this is -- part of this is in reporting about the structures around medication management in an 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.

CO-CHAIR TYLER: I'm not sure I
understand what you're getting at. I mean, we are meant to begin applying these to other contexts. That's part of our -

MEMBER RADFORD: What I mean is that the sins of commission are different. I am agreeing with Michael, they are different than the sins of omission. In addition, the fixes around near misses are organizational fixes. They're not, necessarily, event fixes. And I think that if we -- we risk the possibility of losing the potential fixes, because there's usually more than one, in the -- if we broaden the reporting category. You don't have to report everything to get some good clues about what needs to be fixed.

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. CO-CHAIR TYLER: Okay. MEMBER PHILIP SCHNEIDER: I can rest, if I know that there will be a method developed in order to do that. I notice we've looked at surgical complications, and diced that up a lot of different ways. I went back and looked at, there's probably four different things that relate to -- events that relate to surgical procedures, and the medication used is no less complicated. It's less dramatic, but I think we need to, potentially, tease

1 that out a little bit more than embedding
2 everything in one standard. CO-CHAIR TYLER: So, do you think

4 it makes to have a separate event around
5 omission through monitoring?

9 long as it's captured.
CO-CHAIR TYLER: Michael.
MEMBER VICTOROFF: Since you're asking for a possible mode, I'd like to propose that we keep in mind that we're allowed to add stuff. And I have a whole shopping list to make it up to 40 of things like this. And, for me, near miss events are completely separate, because they're analyzed, captured, and dealt with separately. And I want to put them on, and make sure they get on here, but I don't want to load these boats with all of this diffusing stuff that actually 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

14 next, John.

16 Mike, and in this particular case, I guess, as they matter? Are they important? Rather than concealing -- sneaking in some stuff in these that I already kind of like.

CO-CHAIR TYLER: John. You're

MEMBER MORLEY: Okay. I agree with

I'm looking over the list and the concept of medication errors, I'm becoming more and more of a splitter on this. I think the world of medication errors is the world of safety. It's massive. It's far bigger than we can bite off.

1
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 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.

11 identify a more focused area, or focuses
At the end of a year of data
I'd like to see us be able to within medication, so that at the end of the year when you've collected the data, the boxes are a neater pile of information, not just data, that can be used to drive that change. And you're not going to get that if you have one report on heparin, one report on Coumadin, one on daunorubicin, one on pediatric dosing issues, one on Fentanyl, and so, and so on. So, some mechanism by which you can create more biteable, more fixable sections of medication error would be much more useful for

1 people.

21 and MAO inhibitors fall into that category?
CO-CHAIR TYLER: I was going to check to see if anybody on the phone want to weigh in on that? Okay. Philip.

MEMBER PHILIP SCHNEIDER: I'd like to hear if there's an explanation for the last bullet point in the middle column. I read this many times, and I don't understand it even this morning. I just don't understand what that means.

CO-CHAIR TYLER: The bullet point to which he's referring, "All situations in which two or more medications are administered for which there are drug-drug interactions with known potential for death, or serious disability, only those that result in death or serious disability." I do not know the answer, if there is a specification justification. Peter, can you weigh in?

MEMBER MORLEY: Would meperidine 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.

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.

MEMBER RYDRYCH: Isn't the Right? Not just the potential, thereof. DR. ANGOOD: Right. MEMBER VICTOROFF: This says events that are not intended for capture. What I don't understand is the drug interaction that was known and caused a fatal event, then it should be included, I think. It seems like a paradoxical statement.

DR. ANGOOD: It's more along the lines of what -- as I understand it, anyways, I'm still relatively new to NQF, wasn't part of the genesis of the original list, but I can 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.

6 shouldn't those be reported, John?

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

22 note.
MEMBER RYDRYCH: I think if you rephrase that to say unless they result in death or serious disability. But, you're right, it would make more sense to kind of move that out of the exclusions category.

DR. ANGOOD: I agree. Got that

1
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?
CO-CHAIR TYLER: Okay. We have

CO-CHAIR MEYER: The only thing I would consider adding here is to consider ABO incompatible organs, as well.

CO-CHAIR TYLER: Incompatible organs. Okay.

DR. ANGOOD: Gregg, this is Peter, or was that P.J. I'm not sure, you both sound similar on there.

CO-CHAIR MEYER: It was Gregg.
DR. ANGOOD: Thanks. That topic
that you just brought up actually has
generated a fair amount of discussion in the 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 -
CO-CHAIR MEYER: The organ events
are blessedly, incredibly rare, but they are of great import, and delving into why they happen is incredibly valuable.

DR. ANGOOD: Oh, I certainly agree, and $I$ don't discount the importance of it. It's a matter of trying to keep it clean and crisp between where the boundaries are. You know, if we want to have a -

CO-CHAIR MEYER: So maybe we should
put this on a list of something for the future. DR. ANGOOD: Yes, I was just going to say it may become part of what we actively seek out in terms of solicitations for other

1 SREs, because it's an important topic by 2 itself.

5 no other discussion on that, then we'll move 6 on to the next one.

CO-CHAIR TYLER: Okay. So, maybe you'll look at that in the future. If we have

Okay, 4C. "Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility." Let's see. The added language includes "events that occur within 42 days post delivery, excludes deaths from pulmonary or amniotic fluid, embolism, acute fatty liver of pregnancy, or cardio myopathy." Okay. Michael.

MEMBER VICTOROFF: This, to me, looks like another legacy of the blame paranoia philosophy that I thought we were moving away from. I don't see any reason to exclude a reported death from any cause, because, to me, I'm considering all of these 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
"preventable" is in the definition on the SRE.
CO-CHAIR TYLER: Tejal, is that
you?
DR. GANDHI: Sorry, this is Tejal.
Yes. I agree that we need to know about all maternal deaths, and potentially the DPH or the Board of Registration Medicine wants to know about them, but in terms of actually calling it an SRE, if we're going to keep this term "preventable" in our definition, I think

1 we have to be cognizant of that as we go
2 through defining these various categories.

4 then Kathryn.

6100 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
MEMBER MORLEY: I agree with Mike as they're walking out of the hospital, run over by a car. But anybody that dies within a reasonable time period, or some other criteria, not getting into the reasons. And I think we were talking yesterday about potentially preventable, so I would not want to see an institution get into an internal discussion about whether we have to report to somebody because it's potentially, or not potentially, and argue that point. Just report them all. We sort them out in the end.

In terms of a subcategory that's 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 15 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.

21 for clarification just on the consumer end.
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 high3 risk category?

4

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.

MEMBER MORLEY: It would be high-

1 MEMBER TANGALOS: Well, but that's the point.
2 The point is -

4

7 And how would you measure it?

9 was next, then Michael.
CO-CHAIR TYLER: Right.
MEMBER TANGALOS: I mean was my point, too, is that I thought healthcare facilities should be removed, because if we begin to think about the continuum of care, then a home delivery would be included here, too. into exactly what $I$ thought was going to be the fun part of today, which is to expand the locus of care. I think that's an enormously relevant question, and it gives us -- I would asking what I've been struggling with. Okay,

CO-CHAIR TYLER: Should it apply.
MEMBER TANGALOS: Should it apply.

CO-CHAIR TYLER: I think Kathryn

MEMBER McDONAGH: Actually, that

MEMBER VICTOROFF: But now we're defer it for now, but it's a perfect model for

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

17 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.

DR. ANGOOD: I think that's a good 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.

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.

CO-CHAIR TYLER: Leah.
MEMBER BINDER: I'm sorry.
Christine, can -- I'm sorry, what's your -
MEMBER GOESCHEL: Chris.
MEMBER BINDER: Oh, you are Chris.
Okay. Can you just explain that? I was confused by what you were talking about.

MEMBER GOESCHEL: Okay. So, this 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.

21 hospital. We try to attribute it back to the
CO-CHAIR TYLER: Okay. That clarifies. Stan.

MEMBER RILEY: I was just going to say as a part of that, what we usually do is we usually run down the original hospital. I don't know if John and Diane do that, but we try not to attribute it to the second first one for these events.

MEMBER MORLEY: For HAIs, that's
clearly what we attempt to do. It's not always easy, but that's what we attempt to do.

MEMBER BRENNAN: Pennsylvania does
that in the Health Care Cost Containment Council's reporting. It's not a perfect system, but mostly it gets it right.

CO-CHAIR TYLER: Okay. Great. Any other discussion on this? Okay. We'll move on to the next one, 4D. "Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility." Stan, what have you got?

MEMBER RILEY: I guess the hypoglycemia part, particularly the definition part, where you have a blood sugar of less than 60, if you're a pediatric hospital, for instance, lots of children have much lower blood sugars than that, so one of the real problems is setting the limit at 60 doesn't work for all institutions. And for some, it's

1 just -- it seems sort of crazy, particularly
2 for children's hospitals.

7 the children's hospital community, NACHRI, or
8 another group to give us official kind of
9 feedback on that specific issue.
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? 21 that the only ones -- I'd be curious to know

CO-CHAIR TYLER: Okay. Any other concerns, considerations on this one?

CO-CHAIR MEYER: This is Gregg. It just strikes me that we ought to reach out to

MEMBER MORLEY: I'm not sure that concern is the right word, but $I$ just think 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 -

7 atresia that was not diagnosed.

8
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.

MEMBER RADFORD: Again, for my edification, is that something that NQF does again track, which states do have it as law, which don't? Do you -

DR. BURSTIN: No, we don't, but I'm not sure who does. These are the kind of things I think are kind of holes out there that I think we need to better understand.

MEMBER BINDER: Leapfrog -- there is an NQF endorsed measure which Leapfrog uses on the survey, so we have data on which hospitals are using that.

DR. BURSTIN: Do you also have data about state laws, which state by law?

MEMBER BINDER: No, we don't.
DR. BURSTIN: Okay.
MEMBER BINDER: We just track it by hospital.

1

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

21 of us would have suspected. It was a very
DR. ANGOOD: This is one of those lot of debate, and a lot of discussion. I think removing it would really generate a much more hostile environment, but, you know -

DR. BURSTIN: I wasn't making -
DR. ANGOOD: No, no. No, I know
you weren't.
DR. BURSTIN: I just think it's
important to understand the context that the evidence base is not as firm as I think many surprising evidence report, if you haven't

1 seen it. You kind of leave, and you go
2 really?

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

DR. ANGOOD: Yes, I know.
CO-CHAIR MEYER: This is Gregg. I think this is a -- this being on the list, I probably important failures when they occur.

CO-CHAIR TYLER: Doron had something, and then Leah.

MEMBER DORON SCHNEIDER: I actually
had a comment about 4D, if we can come back, just one comment I'd like to make about that, after this discussion.

CO-CHAIR TYLER: Leah, you're on 4E. Right?

MEMBER BINDER: Pardon me?
CO-CHAIR TYLER: You're on the

1 current one. Right?

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.

MEMBER BINDER: Yes. Just to make
-- I think we should make the distinction, I think what Helen was referring to was the

DR. BURSTIN: The problem is at times you can't tell, necessarily, by clinical exam is what the Task Force really pointed out. So, you may still miss people. You may not be screening people for whom there's not, necessarily -- again, I'm not an internist, that is not necessarily clear evidence that they are hyperbilirubinemiac, yellow, whatever the case may be. So, it's a related issue, but you're right, this is a stronger point. CO-CHAIR TYLER: Okay. Anything

1 else on this rule? Okay. Then we can go back
2 to hypoglycemia.

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

MEMBER DORON SCHNEIDER: Just a breaking that out, and I just point that out.

MEMBER LAU: This is Helen. I concur with that point.

DR. BURSTIN: And in terms of expanding the SRE's, it's exactly that kind of thing that we'd want to get a sense. I mean, 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.

6 Morley 80. I've been keeping track.

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
(Music in background.)

1

2 accompaniment.

4 are on the phone -

7 the phone has music when they put us on hold,
8 I think.

11 to be on any more. Okay.

21 and Four. Based on the fact that almost
CO-CHAIR TYLER: Musical

DR. ANGOOD: Yes, those of you who

MEMBER LAU: What's that?
CO-CHAIR TYLER: Yes, someone on

MEMBER LAU: Oh, okay.
CO-CHAIR TYLER: It doesn't appear

MEMBER RYDRYCH: It kinds of get at the present on admission issue, that if it isn't actually documented, you can't, necessarily, say whether it was recognized on admission, so that's a change we made. But the larger one, which people may or may not agree with, and it had upsides and downsides, was to expand it to include unstageable pressure ulcers, in addition to Stage Three 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

9

11 havoc in the regard of whose documentation we

21 documentation present on admission, I think is
22 the way to go.

1

2 this one? Helen.

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

CO-CHAIR TYLER: Anything else on

DR. BURSTIN: Just point out that

1 for edification on the consumer end. Somebody
2 give me a really quick thumbnail, why would a
3 pressure ulcer be unstageable?

4
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.

21 preventable, and that's helped us tremendously
MEMBER RYDRYCH: I'm not a wound

CO-CHAIR TYLER: Cynthia had something, then Michael.

MEMBER HOEN: Yes, I would have to get back to the group with specifics, but in New Jersey, we have changed our classification of pressure ulcers to recognize things like multi-system organ failure as taking pressure ulcers outside of reportable. And I think there are some other clinical criteria which have been applied, which have been demonstrated to suggest that those are not with respect to focusing in on events which we

1 can prevent, versus those which we are not
2 able to do anything about.

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

21 question, the near death, I'm not sure where we came down on that is that they're still reportable, but that we did get a lot of pushback from people saying if someone is developing a sore in the last days of life because their system is shutting down, that's a different situation than other pressure ulcers.

MEMBER TANGALOS: Yes. I think this is where you're going to have a technical panel help you with this. As we expand into this universe, again, I brought up the hospice the right answers are.

1

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.

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

21 with these ulcers right now. It's a free
MEMBER LAU: This is Helen. I DR. ANGOOD: This is Peter. This unpreventable, or actually could have been prevented.

MEMBER TANGALOS: Again, I think we have to be really careful, because there is a trend with pressure ulcers to throw in the towel, and make the claim that the patient is terminal, and then they get put on hospice. So, there's an untoward action that goes on pass.

2 to get in for a while, and then Doron.

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

CO-CHAIR TYLER: Michael has wanted

MEMBER VICTOROFF: You know, this is just put a big asterisk in the discussion of this thing saying that, you know, to be continued, because I don't think I'll be happy -- as long as the word "facility", you know, this is about healthcare facility. I'm not quite clear I understand for this purpose what the definition is. And when you admit a terminal person who broke their hip, but now 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?

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.

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.

21 see -- I mean, they come in with pressure
MEMBER DORON SCHNEIDER: I'd want

MEMBER TANGALOS: Twenty years ago
I would never see a home patient for any reason have pressure ulcers, but we take care of home patients now with greater and greater frailty, and it is not -- it's just a shock to ulcers, and you just never used to see that.

1
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.
DR. BURSTIN: Again, the TAPs we're


$$
1
$$

Again, I think this one may need to be pretty radically changed in terms of the staging and things like that, to some of the newer ways of thinking about partial versus full thickness, and things like that.
CO-CHAIR TYLER: All right. We'll
move on to 4G. "Patient death or serious disability due to spinal manipulative therapy." Anything on this? Diane.

MEMBER RYDRYCH: Just a comment, that I've always found this one to be kind of odd, because -- not because we've never had 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, as opposed to any other death or serious disability that happens due to the therapeutic process in a hospital.

CO-CHAIR TYLER: Anyone else on this? Mike.

MEMBER VICTOROFF: Well, you raised a question that I've been real nervous about, because so far $I$ haven't found any category of these things that $I$ really felt like dropping. And we're sensitive to the political potential ramifications of our deciding oh, well, we changed our mind, that's not so serious any 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?

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. 21 we're not running the risk of taking it off,

DR. ANGOOD: Well, it's like a lot of things, you know, once you create something, it's always hard to get rid of it. And I think what we need to do on our side is do a little bit more homework on the genesis of why this showed up on the list to make sure 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.

4 the list are open for addition, deletion,
5 modification, and it's just a bigger step to
6 remove, as opposed to add.

8 John.

21 I mean, I think there are some other dynamics
CO-CHAIR TYLER: Chris, and then

MEMBER GOESCHEL: Quick point. I would be curious as to the background, having lived through spinal manipulative therapy in an osteopathic facility where there were serious untoward effects, and it was a clinician, I mean, different ways to deal with that. I think understanding where it came from, and if could go away would be interesting, need to raise that, and I'm not a television person, but the new thing about getting your massage and becoming paralyzed in the process, so whether people would confuse. 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
5 Helen.

21 one. But, also, I don't think there should be
CO-CHAIR TYLER: John, and then

MEMBER MORLEY: I agree with
Diane's comments, and Mike's comments both.
I would just say that this is an example, in my mind, of one of those things that is
already on the list relative to outside the hospital environment. The same with 4H, for the most part. 4 G and 4 H these days frequently, if they're occurring, are outside the hospital environment. Maybe they'll end up being moved over to another list that says outside hospitals.

DR. BURSTIN: And I just want to make a point. It actually doesn't say in a facility, which is one important consideration, and neither does the second 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 perception of whatever the politics may be.

CO-CHAIR TYLER: Okay. John, again.

MEMBER MORLEY: One thing that just strikes me just now is that, as we look at many of the other things on the list, those are things that I have major interest in understanding how those things are happening, and leading to change. Getting this report is one that, towards the point Mike made about an agenda that somebody may or may not have, I'm not sure what I would do at the end of the year with this information.

1

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,

Trying to prevent this. Well, how pracice? ong sone a direct impact on the patient.

DR. BURSTIN: That raises an 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.
CO-CHAIR TYLER: Okay. Well, we'll

11 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.

21 mentioned -- this is Helen. Someone mentioned
Next, 4H. "Artificial insemination with the wrong donor sperm, or wrong egg." We already had a comment on this. Anybody else have any others? Okay. Nothing on -- anybody on the phone? You guys still there?

MEMBER LAU: Yes. Someone early on this might be potential moved to

1 another list, not in a hospital setting. I
2 tend to agree with that.
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.

11 Now we're in 5A. "Patient death or serious
12 disability associated with an electrical shock
CO-CHAIR TYLER: Okay. All right. while being cared for in a healthcare facility." Let's see, the language. "Excludes events involving planned treatment, such as electric counter shock, electrocardio version." Okay. Doron.

MEMBER DORON SCHNEIDER: I'd just throw into deliberation, should it be patient or staff?

CO-CHAIR MEYER: This is Gregg.
That was the addition that I would make, as

1 well.

21 that exclusion in front of me here, but I
22
CO-CHAIR TYLER: Okay.
MEMBER RYDRYCH: I'm wondering, why do we exclude electroconvulsive therapy? I mean, certainly -

CO-CHAIR MEYER: It's not electroconvulsive therapy that's being excluded. It's defibrillation, and cardioversion that are for restarting the heart. So, death during ECT would be -during electroconvulsive therapy for depression would be reportable.

CO-CHAIR TYLER: Actually, Gregg,
in the implementation guidance it does say, "This event is not included to capture patient death or disability associated with emergency defibrillation, ventricular fibrillation, or electroconvulsive therapies." So, Diane is right.

CO-CHAIR MEYER: Well, I don't have would say we should revisit the ECT one.

1

2

7 agree.

21 any reason -- I'm not a physician or
MEMBER RYDRYCH: Yes. I mean, certainly, death or serious disability during ECT was not the intent of that therapy.

CO-CHAIR MEYER: Yes. I think that's very different than the others.

MEMBER LAU: This is Helen. I

DR. ANGOOD: Although, I think the original intent of this was -- again, this is environmental issues. You shouldn't get shocked from some environmental exposed wiring, or faulty equipment with wiring, et cetera, as opposed to bad outcomes from medical treatment, which is what ECT is, or cardioversion, et cetera. And it's a differentiation here, I think we need to be cognizant of.

CO-CHAIR TYLER: Okay. Philip, then Michael.

MEMBER PHILIP SCHNEIDER: Is there 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.

21 ones, do have ASA limitations, so that a low-
MEMBER RADFORD: Again, I think it gets to the intent of this -- I'm a cardiologist, so I'm chiming in here. I mean, deaths associated with medical care. It's kind of like a death after surgery. You know, some people are ASA 5, and stuff happens.

MEMBER PHILIP SCHNEIDER: That could be said of medication therapies, too. And we actually did -- on some of the other 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

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.

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

21 safety hazard thing, no one should get

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

MEMBER MORLEY: The patients that undergo not ECT, but cardioversion that have an adverse outcome like death, the ones that would interest me, that would be excluded, I think, if we were to eliminate associated with that, are the ones with an anesthesia issue, an airway issue, an overdose of a drug, or those types of things that may not have been recognized as an overdose of a drug, may not 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
5 think it's a different category

21 sometimes they do. So, I think it could end
MEMBER RADFORD: I concur. I just

CO-CHAIR TYLER: Okay. Philip.
MEMBER PHILIP SCHNEIDER: Yes, I think I would agree with that. I think it's kind of like a medication error. It's a treatment that results in a preventable injury, so environmental hazards versus treatment hazards -- I think maybe this is a splitter category, like Michael suggested.

DR. GANDHI: This is Tejal from the phone. I agree, as well. I think that sounds much more like a care management type of issue, as opposed to environmental. And then you can broaden it. There's a whole lot of other categories of treatments that we give, that you don't expect someone to die from, but up opening a lot of other options, but I think

1 it should be under care management, as opposed
2 to environmental.

6 move this to care management. Leave it in
7 tact, but potentially just move it.
MEMBER LAU: This is Helen on the phone. I agree.

CO-CHAIR TYLER: So, potentially

CO-CHAIR MEYER: This is Gregg. I agree, as well.

MEMBER BRENNAN: Me, too.
CO-CHAIR TYLER: Okay.
MEMBER LAU: This is Helen on the phone. If we move it to care management, I think someone suggested earlier, on patient and staff, $I$ think we need to remove the staff.

CO-CHAIR TYLER: Remove the what?
MEMBER LAU: Someone suggested
earlier on patient or staff.
CO-CHAIR TYLER: Okay.
MEMBER LAU: So, we need to remove the staff, focus on patients.

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 4 in environmental, but then the one that's mor
5 of a treatment-related issue would go to care 6 management.

DR. GANDHI: But I thought we were

MEMBER LAU: Okay. Good.
MEMBER DORON SCHNEIDER: I would hope the staff wouldn't die during those treatments, as well. It should be reported. CO-CHAIR TYLER: I concur. MEMBER VICTOROFF: Okay. Just to get even more splitty, the staff is subject to characteristic misadventures during treatment, the most common of which is needle sticks. And getting zapped, I mean, I've burned myself with a Bovie too. I shouldn't say that, but there probably is another category for hazards of providers in the course of care. But, typically, we don't die, or die right away, or die from the same cause pathway as the patient does. So, for me, that suggests different

1 definitions, and different remedies, and
2 probably then different categories.

5 mean, staff certainly could incur serious
6 disability from -

9 reported.

21 instances where oxygen was hooked up to IV
MEMBER VICTOROFF: Yes, if I get
Hep C from a needle, that should be definitely

CO-CHAIR TYLER: Right.
MEMBER VICTOROFF: But then that's another category, for me.

CO-CHAIR TYLER: If we have nothing
else on this, we can move on to 5B. "Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas, or is contaminated by toxic substances." Cynthia.

MEMBER HOEN: This is one of those areas I think is too narrow. We've seen 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. CO-CHAIR TYLER: John. MEMBER MORLEY: I agree, and I would feel very strongly about that. We've certainly seen and read a number of different cases, as have been described. I think those things are preventable, very preventable. I think that we used to see a lot of different gases being hooked up, and I think the engineers were always, always, always looking for an engineering response. You know, it's not a bad idea to have a meeting in a place where you can't get a signal, that way people don't play around on their Blackberry, or whatever. It's an engineering solution to a problem. And they engineered the fact that

1 oxygen tanks can only be hooked up because of

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.
CO-CHAIR TYLER: Okay, Doron.
MEMBER DORON SCHNEIDER: So, I concur entirely. However, I think that they're two separate issues, very similar to our last discussion. This is an environment of care consideration that is structurally different than process of care, so I think that we need two categories here. You can have this in your facility if you've mislabeled your lines, if you have tubing misconnections, that's more nursing or care processes, not environmental events. 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

7 something?

8

9

MEMBER RILEY: I guess for Doron's comment, I'm not sure that I've ever seen on that was the lines mislabeled, at least not in the wall in terms of the facility. But in terms of plugging things up, just like John has said, we've seen, certainly, the oxygen plugged into the feeding -- I mean, the feeding tube plugged into the oxygen, everything, every kind of combination of tube plugged into the wrong thing that you can see, we've seen. So, I think that's a huge thing that needs to be captured somewhere. DR. ANGOOD: Yes. I'm sort of struggling with how we deal with this, because 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.

21 would actually welcome this.

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.

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
MEMBER PHILIP SCHNEIDER: Just for the sake of completeness of the record, in the oxygen line being attached to an IV line, although $I$ guess it's technically possible. Since we're going to -- this will probably be part of our permanent record, $I$ think that's a more common, and often fatal situation. DR. ANGOOD: We can put that under the air embolism one. DR. BURSTIN: Just as a process point, you should feel part of the role of the 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. 21 this one before we move on? Okay. Hearing

CO-CHAIR TYLER: Anything else on 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?

MEMBER DORON SCHNEIDER: Or staff,
5 and staff.

7 least Doron is standing up for the staff.
CO-CHAIR TYLER: Well, I'm glad at

MEMBER VICTOROFF: And, again, I -when we're thinking about criteria, I think about can we identify it as a precise -- is there an intervention? Is it important? And when I look at burn in its own little universe isolated, I say well, yes, that's important.

But there may be other injuries like burns. You shouldn't drown, you shouldn't be scalded. Do we mean scalding, including burns, or how about slips and falls, and how about lacerations?

I'm content leaving it burns, because burns are good. Let's not lose the burns, but do -- for future consideration, my 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

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

21 like the Bovie example earlier.
CO-CHAIR TYLER: Stan.
MEMBER RILEY: And, I guess that if it's one of those splitter kind of things, again.

DR. BURSTIN: We do currently have a measure in the ambulatory surgery environment on OR fires. It's actually, unfortunately, not as rare as one might hope. And I assume this would be covered under that. But, again, the blending to care management is going to get a little tough on some of these,

CO-CHAIR TYLER: Any other thoughts

1 or comments on burns?

7 all been minor, but they've been pretty
8 alarming events that galvanize a lot of
9 action.
MEMBER BRENNAN: I just wonder about whether it should be limited to death or serious disability. Reporting less serious events could have a significant impact on safety, as well. We've had burns, and they've

DR. ANGOOD: Yes, I think, P.J., this is Peter. That's a good point, and I'll put my old Joint Commission hat on. Huge 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 anyway, but we don't have to tell anybody. So, I think that's a good suggestion that the group should think about.

CO-CHAIR TYLER: Doron.
MEMBER DORON SCHNEIDER: We talked about the selective use of the words, "or risk thereof", and this would be an example of the

1 time to use it. CO-CHAIR TYLER: Diane. MEMBER RYDRYCH: Well, just an observation. I think part of what's difficult about this is that we've set the system up so that we have death or serious disability, or neither, which is sort of this no harm category. I'm not suggesting that we add some other level of harm, and then define it, but sometimes it is difficult to figure out what's that line between no harm and serious disability, and is there a need for kind of a middle ground? Because if somebody has a teeny little burn versus something that does require some treatment, there's a gray area in-between there that can be difficult to define.

CO-CHAIR TYLER: Michael.
MEMBER VICTOROFF: This is illustrative of the difference between an end point, which a burn can be, burn being the end 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. 21 Then we'll deal with homes, and hospices

So, okay. That's a long way of
saying here's where I would invoke the exception clause and say get rid of death or serious disability. And I would just say any burn to patient or staff, unintentional -- any unintentional burn that occurs in a facility. later.

1
2 issue.
burns?

Helen?

MEMBER TANGALOS: It will be a huge

MEMBER VICTOROFF: Much larger than
it is in the hospital.
MEMBER LAU: This is Helen. For
clarification, does that also include chemical

CO-CHAIR TYLER: The question is
does it also include chemical burns. Right,

MEMBER LAU: Yes.
DR. ANGOOD: This is Peter. My interpretation of it over time has been yes, it's any kind of burn. We tend to think about it, electrical, et cetera, but a burn is a burn. It shouldn't happen.

CO-CHAIR TYLER: Scalding, as well.
DR. ANGOOD: Yes, scalding would be part of that.

CO-CHAIR TYLER: Philip.
MEMBER PHILIP SCHNEIDER: This is
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?
4
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. CO-CHAIR TYLER: John.

MEMBER MORLEY: I just heard Martha make the comment about second degree burn. But $I$ agree, Peter said burn is a burn, is a burn. But is there any limitation in terms of first-degree burns, if somebody has a heating pad on the operating room table, and they're on the OR table for several hours, end up with some erythema on their skin. So, perhaps second-degree burn. I don't know.

DR. ANGOOD: Well, it's like a lot 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.

8
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,

DR. BURSTIN: I do think, though, 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

CO-CHAIR TYLER: Diane.
MEMBER RYDRYCH: Just a brief comment. I was glad that we added that risk thereof statement in one of our definitions, but just to throw another thing out there, we never really did talk about how we would 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

21 associated with a fall. She said she would
CO-CHAIR TYLER: Doron.
MEMBER DORON SCHNEIDER: I just want to capture radiation burns here, as well. CO-CHAIR TYLER: Anything else on burns before we move on? All right. Moving on, 5D, I believe. Right? "Patient death or serious disability associated with a fall while being cared for in a healthcare facility." New language, "Includes, but is not limited to fractures, head injuries, and intracranial hemorrhage." Any comments?

DR. BURSTIN: I'm being Deborah, who had to leave. She handed me her notes. This was one of them. She had concerns about this one, specifically patient death 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.

MEMBER BRENNAN: Agreed.
MEMBER LAU: Agree.
CO-CHAIR TYLER: Diane.
MEMBER RYDRYCH: I have one
question. Is that second -- is the exclusion under implementation guidance from a different 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.

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.

CO-CHAIR TYLER: Do we have implementation guidance for that that can be plugged in, or just -- no, we're just kind of missing it. Okay. Helen. Leah.

MEMBER BINDER: I would agree care management approach on this one. I mean, I really do see, even issues that are environmental, in some of the hospitals that we've seen, they've anticipated those 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
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

21 not necessarily significantly increase the
DR. BURSTIN: Just going to make categorized in this way, care management versus environmental. And why not come up with events that are logical and make sense, that's more patient-centered.

And then, lastly, might there be a
group of these sort of more environmental things - I told you I was a lumper yesterday that you might be able to lump together, to size of the list, but just thoughts.

MEMBER RYDRYCH: I would say from our perspective, the categorization doesn't really matter that much, because we focus on what works to prevent them. It's not environmental events only -- we only focus environmental solutions on those.

CO-CHAIR TYLER: Okay. I think we can move on, next one, 5E. "Patient death or serious disability associated with the use of restraints or bed rails while being cared for in a healthcare facility." Does anybody have any thoughts on this?

DR. BURSTIN: In essence, same as above. This is a care management event, not environment. So, perhaps if we just exploded that, it's okay.

CO-CHAIR TYLER: All right. John, and Stan.

MEMBER MORLEY: The question just comes to mind of the issue that CMS is tackled with physical restraints versus chemical 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.

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 -

21 use of medicine, so this -- the chemical
CO-CHAIR TYLER: Philip.
MEMBER PHILIP SCHNEIDER: Might that also fall in the category of medication errors. And we've started to tease out some things, like hypoglycemia, that relate to the restraints might fall into the category of

1 medication error.

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. 21 right track. Again, what started off in `02-

CO-CHAIR TYLER: Okay.
DR. ANGOOD: Sorry, if I could. Actually, the last five, ten minutes, for me, is helping me understand that maybe as part of what our group needs to do is to not just look at our individual events, but perhaps we need to look at the categorization of these events, as well, and make sure we're still on the 03, isn't necessarily the same as right now,

MEMBER TANGALOS: Actually, there


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

5 else? Yes, Michael.

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.

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 15 over time, but conceptually, it helps you sort 16 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.

MEMBER LAU: This is Helen on the phone. Something just came to my mind. I'm not a behavioral health or a psych area expert in that area, but $I$ would think that a situation, some of those psych patients may be locked up in certain area, that will also define as restrained in that case. So, these examples here, I don't see those really mentioned there. Should that be included?

CO-CHAIR TYLER: Okay. Making note
of that. Helen, can you repeat what you like to be included specifically, just so we'll make sure we note it.

MEMBER LAU: I would like to have some language around the behavioral health and psych patients being -- I don't know what the term is, that they are in seclusion. That might be expanding the whole restrain -

CO-CHAIR TYLER: Okay.
MEMBER LAU: I don't know.
CO-CHAIR TYLER: Okay. Well, we 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?

6 on seclusion, that got locked up.

9 included.

21 to follow that metric?

1 thing from Michael.

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.

11 having, as a trauma surgeon and background,

21 you couldn't do an adequate physical exam. I
DR. ANGOOD: Yes, we haven't actually given them a lot of thought. And looked after a lot of those criminal types, and those criminal environments. They get very poor care, and so I think it's a sub-category that we need to not overly profile, but certainly not forget.

DR. BURSTIN: Actually, the bigger issue, from training in a public hospital, the bigger issue is the care that we provided to prisoners who were chained to their beds, when mean, there are real issues there in our

1 healthcare facilities, as well.

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?

21 it the within one year, is it anybody? What's
CO-CHAIR TYLER: Well, your mention of corrections kind of gives us a nice segue to criminal events, which is the next section, phone want to weigh in? Okay. Hearing none, -

DR. BURSTIN: It seems like there may be some harmonization concerns, our whole code pink discussion yesterday. It sounds overlapping, to me.

DR. ANGOOD: Yes, that's the one -that was 3A. It was the infant discharged to the wrong person. And we had a discussion, if you might remember, is this just newborns, is competent, what's not competent, that whole

1 discussion which we had.

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.

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
CO-CHAIR TYLER: Cynthia, you may

MEMBER HOEN: Yes. When you get to police take over that, as opposed to a discharge to the wrong parent, or something that's more controllable by the hospital and its environment.

CO-CHAIR TYLER: Okay. Martha.
MEMBER RADFORD: With this one, and the next one, I wondered about staff, as well.

CO-CHAIR TYLER: Okay. Good thing to add. Okay. Michael.

MEMBER VICTOROFF: And also for 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.

20 think that that might be the model I want to
21 use for some of these other things, where the

1 left column.

6 don't.

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

21 the question.
(Off mic comment.)
CO-CHAIR TYLER: P.J., do you have
a comment on the phone?
MEMBER BRENNAN: No, I'm sorry, I

CO-CHAIR TYLER: Okay. I just want category? Chris.

MEMBER GOESCHEL: I just have one question, and that is, if we're taking this from patients to providers, is there any room in here for visitors? I mean, those things happen, and we're getting -- we're talking about criminal events. And there have been times when our providers have allegedly assaulted families or visitors. I just raise

CO-CHAIR TYLER: Doron.

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.

9 favorite term, where you can just simplify

21 I mean, they're all undesirable events, but is
MEMBER DORON SCHNEIDER: Just as a it applies across all.

DR. ANGOOD: And this may be one of those lumping categories, to use Helen's that no criminal events should occur, period. And in our definition footnote, dot, dot, dot, dot, dot. And that allows you flexibility in the individual states, et cetera.

CO-CHAIR TYLER: I certainly would think that visitors should have an expectation of safety when they come. Pretty basic to me.

MEMBER PHILIP SCHNEIDER: Just a question of whether the NQF focuses on care provided to patients or the running of an organization, as we continue to broaden these. 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.

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.

21 was well, look, we get one or two of these

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.

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. CO-CHAIR TYLER: Just to be clear,

MEMBER VICTOROFF: Well -- so, I -this is almost a time for an expert panel for this one, because I'll tell you that it's one of the longer and more tedious issues that we 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.

11 of the hospitals, an assault, to me, as a CO-CHAIR TYLER: Cynthia.

MEMBER HOEN: From the standpoint lawyer, and when we report this is when the patient or somebody else alleges that there was an assault, or a battery. It's not the in-office, allegedly improper touching by a physician with a patient, where the patient could then go complain to the Board of Medical Examiners. This is where it rises to a level where I believe under the law, I'm required to report it to the police. And that's when the patient says I've been assaulted. I've been 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 14 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
22

And, as we all know, there's a
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
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. 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.

21 celebrated case going on in Minnesota right
CO-CHAIR TYLER: Okay. If we have
(Off mic comment.)
CO-CHAIR TYLER: Oh, we do have one, one more, so close, so close. All right. We're not done. One more, 6D. "Death or significant injury of a patient or staff member resulting from a physical assault, i.e., battery that occurs within or on the grounds of a healthcare facility." Michael, then Diane.

MEMBER VICTOROFF: And, again, here, for me, the argument is, do we want to broaden it to include any, and are we able to define it, if we broaden it to include any?

MEMBER TANGALOS: Well, we have a 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.

CO-CHAIR TYLER: Diane.
MEMBER RYDRYCH: Just two short observations. Just, one, this is the only event where we talk about significant injury, rather than disability. So, for consistency's sake, we might want to deal with that. The other issue is, we have, in the past, had physical assault events that involved only staff members, staff members assaulting each other, so we probably want to be clear, if there's no patient involvement at all, whether that -- whether this category was intended to capture that type of event.

CO-CHAIR TYLER: Anything else on

1 this? Helen, you had something.

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. DR. BURSTIN: I just want to
follow-up on Diane's point about significant injury. I do think we need to go back and

CO-CHAIR TYLER: Okay. Anybody on the phone have anything on this?

CO-CHAIR MEYER: This is Gregg.
Just responding to, I think it was Diane who made the earlier comment, my interpretation of this is that staff-on-staff violence would be included here. And I'm not sure if -- we should be hearing from the folks in the states if that's their interpretation, as well.

MEMBER RYDRYCH: I think that was 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

11 huge issue, too, mostly because everybody
CO-CHAIR TYLER: Stan.
MEMBER RILEY: I think, for us, that we would agree that staff-on-staff is a deserves to have a safe place to have treatment. So, if that environment is there, it frightens everybody.

DR. ANGOOD: Sorry. While you were finishing your comment, Stan, I was just reminding ourselves that before we take our break, we should ask if there are any members of the public on the phones, so, operator, if you could please check. And then if there is, do any of those members of the public on the phone have questions or comments around what

1 has been discussed so far this morning.

9 take a break, stretch your legs? Okay, see 10 you back then.

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.

6 are you going to do the TAPs first?

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.

21 just kind of musing that well, here we are at DR. ANGOOD: Thanks so much. And Now, in terms of my comments, I was 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.

21 developing and reviewing the existing current

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.

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
We will, as we've said, solicit wanted to further clarify that for you.

DR. BURSTIN: A point of
clarification. The real distinction is the fact that the actual steward of the Safe Practices and the SREs is NQF.

DR. ANGOOD: Yes.
DR. BURSTIN: So, we are
responsible for the content and the maintenance, unlike the measures, where an external steward is responsible. So, we 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.

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,

21 these areas. And we, initially, worked towards 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.
And then, depending on how this
deliberation goes will drive the Technical Advisory Panels that we'll put into place and get the technical experts on those TAPs to help us take our new definition of the SREs, and to sort of begin generating some of the ideas around what are the appropriate SREs for those different environment clusters. Okay? Clear so far?

The use of the TAPs are expert input, but it's still the Steering Committee that makes the choices in the end, based upon 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?

12

13

14

DR. BURSTIN: Good. It is logical,
and I figured you might question home health.
So, there you go.
DR. ANGOOD: Yes, so here's our
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.

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.

MEMBER TANGALOS: Well, there's nothing wrong with the items that are there, 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
nursing homes.
MEMBER TANGALOS: Well, we don't
call them that any more.
DR. BURSTIN: I'm just saying, but
CMS list -- that's where that comes from.
MEMBER TANGALOS: But if that's what it was, it -

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.

11 think about what the logical groupings of
MEMBER TANGALOS: Skilled nursing

DR. BURSTIN: And just to be clear,
the only intention of the reorg is to try to experts might be who could think through these issues. That's all. You guys will have a chance to do further work on any of these. It's just a question of who are the logical people who would logically come together? So, that's why I think a lot of that last group, we'd want to make sure we've got nursing, geriatrics, rehab, those kind of folks. For the ambulatory care, you want to make sure you bring the voice of primary care, and others. So, that was the logic, but I could certainly

1 -- the home health was the one I thought might
2 be questionable.

4

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 overlapping skill set to those things. However, very few of them monkey around with dialysis units, and the nature of the way dialysis is run, organized, paid for, staffed, and administered is a different beast from those others. So, I have to just sort of question whether the TAP would feel confident -- whether they would think their own skills would need to be augmented. And my answer, if I were on that committee, would be yes. All 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.

9 concur.

MEMBER LAU: This is Helen. I

DR. ANGOOD: Okay, thanks. And just in your pre-meeting packet, we did you that listing of the so-called 10 environments. But that was just a starting point.

MEMBER RADFORD: It's on page 87.
DR. ANGOOD: Page 87 of the packet.
Thank you, Martha. If you, as a group, want to make up three new different ones and cluster them, so be it. It'll take us a little bit longer, but we're trying to stick with ambulatory environments, the inpatient setting, and then sort of that intermediate zone in-between the ambulatory and the

1 hospital setting.

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.

21 discipline is more than the site-specific
DR. BURSTIN: And just one more clarification. We're talking about bringing people together in person. We've got funds to

MEMBER TANGALOS: Well, even in
long-term care, wherever that continuum is, the dialysis piece does separate out. It's just in its own world. Again, when you think about rehab, that one actually crosses all of these things, but it's not just rehab. It's speech, occupational therapy, PM\&R. And, again, you can have them in any site, but the stuff, as far as I'm concerned.

2 the 10 sites, rehab.

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

21 long-term care?
CO-CHAIR TYLER: That's not one of

DR. ANGOOD: That's a good clarification. Why did we bring that one back kind of took it back to nursing and rehab -rehabilitation centers.

MEMBER TANGALOS: But I would put the skilled nursing in with that other longterm care, because those provide -- and those patients bang around back and forth, as well. So, that's a logical connection with that group.
DR. ANGOOD: So, just SNFs and

MEMBER TANGALOS: Actually, the

1 umbrella is long-term care, and within that
2 you've got the SNFs.

4 13 sense.

22

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

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
DR. ANGOOD: Okay.
MEMBER VICTOROFF: My question I

MEMBER TANGALOS: Well, it doesn't, 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.

CO-CHAIR TYLER: Cynthia, and I
8 think, Stan, you also want to -- Cynthia 9 first.

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 opening comment, it's far from a perfect clustering. And we chose, initially, that the ambulatory surgery would be in the ambulatory setting, since there's -- obviously, many of them do occur as part of hospital settings and 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.
MEMBER RILEY: The ambulatory
8 surgery care was my question, as well.
DR. ANGOOD: Okay. Thanks.
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 the others in that first group is ambulatory surgical center, because they're paid for, administered, managed, and staffed, and operated quite a bit differently from an outpatient clinic.

1
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.

21 Rehabilitation, and Long-Term Care." And it
Again, I think you're going to get

DR. GANDHI: This is Tejal from the
phone. Do you mind reading out what's on that first group to me on the phone?

DR. ANGOOD: Sure. It's
"Ambulatory Care, and Home Health" is the main
title, and that is bracketed with [including physician offices, outpatient clinics, dialysis facilities, and hospice settings].

For completeness, the second bullet is inpatient hospital [including related inpatient services and emergency departments]. And then the third one is "Nursing, 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

5 settings.

MEMBER TANGALOS: Long-term care

DR. ANGOOD: Yes.
DR. GANDHI: So, ambulatory surgical centers is in that first bullet.

DR. ANGOOD: Yes.
DR. GANDHI: I think it's a reasonable place to put it, because some of the ambulatory clinics also are doing significant procedures, and so I think a lot of the procedural issues, even though I know that ambulatory surgical centers are different in a lot of ways, but I think a lot of the safety issues do overlap with some of the more procedural ambulatory specialties.

CO-CHAIR TYLER: Chris.
MEMBER GOESCHEL: Could I just ask just to clarify, so long-term care settings 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.

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.

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.

MEMBER RADFORD: Right.
DR. BURSTIN: So, I think it would
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
910 columns, eventually, except for you'd have
10 to get 17 inch paper. Oh, well.

21 that matters unless, for some reason, we're
CO-CHAIR TYLER: Leah, Doron, and then John.

MEMBER BINDER: By dividing these into three categories, $I$ assume it's more of a -- just for interest, as opposed to any kind of use. The reason I'm asking that is simply because it's odd to me that we're sort of dividing inpatient hospital from their outpatient clinics. So, one hospital, I guess, is in two categories. I don't think 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.

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?

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

21 really just require smaller time out, and those issues.

1

2
3

4

CO-CHAIR TYLER: John, then Eric. MEMBER MORLEY: You struck a nerve when you asked the question about which ones of those are we most interested in. We've got, in New York, a law that was passed two years ago that requires reporting for officebased surgery, so that's an area of intense interest and effort in the last two years. We've had some very interesting information. One piece of information I would like to share with the group, and that's just simply that more and more care is being rendered in that setting.

I need to say that again for my own benefit, more and more care is being, so we're seeing things like renal artery stents, and prostate surgery being done in an office setting, and more than that. So, it's an area that I think we have interest in for lots of reasons, but what caused the law to be passed was some headlines of some patients that had 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.
Dialysis facilities is an issue that keep cropping up around the country related to infection transmission. And one of the more regulated areas by CMS, but not one of the areas where we know a great deal about what happens.

Long-term care, highly regulated in
terms of the skilled nursing facilities, and so forth. I think some of those areas offer us the most opportunity for what I'll call interesting information, actionable information. Thank you.

CO-CHAIR TYLER: Eric.
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.

14

DR. BURSTIN: Just, again, point of
clarification. We're just trying to think about the logical groupings of experts.

MEMBER TANGALOS: No, but that -
DR. BURSTIN: So just think of it
from that perspective. And, again, if there are specific settings, if ambulatory surgery is such a big issue, we'll just convene an 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 just so we can capture it on, perhaps, a fresh slide, and let people see that, those five categories.

MEMBER TANGALOS: Well, ambulatory care is by itself. And I'm disappointed, but that universe may not interface too well with any of these other things. And it's home and community-based services, is what it is. And that gets the home health, that gets the rehab that can occur at home, that gets some of the 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

21 physicians offices". Right? where the expertise resides in those individual camps.
clarify, Eric, what you're suggesting, the modifying language in the parens there, that still goes with ambulatory care.

MEMBER TANGALOS: Yes.

MEMBER TANGALOS: Yes. bite it all off, or pieces of it, but that's

CO-CHAIR TYLER: And just to CO-CHAIR TYLER: That "including

2 be moved.

6 does ambulatory surgery fit?

21 different situations, and I would tend to
CO-CHAIR TYLER: So, that needs to

MEMBER TANGALOS: Yes.
CO-CHAIR TYLER: All right.
MEMBER RADFORD: And just where

MEMBER RYDRYCH: I think part of
the issue here is we're trying to put
something into list based -- groups based on settings, when really we're talking about services. Right? And services that kind of fit better together. Because, for us, we already collect data from ambulatory surgical centers, so, in effect, we're treating them the same way as we do the inpatient hospitals. And we apply the same list to them, and if a certain event happens to not occur at an ASC, then so be it. They just don't report those, but we apply the same list to them. But from a licensing perspective, they're very 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
9

CO-CHAIR TYLER: Doron.
MEMBER DORON SCHNEIDER: I would think it's about the kind of harm that we're trying to get -- find the reporting. So, it really is the services, for me. And, personally, I would think it would be more inpatient like, because of the kind of service, the intensity of the services that we're talking about, as opposed to the procedures, the smaller procedures that are going to lead to different error types in the ambulatory care.

MEMBER RYDRYCH: But I wonder then if we want to change our nomenclature so we're 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
5 service types. sense?

MEMBER RADFORD: So, it's really

DR. BURSTIN: I think what they wanted was to get us out of just thinking of all these SREs and hospitals. So, if you can accomplish that, go for it. Just give us -

MEMBER LAU: This is Helen. I just want to make a comment on ambulatory care. I think we shouldn't forget those groups that run emergency type of ambulatory care, or the clinic, you know, those people that pay some money, and then go to those emergency care settings other than a hospital. Am I making

CO-CHAIR TYLER: Emergency room
service that would not be included under inpatient hospital, is what you're saying.

MEMBER LAU: Yes.
CO-CHAIR TYLER: Because we have

1 emergency department there.

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."

9 make sure that Helen's point -- Helen, does 10 that clarify your point? Is that correctly 11 stated?

21 got that. Thank you. I think, Michael, and
MEMBER LAU: Yes. Yes.
CO-CHAIR TYLER: I just want to

MEMBER LAU: Yes, as long as that includes the group of people who go for those emergency type of care, not in a hospital type of emergency department, or emergency room, but in a separate like clinic type of location. I think there are lots of error in those areas, so I just want to make sure those areas are being captured.

CO-CHAIR TYLER: Okay. I think we then -

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 21 expand, or services, SREs really need to

MEMBER VICTOROFF: You know, I can stuff out of them. We ought to just plough on and starting getting the useful stuff. And then when we go through the process of seeing what we missed, and what we did wrong, and criticizing it, we'll, inevitably, pick up some stuff that we goofed on. DR. BURSTIN: Can I just ask maybe a question a slightly different way for the group? Going back to the question I was trying to ask John. So, what are those sites, that if you said boy, SREs really need to 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

5 offices.
6
7 thank you. You just said exactly what I was 8 going to say.

MEMBER VICTOROFF: Physician

MEMBER MORLEY: I just want to say

DR. BURSTIN: Well, tell me the answer.
(Laughter.)
MEMBER MORLEY: You know, one question for the group, asking the same issue a different way, is do you really want to start coming up with a list for all 10 of these at the same time? And I'm thinking if we picked a few and start, there'd be lessons learned from those few that you would then apply going forward. And each one would subsequently go a little bit smoother, in terms of its initiation.

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
9 P.J.

21 to apply them to those areas, and to pull
22
MEMBER BRENNAN: Helen, this is

DR. BURSTIN: Yes, go ahead.
MEMBER BRENNAN: From my perspective, representing the ID society and healthcare epidemiology, there is significant interest in the ambulatory practices, including physicians' offices, ambulatory surgical centers in terms of infection control hazards that are created in those areas. And HICPAC is going to be working on culling evidence-based guidelines, evidence-based practices from existing guidelines, and trying 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.

11 areas, particularly, the physician offices, 12 and ambulatory surgery. And then the only 13 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

DR. GANDHI: This is Tejal from the
phone. I would completely agree with those facilities, and issues there with some of the stuff that Jerry Gurwitz has done, so I think that might -- if we were limiting it to three or four, I might throw that one, as well.

CO-CHAIR TYLER: Stan.
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
6 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.

10 Martha.

CO-CHAIR TYLER: Cynthia, then

MEMBER HOEN: From a hospital
perspective, $I$ know that we feel put upon that we're more highly held to standards than the ambulatory surgery centers, the urgent care centers, and the doctor's procedural offices. So, I would put in my vote for those things, as well.

MEMBER RADFORD: I'd actually like to put a vote in for weighting on dialysis centers, because they are pretty heavily regulated, and they do have a reporting system around certain things that happen, not

1 everything. And maybe that's the next --
2 that's the wave after the next wave.

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.

21 to get us towards is to actually think of a CO-CHAIR TYLER: Eric. MEMBER TANGALOS: Even though I would separate hospice and palliative care in its own universe, I wouldn't focus there. I

MEMBER RYDRYCH: I would agree with that, and I would say I think we're biting off plenty just trying to deal with a couple of higher priority areas, and not getting into hospice and palliative.

DR. ANGOOD: So, sorry to jump in. We seem to be gravitating on office-based surgery/ambulatory surgery centers, dialysis with Martha's caveat, physician offices, and perhaps SNFs. Can we just sort of take a hand poll on that one, and then -- what I'm trying 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.

CO-CHAIR TYLER: I thought we had said long-term care settings, broadly, and SNFs would be under that. So, is that -

DR. ANGOOD: I was just reacting to somebody's comment here a few moments ago.

CO-CHAIR TYLER: Okay. I thought we were still focusing on -

MEMBER TANGALOS: I think the science and the information is going to be best in SNFs, so you can -- I don't see any problem with still labeling it the whole 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.

7 concerted effort to be neat.

8

21 occur that overlap there, everything from
MEMBER TANGALOS: Right.
(Laughter.)
CO-CHAIR TYLER: Doron.
MEMBER DORON SCHNEIDER: So, this
may take us back to the original list, but there's increasing need and use for home care. I mean, that is going to be where most of our care is going to be occurring in the future. The doctor's visits occur once a quarter, the home care, the frequency of visits are going to go up, and they're going to be a major piece of how we're going to reduce readmissions. There's many error types that 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. 21 make sure we have the list. So, it's

MEMBER VICTOROFF: I hate to do this. Could I propose we vote individually and count the votes for each one individually?

DR. ANGOOD: That's fine, too.
MEMBER VICTOROFF: Because that would teach me something. DR. BURSTIN: Let's look at this, 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

6 surgery. Those were surgical, but more
7 outpatient oriented. Infusion centers was
8 listed. I'm not sure where that would live.
DR. ANGOOD: Office-based surgery.
DR. BURSTIN: And office-based

DR. ANGOOD: That was a secondary
list.
CO-CHAIR TYLER: That would be number two.

DR. BURSTIN: That goes on
secondary? Okay.
DR. ANGOOD: Yes.
MEMBER VICTOROFF: Phase two.
DR. BURSTIN: Phase two. And then
long-term care, and home health are the ones that are currently on the table. Yes?

DR. ANGOOD: Dialysis.
DR. BURSTIN: We moved dialysis, got moved to - they already moved it. Yes.

1 I thought you guys already moved dialysis -

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 -

MEMBER RADFORD: So, we're voting on -- this is the first tier. Is that right? DR. ANGOOD: First tier, yes. And then after we finish this, we'll try to get to a second tier.

MEMBER RILEY: And how many votes do we get?
(Laughter.)
DR. ANGOOD: Each item, one time. Okay?

DR. BURSTIN: But I think it's okay 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.

DR. ANGOOD: So, office-based
surgery/ambulatory surgery centers. Who sees that as an important one?
(Vote taken.)
DR. ANGOOD: And on the phone?
MEMBER LAU: Yes, this is Helen.
DR. ANGOOD: Okay. That's a strong yes.

DR. GANDHI: Yes from Tejal.
DR. ANGOOD: Okay. Thank you. And then we had physician office -

MEMBER BRENNAN: Yes from P.J.
DR. ANGOOD: Thanks, P.J.
Physician offices, and ambulatory care. We've got a strong positive in the room. On the

2
phone?
dialysis on this primary list? Less popular. Okay. Anybody on the phone want it? Hearing none. Martha, you're a strong influence. I'm just teasing.

All right. That takes us to a fourth item, which would be long-term care with focus on the SNFs. Strong positive for that in the room. And on the phone?

MEMBER LAU: Yes from Helen. DR. GANDHI: Yes from Tejal. MEMBER BRENNAN: Yes from P.J. DR. ANGOOD: Okay. Thanks. So, that gives us three groups to get started on. 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.
Where -- I mean, it seemed like there was a lot of consensus around home-based care, but that's not on your list at all now. There seemed to be much consensus on that, I think. DR. ANGOOD: I was just sort of I know there was a lot of discussion.

MEMBER TANGALOS: Well, that's a -
I mean, it's a huge area, but, again, if you're going to do some data mining and look at the science, there's nothing there.

MEMBER RYDRYCH: I don't think we're ready to go there, yet.

MEMBER TANGALOS: No.
CO-CHAIR TYLER: So that would be
parking lot, along with -
DR. ANGOOD: Secondary, yes.
Sorry. On the phone, there's lots of 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
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
MEMBER HOEN: Yes. Just with anything that was recommended, because I think that's going to be a very -- point of contention and discussion.

DR. ANGOOD: Yes. My sense would be a galvanizing statement from NQF, but not easily implementable in terms of actually getting stuff.

MEMBER DORON SCHNEIDER: Can you
please clarify what the second tier would 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?

21 change for improving quality. to be careful about not, necessarily, prioritizing, per se. You know, if we think about those -- we started with a list of 10 from CMS as environments of care. We've gone around, we've come up with three areas that a combination of concern, evidence, and potential to try and create some important

DR. ANGOOD: Well, I think we have people think are good areas to get started for

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.
mean, I'm struck by our questions earlier today to say how many states collect a report?

I mean, even to begin to do some of the footwork on home health, what kind of data is collected? The regulations are very different state-to-state. I'm just wondering if it could be on the list with the understanding that the work that will be done right now is going to be background work to help us get what we need to determine what SREs would like that.

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.
And just a question. So, inpatient hospital is kind of the status quo group that we already have. Is there a TAP that's getting together to talk about the expansion or modifications to the existing list for hospitals, separate from these other groups then?

DR. ANGOOD: You did that yesterday and today.

MEMBER RYDRYCH: Right. But wasn't there also going to be -- because we've sort of just raised some of the issues, but we haven't really fleshed any of them out.

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.
8
9
DR. ANGOOD: Right. But that will

DR. BURSTIN: Does the group feel like a hospital TAP would be helpful?

MEMBER RYDRYCH: I just wasn't sure if there was additional work beyond that kind of initial brainstorming that we had done that needed to happen with inpatient hospital, as well.

DR. BURSTIN: There is, and the question is, are you comfortable that you're the group that will do that?

CO-CHAIR TYLER: And, Doron, I just wanted to close the circle with you, a little discussion about what would happen with that secondary tier, putting home health on. Is that satisfactory to you, or you think -

2 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

21 historically done an every three-year
MEMBER DORON SCHNEIDER: In 2002, , being committed there, and it's just an opportunity.

DR. ANGOOD: I think the short answer is, it's not been determined, because we wanted to see how the deliberations of this group started, and it's up to this group to sort of drive that future direction. We have 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.

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. 21 home health, and home and community-based I'd like to offer that if we're going to do a third one, it should be home health, for the very reasons that Doron has outlined. It'll be a challenge, both of them would be challenges.

CO-CHAIR TYLER: I want to offer up something, and also maybe get some clarification/feedback. Because we use them as though they're interchangeable, the terms services, and they're not at all, not the way CO-CHAIR TYLER: Martha.

MEMBER RADFORD: I'd like to -- we

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 community-based services?

1

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
9 is there, either, but it might be a better 10 challenge, and it might be more worthwhile 11 than the ambulatory care sites.

MEMBER TANGALOS: Well, Sally, the

In fact, I'm not convinced the data

DR. GANDHI: This is Tejal from the phone. I just would put in a plug for the ambulatory practice sites. I think the vast majority of care is given in those sites. I think we have pretty good data, compared to some of the other sites, in terms of what the issues are. So, I just think that has to be one of the things that was on this list in terms of -- I mean, we know there's lots of serious issues going on in those practices, 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. 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.

21 especially after Doron's comments. Because

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.

11 you, and I also agree with Doron, but I'm kind 12 of on Chris' page. We've just started

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,

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.
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.

19 end. Sorry

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

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.

The other thing is that you may have some of the existing SREs that you'd still feel comfortable that they be applicable to a dialysis facility, even if you didn't, necessarily, bring in dialysis facilityspecific events. So, I think there -- you can 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.

7 Michael.

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.

CO-CHAIR TYLER: Martha, then

MEMBER RADFORD: I was just going MEMBER VICTOROFF: Okay. And talking to you from the depths of the grid, I want to reassure people who are nervous about the potential for useful work in the office environment, in this way, using the three Is I've been quoting over and over again, I believe that I can identify the top five or ten injuries and events, and hazardous procedures that occur in the office environment, in terms of importance, using our 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.

9 based procedures or offices?

21 aware that not every state works the same way,
22
MEMBER VICTOROFF: No, unfortunately. And about 54 to 55 percent are cognitive errors, as opposed to procedural errors, and we can debate those. And then the third I is intervention. I mean, is there evidence that we know what to do, and the I could tell you five or six things that I think have at least tentative support in evidence as being effective ways to remediate, mitigate, or prevent those kinds of office-based errors. So, I think there is science. Although, I'm 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.

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

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 goofing up.

DR. GANDHI: This is Tejal on the phone. I completely agree with that.

MEMBER RILEY: I was just going to say, even though CRICO and RMF have data, they of what's actually going on there.

2 It's not hard.

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.
MEMBER VICTOROFF: We'll show you.

CO-CHAIR TYLER: We may have

DR. ANGOOD: Are we all on the same
page up here, Helen? Helen and I have good strong opinions, but not always the same.

DR. BURSTIN: Yes, not always the same ones. There you go. Although, you did teach me that I could get monovision for my near -- it is quite spectacular, so there you go. Very helpful piece of information this week.

> DR. ANGOOD: I'm mollified that you are teachable.

DR. BURSTIN: I am teachable.
There you go. I just find myself thinking that it's probably time to think through some next steps. And I think we've sort of reached

1 a point where maybe that would be useful. And
2 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.

6 synopse, do this and -

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

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 or five that fit, we'll make it work.

DR. ANGOOD: Yes, I tend to agree with what Helen just described. You know, we could spend the rest of the afternoon teasing out the environments, who's got which priorities, and why nots, and all that sort of stuff. But I think, as outlined, that was pretty close to where I was thinking, as well. The group has done terrific work in this day and a half. It's given us good, I think, focus, more focus than I had anticipated. So, setting up the call, whether it's a matrix or a grid, or whatever, it suits my bias, as

1 well.

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
We'll get that circulating
electronically for your guys' inputs and the ideas firmed up, I think that'll really drive us in terms of putting the expansion, or the maintenance document on the SREs together. It'll give us opportunity to set up the messaging within that document where the field will need to go to in all of this.

CO-CHAIR TYLER: I think Leah has something she wants to add.

MEMBER BINDER: It is a question, 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 -

DR. ANGOOD: It would be both. It would be both, because this group will
generate their own ideas. And we may have we're fast running out of time, but maybe we can do through it Survey Monkey, or something like that, solicit your other ideas for the existing SREs, see how that comes. But we had talked about, also, doing an open solicitation for ideas to see what comes in there.

MEMBER BINDER: Okay. If there's an open solicitation, $I$ would just request, as well, that we talked earlier about having the revised definition of SREs -

DR. ANGOOD: That would be out
there.
MEMBER BINDER: -- put out as part
of the call to get comment.
DR. ANGOOD: Yes.
MEMBER BINDER: Thanks.
CO-CHAIR TYLER: Doron.

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.

MEMBER DORON SCHNEIDER: This kind

DR. ANGOOD: Sorry, we have moved to a new platform, and we do utilize Google Docs as one of the platforms. So, I certainly 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.

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?

21 his head.

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.

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. 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

21 National Health Service, where we'll be in input as we can get. Chris?

MEMBER GOESCHEL: I have one question, and thank you for that, obviously, connected to lots of networks, both across the country as part of the HAI work that we're doing, but also internationally in terms of some work on reportable events, and the December doing some of this very same kind of

DR. ANGOOD: And that's exactly why

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.

11 are pretty good with our turnarounds. We have

20 other feedback, things we need to do better
21 for you? It looks like people are hungry, and
22 -- go on.

1
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.

14

MEMBER MORLEY: I will be talking號 so,

DR. ANGOOD: All right. I think that about wraps it up. Any other comments from folks on the phone before we close out? Hearing none, thank you folks who are on the phone for bearing with us, appreciate all your inputs, and look forward to the ongoing documents. And, as I said to everybody here, thank you so much. This has been exceptional work. This group has come together very

1 quickly, and we appreciate that. So, more to
2 follow, and safe travels home.

6 Bye.

8 off the record at 12:16 p.m.)
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22
MEMBER BRENNAN: Thank you.
MEMBER LAU: Thank you.

DR. ANGOOD: All right, everybody.
(Whereupon, the proceedings went

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