THE NATIONAL QUALITY FORUM

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MEETING OF THE HEALTHCARE ACQUIRED

CONDITIONS AND SERIOUS REPORTABLE EVENTS
IN HEALTHCARE STEERING COMMITTEE

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Thursday, November 19, 2009

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

PRESENT:

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

SALLY TYLER, MPA, CO-CHAIR

LEAH BINDER, MEMBER
PATRICK BRENNAN, MD, MEMBER (via telephone)
TEJAL GANDHI, MD, MPH (via telephone)
CHRISTINE GOESCHEL, RN, MPA, MEMBER
CYNTHIA HOEN, ESQ., MPH, FACHE, MEMBER

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

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

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

ALSO PRESENT:

EDDIE GARCIA, CMS

NOT PRESENT:

SUSAN GENTILLI, MBA, RHIA, CPHQ, MEMBER

A-G-E-N-D-A

P R O C E E D I N G S

(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 name, so that everybody on the phone hears, and then we'll go through and see who's on the phone.

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

and Helen, this is your second day with us on the phone, and I know it's kind of a challenging environment to do these meetings, especially when they're day long meetings on the phone, but we appreciate your hanging in there with us, and look forward to see you in person at the next Steering Meeting. So, 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

a very collapsed discussion on what's supposed to be part of Day 2 here regarding the Environments of Care and the Role of Technical Expert Panels, or Advisory Panels. And then we'll see how well we can get into some of these other environments. We probably won't need to spend much time at all, on the inpatient hospital setting, but certainly want to at least begin the discussion on the nursing, rehab, long-term care in the ambulatory settings, get some discussion going on those.

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 process here.

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,

Donald, I forgot to mention to the operator, we're formally open for the meeting. I forgot that part. Thank you.

So, the significant change being that the definition now says "defined as preventable, serious, unambiguous, adverse events that should not occur." Are we all comfortable with that? Leah is not comfortable, for the record. Yes? Not a problem. Michael?

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

word "never" is still appropriate. First of all, not does not differentiate these events. The word "not" does not differentiate these events as special. The fact that we say they should never occur does not mean that they, in fact, never occur, any more than when we say an airline crash is a never event.

We know it actually does occur, sometimes. It's just something that is such an awful outcome that we set a very high standard for how much we want to prevent it, which means we say never, never, never. And except that, unfortunately, it might happen. So, setting the standard at never has captured the imagination of the public. I mean, there is nothing that I can -- I've said it before yesterday. It is something that people really respond to, and understand, that the healthcare community is setting a very high standard around certain events that are so catastrophic, and so awful to families and patients that they're really going to make

sure there's zero tolerance.

"Never" is the word that has captured the imagination. "Not" does not differentiate these SREs from anything else, and it shies away from a high standard that we had already set. So, in doing so, it will, itself, be newsworthy to no longer really put that word "never" on the table.

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

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

I think the downside of the confusion of "never" makes me think that abandoning it is the right thing to do at this point in time. Yet, the overall importance of this, and the public imagination is that they're going to see this information, and that this body is recommending that it be publicly reported by states. And, to me, there is no stronger statement of urgency and importance than 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,

the big drama is that it's now going to be reportable. I think for them, of course, it's reportable. Most people can't imagine why it wouldn't be, so that's not capturing anybody's imagination, to be quite frank.

The word "never" did, and the word "never" set the kind of standard I think that we should all set as a healthcare system. I don't think it's confusing. I think it says we think these events are so bad that we're going to put the word "never" to them. And understand that mistakes happen, and maybe it isn't going to be never, just like an airline crash, just like any other catastrophic event, 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

like that, that do occur, and we know they occur. And that, in fact, reporting near misses can prevent the serious catastrophe. So, I think that it's accurate, and there is something to be said for accuracy, to say these things, to use "not" instead of "never".

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 in a different class of events in some ways, than some of the others.

In my state, when we talk about these, we don't usually use the term "never events." For some, we do, because wrong side surgery shouldn't ever happen, and some of these other events are definitely in that category. But we felt uncomfortable saying even one of these events is too many when it came to things like pressure ulcers, so that was just kind of what was behind some of the discussion, and the decision to move it to "not" yesterday. I don't know if "not" is the 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

comment.

DR. ANGOOD: Thanks, Tejal. John, and then Leah.

MEMBER MORLEY: I certainly do appreciate the emotion attached to that "never" term, but that emotion is something that can be used in a positive mechanism for drawing additional resources, additional attention, additional focus, all sorts of very 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,

or maliciousness.

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 replicated. We've never ever accused anyone of incompetence, nor has it been interpreted that way, frankly. I don't think that has ever been the consequence of the term "never", and why "never" matters.

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 never occur. We should be able to prevent that.

The word "never" does have some emotional resonance, but, frankly, we're talking about things that are emotional to people, that wrong side surgery, removing the wrong limb, I'm sorry, that's a catastrophic event. That's a very emotional event, and I think that the healthcare system by responding and saying yes, it is a catastrophic event. There is emotion attached to that. It's important to us, too. The word "never" gets to that point the way nothing else can, or maybe there's another word, but "never" has, 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

environment, as well. And what our experience is beginning to be, as this list gets propagated and understood by plaintiffs, is that this is a kind of get into jail free card for a plaintiff, that the phrase, which I object to for logical reasons, not because it doesn't emotionally emphasize how horrified we are about things, but because it emotionally trivializes how horrified we ought to be. Because I really can't come up with the alternative list of the errors that should happen, or that ought to happen in your institution at a certain rate, or that you should encourage people to commit.

So, in a way, no matter how minor an error is, it shouldn't occur. "Never" is the goal for errors, but when we get into 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 causing consternation among people who have to make logical arguments in front of juries,

that if some authoritative body published a list that simply said the following items are indefensible under any condition, which is how it's been presented, that it puts us in a very difficult position when, actually, there is a 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

probably a million dollars in attorneys fees. And we've had many others arise in those events, which should not have occurred, and it was unfortunate the expectations of the families and the patients were furthered by the "never" concept. And, thus, became very angry, and uncontrollable.

I agree that we don't want these things to happen, but some of them are not preventable, and "not", therefore, is a little bit of a softer and less accusatory term in those instances.

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 may be some things that are egregious, and should not happen, but maybe less easy to

assure that they never happen, because the care is less carefully overseen than it is in a hospital setting. So, this definition may well have made sense in a highly organized healthcare delivery setting, like a hospital, that may be less easy to conceive of in other healthcare settings.

CO-CHAIR TYLER: Eric.

MEMBER TANGALOS: I'm actually worried about the extended environment, as well, not so much -- we've already heard about the threat of the "never" piece, but on the opposite side, if we just blow it off, because "never" makes no sense, then we lost the middle ground, where we really want to do something about it. And one of the biggest abuses we have right now with pressure sores, which are bad, and should not occur in almost all situations, is you get a free pass when you convert the patient to hospice. So, you've thrown in the towel, so to speak, and I don't want to see that part happening,

either.

CO-CHAIR TYLER: Leah.

MEMBER BINDER: I can't speak to the legal ramifications, except that, as you all know, there are studies that show that if you apologize to the patient, you will reduce the rate of -- the likelihood of malpractice by whatever it is, 55 percent I think was the latest.

That's the extent of my knowledge on that, so I defer to your knowledge that there's -- that "never" is somehow triggering lawsuits. But, again, I think saying something should never occur does not prescribe that this thing -- who is at fault, or why. There can be reasons why it still does occur, or it doesn't occur, but it doesn't prescribe who's at fault. It simply says that this is the standard we've set for this particular condition that we name, and that's why it's considered an extreme case, a serious reportable event. So, "never" says

that like other things don't.

Now, having said that, I'm not - I'm very strongly, as you know, in favor of keeping "never" in there, but if the alternative that this group is going to vote on is not occur, I particularly don't like that, because that implies that there's some - - in that Venn diagram that we did, that there's some other things that maybe should occur. I mean, the opposite is true, or something. I think it would be better just to 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

other side, I'm kind of going back and forth on this in my own mind. I'm concerned about hemming ourselves in for the alternate care settings, but I also -- I'd be interested in the opinions of the rest of the group as to whether or not it's important to either retain, or recommit ourselves to a sense of urgency when it comes to the safety agenda.

It's my feeling that it's not as 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

shouldn't allow to happen in the healthcare system. And that really raised a lot of eyebrows, and that kind of sound byte really was powerful in our discussion. And I'm resonant to the idea of maintaining a sense of urgency, or recommitting. Maybe that's the way I'd say it. And I'd be interested in whether other people feel that that's true, or not. Maybe I'm being too pessimistic.

CO-CHAIR TYLER: Stan, I think was 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

as saying "never".

DR. ANGOOD: And that's probably where in the opening comments trying to weave the SREs, practices, and measures all sort of together over time, because they have their individual purposes, but we need to get them closer together to help reinforce one another along the point you were just making.

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 when this new list of SREs, along with the next version of Safe Practices comes out, I

think that there's a great opportunity for the Quality Forum to really take the bully pulpit and push very hard to say we took a fragmented approach in the past, we're trying to pull these things together to the extent they make sense to pull together, and doesn't -- a completely tight coupling. But that will be, I think, very, very powerful.

And, in the end, you know, my vision is, is that we ought to have the accountability out there with a list of serious reportable events that states are 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.

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 organization, it can't be done in a punitive environment. It needs to be done in a culture

of safety. So, I think what we're trying to balance there is, there's a natural dynamic tension, but I think we can come out with very strong statements.

MEMBER RYDRYCH: I agree on the sense of urgency. And I think I talked a little bit yesterday about the experience we've had in Minnesota, and it's challenging sometimes to balance, talking about the fact that some of these things may not be preventable, but still wanting to make sure that they're kind of held above other types of events, and taken seriously. And that can be difficult to do.

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 there's CMS, and there are all these other things. And when these measures get updated,

people notice that, but that, in and of itself, doesn't really create a sense of urgency. And I don't think the consolidation will, either, in the absence of other action. And it does feel like we need to focus on those corrective actions.

What are -- we've got 27 states that are -- that have implemented part, or all, of the NQF list, and are doing public reporting, and are collecting data. And, in many cases, they're not sharing any of that, and they're not sharing what's working in their states. And there aren't really good mechanisms for that, so there's a lot of good work that's going on in individual hospitals, and in different states, that there's not really a good mechanism to capture.

There might be people who are starting to figure out how you fix some of these things, but it's difficult to really know that. And it feels like that's the way we end up energizing this, rather than dealing

just with the measurement and the reporting side of it; although, that's important, too.

DR. GANDHI: Hi, this is Tejal on the phone. Could I jump in?

CO-CHAIR TYLER: Sure, on the phone, first.

DR. GANDHI: Okay. I just wanted to make a comment about the sense of urgency, as well. I mean, the term "never events" was around for a long time, and at least in the State of Massachusetts, the urgency, I think, didn't really happen until it became a reporting requirement.

I don't think the term "never" got people's attention, as much as the reportability piece. And, certainly, at that point, got the attention of hospitals, who then really starting putting additional efforts towards these things. So, at least in Massachusetts, and Gregg can agree or disagree, but that was, I think, the experience I've seen.

MEMBER DORON SCHNEIDER: One of the goals of the work effort is to lead to further harmonization of efforts, and I wonder if we could gain something by adding a couple of words on, which would, essentially, go something like "that should not occur, should lead to disclosure, and investigation of root cause." That's really Joint Commission language. Leapfrog has taken that on, and it really does put a stamp on it that is a little bit different than well, yes, we want you to 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"

word, but by other mechanisms to increase the urgency, and to support this issue, in general, of reporting.

Some of the things that Doron was just describing, I mentioned at our meeting a few weeks ago that even though we call this a reporting system, there's a lot more to this than reporting. I think, unfortunately, the press hooks onto that word "reporting", and there's a belief out there, maybe that's too strong a word for the press, that just reporting is going to fix the problems. And I've commented in testimony to the state legislature that if reporting were the answer that was going to fix everything, just reporting, we would have fixed things nine years ago.

It's about a lot more than that. So, any opportunity to increase urgency and provide backgrounds, and support for doing more than reporting, for PDCA, would be a major plus for this report.

CO-CHAIR TYLER: I think Leah was next, and then Michael.

MEMBER BINDER: I can only speak from my experience, but I can tell you that I have spoken to New York Times, Washington Post, CNN, I can name major broadcasts, or major newspapers about never events. This captures the imagination.

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 care system, that providers are willing to say no, we are going to go lay down the gauntlet

on certain events that should never occur.

And I want to go back for one second to my airline analogy. An airline crash is a never event. It should never happen. Does that mean that it's always preventable? No, there can be birds that fly into your plane, and you have the best pilot in the air, and he handled it, and the whole crew survived, et cetera, but it's still a never event. It's still -- and airlines still stand up for that. That's a never event. We 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 attention of the public.

CO-CHAIR TYLER: Michael, then

Helen.

MEMBER VICTOROFF: Well, I'm getting more uncomfortable the longer we discuss this. And despite my fondness for Leapfrog, and your very good contributions, I now envision dueling interviews with CNN, where members of groups like our s are going to explain in strong terms why one or the other view about this word is absolutely necessary, and critical. And that bothers me a lot.

I think the "never" word should never have been spoken. It was a mistake from the beginning. It was a rhetorical device. It's scientifically silly. It's logically impossible. And no one in the airline industry uses that word ever about anything. In fact, if there's one thing you never say, it's "never" in the safety business.

I'm particularly wanting to address this issue about urgency. If you look at global warming, or the rain forest depletion,

or any popular cause, there's a great deal of hand waving possible about urgency, and the urgency of the people in the meetings is always dramatic, but I don't really care about urgency. On the front line practicing medicine, living in a hospital, going in as a patient on a gurney, I don't care if people are urgent about problems that can't be fixed.

I think the credibility of this organization rests on being able to move from hand waving and publicity, which are very nice at Stage One. Stage Two of science, where we're able to say and, look, we have a vaccine. It's one thing to say, oh, my God, we're all going to get HIV, heavens. Okay.

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. And I think that this move -- I mean, my interview with New York Times, heaven help us, is going to say as we mature as scientists,

and strategists about remedies, we didn't find it was necessary to use that word "never" any more. We became more refined, and sophisticated. That's my current understanding.

DR. BURSTIN: I just want to make two points, one of which is that NQF has not supported the word "never event" since the origination of the Serious Reportable Events. I just want to make that clear. That's been something that has been stricken from the 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 broader definition. And that, I think, was the basis of most of our discussion yesterday.

So, that broader corridor allows us to get to that list John mentioned yesterday of those 40 things that might be really significant, but would have an incredible amount of discomfort saying "never" associated with, but some of them are equally bad. So, I think that those two things together, we would not support the term "never events", haven't in years, so others may call it that, but just to be clear, from NQF's perspective, they are serious reportable events, they are not called "never events."

And, secondly, the intention of yesterday was to create a broader corridor to allow us to bring in bad things that may not, necessarily, fit a "never" designation.

CO-CHAIR TYLER: Okay. Just -- I'm going to interject to see if you all -- if there is any -- from what we're getting. I mean, we're reinforcing positions, it sounds like, but do people feel the need to take a vote on what Doron offered, as far as adding

some modifying language? Would you offer that again, Doron, just to make your suggestion again?

MEMBER DORON SCHNEIDER: For the intent of further harmonizing, it would read defined as "preventable, serious, and unambiguous adverse events that should not occur, should lead to disclosure, and a search for root cause."

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

like the idea of making it this broad, and I'd prefer to keep the definition a little cleaner. But I would like to see in the text, or somewhere in the explanatory language, I'd like to see more about disclosure and apology, because I think that's something we certainly encourage people to do, but having that be sort of more -- getting a little more weight from NQF around these events should be disclosed to patients, and there should be an 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.

And if you start pointing at each other before you understand what really occurred, and what needs to be corrected, it's very problematic.

So, I appreciate the research out there. I've not seen a decrease in lawsuits because we apologize. We've seen a decrease nationally in lawsuits, because that's the climate, so I'm not sure you can attribute it to that. Although, I do think it's obviously -- we do need to take care of our patients, and be there for them when bad things happen.

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, or step in the management of a terrible event.

Although, we know that, at times,

it seems to be really a good idea, the problem with sticking it in here, and I don't like adding any of it. I mean, what you're saying is logical, but I think it ruins the rhetoric here. I just, for stylistic reasons, I'm going to just say I can't support adding more words now.

But, especially -- even adding to the apology thing for the serious reportable events, a different topic, the reason why we probably wouldn't like that, is because then it would single out serious reportable events as the apology things. And where we're making our great headway is in the not so serious events, where there's a potential to preempt litigation, and not even have it. Whereas, most of the serious events are still ones that are getting litigated. So, when an anesthesiologist knocks a tooth out, we have a chance to not even have litigation, if we apologize, and actually offer some money, early resolution. There are lots of things

you can do to not serious events.

So, putting apology into this document would raise a whole bunch of discussion, for me, in terms of whether the unintended consequences were as good as the intended ones. I haven't even -- I'm not even prepared to think about that yet, so I caution you to ponder it.

MEMBER RYDRYCH: I'm sorry, but if apology is effective in reducing litigation for the non-serious events, wouldn't it also be effective -- I'm borrowing Michael's -- if 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 conducted a double blind trial. But the problem is, I'm very nervous about putting in

too much sentiment with no evidence. You know, if you want to put an appendix that says gee, we should study apology, study the hell out of apology, because, look, it might be good. Oh, I'll subscribe to that. But this is too much toward the front of the document.

MEMBER RYDRYCH: I agree. I don't 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

that -- to cross-reference the serious reportable event with saying that, and by the way, there is this patient -- there is this Safe Practice related to disclosure and apology. So, I think this is a great opportunity for linkage. I agree, it's probably beyond the scope of this document, but I do think it's a good way to link the work.

MEMBER BRENNAN: Leah, would it help your concerns about "never" to include language in the text that speaks to the issue of never, rather than putting it in the definition, and explains that never is -- we believe these events should never happen, but are not always preventable, and should not be -- and to points that Michael made earlier, goes on to make points about the effect, in terms of litigation, and how they should be construed.

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

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

MEMBER GOESCHEL: My point was exactly that. I kept going back to the definition, and my immediate thoughts were scope creep. This is a definition of serious reportable event, not what we do about it, how we do what we do about it.

So, I would be highly in favor of the minimalist approach that we took yesterday. And I just wanted to go on record supporting what Michael and others have said 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

adding in the text of the report trying to capture as much of this discussion, and some of the various thoughts, particularly around "never", and what that concept means to people. Are people comfortable with that? Do we want to actually vote for that?

MEMBER BINDER: I'd like to say something.

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

others have replicated it. So, purchasers have conferences on this all the time. There's one coming up in a month that's done by a big purchaser out in Ohio.

In fact, the Purchasers Coalition in Ohio has dedicated their whole year to eliminating never events, to addressing never events in hospitals, or something. I mean, this -- so, when this comes out, you can bet 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 forward in the way that I have to, to represent my constituency, which will notice

this.

CO-CHAIR TYLER: Okay. Let's go to a vote. The vote would be to leave it as it is on the screen, what we had agreed to yesterday, but elaborate further in the text particularly around "never", and why it's not in the definition at this point. Okay. If you think that's sufficient, that's what you're voting yes for. If you think it's insufficient, then there would be some other remedy. But, do people vote -- is this what 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 events that should not occur." And then we would also in the text of the report really

flesh out a bit about why the term "never" was 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?

DR. BURSTIN: The entire document, definitions, all of it, will go actually first out for comment. The comment is going to be where I think a lot of this debate will happen, more so than the vote at the end. And I guess one question might be, is there a need to think about putting some of these definitions out for comment, even in advance of the call for SREs. We'll have to think that through.

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 definition, for those on the phone, this is the second slide that was sent out earlier today. "Current set of SREs is not intended to capture all events, but the events are of

concern to both the public and healthcare professionals and providers, clearly identifiable and measurable, thus, feasible to include in reporting, and of a nature that's such that the risk of occurrence is significantly influenced by policies and procedures of the healthcare facility."

We did not change any language in this one, so we'll presume that everybody is still comfortable with that. I'm not seeing any heads nodding in the opposite, so the next slide.

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 for public credibility, or public accountability." Any further discussion on

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

And then this slide is defining the individual terms of the larger definition. We have "event", which is unchanged, means "a discrete, auditable, and clearly defined occurrence." "Adverse", we got rid of the latter part of that definition, so that it now 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

term "or risk thereof."

And then the final term, "Unambiguous" was unchanged, and that refers to, "An event that is clearly defined and easily identified." So, I guess we'd ask for comments, or affirmation that that's what we all agreed to yesterday.

MEMBER BRENNAN: Peter, this is P.J. I think these are -- I agree with these definitions. I think I would just like to see in the text under serious, not in the definition, but in the accompanying text, language related to psychological harm, as 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 that was floated around in a few different versions. We tried to clean it up, and we

already have a few shaking heads in the room. And this is an important set of discussions, because my sense was, as we left yesterday, not everybody was on the same page. And does anyone on the phone not have this? I don't want to try to do the -- describe a Venn Diagram to the outside world, if we don't have to.

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 other types of events in the broader groupings that were not necessarily as serious, and not

necessarily reportable, but they were certainly items that needed to be taken into account. And then in our discussions later, we sort of added an extra circle, sort of to recognize that other small subgroups may or may not show up in this realm, not to suggest that we need to make any more of those, but that just their existence over time may occur.

So, I'm going to turn this back to Sally in a moment, but we've got Michael and Diane, who are jumping on us here. So, Mike.

MEMBER VICTOROFF: Looking at this now, it doesn't resemble what I thought I agreed to yesterday, and I don't want to discuss it any more.

(Laughter.)

MEMBER VICTOROFF: Apparently, I didn't even get anything out of yesterday's discussion. I don't see any need for this diagram, and if a diagram like this were to show up in the report, I couldn't explain it. And I don't think it adds anything. That

isn't to say the discussion yesterday wasn't useful, because it really was. I thought that the process we went through taught me a lot. And I think it helped me articulate stuff that I hadn't really. But now that I look at this version of somebody's version of what they thought happened yesterday, I don't recognize it, so I really think the prudent thing to do would be to not have a Venn Diagram, because I don't want to perfect a Venn Diagram today. We've got too much else to do.

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 of the two lists was the reason for the Venn. And we solved the problem of the two lists, in

the course of which, I think the Venn has now become not useful. And, as it looks to me here now, it's definitely not useful, because I don't know what it really means.

MEMBER RYDRYCH: Yes. I think what we had decided on -- I agree with Michael. I don't think we should spend much time on this, but I think what we had decided on was just the big circle of all events, one circle for SREs, one circle for HAIs, and that was it. Because, otherwise, we're created new categories that we then have to define. And what struck me about the discussion yesterday was that we spent a lot of time having these important conversations, but we ended up right back where we started, which was with the statement in the briefing document that said SREs are a subset of the larger set of HACs. And then we were just showing it visually, so I don't know that it really adds much, either.

CO-CHAIR TYLER: Philip.

MEMBER PHILIP SCHNEIDER: I agree.

I think the use of this -- the evolution of this was derived from our attempt to clarify the difference between HACs and SREs. And since we're no longer discussing HACs, I don't see any reason to have it.

CO-CHAIR TYLER: Okay. Given the fact that we did have a good discussion, which sounds like it did get a lot -- people got a lot out of it, and largely did resolve the situation with the two lists, can we take a vote for removing the diagram from the report, but just knowing that we -- what it stands for. Yes, remove the -

(Vote taken.)

CO-CHAIR TYLER: Anybody on the phone supporting removing the diagram from the report?

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

support.

MEMBER BRENNAN: P.J., I agree.

CO-CHAIR TYLER: Okay. Thank you.

MEMBER DORON SCHNEIDER: Just a quick -- Diane's last statement is where we started, and it concerns me that you just said that, because you just said that SREs are a subset of all healthcare acquired conditions.

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.

DR. ANGOOD: I want to just make sure that we're clear, then, that as just articulated, we've got all events that occur. We've got these serious reportable events, and we've got this cluster of healthcare acquired infections, which have their own sets of initiatives. And there may or may not be other types of similar things that occur over time.

We still will need to go back to HHS and say okay, this group does not feel 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

this to capture those. And I think what the group came to was the idea that we have a broader corridor now that can encompass a broader set of events, so that I think from where NQF sits, the SREs, and I would obviously welcome CMS' feedback when we put this out for comment, but our broader conceptualization of SREs should capture that 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

talk to them about that, but I think that, for me, the lower level -- a different level than the plane of defining events, and my confusion yesterday that got clarified was that we're not talking with healthcare acquired conditions, whatever that is, but defining certain kinds of events. We're talking about capturing some reportable stuff that might be good fodder for intervention. So, if that's generally agreed, then I don't have any trouble talking to CMS and saying we didn't say your list is no good, but we see that it fits in a different plug than in the definitions of the bad things we care about.

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 reduction of HAIs. And I think we ought to be in touch with him. That plan was published in

January of 2009, and has five-year goals, incorporates the term "healthcare associated infections". And I think to the extent that we can align ourselves with that, it would help reduce confusion for hospitals, and promote that agenda.

DR. ANGOOD: Yes. No, I certainly agree, P.J., and we actually have had several discussions with Don, and we actually followed up with Don after the State-Based Reporting meeting of a couple of weeks back. And Don is very keen to harmonize with what NQF is doing, with what the State-Based Reporting entities are doing. And, hopefully, in his new position, which was just announced yesterday, he will continue along this HAI action plan, as it rolls itself out over the next few years. But a very good point, thanks.

CO-CHAIR TYLER: Okay. Do you have other to review?

DR. ANGOOD: No, I just -- I mean, I just want to make sure we're comfortable.

CMS, it's the hospital acquired conditions. HHS came to us with this healthcare type of term. And I think with us redefining SREs, we're able to back off that healthcare acquired thing. And I just want to make sure everybody is comfortable with that.

I think it's important, just because the CMS term of the hospital will continue to be a confusion generator, but that's their business, and they can move 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.

DR. ANGOOD: Yes.

MR. GARCIA: Just so it's clear, we're probably going to be creating other terms, such as nursing home acquired conditions, home health acquired conditions. So, we were looking for a term that would encompass all of those as an umbrella. And then my thinking was under each of those, there are SREs, so I think that you've also 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

SREs. And, as we go through the rest of this Steering Committee's deliberations, we'll begin to -- and the use of the TAPS, we'll begin to make them more environment-specific. But another term isn't necessarily needed at this point in time. And it would actually make more sense to have SREs for home health, SREs for ambulatory, if you will. And they may be similar in each of those environments, but that would be another way of identifying, or specifying, as opposed to creating new terms all of the time.

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 List, at the moment, I think what we talked about yesterday was all of those would now fit

in the broader category of SREs. So, I think our hope is, by broadening the definition, we have created something that works for the purposes of what CMS is trying to get at, and I think that's a discussion to follow, that I think we'll continue to have, but I think that was the hope, that we could actually -- if you look at that list, based on the definitions we talked about yesterday, all of those now would fit under the broadened - I'm sorry - diagnosis. I can't help myself, sometimes. The broader definition of SREs, and I think that's our hope, that we can consolidate under one term. But, again, further discussions are certainly welcome.

CO-CHAIR TYLER: Leah.

MEMBER BINDER: I just want to say, I appreciate Helen's comments, because I'm vaguely uncomfortable with it. I just want to make sure that there's harmony with CMS. I mean, I think they've made major inroads. There's been a lot of attempt on their part,

and on NQF's part, to create better harmony. I think that's all of our goals, so I just want to make sure that as we go forward, we're mindful of that. That's a discomfort that I have with it right now. Do we have any opinion from CMS, or have we talked about this to anyone at CMS to get their feedback?

DR. BURSTIN: Eddy Garcia, who's on the phone, was here with us yesterday, and is here with us today, who just made those comments. Obviously, this is a broader discussion, including the payment side folks, which Eddy is not on. Eddy is on the quality side, so we'll have those discussions. I think our goal is, as much as possible, with the majority of the work we do, harmonization is the end game. If there's a way to make that work for all purposes, and get at the magical list John talked about of those 40 events, I'm in. It seems like the way to go, but see if we can get there.

CO-CHAIR TYLER: Okay.

DR. BURSTIN: It's going to forever be that magic list of John's events, by the way, in my mind. Always going to be those -- and if we don't get to 40, I'll be very sad.

(Laughter.)

DR. ANGOOD: Yes, and the way things are, it'll shift from Never Events to John's 40 list.

(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 reportable events. We got, I guess, about halfway through that list, so we're going to

plow on with that, if we can get -- we under the care management events, 4A, if we can get that up. I think when we last left, Eric had updated us all that older people kill themselves by dumping their wheelchairs into jacuzzis. I remember that, that was our - so we've all had a lot to think about 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

potential for death, or serious disability."

Okay. What do we want to comment on? Diane.

MEMBER RYDRYCH: One thing that's never really been clear to me with this event is how to deal with cases where a medication should have been administered, but was not, as opposed to the wrong medication being administered. Examples that have come up, for us, include cases where like a pre-op antibiotic was supposed to be given, but wasn't, and then a patient got an infection, or should have been DVT prophylaxis, that was not provided. And then there ended up being a serious disability to the patient, as a result.

I don't know what the intent was at the event around those types of situations. My guess is that they're not captured. I don't know if they were intended to be captured, or not.

CO-CHAIR MEYER: Diane, this is

Gregg. I think that that's been an ongoing, I think, vexing issue with this. And I think it's one of the fundamental issues with both this work, and to some extent, the Safe Practice work. And that is, is that we largely focus here on execution, meaning what was done, rather than design, rather than was the plan right. And that's, actually, a limitation across much of safety right now, is that we focus much more on you gave the wrong antibiotic in terms of an allergy, rather than asking the question, did the patient need the antibiotic at all. And I would say that that's something that, when we think about what are the areas for future research, and what needs to be kind of focused on in the future, I'd like to see that highlighted here. And, again, that cuts across both this, and the Safe Practices.

CO-CHAIR TYLER: Philip.

MEMBER PHILIP SCHNEIDER: Wouldn't that be covered in the second bullet point in

the middle column, "Occurrences which a patient dies or suffers serious disability as a result of a failure to administer prescribed medicine"? And, secondly, but as an additional point, though, if you think of medication use as being comprised of a number of steps, starting with prescribing, would this encompass a failure to prescribe a drug that was needed, to encompass the whole process, as opposed to simply the administration of the medicine?

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 boundary here, when we say that it was prescribed. There's an order. We saw it, it

was ordered. The order was not taken off, or whatever, didn't get into the right IV. That still is, in a way, an error of commission. I'm opening to hearing it both ways. But guideline adherence is not comprised by this kind of error, this particular error.

I don't see -- you didn't realize that people with heart disease are supposed to get statins or something. We don't have beta blocker, we don't see aspirin, we don't see whenever you have a broken leg, you should put a splint on it. There's a lot of guideline management processes that are not in here at all.

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 pointed out, but this looks, to me, pretty much more like we gave something, and it was

wrong.

DR. GANDHI: This is Tejal from the phone. Another, I don't know if we want to open another can of worms, but the other issue is monitoring. Usually, when we think about the medication process, it goes all the way from ordering, dispensing, prescribing, administering, and then monitoring. So, I'm 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

that any bad thing conceivably having to do with anything to do with a drug, but that's too big for me. So, I'm going to be a splitter in this case.

CO-CHAIR TYLER: Cynthia.

MEMBER HOEN: This is one of those categories that concerns me, because we have a lot of medication errors, but very few of them rise to the level of the definition here. And, I guess, that as we talk about how we share this information going forward in an attempt to broaden our knowledge, and put in preventative measures, or give risk alerts, or whatever you want to call them, to other organizations, that this is one where I would like to consider whether we put in wording that death or disability, or could have resulted in death or disability, such that those events which just because we caught them before they reached the patients, have the likelihood of occurring in other venues, or hospitals, could then get that information out

to the state, for then sharing amongst other facilities.

CO-CHAIR TYLER: Eric.

MEMBER TANGALOS: There's currently a very nice way of starting to look at those near misses in a variety of different environments. And it's through a medication process where you look at rescue drugs. So, you can just do -- and Pittsburgh has done a lot of this work, and Steve Hadler has done. And, again, it's in the process steps, but it starts to address a lot of those questions that now come to the surface, because you can look at drugs that rescue patients from disaster.

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 organization, any type of organization, versus the specific events, themselves, reporting

specific events themselves. So, I'm concerned about where we are on the specificity, sensitivity spectrum here, and, for this particular one, I'm going to go with Michael 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

to ask a question of procedure, because I don't -- I'd like to see included, a method defined where we could include errors of omission from prescribing, through monitoring. Errors of omission in prescribing, dispensing, administering, and monitoring therapy, somehow. I'm not going to fall on a sword to say it has to be in this, but I would like to know how we would go about making sure that those kinds of events are captured, because I 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

that out a little bit more than embedding everything in one standard.

CO-CHAIR TYLER: So, do you think it makes to have a separate event around omission through monitoring?

MEMBER PHILIP SCHNEIDER: I'm not sure I do, but I sense that there's enough people that do, that that would be okay, as 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

ones. So, what I would propose is that when we say oh, you know, there's something else that's kind of like this, but not the same, what I'd encourage us to think is, do we want to dilute, or do we want to add something at the bottom of the list, that then needs the same kind of scrutiny as all the rest. Are they identifiable? Are there remedies? Are there interventions? Can we count them? Do 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 next, John.

MEMBER MORLEY: Okay. I agree with Mike, and in this particular case, I guess, as 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.

At the end of a year of data collection, whether it be for a state, a region, or the country, you're going to have far more information than you can dissect at one time. And the information that's related to the pediatric issues are going to be clearly different than the issues related to chemotherapy, which are going to be a lot different than heparin issues.

I'd like to see us be able to identify a more focused area, or focuses 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

people.

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 and MAO inhibitors fall into that category? Something with known drug interactions that

are potentially lethal. Patients that are on MAO inhibitors shouldn't be getting Meperidine. We're talking a very small -- that's not going to get you a lot of interactions that I can think of.

MEMBER RYDRYCH: Isn't the clarification there just to say that that would only be reportable if it actually did result in the serious disability or the death. 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

my take on it is basically sort of what John was saying in terms of the significant interactions that do result in death or significant disability.

MEMBER PHILIP SCHNEIDER: But shouldn't those be reported, John?

MEMBER MORLEY: Yes.

MEMBER PHILIP SCHNEIDER: So why is it under a list of things that -- the statement above those two bullet points at the bottom is, "This event is not intended to capture", so it strikes me as a paradoxical statement. It should be it's intended to include drug interactions that can be predicted.

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 note.

CO-CHAIR TYLER: Okay. We have anything else on this one? Have you all discussed it thoroughly? All right. Move on to 4B. "Patient death or serious disability associated with hemolytic reaction due to the administration of ABO, HLA, incompatible blood, or blood products. What do we know about this one? Anybody have anything they want to add?

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

trying to decide and differentiate between blood, blood products versus organ donation types of issues. And the way this one is sitting now, it's pretty clear it's just blood, blood product as opposed to bringing in that larger scale of issues. If we want to 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

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

CO-CHAIR TYLER: Okay. So, maybe you'll look at that in the future. If we have no other discussion on that, then we'll move on to the next one.

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.

We're not doing a root cause analysis here. I think if there's women dying from stuff, the only issue that I have is whether there should be dual reporting, because what we have here is a condition that is universally, as far as I know, reportable to State Health Departments under some other rubric than whatever NQF's rubric is. And we haven't even discussed that. But I surely think that every instance of maternal death, regardless of cause, should 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

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

CO-CHAIR TYLER: John, then Eric, then Kathryn.

MEMBER MORLEY: I agree with Mike 100 percent. I think we would want to know all of them. I think there is one area of limitation or refinement, and that would be time limitation. So, not somebody that dies 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

increasingly important issue, we've got this thing called the obesity epidemic, and the obstetricians are more cognizant of that than the average person. We've had two maternal mortalities. We happen to be reviewing maternal mortalities in New York State right now. New York State has approximately 25 maternal mortalities per year in one state. Obviously, some of those are into that category that we would likely say is not preventable, but some are still hemorrhage, and are preventable. But two of the patients that I reviewed, one had a BMI of 60, and the other had a BMI of 70. And we're particularly interested in beginning to track those cases, and start to talk about should those cases be referred to a center that just has the expertise and ability to deal with those types of issues.

CO-CHAIR TYLER: I have a question for clarification just on the consumer end. So, I mean, if someone is that morbidly obese,

would they still be considered in a low-risk pregnancy, or would that put them in a high-risk category?

MEMBER MORLEY: It would be high-risk at 60 or 70 for sure. The obstetricians I've spoken with suggest a cutoff of about 50 or 55. But I would -- but that just goes back to what Mike was saying about I'd want all of them, all maternal mortalities, I believe should be reported. Then let's sort them out at the end.

CO-CHAIR TYLER: I was just clarifying. So, those deaths would not fall into this category, anyway, because this is for low-risk. But you're talking about certainly reporting all. Yes. Okay.

MEMBER TANGALOS: My concern is, as we expand our horizons again, what if a low-risk pregnancy death occurs at the hands of a healthcare provider in the home.

CO-CHAIR TYLER: Well, this just refers to in a healthcare facility. Right?

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

CO-CHAIR TYLER: Right.

MEMBER TANGALOS: I mean -

CO-CHAIR TYLER: Should it apply.

MEMBER TANGALOS: Should it apply. And how would you measure it?

CO-CHAIR TYLER: I think Kathryn was next, then Michael.

MEMBER McDONAGH: Actually, that 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.

MEMBER VICTOROFF: But now we're 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 defer it for now, but it's a perfect model for asking what I've been struggling with. Okay,

when we have the same event that occurs in two different things, two different places, antibiotic reaction at home, tonsillectomy on the kitchen table, whatever it is we're doing. Is the -- don't laugh. Is the problem we have one of defining -- are they really the same error, or is there something about the locus of care change the nature of the error, or does it change the remedy, or the collection process, or the way we're going to report it, to whom we report? And I think all those things are on the table, but for right now, for the purpose of ending this list, what I would say is yes siree, home delivery catastrophe should be one of the things in the 40, the Morley 40. Right? But it isn't this one, because we're just doing facility now. That's what all these are. If you allow me to introduce home stuff, then I've got to go back over the whole list again.

DR. ANGOOD: I think that's a good clarification for us, because the focus right

now is, does the existing list still make sense for what its original purposes were, and with our new definition. Moving forward, then we'll start getting into these other environments, and the applicability of the list to other environments. If we start doing both processes simultaneously, we'll be here until next week, and still looking for clarity.

CO-CHAIR TYLER: Christine.

MEMBER GOESCHEL: Yes, I just have one question, being new to this. So, the spec here that says initially on the maternal/child, in the original things it talked about within 42 days post delivery. Do we no longer have that time? I'm look at the initial -

(Off mic comment.)

MEMBER GOESCHEL: Right. Exactly. So, it includes -- so, one of my questions that I'm sure there's a crisp answer to, I have one of these events after a low-risk

pregnancy at day 30, and I'm home. And I don't go to the hospital, where I delivered. I mean, when we're talking about issues of public reporting, one of the things we always think about is attribution. It begins to get at the continuum of care, but if it's going to be publicly reported that I had 30 deaths of low-risk women, and they occurred 15 days after delivery, but they didn't deliver at my hospital, I think that's just something we need to keep in consideration when we explain what this means, because at an institutional 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

delivery. And we're going to publicly report these deaths. A woman delivers at Hospital X, she gets sick, and goes on day 30 post delivery and dies at my institution, Institution Y, so it's going to be reported as a maternal death at my hospital, but she didn't deliver at my hospital. I tried to save her at my -- do you know what I'm saying? It just gets at the public -- how we use public reporting, not only to improve, but issues of attribution, issues of some of the emotional responses to what the numbers mean or don't mean.

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 hospital. We try to attribute it back to the 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

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

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 the children's hospital community, NACHRI, or another group to give us official kind of feedback on that specific issue.

CO-CHAIR TYLER: Okay. All right. Making note of that. Okay. Next, 4E. "Death or serious disability, kernicterus associated with failure to identify and treat hyperbilirubinemia in neonates. Let's see. And it has a definition, it is defined as "bilirubin levels greater than 30 milligrams." Neonate refers to the first 28 days of life. Anybody have any concerns on this one?

MEMBER MORLEY: I'm not sure that concern is the right word, but I just think that the only ones -- I'd be curious to know if that's happened in a hospital in the United

States in the last couple of years. It hasn't in Colorado. I would have thought for the home deliveries, perhaps, but I'm surprised to -- very little surprises me about hospitals, but I'm surprised that's a -

MEMBER VICTOROFF: It was biliary atresia that was not diagnosed.

DR. BURSTIN: Just as quick clarification. This came up in one of the measures this past year. The U.S. Preventive Services Task Force recently came out, not quite as controversial decision as the one they had just a couple of days ago, with an evidence report about six months ago indicating there was insufficient evidence to routinely recommend testing of bilirubin prior to discharge on all neonates. So, there may still be some confusion in places. I know in a lot of places, like in D.C. when I deliver, there wasn't any choice. It was D.C. law that you did it, but there's still, I think, perhaps some issues around the lack of clear

evidence that, unfortunately, tracking bilirubin at discharge is not always necessarily going to not have kernicterus 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.

DR. ANGOOD: This is one of those topic areas, this particular one, that generates a lot of debate in terms of the weight of the evidence versus the need. It's in here, it's a part of other major initiatives out there, National Patient Safety Goals, et cetera. And it was the point that Helen just made, I think is still some actually worsening confusion. It's not up to the same level as the whole breast screening this week, but in some circles it generates a 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 of us would have suspected. It was a very surprising evidence report, if you haven't

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

DR. ANGOOD: Yes, I know.

CO-CHAIR MEYER: This is Gregg. I think this is a -- this being on the list, I think, as some folks know, it's a testimony to a small but vociferous group trying to make sure that something never ever happens again. And all the more power to them. I think that regardless of the testing strategy issues, my sense is that these are incredibly rare, but 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

current one. Right?

MEMBER BINDER: Yes. Just to make -- I think we should make the distinction, I think what Helen was referring to was the screening protocol. This is referring to the consequence of not detecting hyperbili, and that's very different. So, I think we need to be clear about -- I think it's perfectly appropriate, regardless of how you feel about the screening tool, perfectly appropriate to have this as an SRE.

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

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

MEMBER DORON SCHNEIDER: Just a quick comment in support of what John was saying before about the specificity of some of these never events. You know, we have this medication error section, and then we have a 4D, which I actually like, and hope we keep, where we can then define hypoglycemia, usually due to insulins or oral hypoglycemics. And if we're going to do that, then it's sort of inconsistent that we don't have anticoagulants, or narcotic sedation, et cetera, in there as separate categories. So, I think there is lack of consistency in 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

events are exactly the ones you listed, plus insulin, so you just named them, and that would be a logical approach, very evidence-based, to add SREs.

MEMBER VICTOROFF: It's now the Morley 80. I've been keeping track.

CO-CHAIR TYLER: The list grows. Okay. Move on to the next rule. Let's see, 4F. "Stage Three or Four Pressure Ulcers acquired after admission to a healthcare facility, excludes progression to Stage Two and Stage Three, if Stage Two was recognized upon admission." Okay. Diane wants to start.

MEMBER RYDRYCH: I'll start with a small comment, and then the bigger one. We've made some changes in how we define the scope of this one in Minnesota, which may be controversial or not. The little one is just to say, if Stage Two is recognized and documented upon admission, because that gets at -

(Music in background.)

CO-CHAIR TYLER: Musical accompaniment.

DR. ANGOOD: Yes, those of you who are on the phone -

MEMBER LAU: What's that?

CO-CHAIR TYLER: Yes, someone on the phone has music when they put us on hold, I think.

MEMBER LAU: Oh, okay.

CO-CHAIR TYLER: It doesn't appear to be on any more. Okay.

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 and Four. Based on the fact that almost always those unstageable pressure ulcers, when

they can be staged, are going to be staged at Three or Four. We do allow people to remove them if they end up being staged at Stage Two, but that doesn't happen very often. We also include, if something progresses from a suspected deep tissue injury to a Stage Three or Four.

CO-CHAIR TYLER: Doron.

MEMBER DORON SCHNEIDER: This documentation piece is creating all kinds of havoc in the regard of whose documentation we will accept, and the physician documentation is, in many settings, the one that is accepted, when we have physicians not really completely understanding it, as well as nursing, and specialists within wound care. So, as we define the implementation guidance, I'd love to see us be able to accept wound care nursing and other specialists that are not, necessarily, physicians in that documentation present on admission, I think is the way to go.

CO-CHAIR TYLER: Anything else on this one? Helen.

DR. BURSTIN: Just point out that NQF has just got out for vote a framework, an updated framework for classifying pressure ulcers based on the sort of latest thinking that, in fact, the actual number stages are very problematic. There's not a logical progression from One, to Two, to Three, to Four. Some people start at different stages. You guys, again, probably know some of this more than me, but the point they made was really trying to look at deep tissue versus superficial, so I'll make sure we share that report with the group. I think this is one we're going to have to come back to and take a pretty serious look at in light of some of the new evidence.

DR. ANGOOD: And we're doing the same thing with the Safe Practices sort of pending this report.

CO-CHAIR TYLER: I have a question

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

MEMBER RYDRYCH: I'm not a wound care expert at all, but, generally, it's covered with -- for the lay person's term would be sort of a scabbing. They're sort of scabbed over, and you can't see the depth of the 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 preventable, and that's helped us tremendously with respect to focusing in on events which we

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

MEMBER RYDRYCH: And I would just say, too, again, not being a clinical person, I'm at a disadvantage here, but I do know that we've had discussion about end of life ulcers, and Kennedy ulcers, and whether those are really pressure ulcers, as well. And that's been a difficult conversation. I think where we came down on that is that they're still reportable, but that we did get a lot of push-back 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 question, the near death, I'm not sure where the right answers are.

MEMBER LAU: This is Helen. I concur. In California, when I review death, that pops up a lot. And I think we really need some other experts to help.

DR. ANGOOD: This is Peter. This is another example of if you don't nudge the reporting to look at all events, then you're not going to learn what's actually out there, and you run the risk of complacency occurring. And the home health pressure ulcer, it's a hot debate, but we want to be able to at least have the discussion, whether it was 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 with these ulcers right now. It's a free pass.

CO-CHAIR TYLER: Michael has wanted to get in for a while, and then Doron.

MEMBER VICTOROFF: You know, this is such a wonderful topic that I totally support the idea that this is for an expert panel. There is an enormous discussion to be had here with pros and cons, terminal care, what do you mean by preventable? What do you mean by something that might be preventable, but we elected not to, because it was inappropriate to take the action that would have prevented it for other reasons that were totally good. And, therefore, what I would do 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

hospital. Have I illustrated why this is a good thing to move off to somebody else?

CO-CHAIR TYLER: Well, it sounds like we definitely need help from TAPs on this one, and maybe developing some separate reporting around this. But, Doron, you're next.

MEMBER DORON SCHNEIDER: I'd want the TAP also to come in on trach care, and pressure ulcer definition, therein, because, obviously, that's a very different set of processes, care processes, that sometimes get intermixed within this larger heading. So, we may need to have implementation guidance on that.

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 see -- I mean, they come in with pressure ulcers, and you just never used to see that.

DR. BURSTIN: Again, the TAPs we're talking about are sort of setting specific, so long-term care, nursing home, so we can utilize the Steering Committee from the pressure ulcer framework to give us -- they are the experts in measuring these things, so we'll specifically bring whatever comes out of that TAP to the Steering Committee for their input.

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

how often spinal manipulative therapy happens, at least in a hospital setting, but because it seems to be focused on a provider, rather than a system. And if you're going to talk about death or serious disability related to one type of therapy, why wouldn't you be talking about death or serious disability related to other kinds of therapy? I don't know why you 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

burlesque. But if there were one on this that I really think is fishy for the reasons you said, and others, it would be this, because the frequency is incredibly rare, and it isn't a hospital event. There's more than one specialty that yanks on spines, but it looks to me as though this one -- am I misreading or do I have the mild odor of a political agenda here?

It's just that -- I mean, really, this one just has a kind of a sense to it, that it's not like the others, and I don't know what to do about that. It's your problem.

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 we're not running the risk of taking it off, when there was a perfectly good reason for it

being on there. So, we'll get that feedback on the history of the genesis to the group.

But, to your point, all items on the list are open for addition, deletion, modification, and it's just a bigger step to remove, as opposed to add.

CO-CHAIR TYLER: Chris, and then John.

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. I mean, I think there are some other dynamics in the general public going on about having

people mess around with pressing on your spine and ending up incapacitated. I put that out there as an aside, public to be aware.

CO-CHAIR TYLER: John, and then Helen.

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. 4G and 4H 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 one. But, also, I don't think there should be concern of a political issue around removing,

or adding, or anything. The point here is, does this remain true to the criteria? Could it be incorporated into another one, I think is a very valid point. We want to try to minimize as much as we can harmonize these events, make it easier on -- John's list of 40 becomes 39, I don't think he'll mind that too much. But it needs to be justified, and 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.

Trying to prevent this. Well, how do you try and prevent this? Do you go to the chiropractor or osteopathic societies and say how do you prevent this, or do you refer somebody for professional conduct issues, or practice? They don't strike me as the rest of the list as process issues, and looking for something that we can do to create a safety net. And one of the things that Jim Bagian, and some other nationally recognized folks have commented on, we would like to reduce errors, for sure, but we're not going to eliminate errors, so let's figure out ways to prevent the error from reaching the patient. And I'm not -- this is an event that occurs between one person and another. It's a single step. And, again, I can't see a process, or anything that would intervene to prevent that, if there's an error made, of having an impact, a direct impact on the patient.

DR. BURSTIN: That raises an interesting issue with me about whether we

should consider our criteria for these around this issue of provides additional information that can be used to drive improvement. Just, again, something -- I'd prefer to have these things codified, rather than feeling like we're -- so, just something to think about, because I think that does add value to the list in a different kind of way.

CO-CHAIR TYLER: Okay. Well, we'll say that we can count on getting some more information about the genesis of this rule. And, after that, we may think about whether it needs to be in there, or take further action. Okay.

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 mentioned -- this is Helen. Someone mentioned early on this might be potential moved to

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

MEMBER RYDRYCH: And I would actually not move it. I think it's typically not a hospital event, but it can be a hospital event, so I wouldn't remove it. I'm just saying that from the perspective of someone who's collecting reports on all of these events.

CO-CHAIR TYLER: Okay. All right. Now we're in 5A. "Patient death or serious disability associated with an electrical shock 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

well.

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 that exclusion in front of me here, but I would say we should revisit the ECT one.

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 agree.

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 any reason -- I'm not a physician or cardiologist, but reason to exclude elective

electrocardioversion? It seems to me that if it's an elective procedure, if there's a death, it's a reportable event, or does this fall under the sitting craniotomy story, where you've got a medical procedure that has such a high risk, that it's just part of the process. But it's -- and I don't know the data. I mean, it could be that elective cardioversion, electrocardioversion is well - is developed to an extent where that really shouldn't happen, a death shouldn't happen.

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 ones, do have ASA limitations, so that a low-risk patient, so that may be applicable here.

I don't want to chase this too hard. It just seems to me that we ought to avoid setting safety nets that are arbitrary.

MEMBER RADFORD: I think if we want to have death or serious disability related to the electrical delivery of care, which is what we're talking about with ECT, I think that's a little bit different than getting shocked from a light switch.

MEMBER VICTOROFF: Okay. That was the point I was going to make. And it seems to me there are implicitly two issues here that should be teased apart. And one of them has to do with using electrical machinery therapeutically, deliberately. And that would include -- unfortunately, that would include Bovies, but the risk of Bovies is the not the electricity, it's the fire, a burn. But however we settle that, and I don't propose to settle it in one sentence, the environmental safety hazard thing, no one should get electrically shocked because there's a short

in the TV in their room, or no one should get killed, crushed to death by falling stairways, or eaten by rats. I don't know what else there is in institutions, so I would really be in favor of pulling out the environmental hazards in a facility safety thing. You know, like there should be non-slip treads, whatever the heck, fire extinguishers, OSHA, OSHA, OSHA. And make sure that that doesn't contaminate this if the intent here is misadventures using electrotherapeutic 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

out about those deaths, and then do a more careful analysis. I would not like to see this eliminated.

MEMBER RADFORD: I concur. I just think it's a different category.

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 sometimes they do. So, I think it could end up opening a lot of other options, but I think

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

MEMBER LAU: This is Helen on the phone. I agree.

CO-CHAIR TYLER: So, potentially move this to care management. Leave it in tact, but potentially just move it.

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.

DR. GANDHI: But I thought we were potentially splitting, because, I mean, the light switch electrical shock thing could stay in environmental, but then the one that's more of a treatment-related issue would go to care management.

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

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

CO-CHAIR TYLER: But this isn't just death, it's or serious disability. I mean, staff certainly could incur serious disability from -

MEMBER VICTOROFF: Yes, if I get Hep C from a needle, that should be definitely reported.

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 instances where oxygen was hooked up to IV lines, or the potential for IVs, or oxygen to

be hooked up to trach ports meant for suctioning. There's any number of opportunities to misconnect lines to line in our environment, and I think that we ought to be cognizant of those so that those devices get pulled from other entities, and those 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

oxygen tanks can only be hooked up because of a pin system to certain lines.

We still hear cases of tube feeding being hooked up to the pilot cuff of a trach, tube feedings hooked up to IVs. There's a number of different types of those connections, and I'd love to see that information, and then an engineering response 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

two rules, one under care management, and one under environmental. Is that what you're saying?

MEMBER DORON SCHNEIDER: Yes, that's what we're proposing.

CO-CHAIR TYLER: Stan, did you have something?

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

it's gas lines, and all those horrendous things that used to happen once upon a time, those have almost pretty much gone away because of the structural engineering strategies. But this broader based topic of tube misconnections is a huge topic. It's not addressed anywhere in here, but as we go to solicitation for SREs, it might be something that we have language for, because it is a huge topic, and we don't have an easy avenue at this point in time to get them corrected.

CO-CHAIR MEYER: This is Gregg. I'm also strongly in favor of creating a separate -- I don't think you can lump it in with this one, but creating a separate issue around the kind of line mishaps that were stated there. And I would suggest that perhaps we can reach out to one of the biomedical engineering societies and ask them to help us craft this. I think that they would actually welcome this.

MEMBER GOESCHEL: We actually have

a small Robert Wood Johnson Foundation grant, and are working with some manufacturers and other to do some of that initial work, so I can pursue that and get you some baseline information and background.

CO-CHAIR TYLER: Philip.

MEMBER PHILIP SCHNEIDER: Just for the sake of completeness of the record, in the first bullet point in the comment section, I would say, "the wrong lines being connected, i.e., enteral feeding tubes connected to an IV line." I don't think I've ever heard of an 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

whether some of these need to be retired. So, I think it would be very appropriate, if you think this is really past its time, to recommend retirement of this SRE, and then recommend the creation of the SRE that you just talked about under care management.

And, again, these are not the usual kind of classic measures that require an external entity to develop a measure to submit to NQF. The work of the SREs was typically done by the Committee. The amount that's actually submitted is minimal, so I think we'll cast the net to say here's our new definition. Here are the sites of care. Please submit your ideas. But the actual work of writing these, is actually you guys with the TAPs. So, just to be clear, it's you, so you've just given yourself some work on a new SRE.

CO-CHAIR TYLER: Anything else on this one before we move on? Okay. Hearing nothing, move on to 5C. "Patient death or

serious disability associated with a burn incurred from any source while being cared for in a healthcare facility." Anything?

MEMBER DORON SCHNEIDER: Or staff, and staff.

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

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

evidence to expand because of importance or intervention, the other things, to some other injuries beside burns, specifically?

CO-CHAIR TYLER: Stan.

MEMBER RILEY: And, I guess that if this is a burn, as in the closet is on fire kind of burn, that's one thing. But what about the burn that happens in the OR, where somebody is using alcohol-based prep, and then the Bovie is on, and somebody has a facial burn, or something like that. So, I think 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, like the Bovie example earlier.

CO-CHAIR TYLER: Any other thoughts

or comments on burns?

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 all been minor, but they've been pretty alarming events that galvanize a lot of action.

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

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,

and a pathway of harm, which is -- the word "burn" is being used, as in this case. We have the endpoint, which is you're dead, and the pathway is you burned to death. And in this case, I think it would be possible to say because burn as a mechanism of death illustrates almost always an important safety issue, that if there's any burns, burns of any degree in the pathway, that the fact that it killed you or not is not as important as there's something to learn from looking at the fact that a burn event occurred to a human, because that's almost never intentional in this context.

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. Then we'll deal with homes, and hospices later.

MEMBER TANGALOS: It will be a huge issue.

MEMBER VICTOROFF: Much larger than it is in the hospital.

MEMBER LAU: This is Helen. For clarification, does that also include chemical burns?

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

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

extravasation injuries, does that fall in any of these categories, particularly ones that require surgical -- surgery?

DR. ANGOOD: Well, this would be my own personal view on that. That, to me, is more of an administration error, and kind of in the medication management area, as opposed to what we're talking about here. But your point is very well taken, because those are 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

line, and do you want to have -- do you want to promote an excess of reporting, just so you're not missing stuff, versus do you want to allow things to be hidden because they don't meet your criteria. And the subjectivity in meeting your criteria is always the bugaboo.

DR. BURSTIN: I do think, though, there is -- I think Diane and John both raised really good points about we still have left the definition of being serious, which at least implies disability or risk thereof. And we've not really kind of gone -- risk thereof is a pretty far place away from pretty bad injury, but maybe not disability. So, the question might be, is there a need, if we want this corridor of these not so bad events, but they're reportable because they're important, and getting back to John's point, I can learn from them. We may need to think about -- I was just looking at the definition of adverse, for example. At least have a definition of

adverse, which is, "It describes a negative consequence of care that results in unintended injury or illness, which may or may not" -- we got rid of the parental part. So, at least there's an injury involved, and what some would argue the question is, you know, is a little redness an injury? And we may need to actually play some of the legalistic games we played when I was part of the Harvard Medical Practice study. Actually, there's a real gradation of injury, and it may not be a bad idea to codify this, although, it would complicate it a bit. But it would give us the corridor for reporting in a way that sticks to our definitions.

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

creating more ambiguity there, because it's what -- how much risk is considered risk thereof, and whose assessment of risk? That's something that we probably have to circle back to at some point.

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 associated with a fall. She said she would consider moving it into care management. I'm

speaking as her now. She thinks that environmental -- as an environmental event, it plays down the role of caregivers and the assessment, and the use of strategies to minimize harm if a patient falls. A fall may not be preventable, but there are effective methods for reducing harm from a fall. So, I think just the fact that it's an environmental here was her concern. Maybe that same issue we've had before, is this really a care management event, as well, or in addition.

CO-CHAIR MEYER: Yes, I would second that. The problem here is not the floor that the patient impacts, it's the management process.

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

defibrillation and ECT. Yes, I'm not sure how I feel about all this splitting, but I do think when I look at the falls that we get reported to us, some of them are environmental still, and some of them are care management.

We've had cases where falls are related to the color of the shower curtain, or the way the door works, or the slippery floor, or the slippery blanket on the bed. I mean, we've had environmental, as well as care management. It definitely mixes up both of 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

blanket, or the shower curtain, or whatever. They've actually looked that closely at their systems to prevent falls, and have really seen results. So, I think, fundamentally, this is a care management issue.

DR. BURSTIN: Just going to make the point that, again, to be -- I think you should feel that this is really your opportunity to kind of explode this list a bit. So, I guess the question might be, and I don't know it from the states' perspectives, but how important is it to have them 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 not necessarily significantly increase the 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

mean, this doesn't suggest a distinction, so I'm not sure exactly how it would be covered.

MEMBER RILEY: That was my comment, exactly. What about chemical restraints?

DR. ANGOOD: I think the original intent - obviously, the way it's worded is to the physical piece. Whether we want to add a second category, or put it as new, I mean, that's -

MEMBER TANGALOS: In this regard, again, hospitals have had the free pass on the chemical restraints. The regulations within the long-term care industry have been there forever, but hospitals are left off of this one.

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 use of medicine, so this -- the chemical restraints might fall into the category of

medication error.

MEMBER TANGALOS: Actually, there is replete literature in long-term care regulation. And it's very complete, and it's very different from what you observe in the hospital. And the physical restraints that you see oftentimes in the hospital, you can't get away with in long-term care at all, so the literature, again, is very prolific with regards to chemical restraints, and how it's taken care of. And, again, a technical expert panel is going to help you with that.

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 right track. Again, what started off in `02-03, isn't necessarily the same as right now,

but we don't want to get wild and crazy here. But we should -- if we're going to do a deep analysis on everything, we should.

CO-CHAIR TYLER: Okay. Anything else? Yes, Michael.

MEMBER VICTOROFF: Well, actually, I'm following up on that tangent. You may want to table this for later, but I envision a grid here that has more columns. And in my fantasy, the categories have disappeared, and we're just alphabetizing or something, or arbitrarily listing the left column, but across the right, my fantasy columns have bullets or stars, or something indicating the relevance and interpretation to several different venues for care. Because the discussion is very different of some of these things, as soon as you move to a different kind of care environment. So, I actually -- I don't think that there are -- well, maybe there are like global comments that apply to them all, but I think the solution to the

categories is to drop them. And then capture the value of what we used to have in categories by looking much more precisely at the venues.

DR. ANGOOD: Well, Helen and I go back and forth amongst ourselves on this, and whether there's a matrix sort of strategy that can be applied, not just to the SREs, but to the practices, even to some degree the measures, and the other side of the matrix would be conditions, environments, even procedures, and to some degree you could even get down to disciplines or teams. Yes, you're building your matrix. It gets hugely complex over time, but conceptually, it helps you sort of frame these things up, so that you're in the home care, and it's a nurse who is looking after a patient with this condition. You kind of know what the issues are. That's a long-term project to populate that type of a framework, but, conceptually, it helps move 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

that we need the TAP to give a lot of input on chemical restraints, which I think would include that. Right? The use of psych and behavioral medications?

MEMBER LAU: Yes, and also one is on seclusion, that got locked up.

CO-CHAIR TYLER: Okay.

MEMBER LAU: That also need to get included.

CO-CHAIR TYLER: Okay. Got it. Okay. Thank you. And, Cynthia.

MEMBER HOEN: Going back to what Peter was saying, it might be helpful if the TAP groups could take a look at what reporting IT equipment is out there, and what buckets they have. I mean, that may be helpful in us determining where certain things may fall, and not turning our systems on their head, if there are already tools out there to capture some of this, what they call them. Do we want to follow that metric?

CO-CHAIR TYLER: Okay. One more

thing from Michael.

MEMBER VICTOROFF: The word "corrections." We don't have corrections facilities here, and there are astonishingly interesting issues that begin to overlap behavioral, and get acute in the corrections environment. And let's not forget them, when we are going to our TAPs.

DR. ANGOOD: Yes, we haven't actually given them a lot of thought. And having, as a trauma surgeon and background, 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 you couldn't do an adequate physical exam. I mean, there are real issues there in our

healthcare facilities, as well.

CO-CHAIR TYLER: Well, your mention of corrections kind of gives us a nice segue to criminal events, which is the next section, moving into Category 6. Starting with 6A, "Any instance of care ordered by, or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider." Any comments? Anybody on the phone want to weigh in? Okay. Hearing none, we'll move on to 6B. "Abduction of a patient of any age." Any concerns?

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 it the within one year, is it anybody? What's competent, what's not competent, that whole

discussion which we had.

CO-CHAIR TYLER: Cynthia, you may be able to shed light on this. I mean, abduction is very -- a legal term. Right? Abduction, it's a very specific term.

MEMBER HOEN: Yes. When you get to this level, I mean, this is an event that you're calling the police about, you're reporting to the state, I think it's good to keep track of it, but that's kind of a secondary thought. You're going to let the 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

facility becomes much more problematic here in each of these. And we're going to have to do more thinking as we spread our rows to the other venues. So, what that means to me is that, if we're -- you're going to have a left-hand column sort of in my fantasy that describes the general definition, then I'm going to have to go back over the list a little, and look at all those ones where we said healthcare facility, and see if it bears just clipping that off, because we're going to address the facility in my right-hand columns. So, then am I happy with calling this sexual assault on a patient or healthcare provider, which broadly means staff. And I think yes, I think sexual assault on a patient or healthcare provider, and then leave the facilities over here on the right.

And, in my mind, I'm beginning to think that that might be the model I want to use for some of these other things, where the word "facility" is now irritating me in the

left column.

(Off mic comment.)

CO-CHAIR TYLER: P.J., do you have a comment on the phone?

MEMBER BRENNAN: No, I'm sorry, I don't.

CO-CHAIR TYLER: Okay. I just want to make sure that we're done with abduction. Right? Before moving onto sexual assault. Everybody is okay with comments on that? Okay. Any more comments on the sexual assault 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 the question.

CO-CHAIR TYLER: Doron.

MEMBER DORON SCHNEIDER: Just as a -- for clarity for me, some of these may not apply in some of the settings. And they just have an N/A when you go down that column, so I wouldn't box ourselves in to make sure that it applies across all.

DR. ANGOOD: And this may be one of those lumping categories, to use Helen's favorite term, where you can just simplify 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. I mean, they're all undesirable events, but is it outside of the scope of the work of NQF to

talk about the quality of healthcare to begin looking at management issues that relate to employees and staff. And I'm not -- I'm just asking a question. That's not an opinion.

DR. ANGOOD: Helen may have a different opinion than I, but we're certainly in this evolving new era for NQF very much focused on improving health quality, and health safety on all fronts.

CO-CHAIR TYLER: Michael.

MEMBER VICTOROFF: And, again, although I have some sympathy with lumping, like any illegal act, here's an instance where I think we might to keep the sexual assaults, or the sexual improprieties, or misdemeanors separate. And the reason I will invoke is that when I went to the Colorado Board of Medical Examiners 25 years ago with a taxonomy of medical errors to help sort disciplinary actions for physicians, what they said to me was well, look, we get one or two of these cutting off the wrong legs things a year, but

we get eight complaints per month about sexual impropriety, or alleged sexual something or other, or hanky panky of some kind involving providers. That's our big problem here at the Board. So, in recognition of that, I kind of think that this very sensitive issue of inappropriate sexual behavior, which has the full spectrum, probably deserves special attention, if not being highlighted in some way. So, that's where -- I wouldn't just lump it in with other batteries, and other theft, you know, whatever else.

CO-CHAIR TYLER: Just to be clear, I mean, the term is sexual assault, so it's not inappropriate sexual activity, which there's a distinction. Obviously, you know that.

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.

We have boundary seminars, we have all kinds of discussion. And I don't know how much of that ought to be reportable, and not. And I don't know the difference between what a criminal definition of sexual assault is, as opposed to a tort. But this is so big for me, that I think it ought -- we ought to move it to a place where we can really focus on it.

CO-CHAIR TYLER: Cynthia.

MEMBER HOEN: From the standpoint of the hospitals, an assault, to me, as a 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,

to me, there's a very clear cutoff line as to when these are reported, and rise to a criminal level.

DR. ANGOOD: Well, this, in my mind, just sort of prompted up, and I really don't think it fits into this activity here, but there is that whole issue of providers who are not just misbehaving in terms of sexual confrontations, but perhaps they're engaged with substance abuse, or all of the elements of disruptive behavior. And that is clearly an element that's getting a lot of attention, and will continue to do so. How we put that in the SRE categories, I don't -- I'm not sure we have a fitting for that, but it does bump up in some instances towards the criminal activities, and there are expectations of what the providers are going to be providing in terms of their interactions to the patients in those populations.

And, as we all know, there's a number of individuals on all disciplines that

will go and practice in different environments, so they know where they can hide. And how do you unmask that? Again, it may not be the purview of this whole set of activities, but it is an issue.

CO-CHAIR TYLER: Okay. One more thing from Leah.

MEMBER BINDER: I really like Michael's suggestion about an expert panel. I actually didn't realize, you're enlightening me that this was something that may be more common than perhaps we might have understood. But it is a -- and I like it as a particular category of criminal offense, because there's such a high level of bodily vulnerability that a patient feels in going into a healthcare setting, that sexual impropriety is probably compounded, and more damaging, possibly, than it would be otherwise. And they're more vulnerable to it, so I think -- and that I'm sure goes for any kind of healthcare facility. So, I do think that it raises an important

issue. I agree.

CO-CHAIR TYLER: Okay. If we have nothing else on this, then we've wrapped up. It was a great job of ploughing through the rest of these, the list of SREs. And now I think we are going to take a break.

(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 celebrated case going on in Minnesota right now. A professional wrestler killed his

roommate. The professional wrestler is with the Alzheimer's disease, he will not be charged for a criminal assault. And it's yet to see what will happen with the facility, but it will be an important issue that has to be addressed, because the facility does have a fair amount of culpability with regards to the 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

this? Helen, you had something.

DR. BURSTIN: I just want to follow-up on Diane's point about significant injury. I do think we need to go back and think about, is that that middle category? Is there another term that's better. But I think that's there because they wanted, I assume, to get broader than serious disability or death, so I just think it might be worth -- and I'm assuming it's not an accident, but it could have just been. We'll find out.

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

ambivalent whether it should be -- whether it should include the brawl in the break room between two staff members. I just think we need to clarify it for anyone who's implementing this, whether it does apply or not, rather than kind of dealing with it case-by-case, or state-by-state.

CO-CHAIR TYLER: Stan.

MEMBER RILEY: I think, for us, that we would agree that staff-on-staff is a huge issue, too, mostly because everybody 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

has been discussed so far this morning.

OPERATOR: There are only Committee members on line.

DR. ANGOOD: Okay. So, I think -

CO-CHAIR TYLER: Okay. So, we can do a break then, which is good. I need one, at least. Okay. Let's say 10:05, I mean 11:05. Will that allow people enough time to take a break, stretch your legs? Okay, see you back then.

(Whereupon, the proceedings went off the record at 10:54 a.m. and resumed at 11:11 a.m.)

CO-CHAIR TYLER: Okay. Well, it looks like we have most of our folks back in the room, so I think we're going to go ahead and start back. And Peter is going to pick up on our agenda on the second day. We're going to try to keep on schedule in terms of time, at least, because we know everybody else has prior commitments, including flight plans home, so we're still going to break at the

same time, which means we're going to collapse some of the things, and rework the agenda a bit, and get through as much as we can in a meaningful way today.

So, Peter is going to talk about -- are you going to do the TAPs first?

DR. ANGOOD: A bit of both.

CO-CHAIR TYLER: Okay. He's going to talk about role of TAPs, and also about how we're going to select other environments of care to expand these beyond hospitals. Okay. Peter.

DR. ANGOOD: Thanks so much. And a slide that we're putting up in preparation for this is Slide 28 from the slide deck that Helen and I had up for you yesterday. Basically, outlines the three applicable healthcare settings. So, just for those of you on the phone, if you want to find that.

Now, in terms of my comments, I was just kind of musing that well, here we are at 11:15 on the second day, and we're just

starting the second day's morning agenda. So, I think that's a reflection on the complexity of this whole topic, and the robustness of the discussion. So, I think I'm actually very happy with where we've landed so far, and I think you all should be, as well.

I'm obviously going to truncate my comments, basically, to sort of give a bit of background further on this sort of concept of other environments, or expanding into other environments, and then however we then agree, and after some discussion, that will drive how we then want to begin utilizing the TAPs, sort of rounding out the processes here.

As Helen made mention, the original genesis of the SREs was a few smart people sitting in a room generating a list, and then it got ratified through the consensus development process. And the Committee at the second iteration was the main driver for developing and reviewing the existing current SRE list. So, there still is a fair amount of

expectation that you will be the ones to help generate the ideas for where we take this current version of the list and move forward.

We will, as we've said, solicit some external, or outside inputs on this, and that's part of what we do with the measures consensus process. But the Safe Practices and the SREs are different than the measures, so we don't run it as -- in the same sort of rigorous expectation for submissions from externals to put into our process. So, I just 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

there is an expectation that you guys will really be the source of the SREs.

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

resources, basically, decided no, we need to really pretty much stick with trying to work on three clusters of environments of care. So, those are the three that we've got labeled up here, recognizing that this is less than perfect, but it represents pretty good clustering, overall. But we wanted you all to have some input, and some deliberation on 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

of process, what the Steering Committee does is submit its final iterations after we go through all of our process up to our Consensus Standards Approvals Committee, the so-called CSAC. And that's where the approval actually occurs, and then the Board ratifies it. So, the TAPs are experts with input, but the Steering Committee still drives the final document, and the final content. And then the CSAC approves, and the Board ratifies. So, any quick questions on that?

DR. BURSTIN: Make one comment on the environments of care. We did do some lumping, as you'd imagine. And I just want to see if what the group thinks is -

DR. ANGOOD: That's where I was headed.

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

just before we dive in, because this group, they like -- you guys are great, actually. I mean, Helen and I both comment, you guys are a great group. But in terms of, we're still going to finish on time this morning. Don't start changing your flight patterns around. The final product doesn't have to be out today. We want to do some brainstorming with you in the last bit after we get through this piece, as well, what other types of SREs would be relevant or helpful in the general list, and then that will help, between this discussion, and initial brainstorming on other SREs, that will drive us for our next several weeks, which we'll continue electronically and by some phone calls.

MEMBER TANGALOS: Well, there's nothing wrong with the items that are there, but they're not organized the way I usually think about it. I mean, they're not even close to the way I would think about them. So, it's very -- let me -- I'm not going to

try to sort it just yet, but we think of home and community-based services nowadays, and that's the concept that we think about. We think about long-term care settings. That's the vernacular that we use. We oftentimes leave hospice and palliative care in its own little universe, as well. And when we think about rehabilitation, we think about it as being at some site, whether it's the hospital, the home, or a long-term care facility. And a healthcare -- a nursing healthcare setting, I can't put anywhere. I don't know what that means. I don't know -- nursing, as a separate 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 -

MEMBER TANGALOS: Skilled nursing facility is another story within long-term care settings, and that has a very definite definition. There's no question about it. But that's how that would be. So, within the 10 environments that we had from the CMS, it would be fine, but the reorg here, you know, it's not there yet.

DR. BURSTIN: And just to be clear, the only intention of the reorg is to try to think about what the logical groupings of 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

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

CO-CHAIR TYLER: Michael.

MEMBER VICTOROFF: Actually, the one that's questionable for me is dialysis. You know, we're playing the game of which one of these is not like the other things. And I can see that a person could be versed in ambulatory office outpatient hospice, as well, because when I think of internists, and family 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.

So, I would actually propose relocating dialysis, if we only are allowed three choices, to the one that's called inpatient hospital, because dialysis looks more like an ambulatory surgical center, or a radiation treatment center, than it looks like a doctor's office.

MEMBER LAU: This is Helen. I concur.

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

hospital setting.

DR. BURSTIN: And just one more clarification. We're talking about bringing people together in person. We've got funds to do that. If you think there are groups that are truly different, we'll just pull them out and deal with them as calls. I mean, that's fine. If you think dialysis truly is just a different universe, we'll try to pull together some dialysis folks on a technical panel, set of technical advisors to advise. So, tell us what should get pulled out, I guess.

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 discipline is more than the site-specific stuff, as far as I'm concerned.

CO-CHAIR TYLER: That's not one of the 10 sites, rehab.

DR. ANGOOD: That's a good clarification. Why did we bring that one back in? Oh, you know where that came, in part, is that -- and I may not have the exact knowledge, but someone was pointing out that SNF, Skilled Nursing Facility, is very specific on the payment side for a particular population. So, we want -- in terms of trying to generate broader-based discussion here, we kind of took it back to nursing and rehab -- rehabilitation centers.

MEMBER TANGALOS: But I would put the skilled nursing in with that other long-term 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 long-term care?

MEMBER TANGALOS: Actually, the

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

DR. ANGOOD: Okay.

MEMBER VICTOROFF: My question would be, and I'm happy to have it either way, hospice has probably 50-50 shared skill set between ambulatory primary care, and long-term care. And, often, it's different docs doing it, but they have the same credential. I would be happy to see hospice moved out of that first group, into the long-term care category, if someone felt that made more sense.

MEMBER TANGALOS: Well, it doesn't, and the reason it doesn't is hospice is time-limited, presumably, six months or less. Long-term care presumes a much different time continuum. And we were just talking about that. We have hospice in the hospital, we have hospice in the nursing home as a Medicare benefit. We have hospice in the community that's freestanding. Hospice is kind of on

its -- it overlaps, but it's kind of its own discipline, and it's becoming more of its own discipline with regards to palliative care. And the palliative care piece is what you really want to capture as you expand this, as well.

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

MEMBER HOEN: Actually, this is probably obvious, but I just need for my own clarification. Ambulatory surgery centers would be included in ambulatory care? And also urgy centers, or are they out of this 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,

as well. And there's a huge accreditation program out there for that whole set of settings, too. As far as the urgent care piece, we sort of felt that was basically ambulatory, but there's debate on that, as well. Sorry.

MEMBER RILEY: The ambulatory surgery care was my question, as well.

DR. ANGOOD: Okay. Thanks.

MEMBER VICTOROFF: Again, it really doesn't matter. We're going to have to do these all -- I'm not going to want to be the one that holds this all up. But if I was looking at the safety issues that one encounters, and the remedies one encounters, and the reporting channels through which one reports, again, the one that doesn't look like 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.

Again, I think you're going to get experts together that are going to be able to handle this. So, I'm not too worried that we have to do it perfectly, because we can't. But if you were thinking about the experts that are all going to feel comfortable in the room together, the SU guys are going to be a little bit out of place in that first group.

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, Rehabilitation, and Long-Term Care." And it was -- yes, the recent suggestion was just

long-term care with some sub-bullets under there, which would be skilled nursing facilities, and others.

MEMBER TANGALOS: Long-term care settings.

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

hospitals, and long-term psych hospitals. We're talking about all of those. Is that correct? Okay.

CO-CHAIR TYLER: Martha, Leah, and then Doron.

MEMBER RADFORD: I'm also, like Michael, not too worried about this. I think maybe we're trying to -- we should do this in three waves instead of two, the first wave being acute care that's already been discussed. And pick the big ticket items. I might leave hospice for a later edition. I might leave some of these other for just a later edition, to get the big ticket items, a variety of others one.

DR. BURSTIN: And if I could just add to that, we said we would expand to the likely -- to the applicable settings. We 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

based on your thinking of our broadened definition of SREs, what sites make the most sense, especially for the state folks. What are the kind of sites you don't tend to get, that you worry about?

MEMBER RADFORD: You know, I like Michael's idea about the grid and the columns. And there's nothing to prevent us from having 10 columns, eventually, except for you'd have to get 17 inch paper. Oh, well.

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 that matters unless, for some reason, we're asking them to do some kind of reporting on

two different bullets. It doesn't matter, but I just want to make sure it doesn't.

And then the second thing is, do we want to -- we had some discussion earlier about home birthing, or freestanding birth clinics. Is that something we want to add to this, as well?

MEMBER DORON SCHNEIDER: So, I think the outpatient clinics are okay with ambulatory care, because the events that occur there are the same that occur in physician offices. My issue is with the ambulatory surgery unit, and what Tejal was saying, in that the procedures that I'm considering ambulatory surgery are those that require anesthesia. And I think if I had to put them somewhere, I would them more in inpatient hospital, and have the outpatient clinic folks speak very eloquently to the smaller procedures that don't require anesthesia, and really just require smaller time out, and those issues.

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 office-based 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

know that we had 600 reports last year, and 30 of those reports on adverse events were deaths. Some of those deaths were dialysis patients after a catheter manipulation, and those patients are high-risk mortality without procedures. But a surprising number of patients expired as a result of office-based 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

thinking that you can divide up the work how you want, but as far as the bullets, I'm seeing five, more than three. And I really see the ambulatory care with its DRGs, with its payment system, relatively unique. Home and community-based services is that catch word, and where that jargon is right now. And then hospice tends to be a unique piece. So, I would pull home and community-based services out of that first bullet, and I would make hospice and palliative care its own bullet, as well. So, I can only come up with five. I can't get down to three.

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

a big deal. We'll pull five people together and have a phone call. Just tell us -- this is really just for you to tell us what expertise is really important, which of these settings you really want to focus on. Are we ready, I think going back to Martha's point, are we ready to do hospice and palliative, or is that something to save for the next time, perhaps? Should dialysis be on its own? Again, we just 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

of community-based things there right now. And you may find that there's no data set, that there's no data set worth ploughing, as there would be with the long-term care settings. Okay? But I still think home and community-based stands by itself. Then the inpatient hospital, then the long-term care settings, and then the hospice and palliative care. Yes, that is the grouping that I kind of see that politically works, and organizationally works. Whether you want to bite it all off, or pieces of it, but that's where the expertise resides in those individual camps.

CO-CHAIR TYLER: And just to clarify, Eric, what you're suggesting, the modifying language in the parens there, that still goes with ambulatory care.

MEMBER TANGALOS: Yes.

CO-CHAIR TYLER: That "including physicians offices". Right?

MEMBER TANGALOS: Yes.

CO-CHAIR TYLER: So, that needs to be moved.

MEMBER TANGALOS: Yes.

CO-CHAIR TYLER: All right.

MEMBER RADFORD: And just where does ambulatory surgery fit?

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 different situations, and I would tend to think of them as closer to -- I mean, just

what seems intuitive to me is to put them closer to ambulatory care, if we're talking just about the setting, but the services are closer to inpatient. So, we seem to be having that tension there, is this about a physical type of setting, or is about the type of services that are being provided?

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

it seems strange to say we're having this technical advisory group on ambulatory, or on inpatient hospital that includes ambulatory.

MEMBER RADFORD: So, it's really service types.

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 sense?

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

emergency department there.

MEMBER TANGALOS: Well, what's emerging is -- or re-emerging, there's a finding, again, of the urgent care centers, which are outpatient. But, even more so, the unregulation of the "minute clinics."

MEMBER LAU: Yes. Yes.

CO-CHAIR TYLER: I just want to make sure that Helen's point -- Helen, does that clarify your point? Is that correctly stated?

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 got that. Thank you. I think, Michael, and then -

MEMBER VICTOROFF: You know, I can see us cutting this pizza endlessly, but at the end of the day, if you tell me there's only three people that get pizza, divide it however you want, them I'm not going to actually worry too much. And what I would think is that any of these groups, as they're configured, or as I could conceive configuring, would work. You'd get useful 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, or services, SREs really need to expand, you think are ripe for serious

reportable events. Let's start with that, maybe, and work backwards, rather than starting from the list.

MEMBER VICTOROFF: Physician offices.

MEMBER MORLEY: I just want to say thank you. You just said exactly what I was going 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

York has an office-based surgery program. I would like to see that started at a national level. I would like to see dialysis facilities. There's a few other things that while I'd like to see them, maybe 2011, as opposed to 2010, seeing dialysis and office-based surgery, ambulatory surgery type things.

MEMBER BRENNAN: Helen, this is P.J.

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 to apply them to those areas, and to pull together some guidance. So, there have been

a number of outbreaks recently that have been related to practices that just seem to fall outside of regulation in these areas, either, in part, because they're not regulated, or because they're seldom visited by CMS surveyors. So, I think that, from our perspective, ambulatory surgery, dialysis, and physician practices are important places.

DR. GANDHI: This is Tejal from the phone. I would completely agree with those areas, particularly, the physician offices, and ambulatory surgery. And then the only other one I would probably throw in there, just based on if we're trying to be a little more evidence-based, I mean, there's been a lot of stuff about the skilled nursing 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

thing I'd add from my wish list, besides the things that have already been spoken about, is infusion centers, which are sort of completely on a different level, you know, cancer infusion centers, primarily, that we see sort of the Wild Wild West. You know, there's not any real reporting for them, and we don't know exactly what happens there.

CO-CHAIR TYLER: Cynthia, then Martha.

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

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

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 know the science is almost non-existent, so it's not -- science is very poor in hospice and palliative care. It is not matured.

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 to get us towards is to actually think of a secondary list that we would put into the

pipeline, because I'm trying to anticipate the discussions with HHS, in terms of well, here's our expanded term of SREs, the definition. Here's our revised list. Here's our tiering approach to where the priority environments need to be, because that's kind of how they're approaching us with this. So, the first step is office-based surgery/ambulatory surgery centers, dialysis, physician offices, and then 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.

Representing the SNF, that universe, we are delighted that NQF is interested in that universe. I don't know about the other parties, but we think it's neat that NQF is interested.

DR. ANGOOD: We are making a concerted effort to be neat.

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 re-admissions. There's many error types that occur that overlap there, everything from mistubing, misinfusions, misadministration,

you know, of medications, et cetera. And for us to not have that on the list, I think is an oversight.

DR. ANGOOD: Well, it's a good point, and I guess it'll be a matter, well, how many do we have on our primary list, and how many do we have on the secondary list. And everyone is always going to have a favorite, or a least favorite. So, if we could, you know, you're not going to be held accountable to it in the long-term, but why don't we just do a little straw poll here on those four items that we listed.

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, make sure we have the list. So, it's ambulatory care including physician offices,

and outpatient facilities. I think that was one of them, clearly. Then there was ambulatory care surgery and procedure-based -

DR. ANGOOD: Office-based surgery.

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

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.

I thought you guys already moved dialysis -

DR. ANGOOD: Well, that was Martha's comment. I'm not sure the rest of the group was with Martha. Well, let's take Mike's approach then. Sorry, we kind of jumping on you here, but we're trying to anticipate our interaction with HHS, I think, and that is -- so, let's go one by one, and just a straw poll. And if something falls off 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

question is, do we really need a technical panel on hospitals, if that's sort of the collective group here. So, one idea might be to jettison the idea of a TAP on hospitals, instead, think about technical panels in these specialized areas where we need the expertise. 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

phone?

MEMBER LAU: Yes from Helen.

DR. GANDHI: Yes from Tejal.

MEMBER BRENNAN: Yes from P.J.

DR. ANGOOD: Okay. Thank you. And then we had dialysis centers, although, Martha made a comment that they're already pretty well regulated. Who would like to have 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,

physician offices, and ambulatory outpatient care, and then long-term, and SNFs, with a focus.

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

everyone is accepting that home health is important, but the science isn't quite there. And, perhaps, we should put that on our next wave of activity. I'm seeing a lot of heads yes in there.

CO-CHAIR TYLER: Cynthia, you had a comment?

MEMBER HOEN: Yes. Just with respect to the physician offices, I agree, that's a good thing to look at, but I would ask that the TAP group also look at the feasibility of those physicians implementing 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

may not be science there, but we, I think, have an opportunity to understand what's occurring there, by having reportable events. If you have somebody in the home that is misadministering medications, or putting the tube feed into the IV line, or these kinds of things that we're talking about, and we're not really asking for reporting of these serious events, there's an opportunity lost, I think. So, what does it mean, actually, if it goes to tier two?

DR. ANGOOD: Well, I think we have 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 people think are good areas to get started for a combination of concern, evidence, and potential to try and create some important change for improving quality.

The second, I would rather than

tier or class, it would be more of a second wave, saying that let's get started on this grouping, and then look for ways, as we get better experienced with this, to then roll out the next wave of environments, which would be whatever we choose, home health, et cetera, et cetera. That's my view on where the group is at, but there's other opinions.

MEMBER GOESCHEL: Could I ask a question about the feasibility of NQF staff, I'm going to say even beginning for these next wave, to begin to do some data collection. I 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.

MEMBER RYDRYCH: Well, I think we even need some of that on the first tier groupings that we identified, because for physician offices, and we don't even know where they all are in our state. Just a question, too. I mean, we know each physician is licensed, but we don't know what all the clinics are. They're not licensed separately, 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.

DR. ANGOOD: Right. But that will -- we kind of ran the list yesterday, and today, and if we can get through this part of the discussion this morning, we were hoping to brainstorm a little bit on other potential ones for the SRE list, which could be mostly on the hospital setting.

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 -

MEMBER DORON SCHNEIDER: In 2002, then 2006, then 2009, so if you're in second tier, does that mean 2012 for the next environment, or are we moving to more of a annual review for the additional environments, or is it going to be a three-year cycle, or is that not determined? And maybe I feel too strongly about the home care, and wanting to know what's going on there. I just -- I know that services that are rendered there are going to just go through the roof over the next decade, and we don't know what's going on there. And I know, we all know that harm is 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 historically done an every three-year maintenance update, but we have moved into an

annual update cycle for the Safe Practices. Again, as Helen said, these SREs are NQF's, so we can move them along in new directions, if this group feels that's important.

CO-CHAIR TYLER: Martha.

MEMBER RADFORD: I'd like to -- we have two definites here, the outpatient procedure venues, and the long-term care venue. And I did not vote for physician office venues, because I just feel like the feasibility issues are just too massive.

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 home health, and home and community-based services, and they're not at all, not the way

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

MEMBER TANGALOS: Well, Sally, the same might apply, you might disagree, that just as we've put a bigger umbrella under long-term care settings, and we will focus on SNFs, you could argue that home and community-based services would have within it, home health services, and focus only on that.

In fact, I'm not convinced the data is there, either, but it might be a better challenge, and it might be more worthwhile than the ambulatory care sites.

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

we've talked about, that's probably the site 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 to offer a comment based on what Eric was suggesting, and that is, maybe it's sort of ambulatory with a focus on, maybe it's home health, or home care settings with a focus on, home care, long-term care with a focus on, SNFs, that kind of an approach. So, we're getting lunch delivery here, so I'll help Sally get re-engaged, so why don't we just go around the table, Leah, then Cynthia, then Diane and Mike.

MEMBER BINDER: Well, I wonder if one criteria we should use to think about what's in the first tier is the level of potential harm to the patient, and their vulnerability to that potential harm. That's why home care sounds very compelling to me, especially after Doron's comments. Because that is in a setting where serious adverse

events could do a lot of harm, and there's very little oversight between the clinician and their direct relationship with the patient, so the patient is particularly vulnerable if something happens. So, it would strike me as a stronger need for reporting, than maybe others. And I think that might be one thing we should at least consider in thinking through what's the tiering.

MEMBER HOEN: Leah, I agree with you, and I also agree with Doron, but I'm kind of on Chris' page. We've just started collecting data with respect to our home care services, and whether it's for profit or not-for-profit, and we're finding some fairly disturbing things, sometimes. But I don't have enough data to even begin to carve out what we should be concerned about, so I don't know if this Committee could make a recommendation that those areas start collecting data on at least A, B, C, and D, and prepare to report on them the following

year, or something like that, so that that could be fleshed out more, because I suspect we don't have a lot of information. But I think it's very, very prime for question.

MEMBER LAU: Talking about that, this is Helen on the phone. I see one suggestion is the home care and hospice area. There's a lot of shortage out there in clinician providing those care, and a lot of time it's delay in service. And that might even cause an unnecessary readmission to the hospital, so if we are looking at getting more data on that, on harm -- and I think one of that could be even on the timeliness on starting those services.

CO-CHAIR TYLER: Helen, what was your last suggestion? You thought that one of them might even be what? I didn't hear the end. Sorry.

MEMBER LAU: The timeliness in starting the service, so you could have a hospice patient should go to hospice, and

because of lack of clinician, they couldn't start the service early, and patient end up go back to the hospital.

CO-CHAIR TYLER: Okay. Thank you.

DR. BURSTIN: I was just going to say, I mean, there are all kinds of ways for us to stage this work. I think we've now heard what's most important, but there's no reason, for example, when we write the call for events, we can't be very broad-based and say these are the potential areas of interest. If we get in 15 suggestions related to home health, we might think differently than we do right at this moment, so I'm not sure we need 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 facility-specific events. So, I think there -- you can kind of play it from both sides. And I think

we might be able to expand the sites to which the existing SREs apply, even without, necessarily, creating a whole new set of SREs. And I think we could stage this to make that work.

CO-CHAIR TYLER: Martha, then Michael.

MEMBER RADFORD: I was just going to put a plug in for Michael's grid. And if we start to build that grid, then we'll know where we need to go, I think.

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

claims that arose because there was a major injury. Fifty-four percent of all of the losses were outpatient in our company, and in CRICO, and RMF, and other companies; whereas, fewer of them were inpatient. And that's in dollars, as well as in numbers. Our big losses are all happening in offices, mostly.

MEMBER RADFORD: Is that office-based procedures or offices?

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 aware that not every state works the same way, and this data is only coming from a few

pockets right now. But I think it's more than enough to get started with.

And the one thing that I'm prepared to defend strongly, is that the big problem is in offices. And home health care, yes, there will be a future quagmire, but it isn't now. The deaths, and horrors, and miseries, and problems that are rising to the level of injury, harm, and urgency are happening in offices more than homes, or even dialysis centers, for that matter, because we insure all those guys, and we kind of know who's 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 have their own insurance data. As a reporting state, we don't have any data from offices in terms of what happens there, so it's a captive population for RMF, and we don't have any idea of what's actually going on there.

MEMBER VICTOROFF: We'll show you. It's not hard.

CO-CHAIR TYLER: We may have brainstormed our list on this. There's some discussion, huh? Pretty satisfied with where we are? Make sense, at least, in the beginning? Okay.

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

a point where maybe that would be useful. And I have a few, and I assume you have a few, but if you want me to start, I'd be happy to start. Okay.

DR. ANGOOD: Yes, why don't we just synopse, do this and -

DR. BURSTIN: Just one thought I had, is I think that we're probably ready to create the call for SREs broadly based on the definitions you've given us, so I think one of the next things we'll do is create a draft of call for SREs, comments on existing SREs, as well as call for new SREs. It will be very broad-based in terms of environments of care. We could potentially indicate the ones that people -- the Committee indicated were highest here, but not, necessarily, limit ourselves to that.

I think we can create the Michael grid, the SRE list, and send it to you with the environments of care kind of listed out, and ask you to, perhaps as a Committee

exercise, populate the ones you think logically could be expanded to other sites of care. And then I think we'll do the call, see what we get in. And I think, at that point, it might be the better time to think about what are the expansion technical panels we want to pull in for new SREs, and new settings of care. I think we probably at least got two 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

well.

We'll get that circulating electronically for your guys' inputs and further ideas, as you think about it further. We'll discuss more in terms of the TAPs, and we'll get that communicating to you, as well. And we shall set up for some follow-up phone call in the next month to six weeks, so that we don't get too far past your guys' thinking. And this is an 18-month process. We've got built into the plan a number of phone calls, obviously email is always there, and as we get 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

membership, or just for us? You said you were 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.

MEMBER DORON SCHNEIDER: This kind of work, in my opinion, is -- could be accelerated if we use some virtual workspace kind of environments, whether it's Google Documents, or there's other methodologies to really see changes as they occur, the thread of discussions. I sometimes get lost in emails where documents are sent, and then it's not the latest version, and versioning control. And I don't know if NQF has embedded within your website that kind of a workspace, but this would, ideally, happen within a workspace that we can log into, and see the documents, see Michael's latest revision, or my comment, or your comment, and kind of build off of that. It will make the phone calls all that much more productive. I just throw that out there.

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

little environment in space to hang out on electronically, and go look whenever we pulse you to go check, is the way to go. So, we'll work on that. A combination of the electronic forum, and the phone calls will be helpful.

Other suggestions, comments, feedback on this day and a half? I always think it's important to get your feedback on how this worked for you, and to get some ideas as to how it might work better. I think Doron's idea is a good one, but others?

CO-CHAIR TYLER: I have a question for the group, actually. How are you all -- have you been thinking about, and do you have any specific mechanisms, if you -- those of you who do feel that you have constituencies you have to answer to, or try to involve in this, to go back and involve them, or are you doing anything like that? If so, what? What are you doing? Anybody. Michael is nodding his head.

MEMBER VICTOROFF: Well, I end up

being, inadvertently, in a lot of professional and social networks, so I have gossiped to everybody about gee, we're going to go over - you know that NQF thing, and that horrible list of stuff, and you have - now is your chance, because they actually let me in, and I can talk. So, I not only informally, but formally have solicited opinions from people I consider authoritative, and informed. And I'll be bringing those. As soon as we have whatever, the groupware site that helps that, I'll be able to even give you sources and footnotes for people that really had a message that is valuable here.

MEMBER TANGALOS: I've already met with the American Geriatric Society Quality Group, which I'm on, and we've discussed this process, and we've had other members on other NQF activities, as well. So, they're very supportive. It will show up in the newsletters for them. It'll also show up in the newsletters for the American Medical

Directors Association. There's an extra added benefit, because of the relationships there, too. And if something shows up that needs membership review, the reason I'm here is because I'm good enough at figuring out what they need to know about, and let them know.

DR. ANGOOD: And that's exactly why you folks have been chosen, in part, not only just for your expertise, but for your secondary networks for us to get -- this is not a bunch of smart people with their own personal ideas. This is all about open transparency, and full inputs, as broad-based 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 National Health Service, where we'll be in December doing some of this very same kind of

conversation. But one of the things I was going to ask as my first committee, is how quickly will we get documents relative to the changes that we've suggested today, because as a newbie to this, I've taken notes, but I have been much quieter than I typically am, to just try to take this all in. And I want to speak the truth about what happened, not what I remember in my head.

DR. ANGOOD: Yes, in general, we are pretty good with our turnarounds. We have fairly rigid processes in terms of all of our meetings. We get the transcripts back. We review the transcripts. We put meeting summary notes usually within a week to ten days.

DR. BURSTIN: And the actual transcript will be posted, as well.

DR. ANGOOD: Yes. Other comments, other feedback, things we need to do better for you? It looks like people are hungry, and -- go on.

MEMBER MORLEY: I will be talking with -- I work closely with different associations back in New York. We'll be talking to them, as well as hospital medical directors. I want to thank you for getting us, for allowing me and us to participate. This has expanded all of our networks, and I'm particularly happy that you've shared addresses, and so forth, on the information you provided. So, we've already connected in a number of areas, and I'm sure we're going to be connecting on a number more going forward. Thank you.

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

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

MEMBER BRENNAN: Thank you.

MEMBER LAU: Thank you.

DR. ANGOOD: All right, everybody. Bye.

(Whereupon, the proceedings went off the record at 12:16 p.m.)

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