THE NATIONAL QUALITY FORUM

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MAINTENANCE STEERING COMMITTEE

NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR SAFE PRACTICES FOR BETTER HEALTHCARE-2010 UPDATE

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Wednesday, August 19, 2009

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The Maintenance Steering Committee met at 8:00 a.m., in Capital Ballroom D of the Embassy Suites Washington-Convention Center,

900 10th Street, N.W., Washington, D.C., Gregg S. Meyer, M.D., MSc, and Charles R. Denham, M.D., Co-Chairs, presiding.

MEMBERS PRESENT:

GREGG S. MEYER, M.D., MSc, Co-Chair

CHARLES R. DENHAM, M.D., Co-Chair
MICHAEL R. COHEN, MS, ScD, RPh, FASHP
DAVID R. HUNT, M.D., FACS
MARY LEHMAN MacDONALD
MAURA McAULIFFE, Ph.D., CRNA, FAAN
PATRICK ROMANO, M.D., MPH

GUESTS PRESENT:

HAYLEY BURGESS
DON CASEY
BECKY LAMIS
ALICE TU

STAFF PRESENT:

PETER ANGOOD
SARAH CALLAHAN
ERIC COLCHAMIRO

STACY FIEDLER
JENISSA HAIDARI
ANDREW LYZENGA
MELISSA MARINELARENA
EMMA NOCHOMOVITZ
LINDSEY TIGHE
CHRISTINA TSIATIS

MEMBERS PRESENT VIA PHONE:

PETER PRONOVOST, M.D., Ph.D.

GUESTS PRESENT VIA PHONE:

JOHN BIRKMEYER
BARBARA RUDOLPH

MEMBERS NOT PRESENT:

JAMES B. BATTLES, Ph.D.

PASCALE CARAYON, Ph.D.

JENNIFER DALEY, M.D.

JULIANNE MORATH, MS, RN

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P R O C E E D I N G S

(8:26 a.m.)

DR. ANGOOD: All right, everyone. Good morning. I think that we'll go ahead and get started, and hopefully a few more of our Steering Committee members will make their way in.

There may have been a small glitch in some of our meeting materials where some of the individuals thought it started at nine as opposed to eight o'clock.

Hopefully you'll have your coffee and your breakfast all organized.

My name is Peter Angood. I am now at the National Quality Forum as a senior advisor for patient safety, overseeing the patient safety portfolio for NQF, and the safe practices are part of that portfolio.

I would like to welcome each and every one of you for taking some time out, especially in a hot August where we should all be at the beach really. I know that I want to

be there.

We have a few folks that will be calling in. Is there any who have joined the call yet? Not yet? Okay. So we'll have, I think, two or three individuals calling in, plus whatever public members, and as I mentioned, a couple other folks will be joining as well who are more local and may be thinking that the meeting started at nine.

Well, first off, in my new position I would like to make a couple of comments, but most importantly, to thank Chuck and Gregg for co-chairing the Steering Committee through the last couple of years and helping all of us to try and get that recent release of the safe practices out in March. So thanks, Gregg and Chuck, for that.

And we certainly can't overlook Hayley Burgess and her hard, hard work in the background. You know, she makes Chuck and Gregg look good. Some days it's harder than others, yes, especially when you're having a

bad hair day, right?

(Laughter.)

DR. ANGOOD: But, no, Hayley, thank you for all of your extremely hard work in making this March version as good and as tight as it is.

What we are going to be doing through this meeting and what we've been doing in the background leading up to this meeting is to do a little buffing and polishing, if you will, of the existing safe practices. We are moving into an annual maintenance cycle because there's actually a fairly good flow of updates in the evidence base, et cetera, that need to be taken into account and then an every three-year cycle for the safe practices is just a little bit too long.

As well, as you'll hear in a few minutes, we'll be expanding the patient safety portfolio overall, and so for us to be able to remain flexible with the safe practices is exceedingly important. So the annual

maintenance cycle will be a critical issue for us.

So for this year it's buffing and polishing. We don't really necessarily want to do major deep revisions because that will put us into a very complicated consensus development process, which we just went through, and I don't know as the field wants to go through all of that again. But we are planning for 2010 to do a much more significant revision to the safe practices with the request for new safe practices at that time and further revisions as needed on the existing safe practices, plus or minus the retirement of some of the safe practices that we already have.

So we'll be reformatting the Steering Committee. We'll be going into that full consensus development process during '010 for the 2011 version of the safe practices.

Chuck and Gregg, did you want to

make a few opening comments before we get into the full part of the agenda?

CO-CHAIR DENHAM: Sure. Thanks, Peter.

For the record, I think also the National Quality Forum staff have done a fabulous job in terms of working on the update to this set of practices, and I think there has been, I think, very ample evidence to the adoption of them. We have about three out of five U.S. hospitals in our research test bed, and we're averaging now in a joint call that we do with the National Quality Forum on Webinars monthly over 1,000 hospital phone lines and averaging maybe three and a half to four people per line.

And so we'd like to thank the Committee members and subject matter experts that are here or may be reading the transcripts for their great support because I think that there is very great interest at the front line in the practices.

And as Peter said, the objective this year, and we really are so thankful that National Quality Forum agreed to kind of move up the delivery of the 2010 update to 1st of January time frame because the hospitals really on a calendar year basis plan an awful lot of what they do, and this really gives them time to really be familiar with them and understand them and understand where they are, what's been changed, what's been updated and be able to really put them to work in adoption as the payers try to tie their payment mechanisms to these practices.

So it's really great that they will have that time, and that is another one of the drivers for this year, an update of the problem statements and the implementation guides, but that as we go through the specifications, you will see, I think, great discipline.

So often organizations want to change everything, update everything, and go

through Herculean sort of efforts in the narrative updates of things, and then those that have to adopt them have some huge challenges adopting them, and many of the hospitals are now tying their quality and safety programs to adopting what the NQF puts out, and so any little change really has some disruption, although we should be very cognizant of anything that could save lives or has better evidence or whatever.

I think the strategy this year is a good one of saying in the 2010 update be disciplined about updates to the specifications because people are still building them into their DNA, as Peter said. The '09 update came out in March. So it is only really a few months old, and in terms of organizations moving their ship to a new course, they're still adopting that, and yet we're going to have 2010 come up in January.

So I think the discipline is a good discipline we're hearing from the field,

and so a lot of the effort for the update will be in the implementation guides that are not formally specifications and not formally the endorsed standards, but that can really kind of help and assist.

So I think this discipline is great. I know that there are a number of folks that really want to see substantial evidence reviews of the practices. I know Dr. Casey is here and has really been a great champion for that, and we had considered doing a big jump on that for 2010, but 2011 I think gives us a wonderful opportunity now to get running room to be able to again have a January kind of release, but still be really able to really go through a thorough review again of the evidence as things go up.

And I think the HAI, the health care associated infections practices that were very thoroughly evidence based through the HAI compendium is a great example of harmonization, I mean, not only with the six

harmonization partners of Leapfrog, NQF, AHRQ, CMS, the IHI and others, the original harmonization partners, but the exciting thing about the HAIs was that added to that group included CDC, IDSA, the Infectious Disease Society, SHEA, the epidemiologists and APIC, the professional infection control specialists.

So I think that harmonization has been a great theme, and we're really thankful that NQF has been able to be a convening force to get them, you know, together.

So those would be my preliminary thank-yous to the NQF staff and to the NQF for actually moving up the agenda for January.

DR. ANGOOD: Great.

CO-CHAIR MEYER: I'd like to extend the same thank-yous.

And one of the things that's a benefit, I think, of these meetings and going back and looking at the work is that speaking on behalf of myself and maybe Mike Cohen who

is the other sole survivor from the original part of this work, that if you look at where we started and what you see now, it's pretty impressive, on the one hand.

On the other hand, I think that this meeting and all the future meetings are going to still struggle with what I see as kind of three essential tensions, and that's why I think the wisdom of the group helps us out, and those tensions are I would say the first one is one between over specifying and being super specific about what we ask a group to do versus being so ambiguous that everyone raises their hands and says, "Well, what do you mean by that?"

So, on the one hand, we could handcuff them by being too specific and, on the other hand, we could leave them scratching their heads asking what we really wanted, and trying to titrate that is always a tension that we need your help with.

I think the second tension that we

have here is around the issue that Chuck mentioned, and that is the evidentiary base in that all of us would like to be able to say, boy, there is super strong evidence, you know, of the highest degree, the kind of thing that U.S. Preventative Services Task Force would say is, you know, top grade, A level evidence supporting each of these, and then, again, balancing that with the reality that there will be some things that we may never have Grade A type evidence for, but, boy, they're really important, and where we strike the balance there.

And the third tension is reflected, I think, just in this meeting today, and that how much we want to keep this up to date with the current evidence versus how we don't want to be constantly moving the goal posts on those who are trying to work out there and make progress in patient safety.

And so I think that while we'd like to be up to date, we'd like to be real

time up to date, on the one hand. On the other hand, I put on my hat when I go back to Boston at Mass. General and say if these things change every three months, I'd just lose my mind.

And so those are the three tensions. I think the clear recognition, I think, is that there's not a right answer to any of them. There's just good discussion and hopefully some wisdom that we can distill from our discussion today in the future that will get us in about the right place.

And I would say, again, taking the perspective of having been at the very first meetings of this group till today that I don't think we've always gotten it perfectly right, but I think we've come out in a very reasonable place without fail, and more importantly, I think it has gotten better.

So we've learned, and it has just gotten better with time, and hopefully this next round will continue that trend.

So thank you.

DR. ANGOOD: Thank you both.

Certainly excellent comments and challenges. I particularly resonate with that over specifying. In my recent position at the Joint Commission in overseeing those national Patient Safety Goals, I kept hearing from the field, "Tell us what to do. Tell us what to do."

And the more that we got specific, the more thy told us, "Don't tell us what to do."

(Laughter.)

DR. ANGOOD: You know? So there is that tough balance in all of this, yes.

Well, I'm going to spend just a couple of minutes going over where we're at this stage looking as a vision for patient safety at NQF and, given the comments that Gregg just made, I'm certainly going to keep those in mind as we try to continue expanding this patient safety portfolio at NQF, and the

safe practices are a pivotal piece in all of this.

We have to, I think, look at ways to not only follow the evidence base, but perhaps move into sort of a grading and scoring methodology on the basis of this because patient safety, as we all know, many, many times, we're trying to do things that seem intuitively right. We've got some examples of successes, but we don't necessarily always have the evidence in place to support it.

So how do we take that into account as we push the field along in terms of trying to get improvements?

And then the whole issue of prioritizing topic areas, we need to continue looking at that and try to make that become a bit more objective and try to help, you know, get towards specific requirements on the prioritizing and try to get specific solicitations coming in so that we build a

nice and fully rounded composite that not only fills out the safe practices, but all of the other components within our patient safety strategy.

So the emphasis on the word on this title slide is evolving. Okay? So what we say today isn't necessarily going to be the same over time, but I tend to look at our programs as sort of umbrellas within umbrellas, if you will, and the serious reportable events are those clearly the things that should not happen in health care. The safe practices are those things that we can and should be doing to prevent the bad things from happening and to also improve the overall quality and safety while we move forward within the different health care organizations.

And then the measures are obviously those tools that we use to try and measure on both our outcomes, but also our processes of care.

The National Priorities Partnership, now 32 member organizations, has developed it six main priority areas. Patient safety is an important one of those six, and the NQF is the convening organization for the NPP as well.

The six priority areas, patients and families, population health, patient safety, the continuum of care, overuse, and then the appropriate end of life care and choices around end of life are with individual work groups in place now, and they're focusing in on specific activities within that, and we're trying to organize the patient safety component of that to help complement what we're doing with the safe practices as well as with some of these other programs. So it's becoming an underpinning for a lot of what we do at NQF.

Obviously measurement and endorsement of measures at NQF has been its mainstay for its first ten years of evolution.

We all continue to think of this structure process outcomes. We're moving towards composite measures over time, and when you look at the 525 or so measures within the NQF database right now, slightly less than 100 of them are what you would call patient safety ones.

And we don't have as much of a breadth or depth in those safety measures as we would like. So we'll be moving forward in that very much.

When I tend to think of health care, there's always the main conditions that are there, and CMS has their top 20 which are mostly chronic conditions, but there's a variety of other top issues out there. Those different conditions are cared for in a variety of environments, the hospitals, the out-patients, the nursing homes, et cetera, et cetera, and they are oftentimes associated with a variety of procedures, and the individual disciplines impact on how those

conditions are managed, if you will.

So we put all of those into this big filter and then we take on the NQF tools that we have existing right now, which are the safe practices and the serious reportable events and the measurement strategies, and that's going to drive out our portfolio over time.

Well, then we have to put it all together because similar to the tensions that Gregg mentioned, there are tensions in all of this as well. So you've got your little Venn diagram with the disciplines right in the middle there, and then we've got the safe practices, the SREs, and these measurement strategies going on. We've got the whole other enterprise of measurement in general, not just focused on patient safety, and they all influence each other overall. How do we make that all function together is, I think, where the hard work is for us as an NQF.

And with a lot of the work that's

been done at NQF, a lot of the new leadership and new leadership strategies that Janet Corrigan is bringing in, we're clearly moving beyond just endorsing of measures at NQF, and we've got a number of grants, as well as contracts in place, one of which is a large Department of Health and Human Services contract that's providing us with good funding and the ability to expand out in a lot of our NQF programs.

We have a fair amount of focus on patient safety in that contract. One of those is to expand the serious reportable events or what they also now want to call health care acquired conditions, not just hospital acquired conditions which the CMS uses, but HHS is wanting us to utilize this term of health care acquired conditions, and the SREs are kind of parallel or a subset of these health care acquired conditions.

Not all HACs will need to be reported, but they certainly should be

reviewed at least at a local level and should be denied us for trying to make further improvements in care.

And we're going to be expanding those out of the hospital environment to all the other environments of care as well. So that's one main component of our project.

And then a second main component of this HHS work is to further develop and expand the patient safety measurements, and to really do that in an organized strategy and with a specific focus on HAI.

As we all know, HHS has a huge focus on HAI, rightfully so. There's the HHS action plan. If you haven't seen that on the HHS Website, I would encourage you to go and look that up. Four main focuses for them on there are the surgical site infections, ventilator associated pneumonias, the urinary tract infections related to catheters, and then the ventilator associated pneumonias.

They also have a specific subfocus

on MRSA and Clostridium difficile, and that is an important set of initiatives because there is going to be incentives based on payment or reimbursement between the federal level and the state-based levels, and if there isn't full and robust activity and successes going on at the state levels on HAI, there will be withholding of payment towards that.

So that's a huge, huge program that we need to continue to pay attention with through our vehicles here.

The third piece of the patient safety work at HHS is on the development of an issues framework report for measurement evaluation and public reporting of these health care acquired conditions, and we'll be convening the various state-based reported agencies. There's 28 of them now. Eleven of them use the serious reportable events verbatim basically, including Massachusetts, and Massachusetts just put out their first report.

But they don't talk to each other, and so we need to learn from all of these individual state-based entities what goes on and folk like Mike have been reporting and prompting reporting forever, and we need to continue to learn and figure out how to nudge our whole portfolio along with all of this.

So those three main components are going to be an important part of all of this, and the conceptual framework for some of this is then -- if you take the top conditions and you take the environment of care and you take the procedures and to some degree even take the different disciplines and how do you matrix that against our serious reportable events, the safe practices, and the endorsed measures.

It looks simple on this diagram, but just kind of envision it out even over 20 conditions, and then try to get, you know, sort of serious reportable events, safe practices and measures for each of those

different boxes.

But, you know, congestive heart failure, top condition is treated differently in the out-patient setting. It's treated differently when it's an acute exacerbation in the in-patient setting. There may be procedures related to that, and then you've got different disciplines of care.

So if you're a nurse in the out-patient setting, you want to know what are my issues that I need to take into consideration, not just with the SREs, but for the safe practices, and how are they measuring what we're doing? Similarly, if you're in the hospital, et cetera, et cetera.

Some of the information in the boxes of this complex grid as it grows will be the same, but we're trying to drive -- have a nice weave or a nice overlay with each of these programs so that we're able to broaden this all out over time.

And that gets us back to the

prioritizing and how do we set that, et cetera.

I'm not going to take you through this organizational chart. It's just a brief snapshot of where we're at in terms of a patient safety structure now at NQF. This is all new for NQF, but on the far left is our main component programs, the SREs, the safe practices, the measures, and the National Priorities Partnership. We've got a variety of little special projects. We're going to be doing some work for CMF to clarify the issues around standing orders. We've got some AHRQ work that we do for the development of the common formats, around the PSOs, and there's some other projects coming on line.

And towards the right there are all new activities that we're getting off the ground, including some robust education and outreach work, of which the productivity from this group is an important component.

And then, of course, we all need

and certainly in NQF we have to pay attention to the funding and how we're going to make all of this work, and that has been perhaps one of the Achilles heel tender points for NQF over time. There's lots of great ideas, lots of things that could/should be done, but how do we make the funding streams consistent so that we can get that work done?

So that's a fairly robust, I think, set of activities. The main goal is to try and weave this all better together. We have looked critically, for example, at how the safe practices and the serious reportable events overlap, and do you know what, there's not much there. You know, there's just not much there, and that's a weakness. We need to get that corrected.

And the measures, as I mentioned, we don't have as many as we think. We've got lots of SSI measures, for example, but we have one urinary tract catheter measure. So we have to bring all of these together more

robustly.

So I went through those for a few moments to try and help you provide what the context of what we're doing with the safe practices and couple that with the comments that Chuck and Gregg made, I think, you know, today's work is certainly highly important, but we can also use this as the teeing up, if you will, for those who like to golf, as to how do we begin to think of growing and expanding and also yet paying attention to those tensions that Gregg challenged us with at the beginning.

So I'll close it at that, Some comments or clarifications? Mike.

DR. COHEN: Well, yes. First, I really have two things that I want to talk about, but the first thing, which relates to what you were just saying about the serious reportable events, I have to be honest with you. I certainly know about them, and I've read them, and I understand, I think, how

they're being used at the state level, but I am at a loss to explain to people how they are actually being used to improve patient safety.

Is it just about transparency? Is this something that actually can be transferred into learning so that, you know, people are actually applying information. Is that what you're talking about as far as bringing the states together, et cetera?

DR. ANGOOD: Yes.

DR. COHEN: Because right now I see it as a count of the various events, you know, that get reported and not much beyond that.

DR. ANGOOD: It's a perfect question because I think a lot of people are thinking the same thing. There's all of these challenges going out and all of these things you should avoid, but what is it that we know in terms of the success or failures of these different initiatives.

The convening of all of the state-

based reporting agencies is just that. Let's try and learn what works, what doesn't work, what new direction should we head with all of this, and then how do we, more importantly, set up for building an evidence infrastructure so that we can accrue the successes and failures over time?

You know, the World Health Organization has an initiative, and there was a meeting, as you know, Mike, just a couple of weeks back in Toronto. Their initiative is part of the Patient Safety Alliance. One of them is on reporting for learning, and there were several countries at this meeting and no other countries got this one figured out either.

So it's not like we're behind or anything. If anything we're a little bit ahead of most countries, and the WHO is certainly looking to see what occurs in the United States in terms of, you know, how we begin to put this all together.

Been throwing these challenges out for a decade or so now, and now is the time to not only make them more actionable, but to do the full assessment. It's part of that HHS contract work. That issues framework will take these issues into consideration, and that will be part of the reporting.

CO-CHAIR MEYER: Can I respond?

Again, this is a bit of ancient history, but the work on serious reportable events and the safe practices derive from the federal government's response to the consumer report. So I can go back to that. Doing the accounts report, it says that NQF will be asked to do two separate bodies of work.

From the beginning there was the notion that they were, in fact, to serve different purposes, and so as originally envisioned, the safe practices were to look at those places where there's evidence that if you do this thing, it is going to have a measurable impact on patient safety, and the

notion here was that this was taking the systems approach and saying we're not going to try to measure the unmeasurable in terms of safety because of where we were at at that point in time with measurement, but we are going to -- what we are going to ask organizations to do is to look at this group of safe practices and then the piece to it was that they would report on whether or not they were doing that, yes or no.

The second piece was to satisfy the call that said, you know, that's all well and good, but you know, there are some times when we just for accountability purposes, we need to have transparency, and we should have a parsimonious list, and that's where the serious report will eventually go.

And so that was, at that time, I think that that was the best thinking about how to go about doing this in a way that respected the need for accountability, but at the same time focused on practices and focused

on putting systems in place.

I think over time, you know, that was now about a decade ago, and so rethinking that now, I think, is the right time to do that. It's to think about how to pull the pieces together. We had very robust discussions early on around the realty that if we got rid of all of these wrong site surgery in the United States tomorrow, would you or I or our loved ones really be measurably safer in American hospitals.

The answer is not unless you have a whole lot of decimal points because they're rare events, and so how to pull these things together, I think, is the next right body of work, and I think coupling the practices, the accountability pieces, and then with the measures to see are we really making a difference is the right next bit of work, and frankly, when I look back ten years ago, I wish we were able to do that, and I don't think we were.

And I think that as a measure of some of the progress that has been made -- you know, I'm a half full guy and so I think we have made some progress on these fronts, but now is the time to try to pull them together.

DR. COHEN: The other area that's bothered me, and I remember discussing it the last time we had this committee together, and that is the focus almost always on acute care, areas that, for example, would be accredited by the Joint Commission. Let's put it that way.

And you know, in my case as a pharmacist I am concerned about what I see personally, the reports that we get, things that we read in the media about the area of community pharmacy. We have problems there, and this is being totally overlooked. I mean, they do not look at things from a systems standpoint as we have learned to do in acute care and other areas.

I always see this area getting

overlooked. Yet we know, every American uses community pharmacy or some type of an ambulatory care pharmacy practice, and it's not just pharmacy. It's other areas, as well, that are not accredited. Why we continue to overlook that I'm not sure, but to me that would be critically important to start getting involved with that particular community, you know, to change the way we're doing things.

DR. ANGOOD: And I think that's very, very important and a high priority. So as we expand this matrix, if you will, we can look at one framework being those top what is it, eight CMS environments?

We've used those environments in the existing safe practices, and we've made special areas and we'll review those as we go through, but as we do this weaving of the SREs practices and measures we'll make sure that it expands into the non-acute, non-hospital settings. That needs to be a very important focus for the next five years.

Other comments?

Patrick Romano, welcome. You've just missed some intro background stuff. So you haven't missed the meat part yet.

DR. PRONOVOST: Peter, this is Peter Pronovost.

I have been on the call, and thank you for -- joining. I had to do an early meeting.

DR. ANGOOD: No problem.

DR. PRONOVOST: But thank you for the comments.

Two thoughts. One was that I agree with not diving into the evidence review now and typically as -- AHRQ is supporting RAND and others to develop criteria for patient safety practices, and it seems that that framework might actually inform how we look at it, how it behooves us to wait till that report is out in January.

And then, second, more of a kind of my hat in the trenches here is Greg's point

about the tensions, I think, are very real, and even perhaps in lieu of adding new things it might be beneficial if we could get some more feedback from the trenches about how these are being perceived and are they used and viewed as useful.

And I don't know what NQF resources, but before we add new ones, some focus groups or talking to some sample of people who are using these to say what is working for you and what isn't working, I suspect, would be very informative to our work going forward.

DR. ANGOOD: Thanks very much, Peter, and your comments actually filled a couple of holes from my opening comments. So thank you for doing that.

This RAND project that Peter just mentioned, I think, is going to be very important in terms of helping us learn further how to evaluate and study and develop methodologies around safe practices, and that

work should be, as Peter said, wrapping up towards the end of the year, early next year.

And, Peter, we are planning to make sure that that becomes part of this scope of work that we're doing at NQF and why I made sure that I was able to at least get close affiliation with that work so that I could follow it in its evolution.

And your second comment around the feedback from the field, as part of our HHS contract work we're doing a fair amount of an environmental assessment work, if you will, to help lay the foundation for some of those activities I described, and surveying the field and getting some feedback is one of the ones that we have in the works.

There's some mechanical issues in terms of how to do that in a timely fashion when you're working under these heavy government contracts, but I couldn't agree with you more. Feedback from the field on the practical realities of these things is

important.

Thank you.

CO-CHAIR MEYER: And I would just note also we count on those of you around the table to do for us, and I have kind of my view of the world as somebody who's trying to put these into place, but I come from a large academic, you know, health center in Massachusetts, and that is not the world, despite what many people up there think.

DR. ANGOOD: Yes, I just felt the quake go through the room there.

CO-CHAIR MEYER: Indeed, indeed. So we do count on Committee members to speak up and say what you're hearing from colleagues or what you're experiencing on your own with what's making sense and where we seem like we're hitting these tensions right and when we're off the mark.

DR. ANGOOD: Any other comments or clarifications or anything?

It's always nice to spend a few

minutes on the broader ideas and the vision and all of that sort of stuff, but we do have some meaty work to get through today.

So we've got Peter on the phone. Patrick is in the room. We've got a couple of other individuals that are going to need to filter in during the morning time, and we're going to make sure that we try and wrap up by 3:30. We've got a healthy set of work.

We also have one specific agenda item that we have to be on the mark for at ten o'clock. Arnie Milstein and Barb Rudolph and a couple of others are going to be calling in to talk to us about the evidence-based hospital referral issue, and there's a separate set of discussions. There's a separate document you should have received regarding that.

So we need to hit that as one hard stop point, but the rest of the day, the second hard stop point is 3:30.

Practical issues, restrooms are at

the far end of the hall. If you need somebody in a bit of help, our meeting assistants are on the side of the room, are just outside, and Melissa and Andrew are here to help us in any other ways, and the technical issues, if you have any, the gentlemen on the side there are excellent.

All right. With that I'm going to --

MS. MARINELARENA: Can we just do some housekeeping?

DR. ANGOOD: Other housekeeping that I didn't mention.

MS. MARINELARENA: Sorry. If we could just go around the room and have everybody introduce themselves for the transcript and disclose any conflict of interest that you have, just technicalities.

Thank you.

DR. McAULIFFE: I'm Maura McAuliffe. I'm Professor of Nursing at East Carolina University in Greenville, North

Carolina.

I've been a part of this Committee, I think, for about four years, and it has evolved and it has really been a great process to be a part of, and when you see the final product, it makes you proud to be part of it.

So I think we're doing good work here, and I have nothing to disclose as far as conflict of interest.

Thank you.

MS. MacDONALD: Hi. My name is Mary Lehman MacDonald. I'm the Director of the Health Care Division of the American Federation of Teachers.

We represent 1.6 million consumers of health care and also 70,000 nurses and health professionals who are covered by collective bargaining agreements in usually acute care hospitals and visiting nurse services.

So, again, it's a pleasure to be a

part of this important work, and I have no conflicts to disclose.

DR. COHEN: Mike Cohen from the Institute for Safe Medication Practices.

We're a nonprofit organization that operates a national medication reporting program for both practitioners, and as of this January, for consumers as well. We have a consumer Website with access to reporting.

And our other major activity is that we also act sort of as a National Transportation Safety Board after there's been an event at a location. We sometimes travel there.

And I have no conflicts of interest either.

DR. BURGESS: Hayley Burgess, Director of Performance Improvement, Measures, Standards and Practices for TMIT.

No disclosures.

CO-CHAIR MEYER: I'm Gregg Meyer, Senior Vice President for Quality and Safety

at Mass. General Hospital and the physician organization there.

And I have no disclosures, sadly no disclosures.

(Laughter.)

CO-CHAIR DENHAM: Chuck Denham, Chairman, TMIT.

And only disclosures are on the form, support of the NQF and support of the Leapfrog Group through TMIT.

DR. ROMANO: I'm Patrick Romano. I'm a professor of internal medicine, general medicine and pediatrics at the University of California, Davis.

I work with the UC-Davis Center for Healthcare Policy and Research, and I guess my disclosure is that I've worked fairly extensively with the Agency for Healthcare Research and Quality on quality indicator development, refinement and validation.

DR. ANGOOD: Thanks, Patrick.

And, Peter, did you just want to

do a second introduction for yourself, please?

DR. PRONOVOST: This is Peter Pronovost. I'm a professor of -- and health policy and management at Johns Hopkins.

DR. ANGOOD: Thank you.

Anyone else on the phone?

(No response.)

DR. ANGOOD: Yes, not at this time. Okay.

Just again for the record, my name is Peter Angood, Senior Advisor for Patient Safety at NQF, and we have Melissa Marinelarena, which I can never say properly, who is Project Director at NQF on patient safety, and Andrew Lyzenga, who is a research analyst for NQF, as well.

Do you want to go around the room?

MS. MARINELARENA: Yes, can we have the audience also introduce themselves?

Thank you.

MS. CALLAHAN: Sarah Callahan. I'm the Director of Education for NQF.

DR. LAMIS: Becky Lamis. I'm a fellow at the Institute for Safe Medication Practices.

DR. TU: Alice Tu. I'm a FDISMP fellow currently with MICA ISMP.

DR. CASEY: Don Casey, Chief Medical Officer of Atlantic Health in Morristown, New Jersey; Vice President of Quality; also a member of the Quality Improvement Advisory Commission for the State of New Jersey Department of Health and Senior Services.

MS. TSIATIS: Christina Tsiatis, performance measures intern at NQF.

MS. NOCHOMOVITZ: Hi. My name's Emma Nochomovitz. I'm a research analyst in the Performance Measures Department at NQF.

MS. TIGHE: Hi. I'm Lindsey Tighe. I'm also a research analyst in performance measures at NQF.

DR. ANGOOD: All right. I think that concludes all of our introductions, and

with that, roll up your sleeves, get ready, put on your seatbelts, and Chuck and Gregg are going to take us through.

We have Andrew here is going to sort of scroll and type as we move along, try to capture the essence. This kind of live capturing of the information is one of being a very useful tool that Hayley and Chuck helped us get refined on.

So Chuck.

CO-CHAIR DENHAM: We want to be very cognizant of our ten o'clock timetable for the meeting with the subject matter experts regarding evidence-based referrals. So we want to make sure, and we want to acknowledge Dr. David Hunt has just arrived, one of our esteemed Committee members and the Chief Medical Officer for the Secretary of Health's Information HIT Coordinators Office.

Hopefully I didn't mismanage that --

DR. HUNT: No, that was perfect.

CO-CHAIR DENHAM: -- introduction too much, and a great champion for these practices and has served on the Committee for the last three years in a great way, really helping us coordinate with both CMS and the Secretary's Office.

So the subject matter for just the next couple of minutes is just to address the time line for the safe practices release, and again, we want to really thank the NQF for being able to target the January 1 release date for the hospitals and the health care organizations that adopt these over a calendar year.

So back-planning from that, the timetable for this set of practices -- and correct me if I'm wrong from the NQF staff. I'm just reading from the list -- is public comment for the September 14th through October 13; the week of the 19th and the 25th, Committee conference calls; November 1st is targeted for the CSAC Committee for review;

and then Board of Directors, presuming that the public review, comments are all reviewed and incorporated and assessed prior to moving forward with the board, presuming that all of that occurs appropriately, which we would probably anticipate it to be fairly simple because the updates to the practices are not substantive. There are just some that are being addressed that the Board of Director would then hopefully approve this set of practices, and then the January sort of release of the practices, again, giving the hospitals a chance to adopt.

So let me stop there and ask the NQF staff if there are any other dates that are important to us that we want to make. And, again, these are targeted dates depending on what comes back from the field.

So Dr. Angood, Dr. Meyer, any comments on the time line or anything from the Committee regarding the time line?

How about from the attendees?

Patrick Romano, yes.

DR. ROMANO: Hi. Just a quick clarification. The issues that were identified for our attention here in the right-hand column of this table are those issues that have been raised by NQF members or by members of this Committee or what's the mechanism them for that?

CO-CHAIR DENHAM: The right-hand column are from all of the above, and more subject matter experts' review of the literature, changes in the Joint Commission work so that the harmonization could occur. So what's in the middle column are the specifications, which are the endorsed practices.

And as we know, the book has grown to north of 400 pages, but a substantial proportion of that are implementation guides that are not formally part of the endorsed practices, and then also references so that because the hospitals and health care

organizations were really seeking to have as much as they could to kind of refer to.

So the both of the endorsed practices, middle column, right column, all of the above, members, subject matters experts, harmonization organizations, and also input of the NQF members.

Anything you want to add, Peter?

DR. ANGOOD: No.

CO-CHAIR DENHAM: So Peter.

DR. ANGOOD: No, I'm fine, and what you will do in moving through all of this at a fairly rapid pace with Chuck and Gregg's guidance is to basically go through each practice. Hopefully you will have had some opportunity to at least scan through the materials.

Hayley, do you want to just remind me again of your edit style in terms of what's an underline, what's covered in blue, et cetera?

DR. BURGESS: Right.

DR. ANGOOD: Use your mic please.

DR. BURGESS: Anything that's underlines black, that's original text that we wanted to draw your attention to, and then the question, we tried to put them directly out to the right side so you would know what we were asking.

If it's blue, then that is a potential change in wording, and red would be a deletion, a potential deletion.

CO-CHAIR DENHAM: So in the table that we have, we've addressed a number of the practice in that first preamble, but I direct your attention just in order to get through by 10:00 a.m.

Practice is Chapter 2, embodies the four practices that address culture. These address leadership, structures, and systems using surveys for cultural measurement and intervention, team work, and team-based interventions, and identification and mitigation of risk and hazards.

And so at this point in time as we go through this -- and we'll have additional Committee calls as we have discussion -- there are really no major issues in terms of substantive change, other than updating certain specifications to synchronize them with other NQF reportable events, for example, and other issues that don't pertain to the endorsed specifications of the practices.

There will be updates which don't have to go out for review to implementation guides and references, and so we're thoroughly going through the problem statements, and just to refresh everyone, the practices have a problem statement. Then there is a practice statement, and then there are specification. And the additional specifications and the practice statement are formally what is the endorsed practice.

The problem statement is an introductory preamble. Then the implementation guide's new horizons, the

practice measures that may be available out of 525 measures that evolve with the safe practices, all embody the non-endorsed practice sections.

So we won't be putting those up for review now, and again, they don't have to be -- they're not part of the endorsed practice, but merely guidance, reference information, and updated information. And so the problem statements will be updated with the latest references both from the medical literature, but also non-medical literature because the NQF has given us the band width over the years to make sure that we can go outside of the medical literature, for instance, in the leadership areas and others.

And so there are updates that will occur there. So as we go through these practices and for time, I think that -- how would you like to do this as we kind of look at our ten o'clock stop? You know, there are some clarifications regarding language.

Gregg.

CO-CHAIR MEYER: I think we should just go methodically through the table and raise the question. I think two things we'd like you to react to the questions that we raise here, but in addition to that, we'd like you to raise other questions as you go through. So if there's something again from your experience or the experience of those you know in the field that you say, "Boy, here is another issue you didn't pick up on," we'd like to hear those as we scroll through.

CO-CHAIR DENHAM: So safe practice number -- go ahead.

CO-CHAIR MEYER: I'm sorry. I just wanted to make one more comment. The balancing act on this will be, as I said in the opening comments, we're buffering and refining and polishing the existing practices. If there's highly, highly substantive change that needs to be made, then we need to go into the formal consensus development process.

If there are issues that don't necessarily change the specs but are issues that should be mentioned, then one of the methods we do use is to move some of that information into the problem statement and then sort of the contextual part of the narrative for the safe practices so that we get the information into the field, but it doesn't necessarily have to change the specs on the practice and kick us into that consensus development process.

That doesn't mean we shouldn't. If there is clearly an issue that needs to be pushed into consensus, then we will go that way. But there is the balance.

CO-CHAIR DENHAM: Patrick.

DR. ROMANO: Yes, I'll just kind of restate a point that I've made over the past year, year and a half, which is that I think that this document or the current version, 2008 version is really a substantial improvement over previous versions and

reflects this evolutionary change that we've been working toward.

But I think I and Peter Pronovost on the phone and maybe some others are still a bit frustrated by kind of a pseudo specificity. It appears in some of these safe practices, especially the first two or three, where there's an effort to verify specifically delineate aspects of the leadership practice that really aren't evidence based. They may make sense, but there may be 100 different ways that organizations can achieve the same goals.

And so that will be a recurring theme in my comments, is looking for ways to move that what I call pseudo specificity because it looks very specific, but it's really not measuring what we want to measure and trying to move that out of the additional specifications, and I think the very first comment is a good example of that.

DR. ANGOOD: And by all means keep

kind of ringing that bell, and it is the tension that you do. In one of the breaks, Patrick, I'll try to give you a brief update on the small portion that you missed because of your flights and help set some context for you and reassure you that we're headed along that path on a broader context overall because we all agree with you. We need to get there it's just a matter of this tension.

DR. PRONOVOST: And, Patrick, this is Peter.

I would also add acknowledging the potential risks of driving health care organizations to one specification when it might not be the optimal, and almost certainly will have unintended consequences.

DR. ANGOOD: Yes, very good, Peter. Thanks.

CO-CHAIR DENHAM: So I think it's really important, Patrick. I think that frequently we can raise the bar of evidence so high that nothing will pass through the bar

and will have the catharsis of the discussion, but not have any specifications, and I think this is the dynamic balance that Dr. Meyer came up with.

So that if there are I think we need as a Committee to discipline ourselves to not challenge word tooling, a narrative or a style because there's not evidence but look at the specification and say if there is evidence that committee members or as subject matter experts have that say that there's a better way for the specifications to be retooled, that that evidence be provided and that we address it and, really as Peter just said, a better way that has evidence, that's the whole purpose of kind of the process of refining and making them better.

I think it's important to strike that dynamic balance though as we go through this of the fact and look back on the history. We now have thousands of hospitals adopting these practices, and actually the first four

practices have had very little push-back in terms of not being specific enough or being too specific or not being evidence based, you know.

So I think that there are not a first set of practices that have not been test run out into the marketplace. They have not had a major change since the 2006 update, the first four practices, and it's interesting that we have many, many hospitals that are adopting them, and we just haven't had from the field that your test is -- you know, are we off track?

We also haven't had subject matter experts really challenging them from an evidentiary standpoint. So I think we should keep that in mind on some of them, you know, as we go through them.

So the safe practice, number one, is divided up in awareness, accountability, ability and action categories. The first comment is regarding the third bullet, direct

patient input, and the question is information from the satisfaction survey is not enough for discussion. Is this wording too strong?

So I want to open that up. Peter, do you want to comment on this one at all? Anyone want to comment regarding this?

MS. MacDONALD: I would just say no. I don't think it is too strong. I think it's fine.

DR. ROMANO: Well, I think that sometimes the problem comes in with the operationalization. I think that we all would agree that patients should have some involvement or patient representatives should have some involvement and input into the management of the hospital related to safety and quality.

The question is what's the appropriate mechanism for that input. The way this particular item was operationalized on the Leapfrog survey was patients and family of patients are formally involved in safety and

quality committees that meet on a regularly scheduled basis.

Now, that's a little bit problematic because in most hospitals quality and safety committees are constituted as peer review committees, and so it's difficult when they're legally constituted as peer review committees to include patients on those committees.

So the NQF language here is perhaps slightly more inclusive than the way Leapfrog has operationalized it, but I would like to hear some discussion about this issue and about whether there are ways of involving patients and their representatives without having them formally on constituted safety and quality committees.

DR. McAULIFFE: I guess I would take the opposite point. I think that they should be to the extent possible allowed to be on the committees. I think they bring a valuable input to those committees. I think

the challenge is to have a structure such that they are educated into what their role is on the committee. I don't think the patient can change, you know, from month to month, but to be educated into what their role is and perhaps have legal counsel inform them what they can and cannot disclose outside of that committee.

But to have their input, I think, is hugely important.

MS. MacDONALD: I just -- I also -- oh, I'm sorry.

CO-CHAIR DENHAM: I was just going to say I think we need to be very careful and precise about what we're doing. I don't think that the Leapfrog, any organization's use of the practices should be a major discussion point here. I think we're discussing these specifications, and I think that if organizations are misusing or changing, you know, it would be one thing if an organization said, "Hospitals are adopting the

specifications as stated."

But you're putting a twist in it in how they have operationalized it, a merited, well merited point, but perhaps a discussion with Leapfrog, not a discussion with the NQF.

So I think we need to be really careful because I think it's very easy when organizations use these practices for A, B or C, but unless they are using them line precisely the way that they've been written, I think we can waste a lot of time.

So I think that Leapfrog is on the call later at ten and if we don't bring up all the 30 minutes that we have for it, that might be a good point to kind of bring it up with them, but I think it's important that we parse out the difference between the two because a lot of challenges of Leapfrog will roll over to NQF, and the water gets kind of muddied, and I think we need to be careful about our specs.

MS. MacDONALD: I did want to ask. It was confusing to me how this would work, and if you have any examples. I mean, I think it's great to have a stronger patient voice. Obviously I agree strongly with that, but it is unclear to me how the patients would be selected and if they would be ongoing and how this would actually work.

CO-CHAIR MEYER: And I think this may be something again in the next larger rewrite. As we add in some of the implementation examples, the big push for Patient-Family Advisory Counsel, so in Massachusetts, for example, State Department of Public Health now requires there to be a Patient-Family Advisory Counsel, which is one mechanism that accomplishes the same beautifully.

And another one is where you can, so peer review rules vary, but being able to put patients onto our Patient Care Assessment Committees in Massachusetts can have them.

It's not true elsewhere.

And so my sense of this is the information from satisfaction survey is not sufficient. It sets the right tone. I mean, the tone here to me when I read that, it says, you know, perhaps necessary, but definitely not sufficient. There are a number of mechanisms out there. Joint Commission is pushing folks as well to develop Patient-Family Advisory Counsels, and I think we can put those in implementation examples with the bigger rewrite.

CO-CHAIR DENHAM: It's also important as we go through these, and we could probably spend a week or two going through how every one of them is worded, but I think to put on the other hat is to say, you know, what harm is done by involving patients and families by having a structure or system in place? Is there harm to anyone to have that in place? I mean, you know, what is the risk-benefit of taking the affirmative approach?

Because we could always say there's no evidence today of a randomized prospective trial that shows that patients and families have caused the saving of lives, but there also is probably no one that will take on a trial to prove that involving patients and families is going to harm patients and families in the future.

So I think it's this practical, reasonable sort of approach that we have to take to each one of these.

DR. ROMANO: Yes. So I think that given that framework, I think the language here is inclusive enough probably and would benefit from perhaps implementation examples, which don't involve classical safety or quality, peer review type committees because that's were some people get stuck.

Just to challenge Dr. Denham's comment a little bit, I think that the problem that we confront is that the Leapfrog survey is an effort by an intelligent group of people

to implement the NQF or safe practices in a survey form, and they've done this as well and as carefully as they could.

And so we have to recognize that if we see misinterpretations in the Leapfrog survey that it probably reflects on lack of clarity in our specifications.

So it's not simply pointing the finger at Leapfrog. It's really saying, well, you know, it's sort of like when I'm teaching and the students, you know, do badly on a test. Well, yes, maybe the students didn't study, but it's also a reflection on me and my ability to convey the concepts that were important.

CO-CHAIR DENHAM: Great. So that's duly noted, and, Dr. Romano, are you familiar with the chapter on patients and family involvement in the current set?

Because I think that is being re-reviewed as well. So I think as an action step as we go forward with the implementation

guides and that new chapter, which was terrific that the NQF allowed that chapter to be put in to provide further guidance because it is an evolving area.

So I think if the Committee is okay, we'll move on to the next one, but we'll duly note that we'll look at the implementation guides section and, as well, the chapter that involves patients and families, and we may even be able to add a sentence or two since they're not part of the specifications to say care must be taken to, you know, apply these principles, or just make reference to that I think is a reasonable thing.

Are we okay with that to go forward? Okay.

In the next section, accountability structures and systems, down in external reporting activities we have "shall include patient safety organizations and SREs, serious reportable events, specifically in

additional specifications and include more supportive language to the implementation example approaches section."

And this addresses some of the evolving nature of other entities, such as the patient safety organizations that now provide some protection for patient safety work product. So, Peter, would you like to comment maybe on this one?

We're just making an attempt to make this set of practices as clearly connected to these other evolving efforts that Peter is actually in charge of at NQF.

DR. ANGOOD: Yes. You know, the external reporting and trying to promote precision in reporting is clearly on a lot of our minds. I don't think that we can be specific in the specifications yet on requiring or suggesting you have to do that, but you know, where we are sitting with this on the bottom of the page there is just trying to be driving the field into recognizing

there's an evolving external reporting strategy going on, and that the organization should be flexing and adjusting to accommodate internal and external reporting and to be a participant, an active participant in these external reporting strategies.

Clearly, the PSO activity is going to take some time over the next five years or so to gain good, strong traction, but the state-based and mandated state-based reporting entities are clearly gaining popularity, and then we've got other voluntary reporting systems like the Joint Commissions, et cetera, et cetera.

So I think we could keep pushing this along and making sure as a minimum we have the PSOs mentioned.

Other comments? Mike.

DR. COHEN: Yes, I'd like to see us do more in this particular area, external reporting, to promote near miss reporting as well.

We mentioned adverse drug events, but near miss reporting, hazardous condition reporting is critically important. We've been to organizations that have had disasters and only to learn that they had the same thing happen before, and it was corrected and it never got reported anywhere, including internally, by the way, not just to external organizations.

So I think that's critically important, and I would add those words, and by the way, I used --

DR. ANGOOD: Sorry. Just on that point though, is everyone comfortable with adding the near misses? Because that's a volume choice sometimes and, you know, we don't always have the methodologies in place to handle the management of near misses.

(Off-mic comment.)

DR. COHEN: I'm sorry?

CO-CHAIR MEYER: You're using an implementation example as opposed to -- you're

not saying --

DR. COHEN: Well, I'm just saying it says "report adverse events," and really do think there's more than just adverse events that the external programs want to capture. For example, in Pennsylvania, we do capture near miss events, and it has been the bulk of the reports that we get, and it really helps to inform our hospitals in Pennsylvania about the kinds of things that are going on.

DR. ANGOOD: David.

DR. HUNT: I think that would be a place in the implementation specifications, and in this situation I think we can do the community a very good service by having as robust a set of how to, where to go sort of guides to allow folks because many communities, small community hospitals, for example, want to, but you know, where do I get started? Okay? How do I report into the FDA?

And this would be a wonderful opportunity for a set of links, a set of

manuals that folks can just take me right there to get started.

DR. ANGOOD: That's actually a very good idea, and almost to the point I think we should as a minimum include it in an appendix, if you will, sort of a here's where you go and here's examples of success, State of Pennsylvania, other specific health care systems. A good suggestion.

DR. COHEN: I'd just like to add, this is a point of interest only. When we use the term "near miss" I think we really have to think about using that term. We did a survey recently. For example, in Pennsylvania "near miss" means that the patient wasn't harmed. Basically the patient wasn't harmed.

A lot of people think that, but we did a survey of our readership, and we have 2,435 responses and 88 percent -- and these are mostly nurses and pharmacists, although we have physicians represented as well -- 88 percent believe that it is an issue where

almost happened but never reached the patient. So that's the way most people are defining it, and yet we're using it in another way in a lot of our patient safety work.

CO-CHAIR DENHAM: So just to deal with this issue specifically, to give you a read-back, I'm hearing that the near miss language with an operational definition or there may not be one that we can import into the implementation guide, but a narrative that captures near miss, near hit, you know, what's being used, but put that in the implementation guide, not in the specifications; is that correct?

DR. COHEN: Absolutely.

CO-CHAIR DENHAM: The implementation guide, but not the spec.

DR. COHEN: All right. Even though there are patient safety organizations that can, you know, provide privilege to the reports, in fact, people are sometimes afraid to report something that they've actually been

involved with.

This is the kind of thing that, you know, was captured, perhaps, before it even got to the patient. There should be no reason.

CO-CHAIR DENHAM: Patrick.

DR. ROMANO: yes, I just wanted to point out, as most people probably know, that the common formats that have been adopted for use by patient safety organizations do specifically include incidents, near misses or close calls, and unsafe conditions.

So bringing in the terminology about the role of the patient safety organizations and reporting to the PSOs I think will cover this whole spectrum of conditions.

DR. ANGOOD: Yes, and we'll look closely at those terms and definitions as used by the common format since we oversee that steering committee. So we'll, again, work at harmonizing.

DR. PRONOVOST: This is Peter.

I want to agree with that statement that the PSO will take care of that. I'm not sure I would put so much focus on the external reporting. I think we need to do it, but I'll tell you at my organization I make much greater progress by focusing on reducing the risk I've identified already, not reporting more --, and so I wonder if we're going to do anything, add an incentive that says that there be some mechanism in the organization to prioritize and mitigate the risks that are implied.

DR. ANGOOD: Okay. I think that's an important one, ongoing efforts at risk identification and risk mitigation. Nice.

CO-CHAIR MEYER: If you move on to the next one, I think it's the poster child of the tension I talked about earlier and also the comments that Patrick made earlier, and this is related to review by government supported senior administrative leaders.

And so the balance we struck, again, recognized the tension between over specificity and ambiguity was we said on a regular periodic basis. Now, we have no evidentiary base to say it should be annual or biannually or triennial, and so we left it quite open and ambiguous.

I think that others could come back, I'm sure, and say, "Well, just tell me what to do," and I think if we put it as it said, no, we changed it to annual, I think folks would go back and say, "What's the evidence base for annual?"

And the answer is there isn't one, and so again, I think this is a good poster child for that tension.

CO-CHAIR DENHAM: And just to refresh us in terms of how we got to these specifications from over the arc of the 2003 practices to the '06 update, to the '09 update, and now we're doing the 2010 update was that in some cases with the practices,

there was more specificity regarding timetables, and in some less. They went out to the marketplace. They went out to the membership of the NQF and subject matter experts. There was considerable response.

We actually also invited certain organizations who were interested to really develop teams to kind of play the eyes of the enemy, if you will, to coin an expression from Boeing, to look at, okay, what are all the things wrong with these if we were to put on that hat.

And so we had some organized formal and informal approaches to kind of field test these, and the net that came back was for some too prescriptive because they didn't really fit with their evolutionary process where they felt they were on a regular basis undertaking things, but didn't want specificity of a timetable as Gregg had addressed, and then in others we got, you know, kind of the counter view.

And what we arrived at was defining a regular and a periodic, but did not specify the timetable. In some cases as you go through the practices, you'll see that instead of it being a specification, a footnote where the committee would have felt very strongly that a certain frequency was really kind of the floor necessary, but maybe there wasn't enough evidence to support it, and we made it a footnote recommendation that was soft. It wasn't a specification. Your feet couldn't be held to the fire regarding compliance, but at least it gave a little bit of information to those saying, "Well, gosh, how frequently do I do this?"

In other cases, we removed the specificity. So as we go back through these, I just want to remind us that these have already been out to the field over two cycles. We got that kind of input from the review, and the way that they exist today were based on a lot of NQF member input and subject matter

expert, not that they're perfect and not that they're may be some evidence today that might want to change you, but this is where this is struck.

The second thing is that we'll now have a glossary in this 2010 update and seek to have operational definitions for certain things like regular, like periodic, like a number of these that we can kind of put a handle on.

David.

DR. HUNT: I would just suggest that sometimes we may be looking because we're sort of pushing the envelope. The evidence that we seek may not be in the clinical community. The evidence for regularity should be found in business or organizational theory. So perhaps the regularity portion may not be in the Journal of Patient Safety, but in the Harvard Business Review.

DR. PRONOVOST: Chuck, this is Peter.

Two comments. One is when you say that we did this field testing, who actually did that and is there a written report? Because I didn't know that we had some formal evaluation about what the field thought about these because that would be real useful information.

And second, as a general principle, when there's uncertainty and there always is and there's always going to be, you know, one approach is to I don't want to say just don't acknowledge it or be softer. A more direct approach that I favor would just simply be transparent and unambiguous about it and say, you know, organizations vary and we don't really know whether it should be a year, two years, 18 months, and just put out that uncertainty to the community.

And if we have consensus of what we think it could be, we could acknowledge it as such, but I think we would probably have more credibility of being transparent and

unambiguous about what is and isn't available.

CO-CHAIR DENHAM: Great, Peter. Two good points.

What we wanted to do, strictly adhere to the process delineated by the NQF while at the same time wanted to really get these field tested. So the "we" were a number of us as Committee members asked NQF members if they would be interested in taking a careful look at the practices.

And so in my case, having a good relationship with the Mayo Clinic who was more interested, who said, "We want to be more involved in providing feedback to the NQF safe practices, and so what we volunteered to do was to give briefings of the safe practices and say, "Here are the safe practices. Here are the chapters. Here is how they are organized. If we can provide any further clarification to you, great. Are you interested in organizing teams to look at the practices? If you are, wonderful, but not

working with any one Committee member, please submit them formally through the NQF process, through the field review process, and don't show your assessments to us. We'll provide as Committee members briefings. Go ahead and look at them, but go through the formal NQF process."

So as Committee members the first time we see them was through the field reviews that are the formal process of NQF. We thought that was the best and most proper way and most transparent way and with the least conflict and the least ambiguity.

And so that's what was done after the 2006 update where there were a number of organizations where we provided Webinars and said, you know, here are the practices. Here are the resources. Is there anybody that we can help provide to you? Please assess them, but don't share with us any one briefing them. Go through the formal NQF, formal field review process, provide them in writing, which they

did, Peter, and then all of that input was then put in the tabular format for the Committee that then was reviewed, and that was the input to which I was referring.

There were not other NQF led sort of field tests or studies that were undertaken. We basically just tried to be really accountable to NQF members and said we want feedback on these practices. What can we do to provide you feedback? Is there anything we can provide to you? But go back through the formal NQF process so that we all get it. Everybody gets the same factual information, and don't show us the assessment until you formally go through it.

So that was the process. I think, Peter, there is a place for us on the second point in the implementation guide to be careful stewards of what we know about the evidence and not know about the evidence, and underscore in the implementation guide that until there is clear evidence as to how

periodic or how frequent work needs to be undertaken or reviews or attention to detail and practices, that until we know that you were kind of delegating that back to their organizations and saying, you know, regular means that you do it on a routine basis at intervals that you deem necessary for your organization. That's about as much as you can call.

Yes, go ahead.

MS. MacDONALD: Yes, I just want to say I don't think we can define regular right now very clearly, but we can put best practices, examples of best practices and how often, you know, people who do this well, how often they meet.

I did want to raise one other question. I don't know if now is the right time to do it, if we're done with the conversation about regular, if I could ask another question.

CO-CHAIR DENHAM: Peter, did that

answer your questions or issue before we move to the next?

DR. PRONOVOST: Yes, it did.

CO-CHAIR DENHAM: thanks.

DR. ROMANO: To me, I don't know about others, but I think that the important concept about regular is that it's something that's planned in advance. It's something that is not prompted by a disaster.

CO-CHAIR MEYER: It's not ad hoc.

DR. ROMANO: It's not ad hoc because it's so easy to say, "Well, things are going along okay. Okay. We won't worry about this."

And then something bad happens and the hospital's name gets in the newspaper. Oh, my gosh, we had better check out what we are doing on patient safety.

So regular can be something that's consistent with the planning cycle, with the budgetary cycle of the health care organization, but regular does mean regular

and not prompted by ad hoc events or inquiries.

MS. MacDONALD: Okay. Thanks.

I've worked in enough organizations. I really applaud this standard. I've worked in enough organizations where I know negative information rarely flows uphill, and there's frequently layers of management whose entire function is to make sure the person above them thinks everything's fine. So I think this is great.

We work with people often on the front lines, you know, on the floors, and they have a lot of frustration about what they see, the information that they have about what they consider to be unsafe conditions and having it flow upwards.

And I'm not sure, and I'd just like your guidance on where that flows in this standard or where that exists in this standard.

We frequently tell the nurses that

we work with to fill out something called an assignment despite objection form or a short staffing form or a form that indicates they believe that the conditions are unsafe, which they then give to their supervisor, but there's no indication that it ever really goes above the supervisor, and then they become very frustrated and they stop filling out the forms.

We had a hospital in New York that had 840 forms in a two-month period of what they believed to be unsafe staffing conditions that never got fixed, and possibly never even got above the supervisor level.

So is there a place in this standard for input from the front line caregivers in a regular way to be able to -- or is it perhaps in another standard?

CO-CHAIR DENHAM: Yes. Well, as you go carefully through the practices, you see the cross-linking of this practice with Safe Practice No. 4, which is identification

and mitigation of risk and hazard, which has that kind of hard circuit sort of information flow up.

But take another look at them to see if you're comfortable with them, but I think you probably will, that there's a hard wire information flow and a cross-linking of Safe Practice 1 and Safe Practice 4.

Any other comments that we want to add to this?

So the action item then would be to acknowledge Dr. Romano's comment regarding regular, and we are putting regular into the operational definitions and make sure that it is very clear that it is a proactive approach and not response to events, and we'll be going through that glossary carefully as the fall unfolds, and we'll be probably adding to it with the implementation guides as well, but very careful attention to the specifics.

So everyone agreeable to that then, keeping that the way it is but moving

with the definition?

And, Patrick, if you want to take a careful look at the glossary and see if you like it after it's composed.

So next? We're at ten minutes before our call. We move to the action structures and systems. Regular actions of senior administrative leadership; purpose of action of governance; direct administration discussion for the Committee.

It's clarifying the statement in the blue underline. The blue underline states, "such actions should be informed, monitored, and directed by engaged governance leadership on a regular basis."

Just for your interest, our dialogue in the committee work on the language of this, again, we had considerable feedback from the field on the language, and you would hear various different takes on the style of how things were written.

So in the '06 update and as we

moved to the '09 update, we were pretty careful to use the same language frequently regarding involvement of leaders, and the informed, monitored and directed was interest by Committee members to really make sure that it just wasn't a general statement, that it really spoke to the issue of responsibility to that information.

Openness went up for discussion. Peter, do you want to add anything to what we want to address here?

Does the Committee feel like there's enough clarity to that?

Again, we went pretty carefully through these, and so some of these that we're going through might be little nits that may not now on re-review be as important, but do we have any problems with the current language as it is?

Okay. We'll move to then safe practice, too. So any other conclusionary comments on Safe Practice 1? Dr. Romano.

DR. ROMANO: Yes. I have to say that this is one of those sections that drives me crazy a little bit, to be quite frank and a little bit ornery. I mean, I don't have any objection to this particular sentence, but just more generically, you know, as someone who works within a health care organization, you know, I look through this page and find the overall tenor of the page a bit difficult and, again, pseudo specific.

I mean, for example, in particular, you know, the idea about, you know, at least annually, annually, the board should document that it has confirmed the behaviors of the organization related to quality and safety mirror its values with respect to patient safety.

So that is such a nebulous and broad statement. I mean, how do we possibly document that the behavior of the organization mirrors our values?

And even, you know, in the next

sentence, again, going through annual training and teamwork, I mean, I think we all recognize the importance of teamwork and we all know that teams fail and there's lots of literature on the importance of teamwork, but yet, you know, how do you actually document that you provided this kind of training in a meaningful way?

Many of us have served on these kinds of boards, and we know how this happens, and you know, everybody says, oh, this is our annual teamwork training. We have to go through this again.

You know, and so at some point this just becomes a check box. It's not really an investment in improving safety in the organization. It's just like, well, you know, NQF says we're supposed to have teamwork training. So we bring in a consultant to teach us how to be nice to each other.

So this is the kind of thing, to be honest, it's probably not the time or

place to address it, but it just drives me crazy because of this specificity, this pseudo specificity that's not really rooted in evidence.

CO-CHAIR DENHAM: Let me address both of these areas, and I think as we review this, Dr. Hunt brought up the point that and underscored the issue of research that's outside of health care, and I think we could be a little bit more specific in this statement and say "stated values."

Actually, the values and behaviors are probably one of the broadest and deepest areas of research in terms of tying values to behaviors outside of health care and aviation and aviation safety specifically and in performance, and Dr. Hunt addressed, you know, some of the publications outside of this.

So I think we could go back and look at this and use the term "stated values." there are stated values and stated behaviors that are very specific for the majority of

hospitals in the United States. I think we could be a little more clear.

That is though tied to evidence that is outside of health care, and the input of this -- and this has been part of the specifications for two cycles -- really came from that evidence, and I think one of the things that we can do as we are tying some of the citations to it, make it more clear, Patrick, so that you can see where that ties to that evidence.

The second thing is are you familiar with the Safe Practice 3, the third safe practice regarding teamwork? Because it does get very specific, probably much of the market thought was over specific regarding the teamwork requirements and the specifics of the topics.

And so I think rather than just copy and paste all of that Safe Practice 3 into Safe Practice 1, I think there is the specificity you seek in Safe Practice 3. In

fact, many of the debates of the Committee in the '06 update were regarding how specific we really were about the number of hours, number of hours, number of people, frequency and the detail of the content.

So I think I would push back and say that might be in your ordinary category because I think I would go to Safe Practice 3, and I would say you might even call that overly specific when you review that carefully because it was very, very specific.

And in Safe Practice 1, we are saying at the end of the practice that it cross-links to Safe Practice 3, which is the one that addresses the teamwork. So you might want to refresh yourself and go back and look at that. It's very specific.

Gregg.

CO-CHAIR MEYER: This is two follow-up things. When I looked at my kind of won handwritten notes, I had question marks next to the exact same passages that Patrick

said what does this mean. I think we ought to look and see if there are some good governance references from, you know, Harvard Business and others that have been publishing on this issue.

I think the second, really following more for Peter, is that as you go and do some sort of field study of what people think of this and how they're using them, this the kind of issue where I'd ask to be able to focus on because this may be driving people absolutely nuts. It may be that people out there are saying, "Wow, it's really great that you're saying that you have to document this."

In fact, I don't know. I know it from my own very narrow perspective, but this would be a great thing to get more data on to see how this is playing in the field to see if we struck it right.

CO-CHAIR DENHAM: Do we have other comments from the Committee? David?

DR. HUNT: Yes, I was going to

again reinforce the evidence for this may be found in rather obscure things like the Navy subsurface training manual. In the Nuclear Service they're relatively safe because the values that they try to promulgate are specifically discussed at meetings.

So the evidence that we seek because remember that you won't find very much evidence of what we're trying to do because we are at the outer edge of the envelope in the places that we are because that's the reason that we need to change, but there may come a point where we're trying to ask ourselves, you know, where's the evidence for primum non nocere.

It is not always going to be there right in front of our faces. That's what I'm saying.

CO-CHAIR DENHAM: Mary, did you have a comment?

MS. MacDONALD: I kind of agree with Peter only because we're involved in some

activities where sometimes management actually has inculcated, you know, the values that we talk about and other times they're just checking the box, you know, that we did this.

At least annually the board should discuss its own competency and document its strategy. There may be a need to define what a competent board would know, you know. I mean, there would have to be some standard for me to measure that against, to discuss our own competency without some kind of external standard for what constitutes competency. I don't think, you know, it's necessarily what you're looking for.

DR. ANGOOD: Well, again, this is part of the tension and the balancing act. You know, we're trying to drive organizations to figure out what their own behaviors are, to seek out other resources as needed to figure out what methodologies they need to use if they don't have things in place without getting too specific because in the absence of

practices like this many places will not have anything. It will be kind of historic practices as usual.

MS. MacDONALD: Well, perhaps it could be an implementation guide that would have examples of what would constitute best practices again in some of these situations.

DR. ANGOOD: Well, you know, the IHI's board is on board and all of those sorts of things.

CO-CHAIR DENHAM: You know, we are at time, but I don't want to cut this up. I'd like to propose so that we could then have our call and have finished this one, that we will go back and tie citations and operational definitions to values and behaviors. It's very clear we're very familiar with this literature, and so there are ample citations. There are ample citations for best practices, and so I think that we can define these terms in the glossary and in the implementation guide and also tie citations or citations to

this section of the specs and put some more clarity into the implementation guide.

Is that a reasonable next step before we go to our call so that we can put this one to bed?

DR. ROMANO: Yes, I agree. I agree completely with Dr. Hunt that the literature that we seek may be in unconventional places. The evidence may be not randomized trials, but there does need to be evidence, and so I think strengthening that base would be very useful.

CO-CHAIR DENHAM: Great. Do we have to do anything to establish the call with the Leapfrog Group?

(Pause in proceedings.)

DR. ANGOOD: So we'll just have one of those momentary pauses, but don't take off on us down the hall. I'm highly attracted to the children's play area down the hall on the left, you know. So we don't want to find you in there with all of the chemistry kids,

but as soon as Barb and whoever else from Leapfrog is joining them, we'll deal with their activity right away and then we'll take a short break.

(Whereupon, the above-entitled matter went off the record at 10:04 a.m. and resumed at 10:05 a.m.)

DR. ANGOOD: Barb Rudolph, are you on the phone yet by chance?

DR. RUDOLPH: Yes, I just got on. Thank you.

DR. ANGOOD: Oh, okay. Good timing, and it's Peter Angood. We have a good quorum of individuals from the Steering Committee for the Safe Practices, and we are at an appropriate time to review your guy's materials and to have some discussion around the topic.

Are there other individuals joining you, Barb?

DR. RUDOLPH: Yes. Dr. John

Birkmeyer will be getting on shortly.

DR. ANGOOD: Okay, and just the two of you?

DR. RUDOLPH: Yes.

DR. ANGOOD: Okay. Thank you.

What I'll do, Barb, is just provide a few background comments. I'll ask Chuck and Gregg to provide a couple to fill in whatever holes I've missed, and then you can make your presentation in terms of the materials you've provided us, and then we'll open it up for general discussion.

DR. RUDOLPH: Great.

DR. ANGOOD: This document that we have up on the screen was forwarded in by the Leapfrog Group following some discussion during last year when the safe practices were revised, and then also emanates from a call that we had with Barb and Arnie Milstein, Chuck and myself regarding some potential strategies.

And there are sort of two

components to this. One is the content of the document that Leapfrog Group has provided and the basic issue focuses around evidence-based hospital referrals. This was a practice in an earlier version of the safe practices. In the revisions, the evidence-based hospital referral practice was dropped and rolled in as a sub-bullet within the informed consent safe practice.

And so the two issues are, one, related to the methodology by which NQF retired a safe practice and was sort of adequate due process undertaken before retiring a safe practice or incorporating it into another practice, and then the second issue is actual discussion on the content of this document, which is how to move forward dealing with the issue of evidence based hospital referrals.

And I think in all honesty it's fair to say that this topic unmasked a procedural deficit that we had in our

management of the safe practices, and we have been looking at our consensus development process overall as part of our ongoing quality improvement efforts at NQF, and we need to pay particular attention for any of the safe practices when there's consideration to retire them or to incorporate them into other safe practices.

Another example that will be coming up soon, just to give you a different flavor from this, is the patient safety event taxonomy that's been endorsed by NQF, developed by Joint Commission, but our sense is nobody uses that thing.

With the PSOs coming on board and with the WHO's international classification, there probably is not a use for that taxonomy at this stage. So we will make movements towards retiring it, but we need to message the field that that's going to occur, and we did not message the field adequately or effectively enough regarding this change on

the safe practice for evidence based hospital referral.

So just to reassure the Leapfrog Group and other entities that have concerns about this, NQF has recognized this deficit, and we are moving forward to correct that and message the field, get inputs on any future retirements for reconfiguring of safe practices.

The second now issue is more related to the content of this evidence-based hospital referral. Because we are doing a light buff and polish for the recently released safe practices we responded back to Leapfrog Group, and I think Barb and Arnie and Leah Binder were all open to this, is that we kind of staged this in two steps.

One, we agreed that the topic of evidence-based hospital referrals is important and continues to gain further evidence that the volume and high risk procedures does reflect on outcomes and so we need to look at

our existing safe practice informed consent and how that bullet is written. How do we accommodate some better language around this safe practice?

And then the second step would be during the more deep revisions going on during 2010 for the '011 release would be to consider having a separate new or revised safe practice on this topic to come back into our safe practices to accommodate this topic.

So I have I haven't confused anybody with those comments, and Gregg, did you want to make some further comments or Chuck?

CO-CHAIR MEYER: I'll make two comments just for those who may not have been able to participate in the discussions that we have around folding the evidence-based hospital in from a stand alone safe practice and moving it into Safe Practice 5.

There were two issues. One was related to the I would characterize this as

kind of a relatively rapidly evolving evidentiary base here, that as it was originally constituted, the stand alone safe practice related to evidence-based referral was quite broad, and that narrowed as the evidence moved forward. Perhaps Dr. Birkmeyer will comment on that.

The second issue was a little bit more of a philosophical one, and it gets down to what are the units of analysis. What are the groups that we're going to be measuring adoption of safe practices on?

And I think to some extent, you know, the notion that consumers should be informed about these relationships and the availability of high volume providers , which would potentially portend for some procedures an improved quality and decreased risk. That, I think that there's no one that would disagree with that. I think practically, the notion that, for example, a small community hospital outside of Boston is going to hand

the patient with a newly diagnosed pancreatic lesion and say, "Here's a pamphlet and the pamphlet says go to the Mass. General because they do more than anybody and they have this volume to outcomes relationship."

That wouldn't be bad, but the truth of the matter is we didn't think that that was a practically reasonable thing to ask and to measure folks on, and so that's where we ended up with this.

So I think that it's just good to have that as context.

Chuck, I don't know if you want to add further context to it.

CO-CHAIR DENHAM: Yes, and I think, Patrick, you brought up the issue earlier of others outside of NQF using NQF standards and the blend and the challenge of teaching out with some precision what is a recommended specification for a standard and then how folks might use it.

And I think, you know, as Leapfrog

goes through their presentation, I think we need to recognize that the evidence based referral practice was in the '03 set of practices.

When we went to the '06 practices and updated them, there was considerable discussion regarding the issues that the Dr. Meyer just brought up.

And then when we went to the '09, there was considerable discussion as to whether with the evolving evidence also that other areas of NQF measures were actually measuring some of these other issues, and there was considerable push-back from the field on this evolving, the all evolving nature and implementation of quality-volume relationship.

So it was with a great deal of discussion that the committee pondered and then decided to retire the evidence based practice. The Leapfrog Group, and we'll ask Barb and the group to share their requirements

of the field actually migrated away from the practice that we had in 2006 as well. So we actually didn't have an apples to oranges sort of comparison, which also I think, Gregg, factored into the potential retirement of the EBM, which was that there is evolution of the literature. There were the challenges that were faced. There were all of these variables.

And then as Peter had stated, we as a committee, there just wasn't a process in place to go out to the field to say a practice is being considered for retirement. There just wasn't one, and I think it's great that NQF is now saying that that is something that we need to have as a process for any time a practice is being considered to be retired or modified that way, that that loop kind of be in there.

So that's kind of a little bit of the historical context of, you know, kind of where things migrated, and then we had a call

recently and asked the Leapfrog Group to really put together a presentation for us as the Committee, this very important issue, and to suggest they have some suggestions regarding how this could be tied into the informed consent practice.

I just want to remind the Committee that the big upgrade to informed consent is anticipated for 2011. This cycle is a short cycle because we want to get the practices out actually to groups like Leapfrog for January so that they can actually tie adoption to a set.

So the balance or the decision was the informed consent would get a forklift upgrade for 2011. The timing of this discussion was a good one because here's a great opportunity for that, but we'd like to hear from the Leapfrog Group and to share what they want to propose at this juncture in time.

So that's a little bit of the context.

DR. ANGOOD: All right. So thanks, Gregg and Chuck, and so the presentation is primarily focused on the importance of the topic, reinforcing our knowledge about that, but our action is to try and figure out how to refine the informed consent safe practice to help accommodate this presentation.

The request for a new safe practices is for a later date. That's not for today.

Okay. Barb, are you happy with those opening context comments?

DR. RUDOLPH: Yes, that's fine. I think Dr. Birkmeyer has joined us.

DR. ANGOOD: Okay. So put --

DR. BIRKMEYER: Yes. Can you hear me now?

DR. ANGOOD: Yes, we can hear you better. Thanks.

And so would you guys please give us a brief presentation on the document and

we'll assume everyone on our Committee has read through your materials.

Thank you. Please go ahead.

DR. BIRKMEYER: Well, if you don't mind, Barb, maybe I could make just a few introductory comments. I don't have a formal presentation, but I do have a few comments to put this in perspective and to give you my own thoughts about how to move forward.

Again, the context is the extent to which the relative performance providers needs to be incorporated as part of the informed consent process, and I think that there's a few basic principles that everybody that's on this call would generally agree about, and that is that, you know, informed consent is imperative, particularly in the context of interventions with substantial risk to patients.

We also would agree that as information is conveyed to patients about the risks and benefits associated with the

specific intervention, that it be tailored as much as possible to the specific circumstances of that patient, and obviously that includes both patient characteristics; you would give a different set of expectations around risk and somebody with unstable heart disease than you would in a 25 year old healthy patient, but also to the provider circumstances, you know, and that is that for some procedures, you know, where and by whom the procedure is performed as a much larger impact on prospective risk than do the characteristics of the patient.

We also finally would agree that the conveyance of a risk needs to consider the risks and the benefits of alternative options, and you know, obviously we're most familiar with that principle in the context of giving people information about, you know, the consequences of non-surgical treatment for those that are considering a specific surgical intervention.

I think you could safely extend that same principle to conveying the risks associated with alternative options in the context of patients undergoing their surgical care in another setting.

On the other hand, I think we all would agree that this would be a very hard conversation to have, and I think Gregg made a comment about, you know, the plausibility of a small community hospital having a pamphlet advising their patients to go to the Mass. General. Well, you know, I think as a practicing surgeon I can imagine how this plays out at the level of the encounter between the, you know, physician and the patient. This is a very hard conversation to have, and in the real world it's only going to happen when the circumstances are compelling and the motivation for doing so is very unambiguous.

I wasn't an integral part of the document with the language underlying the

previous recommendation that came from the Leapfrog Group, although I don't recall whether I read it or gave input, but reading it just recently with a fresh eye, you know, there was a number of problems with it from my perspective that I think, you know, was at least some small part of the reticence of the Committee the last time it looked at the standard, and I think that there's a couple problems with it.

The first is that it applied to a number of procedures for which there's either relatively small variation across hospitals or physicians in underlying risk or for which the existing measures really are not up to the task in terms of discriminating the performance of individual hospitals or physicians. Certainly there's a big difference in the variation associated with, for example, PCI than there is with esophagectomy.

Second, there was, you know, some

of the practicality of applying these measures might vary according to the clinical setting in which those procedures are offered and the extent to which they are elective, and there's time for rational decision making of outside of care and of those for which those procedures frequently, you know, it's more expedient or urgent.

And finally, and I think probably the biggest problem was that the trigger for incorporating such information on performance into the informed consent process was somewhat ambiguous. Exactly how large does that potential for risk reduction have to be to warrant that conversation?

We'd all agree that if that difference was ten percent in absolute terms that that conversation needs to happen, but does it need to happen if it's one percent, if it's half of a percent? Is it .2 percent? I think that, you know, there was a lot of room for improvement in terms of specifying, you

know, when that conversation had to be triggered.

So as I spoke with Barb last week, I had a couple of thoughts about where this could go either in the short term or at the next, more substantial iteration. The first was that I thought that the initial focus should be on clinical settings, i.e., surgical procedures, you know, for which there's not only a strong ethical imperative, but also sort of some practicality for having this conversation, and I think that you could make a very strong argument for requirement information on volume, if not other measures, and performance could be very safely and ethically applied to elective, relatively uncommon, very high risk operations for which there's very incontrovertible evidence of a clinically large difference in outcome according to volume.

And I think kind of, you know, as five years ago, you know, as now the poster

children for those types of procedures are esophagectomy and pancreatectomy.

The second recommendation that I had for Barb is that inoperationalizing these guidelines or these recommendations or practice, that there be more specificity in terms of what the trigger is for making sure that this information is conveyed.

You know, so with esophagectomy and pancreatectomy just to be concrete about it, I think that you could make a strong argument that this conversation would have to be triggered for, you know, positions operating in hospitals designated as low or very low volume centers. It wouldn't necessarily need to be triggered in hospitals that were medium or high volume as opposed to very high volume.

And then finally in terms of recommendations, you know, for the subsequent iterations of this standard, I think that we need to, you know, think about options that

move beyond procedure volume alone, you know, as a trigger or as a mechanism for insuring that performance information gets incorporated into the IC process, and much of the measurement science hasn't changed over the last several years that, you know, the Leapfrog Group has been involving its evidence-based hospital referral standards.

But I think that the one thing that is evolving and is a significant upgrade on where we've been in the paste is the use of composite measures that incorporate volume, but also other parameters into a risk predictor for individual patients undergoing high risk operations.

So that's all I had in terms of my perspective on the over arching issues, but also a couple of specific recommendations.

DR. ANGOOD: Thanks, John.

Good comments and we've got a couple surgeons in the room, and we certainly resonate with this one all of the time.

Barb, did you want to make further comments?

DR. RUDOLPH: Yes, I just want to indicate that, you know, John and I talked about this and we talked about this as -- also I talked about it with Arnie Milstein and others from Leapfrog and the consumer -- disclosure group, and we feel pretty strongly that, you know, some change should be made this cycle, and the one that John has recommended works well for us, and then in the next iteration to take a step beyond what was just a volume based consideration to incorporation of other kinds of information for consumers that would provide them a good sense of what their risk is going into the procedures.

Just as an aside, I think where this really comes into play, we had this last year or actually a few months ago, a conversation with Harborview Hospital in the State of Washington where they do a very small

number of esophagectomies, like three or four.

And the other part, another hospital within their very own system does approximately 40 to 50 of the procedures, and we strongly encouraged them to consider moving those, you know, three or four procedures from Harborview over to their other hospital within their own system.

And I think that's the case in a number of different hospital systems where, you know, they will kind of throw the bone of one or two of these procedures to one hospital and then do the bulk in another. I would really like to see that kind of behavior changed rapidly and to move towards the high volume hospitals.

So I think as the very last paragraph in the document states, you know, the staged approach would be fine with us, but we do, you know, request that in the next major update that a bigger discussion take place about patient survival and the remaining

cardiac procedures that were listed before.

So I'll just close with that, and if there are any questions.

DR. ANGOOD: Okay. Thanks very much, Barb.

Why don't we open it up for some general reaction and comment from our Committee members, see how that goes, and then we'll move towards what type of specific recommendations beyond what's been suggested so far.

Gregg Meyer.

CO-CHAIR MEYER: Yes. I'll go ahead and start this off. I think that, first of all, let me say that I truly appreciate the evidence here. I'm through with the procedures that we discussed. I think the relationship is strong. It's robust. It's something that people ought to know about.

I think there are two issues that I still have that aren't fixed by this change in language. The first one is what was

brought up by Dr. Birkmeyer, and that is, reflecting, personalizing this, I literally had this conversation with my patients last week, who literally said to me when they were in an outside hospital with a ruptured aortic aneurism, said, "Shouldn't I be transferred to the Mass. General to get this repaired?"

His wife said, "You know, you're his doctor there and you do more."

And the answer was, well, yes, but not with a blood pressure of, you know, 70. And so I think that adding in some language around elective versus immersion, immersions are not common, but for that first group, for CABG, PCI, AVR and not so much with AVR but AAA, we see emerging cases.

In fact, telling a patient, "Oh, by the way, you will be better off with Mass. General," is actually doing harm, I think, and that may be a little bit controversial, but I think that would raise doubts in patients when that's not helpful.

I think the second issue I have which remains is that I feel strongly that this make sense. It's a good thing from a population perspective to move patients with these high volume providers.

What I'm less comfortable with is safe practices and specifically the mechanism here of doing it during informed consent as the best mechanism to do that. So I think that the conversation that was had with Harborview was terrific. That's a great example of how a kind of policy maker can work with a hospital group and help them do the right thing.

But when I think about what the leverage points are for change, if you said, you know, let's imagine if we could push the elective volumes to those who do the most and do it best. I don't think the lever I would pull is informed consent by providers. I think I would pull levers that involve payers. I think I'd pull levers that involve

purchasers, levers that involve policy makers, involve general education of the public.

It seems to me that all of those work better than safe practices, and I'm not shutting my mind to it, but it just seems to me that there are other ways to do this that may be much more potent and practical.

DR. ANGOOD: Good comments, Gregg.

Dave Hunt.

DR. HUNT: This is David.

Good to hear you, John. I think I'd agree with Gregg. The night before the procedure as you're, you know, getting the surgical consent, it's just a very, very difficult time to be able to have this discussion. I can't imagine.

I think that further upstream at the level of the hospital executive making the decision not to do these procedures is far, far better. I can't imagine the risk. You know, I always like to sort of fame things out. Imagine you say this to a patient and

they say, "No, Doc. I'd rather have it here," and they have it and something goes wrong. I mean, what is that discussion like afterwards?

I think that there are other places where we can probably effect this change that might be a little bit better.

DR. ANGOOD: Other comments?

DR. McAULIFFE: Yes, I would like to have some more conversation about these composite measures. Volume is one thing, but something else came out about composite measures that would include other things other than volume of cases, and I'd like to know what some of those other factors would be as we develop those measures.

DR. ANGOOD: John, did you want to react to that?

DR. BIRKMEYER: Did you say John? Are you talking to me?

DR. ANGOOD: Yes. Sorry.

DR. BIRKMEYER: Oh, yes.

DR. ANGOOD: I had my thing off.

I apologize.

DR. BIRKMEYER: Oh, sorry. Just a couple of quick reactions. The first is that I agree with both David and Gregg that in terms of where to stop the train for the wrong types of procedures being done in the wrong place, that the informed consent process and the discussion between the surgeon and the physician is obviously not the ideal place for that to be happening. You know, kind of the better and more effective intervention points are certainly upstream of that.

The question that I have for both of them though and for the Committee is that is this useful to have for people for when those safeguards aren't in place and by one mechanism or another patients have gotten to that point in scheduling surgery with a surgeon or hospital. That just doesn't do it.

The question on composite measures, while there's a number of parallel efforts going on in various shops across the

country, I think where most of the work that's come about in partnership with the Leapfrog Group has been done by my colleagues, economists Doug Saiger at Dartmouth and Justin Dimick, who's a statistician and a surgeon here with me at Michigan.

There's been a couple of papers most recently in Health Affairs in this month's issue looking at the extent to which incorporation of both information on procedure volume, but also on either observed or risk adjusted mortality does a substantially better job in terms of predicting subsequent risk and in discriminating real performance, i.e., real outcomes across hospitals.

There's another paper that was published last year that was by Staiger, et al., showing that the incorporation of additional information about performance with procedures that are correlated with the procedure of interest as an input makes the composite measures better still.

So I think that we're very close to being able to operationalize those measures, and I know that other committees within NQF have been deliberating about those measures and when to implement them.

Perhaps Barb has additional comments on the logistics.

DR. RUDOLPH: Yes. In terms of the survival predictors, they have gone through and they've passed the Steering Committee and they've passed the CSAC and now they're up for potential ratification at the Board of Directors in October.

And we at Leapfrog have actually incorporated these measures this past year and have them out now in the public domain on our Leapfrog Website, and there's also more information out there if you want to, you know, take a look at what's in the measure and how it's actually working for hospitals today.

But, again, that conversation we would see as part of the next iteration, not

what we're looking to add in at this particular point.

DR. ANGOOD: Okay. Thanks.

Again, we're trying to stage this. How do we accommodate what we have, then move to a more substantive individual safe practice.

Patrick Romano has a comment.

DR. ROMANO: Yes. I think I would just agree with what Dr. Hunt and Dr. Meyer said about the decision point. The place to have this discussion, the place to exercise leverage, and I would highlight. I was just going back to look at the, you know, text that was in the document that we released, and so what we said at that time was two practices were retired because other measurement strategies are being used to nationally target the same adverse events.

And I think that's correct. I've been a strong supporter of those measurement strategies. We've incorporated volume

indicators into the AHRQ patient safety indicators or the AHRQ quality indicators, and certainly I and others have strongly advocated the use of volume as a way to educate patients, as a way to make markets work more efficiently.

It doesn't seem to me either that this safe practices is really the appropriate setting for this to be imbedded. Our focus here is on specific practices that health care professionals and provider organizations can adopt at the point of care that will improve the safety of the care that they provide, not so much to make the market work more efficiently or to achieve broader regulatory goals, but specifically to make their own practice more safe.

So I think in this case separate is not unequal. We can say that these volume -- this volume standard, if you will, is very important, but it doesn't fit very well within the domain of informed consent under the safe

practices.

DR. RUDOLPH: This is Barbara Rudolph. Can I respond?

DR. ANGOOD: Yes, go ahead, Barb, and then Chuck Denham has a question to follow.

DR. RUDOLPH: Yes. You know, we did not make the choice at Leapfrog or the disclosure group to have this added into the informed consent. It was put in by the prior maintenance committee, and we are responding to the notion that, you know, we were not given an opportunity at the time the safe practices were changed, and our Safe Practice 24 was removed.

Yes, this isn't ideal perhaps to have it here, but it's also not ideal to completely exclude this information from the set of safe practices that are going to be coming out.

I think it's not a perfect world, but yet, you know, we know that the safe

practices do make a difference or we wouldn't be including them in our survey if they weren't, and we know from hospitals that they do pay attention to this.

And I think that it sends a clear message to hospitals that are low volume providers that this is not going to be tolerated or at least consumers should be given the information that there are better places to have these procedures done.

And I think we had a number of consumer entities respond in comments during the voting period when we couldn't actually vote whether or not it should be excluded, but there were a number of groups that commented saying, please incorporate this information back into the safe practices, and I think the number of purchasers outside of Leapfrog had also submitted comments to that effect.

So I think that, yes, maybe this isn't the best place, but it needs to be here somewhere in the safe practices, and since,

you know, there wasn't a process for doing that smoothly, I think we're going to have to settle for some bumps here and lumps in this informed consent process.

DR. ANGOOD: Yes, thanks, Barb. Those are appropriate and well timed comments. You know, you can use the surgical analogy. We're not doing a major revision here. We're trying to correct from an amputation that was kind of partial. So we're trying to do a little reconstructive surgery, if you will.

Gregg has one?

CO-CHAIR MEYER: That's right. I do feel compelled to respond to your comments, Barb, because I think that, again, when I think about the mechanism just accept that this is important to inform patients about, and I agree with that wholeheartedly and would work hard to do it.

But at the end of the day, I don't think that the effort to do that is going to be damaged by us not adopting or not changing

the safe practice.

I think the reality of it is that I think the wording that went out around that decision, the process was flawed. We understand that and are trying to fix that, but I think the final word is not that there are more appropriate and more robust mechanisms to do this than inclusion here. I would stand by. I think that that was correct, and to my mind we're going to as a provider, we're going to let people know about this relationship because (a) we participate in Leapfrog and we care about it; (b) because we know the evidence and it's the right thing to do.

And I would have to say I can go through (c) through (y) before I got to maybe Z because it was a safe practice. It's not a compelling or at least in my feeling it's not a compelling reason to do this, and frankly, I think its power will not be either diluted or significantly enhanced by making the change

proposed here.

DR. ANGOOD: Okay. Thanks, Gregg.

And Chuck Denham has a question or comment?

CO-CHAIR DENHAM: One is just to make sure that we reinforce and underscore that the retirement of the prior practice was a practice that was not synchronized with the Leapfrog standard because -- and if you remember, the Leapfrog standard changed, and so when we looked at the safe practice, the Leapfrog standard had actually changed, and so we weren't retiring a practice that was a one-to-one correlation with the Leapfrog practice.

So I think that's important that the Committee remember that that was one of the cases, and that was very acutely brought to me because we are the biggest champion for driving adoption in the country of these safe practices. We put an enormous amount of resources behind driving adoption, and for every meeting we were in, how come the

Leapfrog standard is different than the NQF safe practice?

So this was a dilemma, and so I think, Barb, one of the most important things is as Leapfrog continues to develop great standards and do a great job at really tying transparency to adoption, any of the standards that got migrated, it would be great to take them back through the NQF process and get them hammered out so that there's a one-to-one correlation. So that is the comment.

The second one is to put up for the Committee that Leapfrog has done a great job of organizing their thoughts, their facts, their document. They've really, I think, communicated it well, and we should as a Committee look at their proposal in the document that's part of our package regarding the specific language that they would like to have inserted into the informed consent now that we've heard the discussion and discuss whether this language (a) is something that

should be changed on the informed consent practice; (b) if it should be changed, should it be this language or some other language; (c) in parallel Leapfrog would be welcome to resubmit a new safe practice for the next round for 2011 whether or not that happens.

So kind of to parse out our discussion is do we make any changes to the informed consent practice in this area. If we do, would it be the language that they're submitting?

Another issue is do we recommend that a stand-alone be resubmitted, you know, the next time around.

Those are kind of what we've got to discuss here so that we can make decisions, but the other thing that -- now, those are comments. The question back to Dr. Birkmeyer and Barb is: is there any evidence in the literature or do you anticipate funding some research or seeing some research come out in the evidence regarding implementation?

Because I hear from Dr. Meyer and as we kind of talk about how this gets implemented at the front line, having some evidence and, you know, more work on implementation of the practice, not just the evidence for the differences in mortality and differences in results, but on implementation which sure helped this Committee a whole lot to say, "Wow, you know, people have been doing this in multiple sites, and it has made a difference, you know, although that's hard to get funded and that kind of thing."

But I think evidence regarding implementation is a theme that I'm hearing. So is there anything anticipated before we kind of come back for the discussion on the other issues?

DR. BIRKMEYER: So when you talk about evidence of implementation, are you referring to evidence that similar guidelines vis-a-vis the informed consent process have a meaningful impact on clinical decision-making?

CO-CHAIR DENHAM: Or even broader, just successful adoption of such methods, kind of just the broad band width of, you know, I think it's so important, and I think some of our Committee members have brought up over and over again implementation, the challenges of taking specs and then putting them to work.

You know, any research that might be published out there by the next cycle could sure help the Committee and awful lot to see, you know, that people are actually putting this to work. They're actually adopting it. You know, they've been successful in adoption, even if it hasn't translated, you know, to outcomes in a very pure sense.

DR. BIRKMEYER: Well, I'm not sure how broadly you're talking, but we do have a paper that's in review now that suggests that between 2007 that there's been other substantial immigration of patients away from low volume centers for many high risk operations, particularly cancer operations

attributable, in part, to a variety of factors, of course, but no doubt a large part of that is the efforts of the Leapfrog Group.

That doesn't, of course, get to anything that is specific to the practice that we're discussing now, which is the consent process.

DR. PRONOVOST: This is Peter Pronovost.

John and Barb, thank you so much for your presentation.

The issue that I'm struggling with is I have no doubt that or believe the evidence, John, is exceedingly robust for this, and what we're here with, as Barb said and I completely agree, is really a failure of accountability of other levers that may be more effective, but the reality is consumers are being exposed to risks that they are unaware of and at least I believe they should be aware.

What I'm struggling with and

perhaps you could ask is these operations are one of many organizational level risks that patients are exposed to unwittingly, and what's our process for deciding which one of those risks we may public?

You know, as I was hearing it, I said, oh, well, should we add ICU staffing to that because we feel quite confident that patients are getting exposed to risks. Should we add their infection rates or some of the NSQIP measures?

And, you know, John, I think you eloquently discussed to say, well, what does the risk reduction have to be before it's a real risk, but I see this as Patrick was saying. It's really an organizational level risk, and that consumers need to know, but how are we going to decide which one of many risks that are best to include in this?

DR. BIRKMEYER: Well, Peter, just in response, I totally agree with you. Volume or mortality information around a specific

type of procedure is one of a much longer list of variables that both describe as well as predict prognosis, you know, for subsequent care at those facilities, and certainly ICU staffing is an area that you have mapped out very nicely.

But you certainly could put a long list of other things. You know, many would argue that is a slippery slope in terms of where to draw the line about what sorts of information are required to be disclosed in some form, but at the end of the day I think that you need to, you know, be explicit about, you know, how important and or what magnitude of risk difference is sufficient to get you to that level of accountability.

And so I don't have a nice answer though about where to draw the line either in terms of scope of variables or in terms of difference in risk.

DR. ANGOOD: Thanks, John.

Any other comments from our

Committee? We're going to have to wrap this up because we've got a busy day and 33 other practices to consider as well. We've done almost an hour on this one.

Other comments? I'm not seeing any per se. Any other closing comments, Barb or John?

DR. BIRKMEYER: no.

DR. RUDOLPH: Just again to refer you to the last paragraph where we indicate more specific language for subspecialty and -- as opposed to the language on the front page.

DR. ANGOOD: Yes, thanks for clarifying that because we have sort of three items. There's the currently existing bullet under informed consent, which is basically one sentence, and that's on the first page. There was the paragraph on the first page, which was the suggestion for the 2009 update that never got incorporated, and then there is on the very last page general direction that you guys are suggesting in your recommendations.

DR. RUDOLPH: Right.

DR. ANGOOD: And so for us since we are trying to keep this revision of the safe practices, just a light buffing if you will, I think that we need to look at the existing bullet within informed consent and come up with some language that helps to clarify some of the issues that have been discussed and yet not make it so extensive that it's going to knock us into needing to do a whole formal consensus development process overall.

I think there's clear unanimity in the room. This is an important issue that needs to be addressed in some fashion, and I think Peter Pronovost's last comments about all these other risks that are out there as well kind of puts this into perspective of, well, this particular example can be a driver for how to address some of these other risk points, but maybe the safe practices is not the best platform to be doing all of that.

What I would suggest in the interest of time and to not have us get into micro editing, as a group -- that's always a problem -- is perhaps, Barb and John, you could look at that bullet, look at a way to clean up the language and the specificity of that language a bit for us for us and submit it, and we will distribute that around to the committee members for their comment on that. Again, trying to strike this balance that we're trying to just do a light buff, and recognizing that, we will delve deeper into these issues as we go into the 2010 clarifications overall.

Does that make sense for you, Barb and John?

DR. BIRKMEYER: yes.

DR. RUDOLPH: That looks fine.

DR. BIRKMEYER: Chuck has a comment.

CO-CHAIR DENHAM: I just want to clarify for the record, Barb and John, that

what you're proposing in the very last paragraph of the Word document that you sent, that the verbiage that states, "This information should include comparative hospital mortality and volume for esophagectomy and pancreatectomy for hospitals and the patients' medical service area by those providers with lowest volumes"; that one sentence you're proposing to be added to the last bullet of the specifications that are on page 108 of the current practice. Is that -- I just want to make sure I understand clearly that you would like that sentence added to the last bullet of the specs; is that correct?

DR. RUDOLPH: Yes.

DR. ANGOOD: Either added or that bullet modified to accommodate the intent of that sentence.

CO-CHAIR DENHAM: That's what I mean.

DR. ANGOOD: Yes. We want to keep it clean, crisp and as short as possible.

CO-CHAIR DENHAM: But my thought was rather than take this through a cycle through the Committee, we're so close, I think if we spend -- if you could indulge us like three or four minutes, maybe we can -- that bullet states for you on the phone, "The risk that is associated with high risk elective cardiac procedures and high risk procedures with the strongest volume outcomes relationship should be conveyed."

If that sentence that you are proposing, "this information should include comparative hospital mortality and volume of esophagectomy and pancreatectomy for hospitals in the patient's medical service area by those providers with lowest volumes," it sounds to me that that sentence added to that one sentence of the bullet is what you're proposing.

I just want to know for clarity if that's what we can discuss as a Committee for just a couple of minutes, maybe we won't have

to go through the cycle. I just want it for my own clarity to know that that's what you all wanted at Leapfrog.

DR. BIRKMEYER: Well, this is John.

I didn't get a chance to review or to provide feedback about the submitted version, but I would propose a greatly simplified verbiage rather than just adding on an additional sentence to what was proposed earlier.

DR. ANGOOD: Right.

DR. BIRKMEYER: And I think that the language would be something that, you know, was something almost as terse as for patients in need of particularly high risk procedures, comma, particularly esophagectomy and pancreatectomy, that physicians in low or very low volume hospitals make patients aware of -- and I'm paraphrasing here -- volume outcome associations with that procedure and the option of referral to a high volume

center.

DR. ANGOOD: Okay. So we already have enough discussion going on and into the micro editing. We'll have to -- John, if you can recapture what you just said because I always know how tough it is to repeat what you just stated, but you and Barb clean that up a little bit and keep it short, crisp, and concise and submit it to us.

We will rapid cycle it through our Committee on E-mail and make sure it's included after we get through, you know, our electronic approval of it and have that or a version of what you just described as a modification to the safe practice bullet, and then we'll continue to work with you all in terms of the processes of submission for a fresh safe practice that delves into this, and it will generate more of the discussion and the framing of the discussion points that came out in the last hour.

Does that work for you?

DR. BIRKMEYER: Yes.

DR. RUDOLPH: Yes.

DR. ANGOOD: Does that work for the Committee?

Patrick has one last comment.

DR. ROMANO: Yes, I just wanted to say that I think what I heard in Dr. Birkmeyer's restatement, it made this a little bit more acceptable to me and perhaps to other members of the Committee, is the idea that this is not necessarily imbedded in the informed consent document that a patient is actually asked to sign as they're being wheeled into the operating room, but this is part of a broader process of informing and empowering patients.

So if there's a way of capturing that distinction and, therefore making it clear that this is not -- it doesn't fit exactly with the previous points in the safe practice because it's not about the patient simply being able to restate that they're

going to have their leg chopped off, but it's really about being more broadly informed about the context for what type of surgery they're going to have and where they're going to have it.

So if there's a way of doing that, I think it might be more acceptable to some of the members of the Committee.

DR. ANGOOD: Okay. That's good. Thanks, Patrick.

And I'll just remind the Committee as well as John and Barb. One of the other mechanisms that we have that doesn't kick us into full consensus development is adding a sentence or a paragraph in our problem statement that sort of highlights or brings up the issue, and we can look at how to add a little bit of language in there as well without modifying the specs heavily enough.

So, John and Barb, thank you so much for the time. Thank you for the document. That was very well done, and the

presentation today. Hopefully our Committee's deliberations are support of where you wanted to go, and thank you for working with us as we resolve how to manage this problem.

DR. RUDOLPH: Thank you, Peter.

DR. BIRKMEYER: Thank you so much.

DR. ANGOOD: Okay. More to follow. Thanks so much, everyone.

Why don't we take a quick break? Lunch is probably going to be coming through at what, roughly? It will be a working lunch since we still have 32 practices to go through now.

MS. MARINELARENA: Lunch is at 11:45.

DR. ANGOOD: All right. Well, it's exactly 11:00. Why don't we take ten minutes and freshen up? And then we'll get back in here and keep cranking.

Thanks.

(Whereupon, the above-entitled matter went off the record at

11:00 a.m. and resumed at 11:15 a.m.)

DR. ANGOOD: All right. Well, hopefully Peter Pronovost will be able to join us again. I know he's trying to balance a few different things.

The last few minutes of discussion around the informed consent and the Leapfrog, as we received their proposed change to the language, again, I'll just reemphasize that we're looking for just a buffing and a polishing of the existing language, and if they want to submit something for consideration as another safe practice, that will be done during 2010.

And there are obviously several ramifications around this, both on a practical, in the hospital organization level as well as political and policy ramifications, and so I think it's incumbent at least from my perspective on the Steering Committee to really give serious consideration as we move

forward with this particular issue.

And what resonated for me actually the most was Peter Pronovost's comment about, you know, there are numerous risks in ever organization, and they are not the same for every organization, and so what makes this one so special that it needs to come up to the level that the Leapfrog Group is trying to do?

As a surgeon I'm not discounting the importance of that, and I clearly have recognized over time how volume and expertise changes outcomes, but science and the methodology of it may not quite be there for functioning within a safe practice.

Gregg or Chuck, did you have any other perspectives on the last hour of discussion?

All right. So we have a lot of work to do. We'll do a working lunch. The discussion so far, I think, has been very fruitful, and we're going to rely on Chuck and Gregg to keep pushing us, pushing us.

Oh, I had one last question. Sorry. Who's got what flight times? Patrick, are you staying tonight or are you going back tonight? Staying tonight. You're just going across town.

About six, you're here. That's right.

Mike, you guys are going back when? Fivish?

And you guys, Gregg? Okay. So I'm not going to take advantage of your time, but I have a call with Janet Corrigan at 3:30. So I'm out of here at 3:30, but, no, we'll push hard and we'll bear on your patience but also your efforts to help get us through that mark.

Chuck or Gregg?

CO-CHAIR DENHAM: So moving to Safe Practice 2, this practice nothing substantive is being brought forward on this practice, and we had a team of a number of the culture researchers that were representative

of the broad array of culture surveys that the team is looking back with in terms of the problem statement, the references, the eight specific requirements. And so we're not bringing anything substantive back to the Committee today for approval or submission on either Safe Practice 2 or 3, other than on Safe Practice 2 on culture that we will be coming with that input to the Committee, and we'll cross-check again those specifications for anything substantive. The same with three.

And both with two and three, synchronizing those practices with the latest evidence, making sure that all of the latest citations, implementation guides would be addressed, and both are scheduled for a thorough re-review for the 2011 update.

Specifically on Safe Practice 3, the teamwork, team training and skill building is looping back and synchronizing that with a lot of the work that has been done through

funding by AHRQ with the TeamSTEPS programs and other work.

Both practices have held up very well over the last two cycles, but again on the 2011 deep dive fork lift upgrade review really taking them apart and maybe at some point later in the day we'll talk a little bit more about the evidence, the potential grading of the evidence for the 2011 set of practices, and at that time going through that thorough review that may dismantle them completely and kind of rebuild them in a somewhat different manner.

But more work will be done in the next two or three weeks on both of these, and Safe Practice 4.

Yes, sir.

CO-CHAIR MEYER: This, again, when you go out to the field and however you're going to assess the way the field is using this, Peter, in terms of the safety culture survey in terms of the periodicity of it, we

showed it last time. We had a lot of discussion, annual, biannual, what's the evidence base.

I think it's just a great place for us to biopsy what's going on out in the field with that because we struck a compromise, and I'm not sure we hit it right or not, but I think we ought to ask the question and know.

DR. ROMANO: Yes, that's exactly what I wanted to comment on, which is I can't speak broadly for a large number of organizations, but within our own organization, UC-Davis Health System, we have found in our own experience and our own review of the literature that for better or for worse safety culture doesn't seem to change that quickly. It doesn't seem to be as rapidly responsive as blood pressure. It's more like bone marrow density.

So we've actually made a deliberate decision to use our resources by

doing the safety culture survey every other year, and that really seems to be the optimal interval for us to be able to implement changes and then look at the impact of those changes. So we've done that now in 2004, six and eight, and planning for 2010.

So I'm not sure if that resonates with any other experience as well, but I think we do need to keep in mind that some of these time intervals may be, again, a bit dubious in their specificity, and perhaps we should consider allowing a somewhat broader range of intervals based on experience in the field.

CO-CHAIR DENHAM: Are you aware of any literature that supports moving to two years so that we could examine that?

DR. ROMANO: Well, I'm not actually aware of any literature supporting every year. So I think different organizations have just been trying different things, but I'm happy if others are aware of specific literature that I'm not. I'm happy

to look at that.

CO-CHAIR DENHAM: So we aren't bringing forth to the Committee any substantive changes to safe practices two or three. We'll come back after some synchronization with some of the activities that are going on, but most likely the problem statements will be thoroughly updated with the latest literature that establishes those things in the implementation guides, but will be coming back, you know, to the Committee after review of those.

On Safe Practice 4 --

DR. ROMANO: I'm sorry. Can I just get some clarity? So at what point would be the opportunity to revisit the specification of annual in safe practices two, three and four?

CO-CHAIR DENHAM: The first one would be whatever evidence there is evolving over the next year or some on this, looking at how amenable and how quick it is to change.

CO-CHAIR MEYER: I think the second one is whatever information we get from the field about its practicality. So I would say it would probably be the next big rewrite. For now I think we can leave it at annual, but we're doing the same thing. We moved to every other year because we didn't see it changing that fast.

MS. MARINELARENA: Can I just say during the comment period we can be very specific about what kind of comments we're seeking, and that would be a good opportunity to get feedback from the field as to how they feel about those time intervals.

CO-CHAIR DENHAM: Great. That's a great suggestion. Thanks, Melissa. That's super.

We'll direct your attention to Safe Practice 4, identification, mitigation of risk and hazards. In this suggestion is the addition of three levels of events, serious reportable events, sentinel events and adverse

events in terms of some clarity there.

You can see the underscore suggested changes. Peter, do you want to kind of comment on these?

DR. ANGOOD: Well, I don't actually have a lot to comment on. We sort of got back towards some of the discussion about the near misses and the importance of reporting not just the bad stuff, but even the littler stuff, if you will, if "littler" is the right adjective.

And it actually ties back in closely with the culture piece, doesn't it? Because if you've got the right culture then you've got the willingness to report and learn. Was it this past weekend or in the last couple of weeks there was an article about Virginia Mason and their high reporting, but it keeps making them look bad?

You know, it is that old dilemma of trying to run that balance. So those are just general comments. I think that what

we're trying to add in here is to just keep reemphasizing the importance of trying to not only encourage reporting, but to help build that culture of wanting to report and put the systematic processes into place.

CO-CHAIR MEYER: Asking a clarifying question, when you look at the third edition here under adverse event reporting, so the blue is the lines you would put in and the red is what we delete, and the issue here I have is the following four words: "for every such event."

And so, for example, you know, you can review many, many reports and you triage them, and some we spend very little time on and some we really dive deeply on. Would that qualify that says we did every such event?

So that's the question I have, is how -- so the same process for identifying, managing and analysis of events. Well, we don't do a whole lot of analysis of some of events, and we have a -- for one reason or

another we feel that there are others that are higher priority, and so my concern here is that unless you kind of sit down and say, "Yes, we've nailed every single one of these," that you're not going to be in compliance with this.

DR. ANGOOD: Yes, I guess that's at some level a semantical question.

CO-CHAIR MEYER: I know it is. I wonder how --

DR. ANGOOD: Everybody is triaging.

CO-CHAIR MEYER: Might you look at hundreds of reports? You know, do you think that you'd, when you read this, yes, we do look at every --

DR. COHEN: The method that we use is, well, first of all, we get individual reports from practitioners. They're not incident reports. They're rich with information, and basically because we use this, our whole purpose is for communicating

nationwide through, you know, other organizations.

We look for things that are particularly serious, newsworthy because we haven't covered it before, things that are easily correctable. It's like a mixture of things that drive us.

CO-CHAIR MEYER: Prioritization mechanisms.

DR. COHEN: Yes, and we are influenced, too, by data from other programs. We have access to the MEDMARX program and the Pennsylvania Patient Safety reporting system which, you know, they're data driven reports or programs.

So we can see the frequency of something occurring, and that also helps to inform our arguments.

DR. ANGOOD: So I think, Greg, apparently everybody is triaging and making value judgments, and maybe we need to add a bit of modifier language in here, if you will,

that we recognize that.

CO-CHAIR MEYER: Or alternatively you can remember the last four words. If you said "process for identifying and managing and analysis of events should be defined and implemented," period, because it's the every such event.

DR. ANGOOD: Mary?

MS. MacDONALD: You could do that. I was just saying as a lay reader it seems to me that that includes within the idea that you're defining a process includes within it, you know, the possibility that triage is part of that process.

DR. McAULIFFE: I just have one comment. I like the -- the level of analysis doesn't have to rise to a very, very high level. I mean, you can triage it if that's the word you want to use. So I think the analysis sort of takes care of it, and you can get rid of every such event.

But I like the next statement.

When you're closing the loop and you're putting it back into opportunities for improvement, and I think that's the point of it, and it's back to the education point. Are we eliminating that?

MS. MacDONALD: Is that being eliminated?

DR. McAULIFFE: Are we eliminating the opportunities?

CO-CHAIR MEYER: So a read-back on that is what you would propose to say, it would read process for identifying, managing and analysis of events should be defined and implemented" --

DR. McAULIFFE: To identify opportunities for improvement.

CO-CHAIR MEYER: Yes, "to identify patterns of opportunity for improvement." That works I think.

CO-CHAIR DENHAM: So that language, I think, will be in the transcript. So I think that's a reasonable change. Is the

Committee entirely in agreement with that verbiage, the combination of those two sentences as stated? Good.

DR. COHEN: Just one more comment. Getting down to the bottom where it says external reporting source input, I have to say that, you know, so many of the hospitals and other organizations are at risk of, you know, what we're seeing reported by other organizations, and I think that, you know, to me, and I've been doing this for a long time now; I see that as critically important, as using the information from the external programs rather than -- I mean, it's just going to be so rare that you have one of these events, thank goodness, but you don't want to.

And so I think learning from the external reporting programs that exist, and we're going to see more and more of that with the PSOs, to me that's where a lot of attention should be paid and it's not right now.

CO-CHAIR DENHAM: And, Mike, we've got that in SP-1 as an input, but I think it's a really good point to put it in the implementation guide of this practices. So let's add that if that's reasonable to the Committee.

I'm getting nods around, to add that just to underscore that in the implementation guide of SP-4, although there's a hardwire input on SP-1 for that. But let's just underscore it with a sentence that could address the opportunity in the implementation guide.

Are you happy with that? Okay.

DR. COHEN: Yes.

DR. ANGOOD: Everybody happy with that approach? Okay.

The next page on SP-4 was really just a formatting change with nothing substantive. If we moved to safe practices for the section regarding performance improvement programs, just some, again,

glossary, we're doing a little bit of clean-up and defining the term "systems solutions" in our glossary and teasing out. You know, most people who are not the technology field don't realize that a technology doesn't meet hardware/software or information technology; that technology can include a method, and that solutions are combinations that saw problems.

So I think we're going to be really careful about using some defined terms that come right out of the dictionary and right out of some of the terminology that revolves around technologies just so that we're careful not to migrate and create new operational terms that cause some conflicts.

So, David, you know, as a chief medical officer in the HIT area, you know what we're talking about is just being really careful about terms, solutions, technology, information and that kind of thing sot hat our glossary is really tied to references and not just operational terms we kind of pull out of

group think.

So if the Committee is comfortable with that as we bring the glossary forward, define that term and then the Committee will have a chance to kind of review the whole glossary.

So in the interest of time, we would move the next page. Committee discussion, regarding remove or reevaluate risk assessment and mitigation activities listed for the 2011 update.

This is for 2011. Some discussion regarding -- and this isn't for the Committee to make any decision on now. This is kind of a note to the Committee as we go for the update. It was just as we re-reviewed, and some of the folks, not everybody, reviewed the practice, it appears to be there's a little bit of redundance in terminology, but we're not recommending any substantive change. This is just for the 2011.

Because we're on a shorter cycle

this year, we're really kind of going through carefully everything so that we can then look at the 2011 upgrade and say, "Okay. Now when we really kind of take these apart, look at the evidence, update them, you know, what might be considered?"

And just as we read that practice, one of the suggestions is that it might be removed, but then the counterpoint is that many organizations cut each one of the practices separately as a stand alone activity and hand it off to risk or hand it off to pharmacy or hand it off. So even though the document in total looks like of redundant, sometimes, we know operationally as soon as they get the NQF report they're parsing out sections of it, and for clarity we may make it more unclear.

So that's kind of a note to our Committee regarding that section. So there's nothing substantive there that we want to address. So that takes us through one through

four.

We have covered Safe Practice 5 only in the context of the Leapfrog suggestion. We haven't addressed other issues that are pertaining to informed consent. This one will likely undergo, again, kind of a forklift upgrade, major surgery for 2011. The only substantive thing we're considering at this point in time, again, with the idea of the light review this year because we're actually at a half year. This is going to come out in January. so our work will go to the board, you know, shortly and they still have the 2009 practices that they just got the 7th of March. So it's not like we've got an exposure period between now and, you know, then.

So the concept is keep this one relatively intact knowing that we want to really revisit this one carefully, but I'd maybe go back, Peter, to your prior life with Joint Commission. Anything?

We had the discussion regarding anything that we might want to synchronize. Do you want to maybe address this just before we move on from consent?

DR. ANGOOD: Well, actually, no, not really. I think the informed consent piece is critically important, and you know, there are other groups like the Joint Commission that are pushing this along fairly fast and hard, and what is the true extent of the informed consent and how do you evaluate the comprehension of the content of the informed consent, and that gets us all into the whole issues of, you know, communication and diversity, et cetera, et cetera, et cetera, which may well be too robust for this particular safe practice.

But I think we do need to keep paying attention to those things. So that would be my only comment.

Patrick or David and then Patrick.

DR. HUNT: Oh, okay. I would just

say I'm looking at the use of the fifth grade level, which I think is still appropriate, and many of the statutes that we have to work on with regard to language used the term "referred language" rather than "primary language."

DR. ANGOOD: Patrick.

DR. ROMANO: Well, I actually wanted to just put a comment on the record regarding Safe Practice 4 and the last comment that you made on Safe Practice 4, which is that I would strongly encourage us to consider opportunities to reduce overlap and reduce redundancy across safe practices because I think in the long run that facilitates implementation and improves clarity.

So you know, falls, for example, are already covered under another safe practice. Pressure ulcers is another area where risk assessment has emerged as very important, I think, and that's really covered under another safe practice.

So if we were deliberately going for overlap, then pressure ulcer risk assessment ought to be in Safe Practice 4 as well, but I would prefer to move in the direction of reducing overlap and thereby if there is specific areas where we think that specific risk assessment and mitigation is necessary, that that should be more clearly delineated in separate safe practices and not sort of rolled up here under Safe Practice 4.

And pneumatic tourniquets, I'm not sure even whether that's still, you know, as relevant as it was when this was written.

So I think we should take advantage of our opportunity moving forward to try to again simply further and remove some of this detail here that probably doesn't belong here and maybe better fleshed out in separate safe practices.

DR. ANGOOD: I think that's the tip of an iceberg on a bigger set of issues, and you know, I think we need to continually

need to continually reassess with each version how do we keep these clean, how do we keep them simplified so the field can use them.

I can't quote it out, but a few months back I looked at the evolution of the safe practices and almost half of the original safe practices are now gone. Several are renumbered, and when you're a user out there, how do you keep up with these changes even on an every three-year basis, and I would say we even take it to a point of getting rid of the numbering system because you can't follow it. You want to more group it around the concepts or the theme of a practice.

And so those are things that we'll work towards in terms of making these practical and actionable in the field.

Dave.

DR. HUNT: And I would also encourage us to continue to use some more of the more up to date tools like hyperlinks, you know, documents like that. Most people

fortunately or unfortunately read off of a screen now. So prepping the document for that type of a review because all of these could just be hyperlinks then.

DR. ANGOOD: We've got our communications folks working at least trying to make this existing document much more user friendly along that line, and my goal is to get all of those things I talked about in my opening comments basically on electronic formats, and we're not really relying on paper at all.

CO-CHAIR DENHAM: Other comments?

So is the Committee comfortable then moving to -- so informed consent, were there any other comments regarding informed consent other than what we covered with Leapfrog?

All right, then to Safe Practice 7 or -- I'm sorry -- life sustaining treatment. This practice, again, is one scheduled for thorough review for the 2011 update and we are

not bringing substantive changes to that practice at this point in time.

CO-CHAIR MEYER: So the only comment I would add is that, as I said in the past, this falls into that category of one of these things that's not like the other. In the past we've asked NQF to look and see if it fits someplace else in your portfolio, and in the past there wasn't a place for it. It has been orphaned.

So we've kept it in but just ask you to look at that again. One other thing you could say is if you want to buff these up, we could just call this the death panel safe practice.

(Laughter.)

CO-CHAIR MEYER: That would probably be very popular these days.

DR. ANGOOD: I know. The elder death panel, you know. We won't say who did that quote, but one of the priorities within the NPP is the whole appropriate end of life

care, et cetera, and as that work comes together, there's an automatic --

CO-CHAIR MEYER: People are still kind of scratching their heads and saying safe practice.

DR. ANGOOD: Yes, it's good. So any comments on Safe Practice 6?

Safe Practice 7 is the disclosure practice, and I would draw your attention to the pH with the underlined statement. The Committee discussion of the statement regarding malpractice liability carriers and error disclosure policies, and this addresses that. So let's just read it.

"Health care organizations should implement a procedure to insure and document that all licensed practitioners are provided with detailed description of the organization's program for responding to adverse events, including full disclosure of errors that may have caused or contributed to patient harm. This is done with the

expectation that the LIPs will provide this information to their individual medical malpractice liability carriers in the event that they are provided liability coverage from entities outside the organization. All new employees should also receive this information.

This has been a discussion area where we've had M.D./J.D.s and a number of folks kind of looking at these. The way that things are handled in large academic centers where all of the physicians are employed are dramatically different scenarios than independent practitioners who might have a whole array of malpractice coverage, and it also is an issue pertaining to nurses and other care providers regarding what statements that they make, and as we will see in the care of the caregiver, this continues to be an area of evolution in terms of how organizations are managing disclosure, but also care of the caregiver after an event occurs and not

driving them all to layer up the moment an event occurs, but also providing them the opportunity and the knowledge that they really should be entitled to have some representation or some advice as they go through it.

And, Mike, I think the disclosure and care to the caregiver are kind of like Siamese twins. They kind of come together. You have to kind of look at them together. We continue to have a big problem with caregivers being indicted for criminal offenses involved with system failures that occur at hospitals.

And some people have said in the past, well, disclosure shouldn't be a safe practice, and neither should be care of the caregiver. Yet the information that's gleaned from it and the barriers that these issues pose have a huge impact on patient safety, probably far greater than many of these other practices, and we know that out in the field, and it is actually being documented in the literature as well.

So this is an area where we're carefully going through the disclosure practice, the care of the caregiver practice with people like Tim McDonald, University of Illinois; Rick Boothman, University of Michigan, who are very active in this area of disclosure, care of the caregiver, Lucian Leape in Boston. We're carefully going through these and thoroughly re-reviewing them again in light of what's evolving in the literature and how we can strike the right balance, you know, with these practices.

But I kind of open it up. Mike, you've got some thoughts in this area I know and with a lot of the recent things that just keep going on in disclosure.

DR. COHEN: One of the things unfortunately that I've observed personally is a situation where it's almost like the practitioner is left to hang out to dry. I mean, there is no information that's given to the patient about many of the system failures

that set up this practitioner to make the AHRQ, and that's pretty worrisome.

I think there's a situation that's brewing right now where that's the case. So I really think that's an important aspect.

DR. ANGOOD: Yes, I couldn't emphasize that enough. You know, as a practicing surgeon for 25 years there was my share of little accidents, nothing major fortunately, but each time that occurred, I always was totally uncomfortable that it wasn't -- you know, even if the anesthesiologist was messing up on my case, it was going to come down to me, you know, and Dave is shaking his head. He knows that, and we all have examples of that.

(Laughter.)

DR. ANGOOD: It's always the damned nurse.

But, no, it's systems; it's a variety of things, all well intended people, but it lightning rods down on the individual

practitioner so often and we have to worry about how we use the practice to help drive that change.

DR. HUNT: Just to go along with the theme that the way to make a practice or implementation reliable, take the physician out of the loop, would be to also suggest that the hospital provide that information directly to the malpractice carrier. Every place that I have privileges at I write down who my malpractice carrier is, but then there is a second independent step where the hospital accreditation board, they actually make sure that, yes, I actually have coverage with NCRC, and they get a certificate back completely independent of me.

That's the opportunity for that communication channel, for the hospital to also provide, to, you know, let it be a two-way street, have the hospital provide that information to the malpractice carrier where this individual is getting privileges at our

institution. They put you down as the carrier. These are our basic principles.

And that way we can be more assured. The idea of me actually sending something to my malpractice carrier other than a check, I don't know.

DR. ROMANO: Yes, I guess that's exactly what I was curious about. I mean I certainly agree with the tone of the discussion here, but to link us to this, I guess the specific sentence here that we're talking about is the sentence regarding the expectation that LIPs will provide information to their individual medical malpractice liability carriers.

So it seems a bit unrealistic, I think, to expect that communication to occur in that direction, although certainly we do want to facilitate communication among all the organizations that are involved in the liability process, but that particular channel of communications seems a bit unrealistic.

So are we proposing the deletion of that specific sentence? Not the following sentence, right? All new employees certainly should continue to receive information about their organization's policies, but I would support the deletion of that sentence about the expectation on LIPs, if that's the proposal.

DR. ANGOOD: Do we need to delete the sentence or change the word "expectation"?

DR. HUNT: I would make a recommendation to include the expectation that the health care organization and/or the LIPs provide information to their individual malpractice carriers.

DR. ANGOOD: Other comments? Or, Hayley, did you want to provide further context?

DR. BURGESS: I was just looking in the example implementation approaches to see what we had as far as that goes.

CO-CHAIR DENHAM: We brought this

up. We're not bringing this one forward. There's not enough specificity in the column. This was an update to the '06 to revisit, was accepted. The dialogue was with a number of lawyers.

If you look at the 2009 update, these are not ads, and I think that's just a bit of an error there, Hayley, because if you look at the specification, this is what we had. We're revisiting it to just see if there has been anything that has kind of morphed in the marketplace.

It came from dialogue with a number of NQF members that said, "Hey, how are we going to deal with this issue?" And it was hammered out to then take back out to the marketplace after we got input through our review.

And so I think there's a bit of an error here.

DR. BURGESS: Well, the black is original language.

CO-CHAIR DENHAM: Yes. So we're just bringing it up as a revisit with an abundance of a kind of caution around this issue?

CO-CHAIR MEYER: Well, I think David's proposal of saying maybe we should say that the LIPs or their organizations because I agree. I don't think it's hanging there, putting it on the provider to do this every time. It's not going to happen.

CO-CHAIR DENHAM: So, David, do you want to restate what you did just so that we have that in the record?

DR. HUNT: Yes. I would just say that starting with the underlined sentence this is done with the expectation that the health care organizations and the LIPs will provide this information to the individual medical malpractice liability carriers.

CO-CHAIR DENHAM: And the second statement, the second sentence, just for clarification, is in the 2006 update and was

not supposed to be changed or removed. so I think we could have been more careful about how we word tool that for you.

So, David, that's your recommendation. Patrick, you proposed to remove it?

DR. ROMANO: Okay. So just so I understand, this is exactly the text that's in the current 2009 version without underlining, right?

Okay, and that sentence about this expectation on LIPs you were saying has been vetted.

CO-CHAIR DENHAM: This has already been part of the standard. It was hammered out after input from multiple members in consultation with a number of members who have their risk M.D./J.D. malpractice experts -- some of them are malpractice; some of them are on the risk side of the hospitals -- and was an agreed verbiage, and we're just coming back to the Committee with an abundance of let's go

back, take a look at it. Has anything moved in the market?

We don't think anything has moved that would require changes, and I think it's reasonable, David, to go back to the team that kind of worked on this and say does that seem like a reasonable -- we were not submitting it to have anything removed, Patrick.

DR. ROMANO: Yes, I mean, I guess I would say that I don't recall that discussion, whether that came to the Committee or not. I might have missed that phone call, but it just does seem unrealistic.

I mean, the way this operates in practice is that, you know, a physician or other licensed professional finds a malpractice carrier and sends them a check and they kind of take the terms of the liability coverage that they've been provided and there isn't really a mechanism for this type of ongoing communication.

So I guess I'm -- I don't mean to

challenge the process, but I don't see exactly what the safe practice is here that could be implemented, that we're seeking implementation of.

If there's an example of how this type of communication has occurred and how it has been shown to improve safety, I'd be open to that.

CO-CHAIR DENHAM: Well, I think what we can do, lunch is outside. Dr. Angood has just notified me of the nutritional rounds. Let me propose something to the Committee, that we go back with the add of Dr. Hunt's add, go back to they implementation guide with the team that worked on this and hammered this out actually with NQF members, revisit it just to see if there's anything that's changed in it, see if that recommendation sounds reasonable to this legal team that kind of looked at it, and propose to kind of move forward with this particular version.

I understand the practicality issue, but this was a compromise farther away from declaring you shall do this and state the expectation is that, which gave it more flexibility, less specificity, more acceptable to the market, and actually it has held good stead, and we've had no complaints on it as it has been out in the field at least since it has been released. So I think it's reasonable to make the add, see if anything has changed. If nothing has changed with the team kind of thoroughly re-reviewing it, at least for the 2010 update, reasonable to kind of move forward with it, and we'll look at the implementation piece, Patrick, just to see if there's anything that we can suggest there.

But this is a soft recommendation that the organization will inform the care providers to say that that is an expectation but not a declaration of thou shalt do it and be out of compliance if you're not doing it.

DR. ANGOOD: Is everyone hungry or

do you want to keep pushing for a little bit longer? We've been going since eight, 8:30, one short break.

Hungry, hungry, hungry, yes, I know. Okay. So let's gather some food. We'll continue on as a working lunch, and during lunch we'll try to keep pushing on this and we'll talk about prioritization and scoring and all of that of literature a little bit later on in the day.

So it's just outside.

MS. MARINELARENA: Can we just make sure there's nobody on the phone that wants to make a comment? We did build in a public comment. I don't think there's anybody there.

(No response.)

DR. ANGOOD: No.

MS. MARINELARENA: Right.

(Whereupon, at 11:56 a.m., the meeting was recessed for lunch, to reconvene at 12:15 p.m., the same day.)

AFTERNOON SESSION

(12:16 p.m.)

DR. ANGOOD: We're going to try and get back here on track, and with this fluctuating schedule that we have, we didn't quite get to scheduled public comment phase at around 11:30, and Don Casey is here and he does have some comments that he wants to provide. So we'll open up with our working lunch to have Don provide the opportunity of some comments that he has.

We have checked a couple of times. There has not been public members on the phone, but we'll keep an eye on that during the afternoon as well.

And then after Don's comments and whatever related discussion, Mike Cohen wants to take us back to a point that he thought needed further emphasis from one of the earlier practices, and then we'll keep moving on.

So, Don, are you about ready?

Yes, by all means. That's easier, and we're small enough. We can be informal. I don't know as I like the size of that binder though.

(Laughter.)

MR. CASEY: So these are the safe practices, the safe practice document that we use at Atlantic Health, and we use it effectively, I think.

We are nowhere near achieving the success of implementing everything that's in here, and I want to give Peter, Gregg, and everyone here in the room, especially Chuck, kudos, Hayley for her support, for moving this forward, and we look forward, again, to follow you on what we describe as a journey, not a destination.

So with that in mind, we are a two-hospital system in northern New Jersey, Morristown Memorial and Overlook. We are a large health system. We have over 1,200 beds between the two hospitals, full services,

everything except transplants. We're in UHC. So I know Dr. Meyer's outcomes at MGH right now, and that helps us a lot.

So what I want to do is really provide, if it's okay, Chuck, some generic comments. Some of them will be specific, but I wanted to in no particular importance of order or importance, give you some thoughts and then perhaps if it's feasible and you think it's usable, submit some of these or all of them in writing just in summary format to the group.

Some of these will be very specific, and some of them will be more generic. I'm not going to get into the micro details that you're working on here, but I do want to hopefully set the expectation now that Peter is here that one thing we get agita over is this notion of harmonization with the Joint Commission national Patient Safety Goals, and we really hope that happens as quickly as possible so that we're not playing two

instruments.

So that would be helpful. Right now I want to harken to the NQF criteria that are supposed to be used to evaluate measures and, say, practices. I don't see those criteria. I assume the Committee is familiar with them, but I'm not getting a sense of how well you're following them specifically related to this notion of evidence that I know you're going to talk about.

And, Chuck, you and I have talked on the phone. Peter and I have talked a bit. We think that -- and not just we, but many other folks that I know of at the provider end -- believe that developing a relevant taxonomy of the grading of the evidence and the classification of recommendations would be extremely helpful. We don't think the U.S. preventative Task Force services criteria are appropriate for this and we would harken against the generic recommendation that people just think that's going to be it.

We think, too, that there's an opportunity in the context of what Dr. Hunt said to provide this classification scheme against other industries as well in terms of evaluating the evidence.

But let me make an important distinction, Chuck, because I think that the goal here isn't to say that things that don't have a high quality of evidence aren't important or that we don't do this. I think people are getting worried that that's going to be weaponized and I don't think it should be.

I think what we should do is instead use it as a tool for several reasons. One is to provide transparency to all end users about the quality and strength of evidence, and secondly to allow organizations to prioritize.

As an example, if you are familiar with the Society for Hospital Epidemiology of America, they issued a consensus based

document in October that had 111 recommendations with classified evidence in each of those recommendations in six categories to prevent infections.

And we've taken those 111 recommendations and reordered them and tried to use them more strategically because there are 111 of them to implement those that we think have the highest quality of evidence. Incidentally, hand washing had a low quality of evidence, but that still remains a high strategic priority to us.

So we're not using this to decide what's better or not. We're simply using it as a way to help us make decisions, and I think that in the interest of transparency, I think the public, the purchasers, whoever else sees these things should be aware of this.

So the taxonomy should be developed in the sensitivity to the fact that we're dealing with a lot broader audience than people that do clinical trials who are

cardiologists. So that's one strong suggestion.

And in the NQF endorsement criteria spelled out by the Board of Trustees, there's a very clear set of language specifications that need to be enhanced, but might be useful in your deliberations as you move forward to go back to and really look at because I do think these are spelled out.

I did send in the comment period on behalf of Atlantic last October, I believe, a letter that several of you may have seen that talks about this in detail, and I could provide that to the Committee. I know it's a bit terse, but I did think it was an elegant summary of the issues and might serve as a guide post. I hope you agree, Chuck.

The other thing is around priority that, you know, for example I can't remember what the discussion was about culture surveys. Dr. Romano mentioned that and the discussion of the evidence. The evidence I have is going

into my CFO's office and saying, "Can I pay for another one this year?" So that's how we use the evidence at our organization.

And I would say that the point isn't so much to debate the frequency of that. We're doing it every other year for a variety of other reasons, because we've surveyed the heck out of our individuals already and we're worried about survey fatigue.

But also, you know, more generically we think that each of these practices should be -- we should have some financial people in the room talking about fiscal notes both in terms of resource inputs as well as cost savings and, in essence, trying to connect these two, you know, as exact a measurement of efficiency both from an individual episode of care to the organization as possible.

You know, we spend 100 hours-plus going through this document every six months to evaluate where we are, and it's a huge time

commitment, but also a time sync in many people's minds, and we're not sure we're doing it efficiently. TMIT helps us.

So this notion of the transparency, that's really the issue I'm after of using an evidence based taxonomy is important, not the argument about whether a recommendation based upon professional consensus is better or worse than one that has randomized clinical trials on it.

If you look at other organizations, they let it fall where it may and they publish the evidence and let people decide. So why should we be afraid of doing that if we do the taxonomy correctly?

I also think that we should get disclaimers or we should exact disclaimers from organizations who use, say, practices we believe incorrectly as a measurement system. We don't think, even though we fully participate in Leapfrog and get paid by it, that that's -- it's not clear to everyone.

They're sort of acting as if don't steal my lunch, that the measurement scheme they use, which we actually find useful from a quality improvement standpoint, should be made, directly connected to an endorsement.

So I think there's this tacit endorsement that I think we need to be more explicit about because I don't think, at least from the provider end, we think that's a direct link, and that needs to be tested and current evidence available shows that there's no direct evidence, as Dr. Cohen was getting to, between the scoring system and improvement.

And I have a handout to provide that evidence to the group if they'd like to see that.

So we think that such measurement systems are useful for quality improvement, but most definitely not at this phase for public reporting, accountability, pay for performance, and ranking, at least according

to NQF's criteria even though others are using it and sort of developing their own way to do it.

We think that there are lots of silos with NQF. I think Peter's grid got at this notion, but direct linkages to other NQF endorsed practices and measures would be extremely helpful going forward so that we know how all of these things tie together.

I know that's going to be a lot of front end work, but it will pay off in the end. The sensitivity and specificity of, say, practices and measures that reduce harm and have clear and indisputable linkages to outcomes should be evaluated, and some of these will only be evaluated in a qualitative sense, but this notion as we were talking about earlier -- in the micro details you were talking about it with Peter -- about the specificity and sensitivity not just in terms of English language, but in terms of epidemiologic rigor, would be very helpful.

We think that relative to your comment, Chuck, highlighting new and high and low tech innovations that support more efficient and effective implementation of the safe practices should be detailed in the specification so that we at least have examples that hopefully have some connection to real world results.

I realize that could turn into a marketing and advertising spree, but I think we're big enough to know the forest from the trees on that.

Patient centered safe practices, I can just tell you based upon my own experience if you want to have a beer afterward, you know, my ten or 15 near miss or close call events for my own care, that if I weren't a physician would have been close calls or near miss, such as the unintended administration of an access dose of contrast material that wasn't necessary for a procedure based upon poor communication that I intervened on

myself. I physically went up to the office where the doctor was and got the order that he had written after the radiology tech had said, "No, they said do it with infusion," and gotten the right thing because they weren't going to do it without infusion.

I didn't need the test anyway, by the way.

(Laughter.)

DR. CASEY: I think relative to Dr. Cohen's experience in Pennsylvania, he's very lucky to have that. In New Jersey, we're not very lucky because we don't put any resources into this serious preventable events as the state likes to call them. I've learned you have to have a different twist in New Jersey than from the rest of the world, but that's all right. I'm from Chicago. So.

But making these reporting systems especially at the state level really accountable back to the citizens, that is, demonstrating the real impact on the return on

investment of taxpayer money, as well as all the time and effort we spend on these things in terms of impacting patient safety, we know the reports are going up, and there may be some tangible evidence in Pennsylvania because they have some systems, but we really have no clue as to what the impact of the reporting system in New Jersey is, and I've been told by people there who are no longer there because they retired that the state would never be able to do that because they don't have the resources to do it, and I'm like, "What up with that?"

So I just think we need to have due diligence, you know, spending taxpayer money on this. I mean, that's an obligation, right?

Clarify the role of this work in health system reform. I don't see you guys having as much of a footprint. I know NQF does, but it seems like in the context of several other things that I'm going to mention

and then shut up, this would be helpful, especially the impact on my ability reform.

Now, right now we don't have positive incentives to avoid defensive medicine. Tort reform doesn't do a darn thing in my opinion to defensive medicine. That's a mindset, and I can tell you that the CYA activities that go on every day in this health system in excess lead to their own errors. So what's going on here?

We've got to fix that root cause before we just apply more safe practices to things that aren't necessary. So how do we engineer that? I think you can be creative, and you have enough people power in this room to hopefully get that into people's mindset now especially.

Cross-boundary accountabilities that promote collaboration through better incentives to cooperate. In summary, if we have a pressure ulcer issue, we try to get the long-term care facilities in the home care

agency together in the same room, as well as people in the ED, the ICU, and the floor to understand that these things just didn't crop up in one spot.

And by creating that accountability, we've been much more effective in reducing our pressure ulcers. We're nowhere eliminating them, but we've gotten better. We were semi-finalists for the Codman Award last year on this, and we lost on a technicality, which I won't go into.

But I think that could be a safe practice honestly, and I know you're getting at it, but, again, having safe practices for home care, long-term care, physician offices seems to be backward to me.

So I know you're trying to get that. I'm almost done.

This is one that we really need help with. The lay press is unfortunately pejorative about all of this and, quite frankly, promotes the notion that health care

-- and this is from our perspective -- health care providers are criminals and that health care settings are crime scenes.

And so how can the safe practices influence this? I don't have the answer, but how can they do it in a constructive way? Because when it happens, it drives this right back into the hole, and anyone who has tried to talk to a press person about anything knows that nothing is going to be spent; no time is going to be spent giving credence to all the good things we're doing.

So to me, again, what's the system that we're in and how do we improve that?

I think, and maybe you've done this before, that having had the pleasure and opportunity to work with a compatriot of James Reasons, John Riebow who is on the Taxonomy Technical Advisory Panel, that having John in the room as a safety expert with experience in nuclear transportation and other high risk industries has been enormously helpful to us

in our work on what we call close calls.

For example, he has documentation that if you don't create a way to report near miss or close calls in a shorter time frame than 90 seconds, the frequency by which people report those drops way off.

Well, there's good evidence right there. So you know, why don't we get some of those people in with you? It may cost a little more money because I know they can be expensive, but they're good people.

And then the last thing is that -- and this is really more of a complaint of NQF -- I'm concerned being on the Steering Committee for the outcomes and efficiency group that just promoted the measures for evidence based hospital referral that this group hasn't seen that discussion or understood that there was a lot of polarity in the discussion here. Why aren't we being transparent with this group? Why are my colleagues and compatriots from Leapfrog

coming in here and not mentioning that? And why don't we have that as part of the discussion so you can see that, in fact, there's a lot of imperfection?

Now, certainly when you're getting at the ones that are very low volume I'm hedging towards believing that's the right thing to do, but still even though it would be self-serving to us because we are high volume, top performers in UHC on all of these, that we think moving this directly to informed consent is a little bit ahead of the game, and so I would just caution this group and suggest that you do maybe not look at all the details, but take advantage of the work that this Committee and the technical advisory panel did around all of those evaluations, which were summarized elegantly.

And those are my comments.

CO-CHAIR DENHAM: Thank you so much, Don.

First off, I think that we owe you

a debt of gratitude for your steadfast support, continued communications. You have always been kind of a voice of "hey, how about the evidence? Hey, I'm a front line organization."

Your organization, your leadership, people like you and the membership of NQF are what really will make it valuable because you're right there at the front line keeping us out of the academic sand, getting our heads out of the sand to say, "Okay. What's up? What do we really need to do?" and really get prioritized on that.

DR. CASEY: Chuck, I should disclose I'm an associate professor of medicine at Mt. Sinai, too.

CO-CHAIR DENHAM: All right.

DR. CASEY: Does that help.

CO-CHAIR DENHAM: That helps.

I just want to maybe respond to a couple of these points that I've been taking notes on just to maybe fill in a little bit of

as a context and then kind of maybe open -- have Peter and Gregg respond and then the Committee, but since you've kind of addressed me, I want to make sure I want to kind of address a couple other things.

First off, the harmonization issue. The harmonization issue actually was a bet that we took in 2005, and David remembers this, where I met with the heads of each of these organizations and said, "Take a bet on this Committee that we can get everybody to agree down to the line item specification."

And every one of them said, "These guys are not going to do it. Those guys aren't going to do it."

And said, "Why not try? Let's see if we can do it."

And that was a successful process. However, now when we look retrospectively through the retrospective scope at the specs and you can hear the debate and, you know, the

critical thinking and, you know, comments, I think, like Patrick's, you know, regarding this lack of specificity on some of these things. We're actually part of the sausage making process of getting six organizations who had never worked together to get right down to the spec level, which we were very pleased to see. It was a first.

Now, NQF with the National Priority Partners has built on that, and actually the truth be known, the HAI compendium was a work product that they sat down with us and we actually quietly advised them on how to get their quasi computing organizations to work on that document that created that evidence, and actually all of the specs and HAIs were thoroughly cross-walked from that evidence based approach, and I was disappointed and we all discussed we really want to grade the evidence of these practices for even this year.

With all of the things that are

going on with the financial collapse and the focus of getting the practices out for January 1, I personally was disappointed that we didn't really tackle them to get them using a grading system that would be felt to be appropriate, that we had graded everything on the current set of the 34 and actually some others, but that I know, and I think Gregg will respond and Peter will respond that there is every intention, in fact, passionate desire to do that because of the importance of it and the critical nature of what it allows us to do when we go out and really say, "Hey, we want to see you adopt these." It's vital, absolutely vital to do it.

So this group has really wanted to do it. It was a matter of timetables and all of the powerful events that are kind of a flurry

That said, however, this is the most harmonized set of practices ever created, and if it hadn't been for that first Committee

work of the 2005 work that led to the '06 update, likely the HAI compendium would not have happened, which then gave us an output that was so thoroughly reviewed by the experts that allowed us to actually import them right into those practices, and I think if you said, "Well, what are the best, most evidence based practices we have?" it's going to be that subset.

A lot of the practices one through four, we've got good evidence from other industries, but frankly, we just haven't funded leadership, values grounded focus, risk a management, risk identification, and we're dreaming if we want to be critical thinkers and then pot shot our own practices because we don't have the evidence. It's, you know, entirely in the other areas and other industries like health and human factors research, which actually is grounded in those.

So harmonization, not there yet, but I can tell you that I really believe that

our next go at this for the 2011 could be even more because we had probably nine or ten organizations harmonized on the HAIs.

So harmonization, although not perfect yet, I think, you know, it was a winning combination. I think David and I commented over and over again how prayerfully and thoughtfully we were holding our breath to get to that final cut on the '06 update believing that maybe somebody was going to back out and they didn't.

So the second point was about evidence based grading. We agree 100 percent that a thorough look at how it would be done, what classification would be done and how those would be tied to the practices has been a disappointment that we couldn't do it this year. I think we all wanted to do it, but it was a disappointment that could it be pulled off this year, was the challenge, and we said, okay, for 2011 you can hear our notes to self all the way through here. Hey, let's relook

at this. When we go to 2011, let's look at this.

The criteria actually were used. The criteria that are in the practice, that are in the document, and we failed you in this meeting to not bring up and start the meeting with this table because this table actually was used, and all the way through the process even the term "generalizability," which ends up popping up in Word as not being a word, but this idea that this should work for a six-bed hospital in Idaho and a 2,000-bed hospital in Orlando is foremost in the mind of everybody that has worked on these and the tests that we go through, although not perfect, and the criteria not perfected to a very detailed checklist, every one of them go through that, and you can see that's where then we get criticisms for it's too specific or it's not specific enough.

One of the reasons is that we are trying to meet two beds or six beds in Idaho

and 2,000 beds in Boston, and that is part of the dilemma, but I think we could be more transparent about the fact that this practice has been through the checklist of generalizability, and for the reasons that it has to fit for two beds where there's no patient safety officer and 2,000 beds when they have a Performance Improvement Department and black belts. Trying to get specs that they both could say we are in compliance of is kind of a dilemma, and I'll go through your comments very quickly here, but that criteria, I think it's great. It would be great to relook at this for the 2011 or even sooner.

And we know that because we fund probably more adoption implementation work than anybody in the country, and we want to get a return on our investment, and that generalizability is really key, as is the evidence.

Financial people right now over the next year, we are probably spending, I

would guess, in our organization 60 to 70 percent of our resources on the finance issue of being able to validate CFO-validated numbers and models to be able to go in and make the case so that the CFO is the first vote you have before you even go into the room.

So I think you'll see that it isn't in the body of these. We've teased and got it in. There's not a lot in the evidentiary base, but it's a major focus of a lot of us that are working, and I'm not speaking for NQF, but I'm speaking as a funder of NQF and a funder of the work for the safe practices, major focus.

We couldn't agree with you more, and that we need to have that. The transparency regarding the evidence, I'll defer to Peter, cross-linking the NQF work defer to Peter, but great work is going on and folks at NQF, I think, are coming out with some good product.

Now, are we seeing it here? We probably are failing you to share that we are having that dialogue, but I think I'm glad you brought it up. It's really important. Specificity and sensitivity, I think, you know, we've had this conversation with Gregg, and I don't want to dominate the discussion, but I do want to come back and not just say thank you for you comments, Don. I want to address them in a line item fashion because I think they were all excellent.

Implementation by technologies, it's really difficult to strike the balance of conflict of interest here, and we've been very, very careful about it, and one of the reasons why we were careful about bar code this year and having some reference to bar code as we get into that and CPOE is to have that balancing act of not endorsing any one area.

I will telegraph that we have funded a report that will come out in the

first part of December by NQF on automated infection identification and surveillance systems.

Now, because we all have conflicts of interest because we've worked with various people over the years, we're actually making sure that a completely unbiased group is assessing all of those vendors so that you have a really, you know, completely thoroughly transparently generated report by a third part completely unrelated to anybody in tech assessment that then will kind of come out and Peter is actually and Janet Corrigan are going to present that in the first week in December. So it's not that these things are not being addressed. It's that they're not all being addressed in every area, but this HAI area is so hot, so important that I think that that will lead to some great things, and I'll have Peter maybe comment, you know, about those.

In terms of the liability and the health care reform and this press issue, let's

take those all together. The safe practice force held up very, very well, risk identification and mitigation of risk and hazards.

Our organization is embracing the journalist and saying, "Listen, guys, you really need to get panels of experts before you go criminalizing these things, but you also need a balanced view."

And the other side of it is, Don, that a lot of the biggest payers for media are hospitals, and they spike stories. So there needs to be an opportunity for some balance nationally, and we think there's a national opportunity, and we can talk with you more over coffee or whatever about that, but a hot area, an important area, and an important one that drives safety, the human factors issue, one of our Committee members actually -- Greg recommended one of our Committee members who is not here today is a human factors expert who we had come on just because of your issue

about human factors and what to learn from those other issues. She's not here today, but had input on the '06 and the '09 practices.

And then the issue of those using the safe practices, as somebody who has supported Leapfrog and supported NQF, I agree with you 100 percent that clarity around if an organization is going to use the practices en bloc and say are you adopting these versus are you morphing them and then attributing, you know, your measurement system to a partial utilization of them has to be more clear, and I think this morning when I was telling Leapfrog -- and I want this on the record -- that Leapfrog, if they're going to migrate away from a spec of a safe practice, they need to make that very clear, and if they do resubmit it to Leapfrog.

But we were put in a dilemma on the evidence based referral practice of Leapfrog migrated away, but referred to it; we were out there helping drive adoption and the

first question that we got every day was how come the Leapfrog requirement is different than the NQF standard.

So I think we need to encourage the NQF partners and members that use them to say if NQF is the clearing house, if it has the process, we all need to take measurement systems through the process that's transparent and be more clear about it, and I think that's something we all just need to do together to encourage that.

But I think you heard that this morning, was, hey, guys, you know, I wanted to keep reminding us all they migrated away from it. We removed the practice. You can't say that we harmed anybody because your modification of it was dissimilar from the standard, which wasn't clear.

So I think every one of your points was great. Sorry for my long winded answer, but I think your thoughtful delivery merited a line item approach, and I'd like

Peter maybe to respond and then Gregg.

CO-CHAIR MEYER: A couple of quick responses. First of all, I think I appreciate your comments, and I think that they are for the most part right dead on. Adding the financial analysis and safe practices is actually a huge bit of work, and I'm anxiously awaiting for the work product of Chuck's efforts on that.

In terms of the transparency of the evidence base, there is a work group that Peter Pronovost is leading funded by AHRQ, done by RAND. Peter Pronovost is one of the leaders of it, and both Peter Angood and I are on that committee because we see ourselves as the important end user of their product.

it's a work in progress, and it's supposed to be done early in the New Year, in January. Boy, between there and where we are today and there seems like a very long distance still, but I'm hoping they pull the rabbit out of the hat on that one.

In terms of the way that people use these, the only thing I can share on that is my experiences at AHRQ, which is that we did a number of products. One that I was involved very closely with Peter Pronovost's wife, Marlene Miller, I was developing the patient safety indicators, which were developed for a very clear purpose, which was kind of hypothesis generating, and it became very clear that people used them for things that we really didn't think were right.

We used to term that off label use, and in fact, the reality of it though, as soon as you put something in the public domain, people are going to use it off label. And I think we would love to have people put an asterisk and say, you know, not endorsed and all of the rest, and to the extent we can do that, it's important.

But this off label use phenomenon is really a very big general issue.

Finally, I would ask Peter to

comment further. The issue you raised about the CSAC and the review of those measures I think is an important one. I pointed that out to Peter earlier today, and Peter was going to address it with the group anyway. So you just prompted us to do that because what you said is a very important message for people to hear.

DR. ANGOOD: Well, we're now getting so that we're talking more than you did, Don. So obviously your comments have sparked some -- your critique has sparked some thoughts that are highly relevant, and I won't continue to belabor it, but I, too, though would like to thank you for your insightful comments, and I would encourage you, please, to transcribe it down and send it in as a formal document for us because that would be very helpful.

And I agree pretty much with all of the items that you brought up, and we are, as I made comment, although it was a brief

presentation this morning in my overview and vision for patient safety, we are pretty much going to be trying to address all of those different components as well.

The evidence based, the grading of the evidence, all those other items, all very, very important, and yet I think we have to recognize that NQF as an organization is in a period of transition as well.

We have got still relatively new leadership. We're in rapid stages of growth, and we've got new sets of programs that are coming on line, and so we're not only having to reincarnate a little bit internally, but we have to also train the field that we're a new and different NQF as well. And so I think we just have to ask for a little bit of patience as we go through this phase.

The last comment that Gregg asked me to sort of expand on, which basically comes down to internal communications and making sure that each group knows what the other is

going on, I think it's certainly a priority of mine to make sure that safety is everywhere in NQF and that if they -- other departments in NQF aren't talking to us, we're certainly talking with them, and we actually have a couple of members of our staff who are on that outcomes group, and they help to keep these issues in the forefront, and we've got interactions with all the other departments within NQF.

I think that as we in safety challenge the organization to do this cross-communication it's fair to say that we will continue to learn a little bit and make sure that we don't get siloed up.

If you look at this large, HHS contract that we have and then you look also at the National Priorities Partnership, if you're an organizational behavioralist, there's just a dozen silos waiting to happen, and our challenge will be to make sure that that does not occur.

And certainly as we try within the safety world, as I said, we'll do our darndest to -- we can't break down silos if they have them, but we can certainly figure out how to talk and communicate with silos, and we will do that.

And the other point that I wanted to continue to emphasize is as we build up other advisory committees and steering committees and technical advisory panels, we will be looking to populate those groups with cross-disciplinary experts in the different fields, and very much high on everyone's list is the whole issue of human factors and organizational behavior, et cetera. Because without that we can't really get to the nut of this, and I couldn't agree more with you on the need to continue to look and learn from high reliability organizations, and the principles around high reliability.

I'm not necessarily a proponent of any particular methodology, but the concepts

clearly have to come in there, and we need to do what's right for NQF in our programs.

So I want to leave those as my comments, basically agreeing with all that you said, try to reassure you and re-emphasize that we're addressing all of those and we're still in a period of some transition.

But thank you again, and please submit your stuff.

DR. CASEY: Thank you, Chuck.

Can I just take 15 seconds of the Committee's time?

CO-CHAIR DENHAM: I'm going to ask Peter because he's paying for your microphone.

DR. CASEY: In summary, transparency of science behind the safe practices, number one.

Number two, for lack of a better phrase, insuring that disclaimers are properly affixed when other organizations re-engineer what has been endorsed by NQF.

And the third is demonstration of

accountability to the public taxpayers who fund programs both from a clinical outcomes standpoint and a fiscal responsibility standpoint are my three main messages.

CO-CHAIR DENHAM: And, Don, if you could just articulate a letter. You were very articulate; no question. But I think, you know, your prior communications had some great points in them, and what you articulated today, if you could, as Peter said, put that in a letter to the Committee that we can really kind of then create a table and go right over and then respond to you, I think that it will be helpful for everybody.

I think every one of them were excellent.

DR. ANGOOD: Mike?

DR. COHEN: Yes, could you go back to Safe Practice 3 just for a second?

DR. ANGOOD: Sorry. Perhaps before we do three, are there any other comments on Don's comments? I just want to

make sure. It was a very thorough discussion, and we thank Don for that.

Okay, Mike. Go ahead and take us back.

DR. COHEN: Okay, and it would be the next page down, I think. There it is. I'm going to use my little laser here.

Rapid response assessment, I want to just touch on that. some of the discussion before lunch reminded me that we never touched on this, and I wrote it down on the wrong page. I meant to, and that is the patient activated rapid response assessment or rapid response team.

And you know, this may be one of those areas where there's not a lot of evidence, et cetera. Maybe there's been some evidence at least with rapid response teams that isn't necessarily positive, but I have to say we've repeatedly over the years seen situations where family members recognize that, you know, things are not going well

here, and they question it.

We published the situation just last week that I thought I'd share to bring this home, and these are two individual cases that both happened within a couple of weeks reported to us, and they both involved healthy kids who had surgery and then post-op they were given fluids that lacked enough sodium chloride. So they developed hypernutremia and water intoxication. One was at the wrong rate. It was given much too rapidly because of another error.

And in both of these cases when the families questioned the situation because they saw pretty rapid deterioration, they both had seizure disorders, one of which was characterized by a nurse as response to pain medicine. The child was obtunded, and the other one was phenothiazine had been administered, and so the child had supposedly, according to a physician, extrapyramidal effects and then continued to deteriorate and

neither one of them were appropriately treated.

These were both situations where the family had called attention to it. We've seen this before. I'm sure all of us have at one time or another, and it just hit me that, you know, we should probably at least think about that, and that is adding, you know, the idea of a patient activator, not patient, but family activated rapid response.

CO-CHAIR DENHAM: Mike, not part of the specs, but we have a section for strategies of progressive organizations, also new horizons, and there's an opportunities for patient and family involvement. They're on page 89 if you've got the full document, but we can pass it around to you, but because the evidence -- and we've kind of gone -- there isn't anything substantive yet that we've seen that would allow you to say that hit the criteria of the table, but those two are good places, I think, for a reasonable placement of

them because there are enough of them out there for people to be aware of them.

The new horizons and opportunity for patient and families, they are, again, not specs, and so a proposal could be to insert those into those, and they're part of what we've been calling the implementation guide, and that might be something you might want to recommend.

Are there other comments regarding this one?

DR. ROMANO: I just have a very technical question which is prompted by Michael's comment, which is is there a way to actually bring the full document into our computers because I can only find through the NQF Website an executive summary. I can't actually get the full document.

CO-CHAIR DENHAM: We've sent it to you. You have the full document in PDF. We can send it to you again.

DR. ROMANO: No, send it to me

now.

CO-CHAIR DENHAM: Do you mean right now?

DR. ROMANO: Give it to me right now.

CO-CHAIR DENHAM: Are you online?

DR. ROMANO: Yes.

CO-CHAIR DENHAM: Yes, I'll E-mail it to you.

DR. ROMANO: Okay.

CO-CHAIR DENHAM: Why don't you send it to the whole Committee? Just resend it. It's about a three mg file. It will take a little while with wireless, but you'll have it.

CO-CHAIR MEYER: I think now we'll try to move on to Safe Practice 8, and the issue with Safe Practice 8 that we just wanted to highlight is that, in the middle of the page there, that there was an addition that we made really towards the end of the process last time around caring for the caregiver and

trying to practice kind of a just culture. It was that if after an event investigation the organization is contemplating a corrective action that could result in a serious loss of livelihood of an individual, that individual should be notified of the potential action, and he or she should be advised that he or she may want to exercise the opportunity to seek the advice of legal counsel before providing a formal statement about the corrective action.

And that actually came in. That was not in our original discussions. That came in as a comment from the field when it was vetted by the NQF. It was a hospital in Florida I remember was the one that spearheaded this, and after some discussion, this was language that we landed on for that, but this was really a case where we were responding to the feedback from the Quality Forum's public review process.

To me lawyers are going to be

involved sooner or later. So getting involved sooner doesn't seem to be a big problem, but we wanted to make sure that people understood that that's where that came from.

CO-CHAIR DENHAM: And, again, this one is being just brought up because it was one of the changes that we made last time around. So nothing is proposed to be changed at this point in time. This is only kind of an abundance of caution or an abundance of attention to detail that we bring it up.

The process that we followed was that the formal input came through the formal NQF process on this practice, and then a very large hospital with multiple hospitals from 25 beds to 2,000 beds and a legal team had reviewed it and had submitted a little bit different language.

And so what the Committee did is engage its medical-legal subject matter experts that were really, really familiar with this issue and carefully worked through

wording that then became acceptable not only to that organization, but then we deployed this section to other NQF members and hospitals to say, you know, here's the way it was. Here's the challenge and here's the request for the change. Here's the compromise language that meets both issues, not perfect, but this is acceptable to the NQF members that had a problem with it. This is acceptable to the medical-legal team that are the experts that worked on the practice with us, and it's also acceptable to a field group of NQF representative organizations.

And so we're just bringing it back to you to say no new changes on it. We have had no complaints on it since it went out as the formal report, but it went out, you know, March 7th, and we're revisiting it again and will come back to the Committee if we think that anything has changed, but it's just an abundance of attention to detail that we wanted to bring it back to you.

So we just kind of went through the care of the caregiver. So good.

Nursing work for us, this practice has actually stood the test of time relatively well. We've returned to the subject matter experts, nursing leadership subject matter experts that were involved with the practice and revisited it. It's having a thorough update in terms of the problem statement because there's some rich material in the nursing literature that will be added to the problem statement specifically regarding training of new grads and the challenges that are faced.

But actually as we went through with the subject matter nursing team and this last couple of weeks we had another team of nursing leaders from all across the country from critical care nursing leadership from AACN, AORN from the surgical nurses and perioperative nurses, AONE, and then we had a number of other chief nursing officers and

said, you know, "You all haven't had problems with it, but maybe you haven't looked at it. You know, is there anything that we need to address?"

And really the two areas of update are the problem statement and the implementation guide, but the specs, everyone and nurses out in the field have said, you know, the one thing that we will likely bring to the Committee for 2011 is a recommendation, and we've been field testing this as well and asking members of the NQF about this. Is it reasonable at some point in time to have a nursing leadership practice like what we did in 2009 update for a pharmacy?

And that has been really well received, and the pharmacy leaders have loved it. It's really helped them an awful lot get organized, get focused, and we'll have maybe Hayley comment in a little bit, but it's likely for the 3011 that it's reasonable to take some of the content of this and organize

it around nursing leadership because there's enough evidence to really support the two issues, work force specifically but nursing leadership.

And in the same vein, it's very likely that a leadership practice for infection control will likely be one that will be submitted, and this will be in collaboration with APIC and IDSA and SHEA, and have them really kind of be the champions of it.

But these leadership practices then really put some tactics. It's not that it's a general soft leadership, "be a good leader." It's actually the tactic and the specific evidence based activities that a leader needs to make sure happen in that area is a more reasonable way to kind of organize them.

So we'll bring that back at a later date on the 2011, but in terms of both the direct caregiver and the nursing practices

we don't see any substantive changes.

Comments, Peter?

DR. ANGOOD: No, other than on your last comment about a nursing specific one, I think it's important that we work toward activity that's relevant for the main disciplines within health care, but also within those 90 some odd other kind of allied health professionals. You can't bucket them all into one and the same, and as we have learned through the nursing sensitive measures, this winds up being quite contentious at times, and we know certainly within the physician world as well the whole area of measurement and telling folks how to do things, et cetera, gets to become contentious.

So I think it's a set of issues we need to address. It's just going to be fraught with minefields all the way through, and we shouldn't allude ourselves otherwise. Not everybody is going to be as open armed and

warm and cuddly as the pharmacist.

(Laughter.)

CO-CHAIR DENHAM: Mary, Maura, do you all want to comment on the nursing since you all were both very active and really great collaborators on --

DR. McAULIFFE: We were very happy with the outcome. I hadn't thought about having a nursing leadership safe practice, and this is the first I've heard of it. So I have to think a little bit more about that, read a little bit more about what pharmacy did, and see where that might go and talk to you all a little bit more about that.

I think it probably has merit, but I need to think about it.

MS. MacDONALD: I absolutely agree with that. I think it would be a terrific practice, and I hope that the group of people who develop the standards include a wide range. It also would include staff nurses, you know, as well as managers and leaders.

So thank you. I think it's great.

CO-CHAIR DENHAM: And on this particular practice, we sought input from staff front line nurses, again, just to see. We just weren't getting any criticisms of it, and so we road tested that, again. Is this timely? Is it still up to date? Does this still make sense? Is it relevant and that kind of thing?

Hayley, could you just comment just for a couple minutes or a second, couple of seconds, just regarding how well received the pharmacy leadership practice was and the fact that it was really specific and detailed?

It wasn't a soft just leadership, but it was really specific and tactical with evidence.

DR. BURGESS: Right. The pharmacist leadership practice, which is Practice 18, and that was new this year, when we looked at the medication management chapter from 2006, there were multiple practices

around medication management, though even amongst ourselves we felt that we had made MedMan disjointed.

So we really started looking at that and decided it would make much more sense to put pharmacists in the leadership role that they deserve and create a road map for them around medication safety programs.

And I will tell you as Chuck and I talked about medication management and medication safety -- and, Mike, I know you can attest to this -- many will come to us later and say, "How do you create a medication safety program that's comprehensive?" and these are smart pharmacists, nurses, physicians coming to us.

So this practice made a lot of sense because what we did is model it after the first four practices: so leadership, culture, teamwork, risk identification and mitigation.

So that was the framework which

makes complete sense and is consistent with the practices, but then taking the processes of pharmacy administration, dispensing, high alert meds, all of those pieces and parts, cross-walking that with what's already out there so certainly involving Joint Commission in some of the standards though, not a regurgitation of what they've already put out there, but really streamlining those activities that are most important and relevant at this time.

And currently we're working very closely with ASHP, the American Society of Health-System Pharmacists, and we're going through each additional specification and looking for all of that literature that ties specifically to those specs. So, again, getting ready for the 2011 where we'll start grading that evidence, but we're beginning that work with the pharmacist leadership practice.

It has been very well received

even through public comment. We did expect some push-back maybe from other professions or organizations. We just did not receive that because it completely made sense, and what it does is give pharmacy leadership a nice road map for a comprehensive medication management program, and it also gives them some insights to be part of their senior leadership team because they absolutely have to be. Medication touches every patient in almost every way, as well as the technology.

So it has been really an excellent addition. Mike, is there anything you'd like to say about it?

DR. COHEN: No, I just echo what you said, and you know, when we look at our -- I was saying I echo what she said, but also just add that when we look at our database, about 25 percent of the medical adverse events are medication related. So it is a big chunk.

CO-CHAIR DENHAM: So any comments regarding the nursing or direct caregiver,

which really mirror each other, and we're kind of looking at them together?

(No response.)

CO-CHAIR DENHAM: So that being the case, we'll move next. Now, is Dr. Pronovost still on?

DR. PRONOVOST: I sure am.

CO-CHAIR DENHAM: Peter, would you like to comment regarding the intensive care unit practice and specifically each year, you know, we come back and revisit with you. What Mike had brought up was rapid response teams, level of evidence, and just explain to the Committee what transpired.

Over the last two cycles that has been brought up as a potential safe practice. Although relevant and important, it lives currently in Safe Practice 3 regarding teamwork as an example, implementation area, and it has mentioned in a couple of the others, however not yet a stand alone, and we've relied on Dr. Pronovost as a critical

care expert and our in-house expert. We're lucky to have him for so many different areas, but this is right up his alley.

Peter, comments?

DR. PRONOVOST: Sure, yes. I had to step out earlier. I missed the rapid response discussion, but I'm sure the group is aware of it.

There are, I think, now three or four systematic reviews evaluating that topic. So I suspect you have those references in there, but the field, no doubt, will be aware of them.

For ICU staffing, the bottom line is I don't think there is any evidence that would make us change our recommendations. There was an observational study that was negative, though a lot of the commentary questioned the method, and there was one further study that was positive.

There was also an additional study that looked at the relative value of 24

versus, you know, a daytime staffing and consensus. I have a group because we evaluate the Leapfrog standard that reviews this, and that group and I really felt that there wasn't sufficient evidence yet to make that recommendation.

So I think though there are a couple of new studies, they wouldn't sway what we have put down.

CO-CHAIR DENHAM: Great, Peter. So as we are updating the problem statement, implementation guide, and the references, we'll be looping back with you in the next week or so. We just wanted to see if there's anything substantive that you might bring up, and we'll be looping back to make sure we've got the best references and then again revisit this in 2011.

And while you were out, Peter, we just talked about the patient activated or family activated rapid response activities as just something that gets honorable mention.

DR. PRONOVOST: I was here for that. I heard you reference an earlier discussion that I wasn't there for.

CO-CHAIR DENHAM: Okay, great. Thanks.

DR. PRONOVOST: Good. So I'll get you those references.

CO-CHAIR DENHAM: Great. Thanks, peter.

Anything you want to add> Peter Angood has also critical care.

DR. ANGOOD: No, I think Peter Pronovost covered it quite well. I come from the world of critical care, as well, and I think we're still well positioned with the safe practice, and I guess the challenge to us is how do we nudge it further if we can at all. There's still numerous organizations who don't have adequate staffing for critical care, and I think we just have to look for ways to freshen up the idea.

DR. PRONOVOST: Well, Peter, and

that's what we were discussing about volume based surgeries and how consumers often don't know the risk they're getting. I don't believe consumers adequately know the additional risk they're incurring by the type of ICUs they select.

DR. ANGOOD: Yes, your point was very well taken actually, peter, and it generated a few sidebars in here that you wouldn't have heard being on the phone, and I'm going to think through further not just necessarily for the safe practices but for our other programs how can we begin to address that issue because it is critically important to not just be transparent but, I guess, unmask some of these risks and figure out ways in which to have them appropriately managed so it doesn't scare the public away from the health care facilities.

CO-CHAIR DENHAM: Great. So if the Committee is agreeable, if we're satisfied with our recommendations, there are no

substantive changes other than the updates with Dr. Pronovost to make sure that we've got everything ship shape there, we'll move on to the Chapter 5, the Safe Practice 12, patient care information.

Again, with this, as Dr. Meyer was stating, the set of this chapter may move fairly quickly for us. I'll take the first one where we went back to our subject matter experts on this. This practice has really stood the test of time. It really hasn't solicited any negative comments.

One of the things, I think, Peter, you may have brought up a potential name change to it for a little bit more clarity, communication of patient care information rather than patient care information. Again, these titles are just simple ways for NQF to get you to the practice. The names were kind of shortened versions or they were just used as almost subject matter topics that would get you to the safe practice.

The other two issues, just so that we can move quickly, was a question regarding HIPAA and how HIPAA might tie together with what we've got here, and then we also had considered this year, and the Committee will probably remember this, handoffs, the transition in care, the handoffs in care as a potential practice for 2010, but because of the short cycle year and the desire to get them out for January and then do a forklift upgrade on 2011, we decided to hold on that and then really look at that very hard, again over the course of the next year.

So those were the three elements for this particular practice.

DR. ANGOOD: Just one.

CO-CHAIR DENHAM: Yes, sir.

DR. ANGOOD: On the HIPAA, we need to make specific mention since we talked about this last -- HIPAA has now been shifted over to Department of Justice or Department of -- Dave, help me out here.

DR. HUNT: I think it's still going to be in the Office of Civil rights.

DR. ANGOOD: Civil Right is it. Yes, it's moving over to Civil Rights and more out of HHS per se, if you will.

CO-CHAIR DENHAM: Are there direct actions that we need to take regarding specifically staff-wise on disregarding HIPAA?

DR. ANGOOD: We just need to look at what our language is within the problem statements and make sure whether or not we need to reflect this civil rights focus.

DR. ANGOOD: Go ahead, Dr. Romano.

DR. ROMANO: Was there some specific concern that the current language is not consistent with HIPAA or no?

CO-CHAIR DENHAM: So no substantive recommendations other, again, than problem statement implementation. We have had subject matter experts review this from the literature standpoint.

So just to remind everybody, we do

thorough literature reviews, go through everything, and then have subject matter experts that are in this field.

So Dr. Gordy Schiff went through all of the information practices with us to just double check to see if there are any references that may have been missed, should be prioritized implementation elements as well as a number of other experts providing input on these.

So for this Practice 12, any more dialogue before we move to 13? And no substantive changes recommended.

(No response.)

CO-CHAIR DENHAM: Okay. Gregg, do you want to take 13?

CO-CHAIR MEYER: Thirteen is read back in abbreviations. I think the only thing there would be when the right timing. I asked Mike to comment when the right timing is to take another look at the list of abbreviations.

DR. COHEN: I was thinking exactly the same thing. This started back in the '90s with the Joint Commission National Patient Safety Goal, and there's a lot more than this. This may be one of those issues that you talked about earlier where we're so specific, not that there shouldn't be some minimum list, but we've maintained a list for years. I don't know if others do as well, but there's a lot more on here, drug name, abbreviations that have been fatal. We had two with the same PTU abbreviation last year, for example, and many others. I think, you know, it does need to be looked at.

CO-CHAIR MEYER: So the question, I guess is whether or not that -- as it reads right now, at a minimum, you know, I think -- but it does. In some sense it has people kind of aiming for the floor.

So the big question, when should we add. I guess we could put it into some of the implementation practices to put a more

robust list.

DR. COHEN: The Joint Commission with a drug name patient safety goal has been referring to the I guess it's the new medication management standard as referred to the list that we maintain, and USP is not involved with it anymore.

So this is another thing that we maintain. It's not just drug related abbreviations but other medical abbreviations as well. I don't know if there's others that you would also want to refer to, but it could be handled in that way, that, you know, organizations should check the list.

CO-CHAIR MEYER: Fourteen was the diagnostic studies, and we did not recommend -- oh, Patrick?

DR. ROMANO: To add something there, yes, I mean, I think there is a bit of a danger that there's an overly formulaic response to this, which is that everybody has their little, you know, index card, a little

thing that is supposed to clip on their name tag with the band abbreviations.

And although we all know that there are specific adverse events or near misses or in some cases catastrophes that have occurred as a result of the use of those abbreviations, in some cases it seems that that may be overly prescriptive, and that there maybe opportunities within particular health systems; there may be issues that arise as concerns.

So at a minimum there's a way of dealing with that, but I would agree that it should be reconsidered.

DR. ANGOOD: Well, if I could add onto Mike's and Patrick's comments, maybe as we going into a deeper review of the practices in '010 through '11 we begin to think about how to create systems and process change as the underlying focus of the practice as opposed to keeping a list, et cetera, because it's the danger of utilizing these lists or

it's the danger of the mislabeled drugs or the same name drugs or similar name drugs, et cetera.

I'm just trying to get this on our record. It's the systems and processes that create this. We're not going to change the industry or the manufacturing very rapidly, as we all know. So we have to keep pushing the field to receive these things to make sure that they put safety -- it's the mitigation of risk issue.

CO-CHAIR DENHAM: So Safe Practice 14 are labeling of diagnostic studies and although not over in the comments section we just need to make sure for the record that we need to cross-link this over with the laboratory safe practices that have recently come out that address this area as well, and, again, not have the overlap or redundancy issue as a problem, but just make sure that there are linkages that we understand kind of exist.

And then I think in the hyperlinked world as we continue to get more and more electronic, they'll be easier to kind of track, but we just want to make sure.

Dr. Romano brought up the issue of redundancy and that kind of thing. Here's a nice example of where this is a practice on labeling. It actually is going to evolve in a number of areas, but there is a safe practice that pertains to this in the laboratory area.

So as NQF continues to kind of bring things into a more and more synchronized fashion, this is one of those examples and we don't have that over in the comment section, but there are no substantive changes recommended on this one.

CO-CHAIR DENHAM: This one needs to be tied back more, again, as well, to the communication of patient information, that continuity of information and not to getting lost, and so it's another way to go at it.

DR. ANGOOD: So comments from the Committee on this particular?

Discharge systems, this is a very active area as we all know during the health care reform issues that are being addressed, and fortunately for this Committee some of the subject matter experts that are most quoted now in the Beltway on the health reform issues on readmission were our subject matter experts, and so we have that benefit of that knowledge and that foreknowledge.

So what's happened over the last 24 months is some of the papers have now come out that support this to some degree.

Now, again, those papers are more isolated environments. Do they represent the front line perfectly? No, but there is some excellent work that's been done by Dr. Brian Jack who worked with us on this, and then we field tested this, road tested this with a number of subject matter experts.

The only thing that's not over in

the comment section that we'll want to do to go back and look at is, again, the operational definitions with the glossaries, and one of the areas that we need to make sure that we address is a discharge to nursing home specifically. The practice was kept in a relatively general-speak language, and although we're not recommending language today, we may bring it back at the next meeting to just make sure that when we describe a setting that someone is being discharged to, that it also includes those transitions in care to a nursing home that need to be addressed.

So I want to make sure that's in the right column as well, and we'll go back and look at that and tied those, again, back to that CMS care settings where appropriate because in the '06 or the '09 update, we tied care settings to the CMS care settings.

And so I think with every iteration of these, more careful attention to

operational definitions and settings and that kind of think, I think we're doing a reasonably good job on. We just need to keep vigilant that way. So we'll be doing that to make sure that we address it.

Do you want to address some of the work that's done in Boston actually in this area?

CO-CHAIR MEYER: Yes. You saw Brian and Jack's paper on re-engineering discharge, and we'll see that this is very powerful. This is going to get a lot of play over the next several months, looking at readmissions. So more to come. I think there will be a lot more evidence.

CO-CHAIR DENHAM: So Committee comments?

So the recommendations to the Committee is there may be some word changes for specifics so that we make sure that it is clear that it includes nursing homes, but apart from that, no substantive changes, and

I'm not sure that would be considered as such, but I just want to be transparent, you know, about that.

So there being no further comments, we'll go to Safe Practice 16. This was formerly Safe Practice 12. This practice, when we took the '03 update to the '06 and then the '06 update, the '06 update was really substantial, and the spirit of the substantive changes addressed the readiness of an organization, not just CPOE. This address doing a risk assessment, the care re-engineering, and a great deal of care was undertaken in developing this practice, and our experts were Dr. David Bates, Dr. David Clasen, myself and Dr. Peter Kilbridge, and we worked very carefully through this with a lot of input from the field.

And it has actually held very well. I've recently looped back with them and met with Dr. Bates day before yesterday to go through this again with the specs. Would the

recommendations for the specs change?

This is our recommendation to you, which we may bring back to the Committee in the next couple of weeks. In all probability, no change in the specs, but the changes will be to tie to meaningful use.

And so, David, we're going to turn to you and make sure that we get it right, but as you know, David Bates is one of the lead players on the Committee, and so what we will be doing is just carefully going line item through this and make sure that there is synchronization with the definition of meaningful use and the timetables, and then, David, the implementation guide section really providing a nice guide to say these are the expectations for 2011; these are the expectations for, you know, each of the subsequent years and where the bar code and the other elements kind of fit because this is kind of our technology adoption sort of practice.

And we had gone through the discussion: do we address bar code as a potential safe practice during this update? And we decided, no, we'll make sure to address it and address it appropriately, but then do a really solid consideration of it for the 2011.

And so David is prepared to be the submitter of the bar code piece and has actually some papers that will be coming out. So I think we made a good decision to say let's put that one on hold till 2011, and I said, "David, do you feel like we made a good decision holding off?"

He said, yes, he thought that the evidence will be more substantive, but the timing of it with everything that's going on, that we probably made a good decision on that one, not that every time we do, but that one we probably made a reasonable decision.

So our recommendations to the Committee are we'll be carefully going through

all the specs, problem statement and implementation guide, and if any changes occur in the specs, they will likely be only in a synchronization mode to synchronize with what the new requirements are going to be, and we'll also address the CPOE flight simulator portion of that. There's some data that will be coming out shortly, and there are co-authors on that data of what the findings were.

And just a quick snapshot is that when you evaluate a system outside by using standardized patients you find out new opportunities for performance improvement and safety. And so that paper will all likely come out through one of the major journals in probably the next 120 days.

So we'd like to come back to the Committee with the specific wording, but it will be with their input, and, David, if we could call on you to make sure we get the timetable right and the language right.

DR. ANGOOD: In a related but not so related fashion, David, this to me represents a utilization and implementation of technology, and from your seat in other activities, I would ask if you could begin to think of topic areas related to technology and implementation of technology that could become part of the safe practices portfolio because that's now becoming a rapidly moving train.

CPOE is kind of old information, if you will, and I'd like us to be as contemporary as we can as we move into that next iteration.

Any idea off the cuff right now? Obviously I'll ask for more input later.

DR. HUNT: Well, you know, Chuck has already brought it up, the meaningful use train has got to be the bucket where everything is kept and I think this is a wonderful opportunity to make sure we link on with the medication management, but we should always remember that one of the great

opportunities will also be with the previous practice because the expectation for meaningful use, not to get into the details, but one expectation will be there will be exchange of information among health care providers and discharge summaries has always for the longest time been highlighted as one very, very good example.

So I think that hopefully if we are really on our end going to be meaningful, to use that word a little bit more than it should be, we should have opportunities to tie into a number of other areas, and I think that will be the case.

It will be presumptuous to jump forward right now because we're in that really fuzzy period, but I think for the 2011, I think it will be a great time.

DR. ANGOOD: Yes, certainly nothing for now, but I don't think -- it's never too soon to start planning for the complexity of this one. So thank you.

CO-CHAIR DENHAM: So, peter, it's such a delight for Peter now not to be the Joint Commission guy talking about MedRec conciliation. So you can take --

(Laughter.)

CO-CHAIR DENHAM: We decided to reduce security. We don't have any bomb threats or anything like that because Peter is not representing the Joint Commission on MedRec, but he will go over the MedRed analysis since he is now our in-house expert at NQF.

DR. ANGOOD: A quick little story. Mike has heard this one, but in my role overseeing MedRec and all those other national Patient Safety Goals, I had some of those age over 50, you know, screening tests in December just as I was leaving the Joint Commission, but one of which was to have a CAT scan following some benign lymphadenopathy that I have, and I swear I was literally on the CAT scan table, arms in the air taking my deep

breath, and the CT tech started railing on me about medication reconciliation.

(Laughter.)

CO-CHAIR DENHAM: And what a nuisance this was because he had figured out who I was and what I represented. So Chuck's comments were on the mark, you know.

(Off-mic comment.)

CO-CHAIR DENHAM: It's a mixed audience, and I did that part, too. I will share since you brought it up.

But I was having that other over 50 test, and I was lying there feeling quite exposed and vulnerable, and there's this flurry going on behind me, and sure enough, the Joint Commission surveyors show up.

(Laughter.)

CO-CHAIR DENHAM: This unannounced survey, you know, and I'm in the midst of about to get my test, and the quick thinking nurse says to me, "You know, aren't you taking this tracer methodology just a bit too far?"

And the more quick thinking gastroenterologist says, "No, this is poetic justice."

(Laughter.)

CO-CHAIR DENHAM: So anyway, so enough of my personal tales, but the MedRed, nevertheless, Greg to make some comments as well, this continues to be one of the more complicated challenges for the field, and it's again, not the issue of whether it's important. It's more of an issue of how do you implement and make it useful.

The Joint Commission revamped MedRec quite extensively and through a lot of different processes, and we made sure that the MedRec patient safety goal was harmonized and mirrored within this safe practices, almost verbatim basically, and then because of the complexities of it, the Joint Commission decided to back off surveying medication reconciliation.

They haven't changed the language

and they're reviewing it, and they continue to review. But they have, as near as I'm aware, not come up with any new language or strategies around medication reconciliation.

And so we chose to not change any of the language in the safe practice. When we were going to press with this particular version, I spoke quite a bit with Janet Corrigan about, you know, sort of strategies on this, and she was quite comfortable with the language as written and for moving forward.

And, you know, if the Joint Commission wants to do something else on its own time, that's the Joint Commission's business, and she was happy with this. And so we did go to press with the current version.

We have checked with Jeff Schnipper, who has done a lot of work in the Boston area as well on medication reconciliation. He's still comfortable with where this sits, and I think that from my

perspective, while it's complicated, I think we should probably let it sit for a little bit, let the field continue to digest and sort of work around it without now creating further change.

But, Gregg, I'd welcome your comments and others from the panel.

CO-CHAIR MEYER: So the experience that Jeff Schnipper described is -- well, I think the importance of face value of doing this hasn't diminished at all. The fact that it's not being scored during survey, I think, is actually not particularly relevant to the safe practices written here.

I do think that the most important message that was more of a decision by the Joint Commission, more of a reflection of the difficulty people had in doing this rather than the underlying importance of doing it.

And so I don't think we need to make any change here unless Mike thinks that there's anything else that needs to happen

from your standpoint.

DR. COHEN: I said we certainly recognize the importance, but you know, quite honestly, we heard from so many people on this that actually assigned it to someone else.

(Laughter.)

DR. COHEN: I really don't have anything else to add, but I do think what you have here for now at least, I know the Joint Commission is going to be looking at this again for, you know, I guess for release in a year or two.

DR. ANGOOD: Everybody comfortable with that? I guess just stay the course?

CO-CHAIR DENHAM: So the next practice is actually the leadership practice for pharmacy. We've already had Hayley kind of comment on how well received that it has been, and so we're working very closely with the pharmacy leadership organizations to just go through and carefully update again the problem statement, implementation guide, new

horizons.

And the other thing I might mention, we're wanting to move through the briskly, but just to also say that we're working on all of the measures section, although not formally, the safe practice, endorsed practice.

Those will also be updated with the right measures that should be referred to out of the 525 that Peter had mentioned.

So, Mike, do you want to make any comments regarding leadership practice? We don't see any substantive changes at this point in time.

DR. COHEN: Looking at other pages besides page 1, I did have some comments, but on page 1 under storage -- that's page 30 actually of the handout -- just to remind you that the Joint Commission has now changed that, and it's a medication management standard. They're asking organizations to do what it states here, but refer to the ISMP

list, which we compile and update.

So that might be one thing that you need to mention.

CO-CHAIR DENHAM: That would be a reference --

DR. COHEN: It's on our Website. We can get you a reference.

CO-CHAIR DENHAM: We should put the citation in there.

DR. COHEN: Yes, it's updated annually.

Under the last bullet under preparing and dispensing, many organizations are now using outsourcing for order processing when a pharmacy is closed. So that might be something you should take a look at.

CO-CHAIR MEYER: Anything specific around the structuring of those outsourcing arrangements that we ought to have detailed here?

DR. COHEN: Yes. They actually have video systems. They have bar code

systems. The orders are actually processed at a central location. When questions arise by, you know, folks at the hospital, they can check with the pharmacy that's centralized. I think it's a safer way to operate, and that is an opportunity that any hospital can -- and there's several organizations that do that.

And then under medication administration, in that first, where it says, "Organizations should consider," I would change the word "consider" now especially knowing that we're going to be perhaps moving to a bar code safe practice, moving toward or preparing for the use of rather than "consider."

I think it is time that they really got serious about this. We're up to about 30 percent of the country that already has bedside scanning. Sixty percent use smart pumps. There are no pumps anymore that are sold pretty much without that drug library. So that's pretty much something everybody can

do.

CO-CHAIR DENHAM: So prepare for probably -- that's substantive, right?

DR. COHEN: Yes.

CO-CHAIR DENHAM: And before we kind of moved to the next one. Do we want to kind of visit about that? I mean that sounds reasonable, I think, from what we know of the evidence that's evolving, that has already unfolded and continuing to unfold, but again, it doesn't have specificity for compliance. It's soft, you know. I wouldn't use the term, Patrick, that it's, you know, quasi or I'm not sure the term you used specific or pseudo specific, but it does show an intention, and we already know we're likely going to be at the bar code level.

But I think that would be a substantive change rather than --

DR. COHEN: Oh, really?

CO-CHAIR DENHAM: Well, I don't know. I mean, it depends on how we define

"prepare." I mean are we going to define it or are we just wordsmithing?

DR. COHEN: I really meant doing, you know, the groundwork, checking your infrastructure, inviting in vendors, things like that, not actually installing it at this point. At least they should be thinking this way though because it's going to happen

DR. ANGOOD: Yes, I think if we sort of keep it along the lines of should consider and begin to prepare for or something like that, that keeps us out of any real substantive changes, but it keeps telegraphing: this is coming, this is coming, pay attention to it.

CO-CHAIR DENHAM: Actually I think, Patrick, this is kind of where we are. The dilemma we face, it is really easy to put on the critical thinking hat and say those things, but you see the dilemma we face is that we want to get intentionality. We're trying to move the market. The evidence isn't

there for preparation in saving lives, but I think this is important, and it's important probably for us to change the word to "prepare," and then define what we mean by "prepare" in the implementation guide.

I think that's where we could leverage the implementation guide to say, you know, so that the market sees, hey, we've made a change. We've said "prepare," and then in the implementation guide say what we mean by "prepare."

And just to give you a read-back, Mike, is start to assess the state, start to identify the processes that need to change, identifying the technologies that they may need to implement and that kind of thing --

DR. COHEN: Exactly.

CO-CHAIR DENHAM: -- and put that in the implementation guide.

DR. COHEN: In fact, there is an assessment for readiness form that's available that was done by the American Hospital

Association, ISMP and the Health Research Education Trust, with a grant from the Commonwealth Fund that people could use actually.

And then, by the way, Hayley just pointed out on the previous page under leadership and culture survey you actually do have --

DR. BURGESS: Readiness planning.

DR. COHEN: -- readiness planning for bar coding.

DR. BURGESS: They already have it there.

CO-CHAIR DENHAM: Do you want to reread it?

DR. COHEN: Only because considering is one thing, but you know, getting ready for it or starting to do planning is something quite different. So I didn't think this was --

CO-CHAIR DENHAM: So let's relook at that verbiage and look at the word

"prepare," and if we're all in agreement.

Patrick, you had a comment.

DR. ROMANO: Well, I was just going to say that I think as Michael, I think, has alluded to, it's important to consider the work flow and the implementation that each organization has to implement these types of innovations in the context of the work flow. We've seen and read reports about some of the disasters that happened with EMR implementation at some facilities when they didn't actually, you know, sufficiently consider those issues in advance.

I think that our safe practice really covers that very well in terms of the computerized physician order entry implementation, the necessity of really planning for that and implementing it in a systematic and phased manner.

And I think, you know, anecdotally we've heard cases of, you know, where bar coding has led to delays in administering

necessary medications because of some issues that maybe could have been anticipated in advance.

DR. COHEN: Exactly. Thank you very much for that.

CO-CHAIR DENHAM: So then just for that piece, before you get to the next one so that we can move quickly, how about if we -- I'll propose to work with Hayley on that piece since we do so much tech work. We'll reword and beef up the readiness piece to follow on what Patrick said that follows along the same thematic sort of trend of the CPOE in the implementation guide and suggest to change the word "prepare" and then cite that word in the implementation guide. "By 'prepare,' it means," and then we could go through those activities.

Then may we run that by you, Mike?

DR. COHEN: Oh, absolutely.

CO-CHAIR DENHAM: And then with Mike's approval, we can fire back to the

Committee. Is that a reasonable set of steps on that one?

I think it's really important because we did decide not to do bar code, knowing that we're going to really focus on it next time. So I think we need to kind of prepare for it and telegraph to the market because this is kind of serious stuff.

Okay. Keep going.

DR. COHEN: The other issue on this page -- well, there's two more, but one is under proactive risk mitigation strategies. This is for leadership, for pharmacist leadership. It calls for annual review using external sources of reported near miss information or actual information, and I don't think annual is enough. I think it should be ongoing. I mean, there are issues that come up all the time that are major that could be handled rather easily by recognizing it.

And just saying once a year isn't enough, I think. So either drop that or if

you want to be prescriptive, make it more often. Say ongoing or that's what I think it should be.

That's under proactive -- where is it here? Right here.

DR. ANGOOD: Mike, on this one is this -- could we just get rid of the time reference in there?

DR. COHEN: I think that would work, yes. When you say annually, it's just not frequent enough.

DR. ANGOOD: Right.

CO-CHAIR DENHAM: Now, here's where we had the debate. We've had this debate every year. Do we say annual so that you can check box? So there's a compliance issue, or do we leave it without a time, which means somebody could interpret that, well, we kind of do that. So we do it.

This is the dilemma we always face, is if we put a time on, is it too frequent, too infrequent; are we too specific.

This is the dynamic tension that Gregg mentioned. If we don't put a time on, there's weasel room to just not do it, and so we went through this debate last year.

So the debate was do we do it ongoing. That's where the terms "regular," "periodic," "annual" or "continuous," and what does "continuous" mean? Continuous, well, we kind of continuously do that.

DR. COHEN: Well, we have this PSO concept. We have the state reporting programs. We have the voluntary programs, and their very purpose is to communicate information, communicate the learning, and if people are just going to wait once a year, which is basically what it says, that's not enough in my mind.

So what I'm trying to indicate here is that it should be on an ongoing basis not just once a year that you're looking at external sources. That's the crux of the matter for me.

CO-CHAIR DENHAM: Just so we can keep going, I'll give you two options. Let's throw out for discussion two options. It should be ongoing at least annual or we can say ongoing and then in the implementation guide specify what we mean by ongoing, that this should be a continuous process.

DR. COHEN: I think the latter.

CO-CHAIR DENHAM: The Committee okay with that?

DR. HUNT: Yes, I would agree with that. I think the implementation guide, that really is the jewel to this whole thing because just having the practices come down from on high from Mt. Sinai, it's the implementation guide that has been my experience that so many people really refer to.

So I would put it there and even make it a parenthetical, for example, annual, ongoing or continuous just to let people know and/or give examples, you know.

St. Elsewhere General does it, you know, annually with these type of results.

DR. COHEN: Monthly.

(Laughter.)

DR. COHEN: And then finally very minor, under evaluation it says perform a medication safety self-assessment, and there are many that are out there now, some very specific. The dispensing cabinets, the bar code self-assessment, the smart pumps, et cetera, et cetera. So I think just dropping A and say medication self-assessments would work.

CO-CHAIR DENHAM: Okay. So committee agreement with that verbiage change.

Anything else, Mike?

DR. COHEN: That's it. Thanks.

CO-CHAIR DENHAM: Anything else from the rest of the Committee?

What we've then got in the narrative of the recording here we'll act on, bring it back to the Committee, and the pass,

Hayley and I will work together to get it to Mike; Mike, have you review it carefully and then bring it back to the Committee.

DR. COHEN: Okay.

CO-CHAIR MEYER: So the next two practices I'll cover. The first one is hand hygiene, and actually with both of them what we chose to do under the safe-practice self is say that the safe practice is to comply with the CDC guideline because we recognize that those guidelines would be changing on a schedule that would not necessarily be the exact same as safe practices update. So we have not gotten into anything more specific there.

The one issue that came up in discussions around hand hygiene is that you'll see in the document -- it's actually page 215 is where Safe Practice 19 starts -- that we reference the WHO hand hygiene guideline.

There was some question whether or not the safe practice itself should say

"comply with current . . . control and prevention hand hygiene guidelines," or we don't think it's worth it, frankly. they're close enough to each other, and there's plenty of examples here in the current document, but I don't think there needs to be any change.

The way this is written, it should be pretty evergreen. It should always stay up to date.

DR. ROMANO: Can that be something that is offered under the implementation guidance that --

CO-CHAIR MEYER: yes.

DR. ROMANO: -- some organizations choose to follow similar guidelines from the World Health Organization.

CO-CHAIR MEYER: Yes, and we already have a fair amount of that, but we can make sure we say that very explicitly.

Other comments on hand hygiene?

DR. BURGESS: Gregg, just one other thing. We did have a conversation with

Paul Schyve and Maureen Carr from the Joint Commission, and if you look under the additional specs, the third one, "insure that all staff know what is expected of them regarding hand hygiene and insure compliance," what Joint Commission is saying, that around that language since we have referenced them, they are changing the 90 percent compliance to continuous improvement.

So just so you know, they are making a change. We won't know until August the 26th exactly what that change will be, but it's not going to change our practice.

CO-CHAIR MEYER: It won't change our practice, what we reference.

DR. BURGESS: Yes.

CO-CHAIR MEYER: The next is influenza prevention, and again, what the safe practices has to do is comply with current Center for Disease Control recommendations for influenza vaccinations for health care personnel and the annual recommendations of

the CDC Advisory Committee on immunization practices for patients.

So that was the change that we made last time, was including the health care personnel piece there. So, again, I don't think there's any major change that we expect here. This will change each season with the recommendation of the CDC. So buckle your seatbelts for what comes out in the next several weeks on this, but I think the safe practice remains the same.

Other comments about that?

Safe Practice 21, central line associated bloodstream infections, and so here, Peter Pronovost, are you still on the line?

DR. PRONOVOST: I am.

CO-CHAIR MEYER: So on Safe Practice 21, and if you have any specific comments about what we have there under the additional specifications or anything else in a lurch that we ought to know about.

DR. PRONOVOST: Well, one potential thing you can do is that our supported effort to spread this work with states is all publicly available at www.safercare.net, and it has a whole bunch of tools and resources, and again, it's publicly available, and that may be of --

CO-CHAIR MEYER: So we can add that into an example of an implementation approaches. So we'll update that. That will be a great addition.

DR. PRONOVOST: And then one other, and I don't know if we put it in the comment, but, you know, one of the things that we've learned is that the largest number of these seem to be preventable, even in a medical sense. So I wonder if we, you know, could phrase it that we are to a large extent --

CO-CHAIR MEYER: So then we could look at doing something in the problem statement just to make sure that we make that

clear.

DR. PRONOVOST: Correct.

CO-CHAIR MEYER: Last question I have for you, Peter, is I was not aware of it. Chuck made me aware of it, and that is that a recent study in iodine versus chlorhexidine, and this has chlorhexidine under the additional specification. It sounds like we have bet on the right horse on this one, but I don't know if there's anything else we need to change in light of that study.

DR. PRONOVOST: And there has been a systematic review in a number of studies that show chlorhexidine reduces risk by about half.

CO-CHAIR DENHAM: Yes, Peter. Chuck here.

There will be a study coming out in one of our major journals on showing, as you say, you know, 40, 50 percent. This is in SSI actually, the clean contaminated subset, but I think we did bet on the right horse, and

the specifics were the two percent.

And, Peter, if you remember, I think about a month ago, six weeks ago I called you regarding the Keystone study and going back, and we're going back to look, and all indications I have is that the concentration matches what the SSI study shows in terms of the use of the chlorhexidine. It appears to be that's kind of the standard solution.

So I think we're pretty safe and we were pretty safe last time when we went with that compendium. Don't you feel like we're pretty safe?

DR. PRONOVOST: Yes, absolutely. I think there's quite good data supporting that.

You know, Gregg, the one controversial thing is, as you know, there has been a number of studies now showing anti-infective catheters, also cut-rates, and biopatch or the anti-infective dressing could

be effective, as well as chlorhexidine wipes that seem to be effective at MRSA and VRE.

Their contentious about when and how to use those. My own recommendation would be to follow the CDC guidelines, which have a statement on that that basically says you try other things, and you're confident you're doing the other things and your rates are still high. Consider these alternate technologies.

CO-CHAIR MEYER: We'll add that to implementation practices.

CO-CHAIR DENHAM: So then moving to Practice 22, surgical site infections, and this is, again, -- Peter, do you want to address the Joint Commission issues and then I'll come back to the chlorhexidine? Yes, the Joint Commission updates.

Hayley, is there anything you want to address here?

DR. ANGOOD: Yes, Joint Commission, you know, continues with its

National Patient Safety Goals, and they are part of the consortium that works on the compendium of these guidelines, and as near as I'm aware, they are just continuing to pretty much support what the compendium comes out with, and they have not changed any of the language in their Patient Safety Goals. So I think we're still good on all of these.

The compendium is the driver for the HHS, HAI action plan, and it will continue to be so, you know, for the next year to two years. So I think that we stay the course without changing around with the language, and most everybody is going to stay in line with that.

You know, we are very well placed with this set of safe practices because of that.

CO-CHAIR DENHAM: We had participated in that process, and coming back to the evidence grading that Dr. Casey mentioned in that compendium, we plan to loop

back with the leaders of that even though their compendium may not be for a year, year and a half out. We're going to re-review and ask for a regrading as we kind of head into our 2011 so that we've got -- and if the classification, Peter, is different than the one that was used as brought forward by NQF, then we'll go ahead and tackle it from that standpoint.

Because this is one of our best sets of graded evidence based practices that we have, and it would be great for 2011, January 2011 to come out with, you know, that as a tip of the spear, and it also helps us with all of the rest of them.

So we'll want to do that, and then the other piece on this one, this is where the major study, the randomized prospective trial using the two percent chlorhexidine showed the definitive big delta in SSIs, and so we'll put that language in and bring it back.

DR. HUNT: Just one quick note,

and it's good news actually. You may see some movement from CMS and the SCIP crew to either remove or change the hair removal measure, and that's again for good news. We've topped out. The national average is around 96 percent with that. Who would have ever thought we actually -- I shouldn't take that.

(Laughter.)

DR. BURGESS: So just to add onto that, what I understand is that the Surgical Alliance had submitted to HHS, CMS, AHRQ, et cetera, an objection to requiring clippers in their surgery, and that the SCIP TAF will be looking at that and may remove testicles as well as brain, cranial trauma from that.

So, Dave, do you want to comment?

DR. HUNT: Yes, they did, and it's so funny because the more things change the more they stay the same. There is always -- and actually, I think that's a good measure of the fact that, one, folks are actually listening to us, and that we've gotten their

attention and that, two, everyone just can't say yes and just do it.

So the technical expert panel is going to revisit that area. We have a number of rejoinders as far as the neurosurgeons are concerned. They have issue that in my mind are really non-issues, but you know, neurosurgeons like to be special. So we'll entertain that.

DR. ANGOOD: The neurosurgeons, just so you're aware, they have also approached us directly to look at this issue, and we're going to do a little special session for the special boys and just trying to get to the core of their issues and sort of help it.

You know, we shouldn't be denigrating neurosurgeons. They're wonderful people, and they do good stuff, but they are ego strong and they do get caught on their issues.

DR. ROMANO: I would just point out in theory, I mean, it's wonderful that

we're topping out on this, but of course, topping out on a practice from the standpoint of SCIP measurement doesn't mean that it should be removed --

DR. HUNT: Oh, no.

DR. ROMANO: -- from the safe practices. Obviously, safe practices are more of a statement --

DR. HUNT: Absolutely. Thanks for the clarification. Absolutely.

CO-CHAIR DENHAM: So are there other comments?

David, do you want to -- and maybe when I stepped out of the room, you know, we evaluated normal thermia as a potential issue knowing that there are four benefits. One is that the randomized studies are substantive enough to support SSI prevention only in colorectal; that drug metabolism is affected by the patient being at too low a temperature; cardiac instability and patient comfort were the four kind of issues, and as we evaluated

that from the SSI standpoint, you kind of came out or we kind of came out that we're safe where we are with these specifications.

Then News at 11, we don't know of any studies that are going to broaden normothermia for colorectal, but if you look at as a composite of safe care of the surgical patient, if we were, Peter, to go where some of the discussion has taken us to composite measures, as we have with the ventilated patient, you know, we broadened with Peter's help, Peter Pronovost's help. We broadened some of the specs from just preventing VAP to safe care in the ventilated patient.

If we were to be heading on a trajectory of safe care, the surgical patient, would the evidence for normothermia then be more compelling since we're not just talking about SSI, but we're talking about the other two clinical issues are cardiac instability and drug metabolism. Would they then be compelling enough to say normothermia might be

a consideration 2011?

DR. HUNT: Absolutely, and you can throw in the coagulation profile, the improvement in the coagulation profile for patients that are kept at a proper temperature.

So much so that there was, you know, the whole narrative of how measures come and go and are formed, born and then die is up and down. The good news is that -- I was going to put an editorial comment in. Good sense prevailed, but I didn't put that in -- that the additional benefits of normothermia have started to carry the day.

Because one particular rubric doesn't have the full flower of strength of evidence, people recognize that it's an artifact of the way we decide to put things together. If you wanted to have a set of practices that were just called really good things to do, normothermia would probably be in there because it goes across so many

different areas: cardiac instability, coagulation profile, surgical site infection, and drug metabolism.

DR. ANGOOD: Sorry. Just as an adjunct, I had mentioned in my opening comments of how we're going to try and have the work of the NPP patient safety section complement what we're doing with these other components. It's looking like we're going to head on a path of perioperative safety within the patient safety component of NPP, and that will address many of the things that David just sort of mentioned, plus teamwork, cross-disciplinary work, et cetera, et cetera, and how do we not just think about it as an operation with five different disciplines in the room, but a whole composite of teams, and how do you take it from the beginning to the very end, which may or may not include the ICU and the floors, et cetera, et cetera.

So perioperative safety just is something that needs to be pushed harder, and

we'll try to do that through the NPP.

CO-CHAIR DENHAM: So just so we're respectful of the open part of this session, I know some people may have early flights. Are there comments, Don, I know you had before your next flight?

(Off-mic comment.)

CO-CHAIR DENHAM: Okay. Bullet points, Don think about a minute or so. Anyone else? Anybody on the line that would like to make a comment?

Okay. Care of the ventilated patient, Safe Practice 23, and maybe we will turn and just ask Dr. Pronovost if he is on if he'd like to make a comment on that practice.

DR. PRONOVOST: Yes, I'm still here. One, I like that broadening, rather than focusing on what outcomes just to say here is what is good care for these patients.

You know, I think the only thing that has come out since we've said it is more evidence about the sedation holiday with a

nice lancet study, but I think that's probably covered in there.

CO-CHAIR DENHAM: Peter, we will come back. We're staging, making sure the specs are all tight, and as we go through the problem statement and the other citations, we'll count on you again if we can to just make another pass with us just to make sure that we've got all the latest, and then in the implementation guide section.

Peter, do you want to maybe address the HHS direction towards new definition or towards a more clear definition, and maybe we could tease that. You know, this report will come out in January. You know, we could at least tease the fact that there appears to be, there will be some clarification on definition of outcome.

DR. ANGOOD: Well, what Chuck is referring to, again, relates to this HAI action plan that HHS has, and there's several subgroups within that action plan, and the CDC

is heading up one component of that, which is helping to clarify the definitions of each of these terms, and that winds up being sort of problematic in terms of getting a clear definition. It's partly related to the radiologic definitions, the sputum traps, et cetera, et cetera, and so the direction will be leaning more towards the processes around prevention and care of patients.

I've just gotten an E-mail on Monday morning from Dan Rosenthal on this, and they are getting closer, but they're not quite ready to sort of release their final versions of these definitions.

Similarly, the urinary tract catheter related infections is undergoing some scrutiny in this process, and so I think it's important, obviously, for us to make sure that as CDC clarifies their terminology as that gets nailed into the HAI action plan that we're reflecting on all of that directly.

There's nothing substantive at

this moment that we need to change, but should CDC come up with these clarified definitions, then we'll certainly reflect that.

CO-CHAIR DENHAM: So our action plan then on the ventilated patient is to make sure we synchronize with those things perhaps in the implementation guide and then return back to Dr. Pronovost to make sure that we've got all of the latest references and are looking at the care of the ventilated patient.

The feedback from the field has been very positive on this, and when we expand it, we thought we might have some push-back as we started to expand beyond just VAP and, you know, we just haven't had any negative push-back, you know, on the expansion of the practice. So, again, this one was at least one of our better decisions, better bets.

We'll move to Practice 24, MDROs, and, Peter, do you want to address how that might overlap with the HAI plan and kind of where things are going?

And then maybe, David, give us maybe a little bit of an update of where from your vantage point, where the MERSA C. diff. lands.

DR. ANGOOD: Yes. Well, bottom line is I don't think we need to change this because it's so fresh and new. The language more accurately harmonizes with the Joint Commission's Patient Safety Goals, and that's where the intent of this was all along.

In the consortium that looked at the guidelines compendium, there was a lot of focus on MRSA, and to some degree C. difficile. At the Joint Commission when we constructed this one up, we thought, well, it's more of a systems and processes issue than particular bacteria or particular microorganisms, and so the attempt was made to construct that patient safety goal along the lines of improving systems and processes, and we chose to reflect that inside this safe practice as well.

And so that's harmonized very closely to the Joint Commission,. and as near as I'm still aware, the Joint Commission is not intending to change its approaches on this either.

David will provide us more specifics probably, but there is clearly a focus and probably to some degree generated politically for taking care of MRSA and Clostridium difficile, and so the HAI action plan has those two specific organisms contained within it as targets, and it will also become part of our other NQF work related to our HHS contract.

But I think from a safe practices vantage, it still makes more sense to push it from improving systems and processes of multi-drug resistant organisms.

But, Dave, any other comments from your side?

DR. HUNT: No. I would agree. The emphasis in the HHS action plan on

Clostridia and MRSA really reflects a practicality from the department's standpoint that we don't really have good actionable plans for discussing systemic change, and so being able to focus in on those two allows us to give very practical advice across the department.

But when you look at the report from the Committee, there was a very, very clear statement that the systemic approach, and that it is not just these two bugs, that multi-resistant drug bacteria or organisms were a real, real issue, and that these will hopefully be -- those two would be the start of a plan of how to approach that.

One of the real challenges, and it's funny because HHS, there's always the issue of you really have to become the change you seek in the world; HHS has really got to and is embarking on an effort to systematically be able to collect, collate and manage information on these organisms

throughout the clinical community, through the public health system, as well as through the quality measurement systems, and that has been a true challenge on the order of the challenge that institutions have been having in making this a systemic solution to this problem.

And I think that this will really be a measure of how well the department is able to effectively organize across a very complex group of agencies. So we'll see.

CO-CHAIR DENHAM: Dave, as we were kind of in an organized fashion providing feedback regarding HACs, and that process unfolded. We found that the front line in our testbed, the fact that even though it was a blunt instrument and even in Tom Valuck's words it represented budget dust in terms of the dollar save and the dollar impact on organizations, it got the attention of the C-suite, and hospital acquired conditions was a "wow." You know, that became the headline.

Can you just address the

transition to health care associated conditions, the HHS sort of? It should like HAC is going to go from hospital acquired condition to health care associated conditions so that it's broader, but will the blunt instrument and the tying of payment -- and I know you can't commit the government to anything or where it's going -- but as we write in our narrative in the implementation guide and the problem statements that even the purchasers of health care are acutely aware of these conditions, we already got that in there in kind of general terms, but can you help us a little with the language and definition of HAC as we kind of start to head -- I'm thinking as much on the implementation and nothing about specs.

But it does help us kind of write the narrative that says new horizons and purchasers are going to do this and that kind of thing. Can you tell us about this trajectory from HAC to HAC but the name change

from hospital to health care?

DR. HUNT: I think this was more recognition that the settings that we deal in, the rubrics that we have are in some ways artificial, and in many ways those rubrics actually inhibit our ability to make change. A great example is the same situation that we had with the normothermia. We used that one SSI rubric as the placeholder for where that will reside, and it inhibited us and we got a lot of feedback and push-back because of the location we chose.

And the same situation actually plays out when you look at these health care associated versus hospital associated. I won't disagree that the hospitals told us that they don't want to necessarily be the only ones in a hot seat because we are talking about a number of different entities now providing clinical services, and that we've got to work across that.

So that was in one measure part of

the reason for the change, and also a very, very clear recognition that the list of things for which we will be able to make a clear and convincing statement that we no longer should provide that perverse incentive of paying more for outcomes that are substantially worse is going to increase as the evidence base continues to increase and we'll be able to make more rational and very, very pointed decisions on things around payment.

So I think it was a recognition that, one, hospitals aren't the only places where we need to be concerned about; two, that the list of topics will most likely increase and that, particularly as the evidence base increases, and the fact that health care services have got to be seen in the context of a full continuity of places that you often will go from an acute care to a short stay facility on, and that everyone on the team has got to have an awareness of these. It's not just your fault or your fault; that we're in

this together working toward the benefit of the patient.

And we've got to have terminology that better reflects the reality that it's not just one setting.

CO-CHAIR DENHAM: So for the tactical purposes of our narrative should we say health care associated condition, parentheses, HAC, end parentheses, and we're safe or is there some deadline where the name is going to change but the purpose is the same? Or has there been -- I'm just thinking so our document is not dated when we have that kind of through it.

DR. HUNT: Yes, I'm not sure of any deadlines, but you know, in the government they love deadlines because how else will we be able to miss them?

(Laughter.)

DR. HUNT: But I think we are in a safe spot if we say health care associated. I think that's the general terminology that's

being used, and I don't think there will be any disagreements or discomfort with using that term.

DR. ANGOOD: Can I ask one minor question? I think it's acquired, not associated, right?

DR. HUNT: Yes, yes.

DR. ANGOOD: Okay. So it's health care acquired conditions, and I think as we have opportunity, I think we'd be on the mark to begin using that terminology. We actually pushed back pretty hard in our contract negotiations for safety on do we want to use this term coming from NQF, and it was very clear that term is here to stay. So let's just get used to it, you know.

It's actually not a bad term.

DR. HUNT: It's not.

DR. ANGOOD: It's different.

CO-CHAIR DENHAM: So for the purposes of our discussion then, as we look at MDROs and we look at the UTIs, we'll loop back

with the compendium leaders just to make sure we're in sync there. Peter will look back to make sure from an NQF standpoint that since you're the representative of NQF on the HHS plan, and so we don't anticipate any substantive changes to the specs. We do anticipates updates to the problem statements and telegraphing that there will be some new definitions. Is that a fair approach on those two practices?

Okay. Any discussion on those? And then we'll move to wrong site, wrong procedure and ask peter to address that one.

Oh, I know we had some interest. Should we take a break or should we press on and wrap up? Don, you wanted to make a public statement, but we could press on and finish. should we press on?

Okay. So, Peter, do you want to take Number 26?

DR. ANGOOD: Do we need a break? We've obviously had a very fluid schedule,

literally and figuratively. If you want to take a five-minute break and just --

CO-CHAIR DENHAM: Maybe we should -- because I know people have flights and there's some anxiety, but no one wants to miss. Why don't we just if people cycle out, we'll do a recap? Patrick, if you slip out and then come back real quick, we'll give you a quick recap and we'll just keep things going perhaps. Because I know people have some flights.

People do you want to take wrong site?

DR. ANGOOD: You keep trying to give m wrong site surgery.

(Laughter.)

DR. ANGOOD: Yes, yes, yes. Again, the essence of this I don't think we really need to change in terms of a safe practice. We clearly don't want to have wrong site surgeries occurring, and the Joint Commission is another example here of how we

tried to really harmonize, and that's the only other group that's out there pushing on the national level in terms of its universal protocol.

And we mirrored that quite closely with the safe practice. The Joint Commission is looking at some modifications on a minor level to their universal protocol, mostly related to who's marking the site and the timing of the time out and a few other minor things, and I think we need to stay very close to that, but that process of theirs is not going to be completed until later this fall as I understand it.

The other component that's out there, and it's almost a competing force, is the World Health Organization's safe surgery checklist, which is different than the universal protocol. It's different than our safe practice, and it does feed into more of the perioperative safety strategy. It has a pre-op, inter-op, and postoperative component

to this checklist, but it hasn't been fully vetted nor approved into a WHO guideline.

It is in the stages of that. The WHO bureaucracy is, as Peter Pronovost knows, is quite dense and at times slow moving, but once product comes out, it's very robust.

My own thoughts were that for this year that we didn't necessarily need to incorporate the WHO surgical checklist into our specs. We need to certainly make mention of it in our other narrative, and then as we get into deeper review with the practices, hopefully the guideline process will be complete from WHO on that surgical checklist and, as well, the Joint Commission will have finished its updates, if any, to the universal protocols.

So having said all of that, I think we're okay with this practice for the moment, but it will need some further revisions next year.

Peter, did you want to make any

comments on that?

DR. PRONOVOST: Yes, Peter. I completely agree. I think I would do that. The only one thing, Peter, potentially to include is to say, you know, despite promulgating these guidelines, wrong site surgeries continue, and to perhaps help, your organization might need to take a little closer look at staff behaviors rather than just do they have a policy in place.

DR. ANGOOD: Yes, I think that's a very strong point. You know, you've got five or six disciplines doing 25,000 cases a year in the same environment. You'd think they'd get it right in many institutions, but the fact is it doesn't get corrected, and this is kind of akin to hand hygiene and medication reconciliation: simple concepts, very complicated to implement. And that's a good point for us to reinforce.

Other comments from the group?

Okay. Thanks, Peter.

CO-CHAIR DENHAM: So our next practice, and so the Committee had no other comments. That would be the approach that we would take, and the other thing we might consider in the narrative piece of the implementation guide on identification and mitigation of risk and hazards, SP-4, I think it may be appropriate to put the checklist in there and put the citation in there.

So for the record, let's take a look at that, the SP-4, since there is so much work going on and the wrong site issue is actually, as we're starting to really report, it looks like it's going up.

DR. ANGOOD: Yes.

CO-CHAIR DENHAM: So the next practice is 27, pressure ulcer prevention. And we wanted to discuss the NQF pressure ulcer framework and also address the skin assessment issues.

Peter, do you want to take this one or Melissa?

DR. ANGOOD: Actually I'm going to bump this one over to Melissa who has been an integral staff member for that Committee framework, and I consider her our local world expert on pressure ulcers.

MS. MARINELARENA: So for this practice we consulted with Theresa Edelstein, who is one of the Steering Committee members on the pressure ulcer project, and she's with the New Jersey Hospital Association, and they did a lot work with the pressure ulcer collaborative. So they had a lot of experience with implementation.

One of her recommendations was including a comprehensive skin assessment, which was a combination of a risk assessment, pressure ulcer risk assessment, and then a full skin assessment as well.

They found in the work that they did that sometimes you had to very specifically state that you needed the two types of assessments. So that was one of the

inclusions that we had there.

Let's see. So, yes, and then on this third bullet when we talk about assessing and periodically we assess each patient's skin and risk for developing pressure ulcer, again, being very explicit that you need to do the two assessments hand in hand.

We underlined the last bullet, perform quarterly prevalence studies. Another suggestion from Theresa was although pressure ulcer prevalence data is reported quarterly, that hospitals should be or facilities should be obtaining it monthly, and that's also in alignment with what the pressure ulcer framework is recommending as far as looking at more real time data versus waiting a full quarter to look at your data and then do something about it.

So if you can look at it sooner and then put into place those interventions to bring down your pressure ulcer prevalence rates.

CO-CHAIR MEYER: So you're suggesting that we change the quarterly prevalence studies to monthly prevalence studies.

MS. MARINELARENA: Yes, as far as internally to collect data monthly even though it could still be reported quarterly, which, you know, the framework would prefer more real time reporting, but that's still a work in progress.

CO-CHAIR MEYER: I'm from an institution that does this already. So I'm not in a good position to kind of -- again, I just wonder where the rest of the field is in terms of their readiness for doing this.

CO-CHAIR DENHAM: Comments from the Committee regarding the proposed changes in blue, underlined in blue?

DR. McAULIFFE: I don't know whether that change from quarterly to monthly would be a substantive change or whether that would be sort of a buffing change or not, but

it seems to me if the evidence is not there maybe we ought to be pushing it forward into the next go-around.

DR. ANGOOD: Yes, I think the benefit and the design of the public comment phase is to get the feedback on those, and if the feedback winds up being exceedingly strong in the negative sense for doing that, then we'll have to adjust accordingly and maybe kick it into a more robust process.

But I am comfortable that, you know, if we just make that one change from a temporal factor, let's put it out there because the rest of it is all the same.

DR. PRONOVOST: But you know, the one other thing we may consider adding, which I think is not feasible with EMRs is moving also to not just prevalence, but incidence.

You know, in my hospital, the clinicians, the feedback that's meaningful is did we give this to this patient and not knowing whether they came in with it or we

gave it to them was a barrier to us engaging clinicians in working, and now that we've started monitoring incidence rates, you know, who did we give it to when they came in, you know, documenting who has an admission, which they have to do anyway, provides much more meaningful feedback for clinicians and generates a lot more activity.

CO-CHAIR DENHAM: Peter, that's a great point, and two places that that could appear in the practice, one is in the measures section where we address process, outcomes, structure and patient centered measures which are not specs so they are not substantive, but they would be a real guide.

So I agree with you, Peter. I think we could propose to put that in that section, also add it to the implementation section, and so we'll throw that up to the Committee to just see if that sounds reasonable.

And then the second piece is what

is in blue, and the question back to the staff, we've got quarterly prevalence studies on the final bullet that's in black. Does that demarcate an add or a deletion?

MS. MARINELARENA: That's what's already there.

CO-CHAIR DENHAM: Right.

MS. MARINELARENA: So we were going to look at it.

CO-CHAIR DENHAM: ?So that would be a deletion.

MS. MARINELARENA: The thing is the framework hasn't been endorsed yet. It still needs to go for NQF member vote. So all of this would be contingent on the framework passing and being endorsed.

CO-CHAIR DENHAM: So the monthly -- go ahead.

CO-CHAIR MEYER: So I guess what I would propose is that we leave it as performed, quarterly prevalence studies, as is for now; add the New Jersey collaborative

information to the implementation examples; and then chase the pressure ulcer framework as we go forward.

So if you have anything more, I don't know how much of a burden this is going to be on folks and how read it is. If we're going from quarterly to monthly, I think it absolutely will raise the question of saying, you know, show me why we need to do this.

DR. HUNT: But if you went from quarterly to daily and then fall back to monthly.

(Laughter.)

CO-CHAIR DENHAM: Is that man from government?

Patrick.

DR. ROMANO: I just want to point out at the practical level that these prevalence surveys are actually quite expensive. I mean for a 600-bed hospital like ours, this literally means having a staff person roll over and inspect the skin of every

one of those 600 patients and finding them when half of them are in the OR or in X-ray or in interventional radiology or whatever on any given day.

So the cost is estimated for our hospital at about $100,000. So I would think a better way to do this moving forward perhaps, as Peter was suggesting, is to supplement the quarterly prevalence survey with ongoing evaluation of incidents, and I think the point is well taken that electronic health information systems make that a little bit more straightforward now.

And of course, all of our hospitals are now into paying careful attention to whether those pressure ulcers are hospital acquired conditions or not for CMS purposes.

So I think that a more cost effective way of doing this might be a combination of quarterly prevalence surveys to make sure you haven't missed any supplemented

by ongoing monitoring of incidents.

So I would support basically Dr. Meyer's suggestion thinking towards how can this type of more frequent monitoring be implemented cost effectively.

DR. HUNT: I will just point out that I was only half facetious with the daily, only because if you're really going to decrease the incidence of them, some staff has got to find that patient every day, a minimum of every day and do that, and so hopefully in the better world that our office is going to provide, they'll be able to just make a quick notation of that on the electronic health record, but that does have to happen all the time, and it's just a matter of whether or not we document it.

and so I was only half facetious with daily.

CO-CHAIR DENHAM: So for the purposes of the record and just to recap the committee's approval of going forward, Dr.

Meyer, could you restate what you propose?

CO-CHAIR MEYER: I propose leaving the language in the additional specifications as is so it would continue to say perform quarterly prevalence studies, and then add the New Jersey collaborative piece to the implementation examples, and then in 2011, we'll have the experience to go back and look and see if we need to update it.

CO-CHAIR DENHAM: Great. Thank you.

Peter. Go ahead.

DR. ANGOOD: And I am fine with that, Gregg. I think that's a more prudent way that keeps in sync. The only other added work for the Committee here is within the existing additional specs, we have underline in blue two areas, which again is coming out of the collaborative, and it is in the first bullet under the second point, which is including a comprehensive skin assessment.

And then the other is on the third

bullet down there. Each patient's skin and risk for developing a pressure ulcer. It's kind of one of those minor points. Oops, you know, we're assessing for pressure ulcers, but we forget to look at the skin part sometimes.

DR. ROMANO: That seems pretty well accepted, I think.

DR. ANGOOD: So I just wanted to make sure we're clear on that, and otherwise we'll follow Gregg's recommendation.

CO-CHAIR DENHAM: So we're in agreement on those edits. Great. So we'd like Dr. Meyer to take VTE and anti-coag, the two next.

CO-CHAIR MEYER: So on VTE prevention, there, again, what we did was we tried to reference other outside protocols and guidelines and did not, I don't think, get overly specific with that, and as a result, even though this does still continue to evolve in the literature, we didn't think that there was anything that required an update of the

actual language of the practice or the additional specifications.

But I want to just hear if there is anybody who feels that there are any other important studies that we're waiting on that we ought to make sure that we reference.

Patrick.

DR. ROMANO: Well, My division chief back home happens to have been a member of the NQF committee on DVT/PE and is very interested in that area. So I may solicit his input on that as well, but both this safe practice and the previous one really bring up that situation that we talked about earlier of the overlap with the previous practice related to mitigation of risk, assessment and mitigation of risk.

So either these should be sort of co-imbedded under there or we should take out that specific list from the earlier SP for consistency.

CO-CHAIR MEYER: So I think you're

suggesting two things. One, in terms of we did work with the other committee to make sure that the two kind of matched up tightly there. I think the future you have the notion that we could roll some together and shorten the message a bit is well taken. I think that would be a 2011 task. I think that would be a great idea.

Any other comments on VTE?

So we'll move to anti-coagulation. Again, we kept what we had here, was quite general. I think the notion that anti-coagulation deserves to be set out is important enough to put among a dedicated safe practice, I think still was the right decision to start, and I think the evidence is it's still the right decision in terms of being an ongoing high risk situation.

So I don't know if Mike or if others have other comments about this.

DR. PRONOVOST: Gregg, the one thing --

CO-CHAIR MEYER: Go ahead, Peter.

DR. PRONOVOST: The one thing you may add, and it was some work done by one of the pharmacists here who showed point of care testing devices, you know, which are used widely here an in the community, have a systematic bias in that, and in about 40 percent of the time clinicians make the wrong recommendation based on that.

I can send you the paper, but essentially the misclassification is clinically informative about half the time. So it will say it's in the normal range when the gold standard lab test says it doesn't or it will advise you to reduce your anti-coagulation level when, indeed, that wasn't appropriate, and it wasn't a matter of just calibration. It was the actual issues with the device.

And I don't know how widely that's known, but it can dramatically change how we manage these devices throughout our system.

DR. BURGESS: Is that something by Fanikos? Is that who you're talking about, Peter, John Fanikos?

DR. PRONOVOST: No, it's Mike Strice and I'm blank on the other guy's name.

DR. BURGESS: Okay. We'll look it up.

CO-CHAIR MEYER: Yes, if you can get that to Hayley and to us, that would be terrific because that is a bit of a "yikes" moment for me, I think, hearing you say that.

DR. PRONOVOST: It is for us, too.

DR. BURGESS: Wow. Thanks, Peter.

CO-CHAIR MEYER: Other comments on anti-coagulation?

DR. COHEN: I don't have any really.

CO-CHAIR MEYER: Terrific. Contrast media. Yes, please.

DR. ROMANO: There are also some Joint Commission National Patient Safety Goals related to this area of anti-coagulation

management. So have we monitored for consistency there?.

DR. ANGOOD: Yes.

DR. BURGESS: Not changing.

DR. ANGOOD: No, they are not changing, and we'll continue to watch those Patient Safety Goals. They are going through a clean-up process as well and mostly language and duplicative, ambiguous terms, et cetera, but you know, that's one of the group that we need to follow and one of the comments early this morning was, you know, the more we can drive practices and the goals closer in terms of harmonizing without being one and the same, then the better off we are.

CO-CHAIR DENHAM: We had a call with the Joint Commission on Monday to just kind of go through where they were on their trajectory and kind of monitoring that as we go just to keep track. But thanks for bringing it up. I'm glad you brought it up.

Mike.

DR. COHEN: You have a glycemic control, but you never really focus on insulin as a safe practice. Has that been considered?

CO-CHAIR DENHAM: I'll tell you what. Let's get this one out of the way, these next two, and then we'll go and have Gregg cover glycemic control.

On the contrast induced renal failure prevention, you know, there is an ongoing evolution of some of the guidelines specifically for MR and gadolinium, and so we're sinking this practice and kind of monitoring those changes and those recommendations along with the American College of Radiology and subject matter experts in that area.

One little minor change, and I don't know if that's even a substantive, but the idea of perhaps retooling the name of the practice a little bit to a title of prevention of contrast media induced renal failure and other adverse events because there are other

adverse events that come and-- pardon me? -- because of NSF is why we're, you know, kind of monitoring this closely, but we'll come back to the Committee with kind of an update on the problem statement with the latest data because this is evolving.

We want it to be closer to the time when the board kind of reviews it to make sure the problem statement has all of the latest material in it, but the goal would be to synchronize the guidelines and the recommendations along with society's.

Any comments there or is that satisfactory to the Committee?

And then organ donation, that was a new practice, Safe Practice 31. It's based on a national collaborative that was very, very successful improving the conversion rate from 50 to 75 percent. We've had very little push-back, and all of the national centers are focused on these best practices, and I think this is really gratifying.

For me, I was actually one of the folks involved in watching this evolve, and our new Assistant Secretary of Health, Howard Koh, actually started a lot of initial work in Massachusetts and then eventually was picked up. Best practices were developed, and the NQF Committee, I think, made a good choice to bring this one on line, and we've had very little push-back. So we wouldn't have any substantive changes here.

We'll loop back with HRSA as we get closer to our deadline to get done with the report to have the latest data, but we have no substantive changes.

Any comments from the Committee on this one?

CO-CHAIR MEYER: The only committee I'd make on this one as well is, again, it strikes me a little bit like the life sustaining treatment. It's just a little bit outside of what comes off the top of the mind for a safe practice. So if there's ever

another home to think about migrating it.

CO-CHAIR DENHAM: The interesting thing is from the life saving standpoint, I think one count just in a year is 4,100 lives saved with this best practice. So if we move it somewhere else, I guess we lose some of our score board, but that's okay. We'll find a home in the NQF scoreboard.

Gregg, do you want to take glycemic control?

CO-CHAIR MEYER: Glycemic control is probably one of the more controversial issues over the last 12 months in the medical literature, and so that prompted us actually to go back and look at what we originally wrote, and so we had a fair amount of discussion about this while we were developing this version. This was a new practice with the 2009 release, and as we went back and looked at this, we think the language is general enough that, in fact, the new literature is accommodated.

What we will do is we will update the references with the latest study on glycemic control. I think the real question comes down to whether or not this should be dropped, and I think that, again, as you read it as it's currently written, it is general enough that the change in kind of the interpretation and the importance of glycemic control and the dangers of tight glycemic control I don't think change this.

But I think I'm open to that. I think we're very open to that discussion. I think this is a good time to have it.

CO-CHAIR DENHAM: And I think one of the things we did because of this anxiety was we got together with the hospitalist groups and kind of reevaluated the whole thing and revisited to see whether last time around were we too prescriptive, were we not, and actually we were pretty comfortable with how it played out.

But I think Mike and then Patrick.

DR. COHEN: Yes. Actually I was thinking maybe more of a focus rather than just on glycemic control, but more of a focus on the medications that are used for diabetes, insulin, for example, and obviously other agents as well, but the reason for that being if you have one for anti-coagulants, insulin is actually more of a problem for us when we look at the database. It's petty consistent across databases, about 11 percent of the patients that, you know, present with serious medication errors or medication adverse events.

DR. ANGOOD: And yet I think, you know, your point is good. Maybe this is more you can bump it up a bit higher and take it towards high risk medications because we've kind of got that buried in one of our other practices.

DR. COHEN: Yes.

DR. ANGOOD: But we don't have specific focus on high risk medications, and

that way we can cover the field better. I think, Gregg, your suggestion that maybe we even get rid of this one is a reasonable one, not for right now, but certainly something that we should seriously think the glycemic control piece, not the medication management piece.

And who knows? In time there may be more stabilization of the literature, but I think it's one that will deserve some critical review.

Patrick?

DR. ROMANO: Yes, I was just going to say that I think that we may have struck the balance about right in the sense that really this is founded on the principle that insulin and long acting oral hyperglycemics are dangerous drugs and that there have to be policies and systems in place to administer them carefully.

Most of the controversy I think that you are alluding to, you know, refers to

what specific targets should be and should an out-patient target be six percent or seven percent or seven and a half percent, whatever. You know, what should our in-patient targets be?

But we weren't that prescriptive about those targets, I don't think, in this document. So there is some latitude still for each institution to come up with slightly different targets based on its own circumstances, but I think the specifications here reflect the fact that there should be a deliberate process for doing that and getting all the stakeholders together to work together on that.

CO-CHAIR DENHAM: Peter, did you want to comment, Peter Pronovost?

DR. PRONOVOST: Yes, I was going to say, Patrick, I completely agree with it. I almost see this as more of a process recommendation than anything to say that high glucoses are harmful. Low glucoses are

harmful, and the evidence about how tight to exactly be is emerging, and I think we should acknowledge all of that, but independent of that, health care organizations need to have a process in place to manage this beneficial, though potentially dangerous drug or these set of drugs.

CO-CHAIR MEYER: So I'm taking away from this that we would leave the safe practice essentially as it is now. We'd update the references with the newest literature, and I think, Mike, what I think we ought to do is think about a high risk medication safe practice that we try to get really tight for 2011.

CO-CHAIR DENHAM: One thing we might consider just from the standpoint that we live with these practices every day with hospitals every day, and one of the things that is not substantive, but might be an ease of formulation might be anti-coag., glycemic control, and VTE all live right now in this

bucket of "other," and it may be that we move them into safe medication management chapter. then we'd end up having the leadership practice, MedRec and those three that might have a little bit NP management in the future because we've talked about that, which we'll kind of conclude it.

Thank you, Hayley.

That might be a natural functional chapter, although we'd renumber them again, but then you end up having them organized around people that are dealing with meds. and high risk, an so that might be a consideration for 2011.

Would we want to shuffle the deck for 2010 and reorganize them again in terms of their order in the book?

I'm not proposing that. I'm saying --

DR. ANGOOD: No, but I think if we're going to do a fairly thorough review during 2010, as I made in some of my earlier

comments, we should look at how we're clustering these, how we're naming them. I would prefer not numbering them and sort of come up with what that year will be, but then begin also to strategically lay out what subsequent years are potentially going to be and begin to message the field so that they're not whipsawed each year, but they know they're going to grow into these things.

Because if you believe in that sort of matrix concept that I was talking about earlier, this is going to get to be fairly complicated over time, and communicating to the field is going to be critically important because we don't want them to be shunning away from these practices.

We've got good traction. We can refine it certainly, but we don't want to over step it and have a negative reaction.

Mike, do you want more comment?

DR. COHEN: Well, as you know, we work with ASHP and another organization -- I

can't recall who it was exactly right now -- to help Joint Commission with the development of the anti-coagulant safe practice or National Patient Safety Goal, which pretty much this matches, and we could easily do the same for opiods and insulin, anti-diabetic drugs in general, whatever. I mean the practices have pretty much been identified. they're in the literature, and you know, they could be listed in whatever.

CO-CHAIR DENHAM: So if we're comfortable we'll move to the next practice. We've got two to finish and then we'd like to make Don make a comment and others who want to voice public comments.

But one aside is that we do have on our list pain management as a high risk area that might be under consideration for 2011, and we've talked with Mike about that and that's kind of been one that's kept surfacing because they're always in the top five of adverse drug events in both PN and

sedation.

So, Peter, do you want to take falls and then I'll finish up with the last one?

DR. ANGOOD: Sure. Well, congratulations to us for getting through on time unless we go seriously off the track in the last 15 minutes, and I've seen that happen before though. And that's not having Don on the microphone.

Falls are obviously a high profile item. They continue to be very much in the lay press as well as in the general health care literature, and I think that there has been a good series of work on how to move towards better prevention and assessment of risk for patients.

I think we've got a pretty good practice here, and I don't think that we need to have any substantive changes. We've certainly not received any push-back on it, but is there more comments or do we need more

specificity on this at this stage?

All right, Chuck, it's up to you to derail us for the last 15 minutes then on your last practice.

CO-CHAIR DENHAM: As a recovering optimist, my hope is that we'll finish this up quickly and Don will be able to start off with our public review.

Pediatric imaging, this was a practice that was submitted by the society's very well substantiated work and really a delight to work with. They followed all of the NQF submission requirements. They got everything organized. It was well done, and then we worked very closely on cross-training radiology. So it was natural to kind of work with them and we've had no push-back whatsoever.

Logical, good evidence, processes are there, and it also from a Web linking standpoint allows us to be able to link people out, and this is the prevention of delivering

excessive doses of radiation to children. Logical, face validity, good evidence, good numbers, and so nothing substantive to update on that practice.

And so to the Committee we would not be updating anything other than the problem statement and implementation guides and tie the citations to those and we've had no push-back from the community.

So, Peter, would you like to open things up for public comment?

DR. ANGOOD: Sure, and again, thank you everybody on the Committee for some very strong work today. All very good comments, and I think the next version of these safe practices will clearly be more substantially crisp and clear. It sets the stage, I think, quite nicely for moving forward into the next iterations of these.

Is there any public comment from the phone lines, anyone who has joined us?

All right. We have Don Casey who

would like to provide some further -- come on up again. There's no one else in the audience, Don -- so Don Casey will provide some further public comments and then we'll do some wrap-up after that.

DR. CASEY: I have to sit next to my old friend, David.

Thank you, again. I'll be brief.

I am currently the co-chair of the Care Coordination Steering Committee, Chuck, that NQF has convened, and I think there's a lot of opportunity, Peter, for us to work with Nicole McElveen on Safe Practices 12, 15, and 17.

We're doing a lot of work on preferred practices as we speak. So I don't think this should slow you down, but I think, again, in the interest of harmonization, we're trying to move from the handoff to what the intent of the handoff is.

So I think you'll gain a lot of perspective and at least even though it will

be -- I don't know time-wise, Peter, how this will go. We may be out for public comment at the same time you are. So we could do some semblance of harmonization there. So that's an offer.

Specifically related to 15, discharge systems, I would say that we recently published in the new updated heart failure ACCHA guideline some statements about heart failure discharge instructions with some evidence that was graded, and I think it would be well worth your while to reference that in that section. Because, again, it's getting specifically to showing the systems of care for heart failure, and this could be, while not perhaps totally specific to the paradigm or totally generic to the paradigm, helpful in terms of the elements that go into this because heart failure has had a lot of work on it.

Specifically, two to 17, and I didn't get a chance to go through the whole

detail of the book in enough time, but I think that, again, we have to think about the intent of what medication reconciliation is, and I think fortunately people are paying more attention to it. Unfortunately most people have now deemed it to be being sure the list is accurate, and again, what's the intent?

So I don't know, Chuck, if you have the space in this update to focus on three other issues, which I'm sure Mike Cohen would agree to. One is the issue at the moment of reconciliation, discussing barriers to adherence, and they could be a variety of different things, including one misunderstanding by the patient, economics, et cetera, et cetera.

I think the notion of saying, "What is all this junk anyway?" if I can be pejorative, leads to being sure we had a system in place when we reconciled to be sure that the prescriptions are appropriate, and that means having some at least back of the

envelope knowledge of potential adverse drug events and drug-drug interactions at the helm of this. So it's not just a list of junk -- excuse me -- but really using the opportunity at every moment every day to say, you know, is this working or not.

So I think we can push the envelope on that. I realize Joint Commission may not be there yet, but I still think there's an opportunity.

With respect to central lines, while I realize that the issue is infections, we've come across some other major issues related to competency, and we're actually working on an organization-wide policy. We found that residents who run codes just routinely put central lines in because it's easy, and we've had serious adverse events related to the misinsertion of the central lines and then subsequent failure recognize complications that went on for a long time by multiple providers.

So to me the opportunity to prevent central line infections should relate more specifically to the competencies. While I don't have all that in writing, I could provide that content to the group we're actually meeting now to make a system-wide policy on the criteria, et cetera for how we do this, and there's pretty good evidence for that.

And then I would speak against trying to lump VTE and anti-coagulation. I think the VTE really, while it involves the administration of pharmacologic agents, it really is broader than that. We've had a program in place now for three years that's organization-wide, and this is more about probabilistic risk assessment and decision making at every point in the step of, for example, in our case a hospitalization. So I feel that that is a related but separate category of safe practice.

With respect to anti-coagulation,

we're also taking very seriously the Joint Commission's notion of the systematic approach. We've actually broadened. It looks like it's kind of focused on the usual culprits here, the heparins, the heparinoids, and warfarin, but you know, if you think about all of the medications that can cause bleeding that are given in cardiology, we've actually expanded that to the full list of anti-coagulation and said that our systems shouldn't just be around those two or three classifications. It should be around the entire spectrum.

And I could provide some background about that. We've done an evidence based analysis on it that I think would be helpful.

I realize on 32 that the numbers are floating around, and Peter knows this better than anyone, but on the other hand, I can say without violating any sort of pre-publication knowledge that in the new STEMI

guideline update that I'm involved with for ACC and HA, we are going to make a specific numeric statement about an upper bound for patients with MI.

So it's getting to not so much worrying about a number, but rather maybe it's focusing on target populations where there really is good evidence at least on the upper side.

We initially had a -- Eric Peterson and I had a statement in the non-STEMI guideline that had a lower bound in the '05, where we've now harmonized that to make it consistent with STEMI, and again, I can't share that with you yet, but it may be out at the same time, and so I'd say a little extra work on that, maybe some collaboration with ACC might at least help you frame MI.

So those are my specific comments.

DR. ANGOOD: Well, thanks again, Don. I appreciate your thoughtful and considerate critiques, which are always

helpful.

DR. CASEY: Peter, could I make one more request? I just have this summary of the safe practices score analysis and would respectfully request that this Committee consider referencing that in the update.

DR. ANGOOD: Sure, by all means. Please submit that. Circulate it and we'd be happy to have a look at it.

The comments that you just made, if you want to submit some written comments from that, that would be terrific as well.

The various comments you made about the MedRec, the CLABS and the anti-coagulation, et cetera, we'll certainly take those into serious consideration. I think that the CLABSI is certainly focused in on infection.

However, the competency of insertion is an issue that's been within the education and maintenance of competence world for some time. Unfortunately not all of the

organizations have adopted assessing competency for the insertion of those lines. Most of the training hospitals have begun to do so, but in terms of maintenance of regular competence for practicing physicians or physician extenders, we still need to have that monitored far more closely.

I remember one particularly horrible case where there was a middle of the night ICU resident that asked to insert a central line by a junior, junior nurse who then proceeded to watch this junior resident try to stick this patient for about an hour, and then the patient arrested. We got there in time to realize this was all cardiac tamponade and got the patient to the operating room, opened the sternum and relieved the tamponade and found no less than 12 puncture marks in the aorta at the root of the heart. So the guy was clearly way off base.

The patient survived fortunately and all that sort of stuff, but you know, we

all have these kinds of horrible stories, and the competency issue is not adequately represented sometimes.

The medication reconciliation piece, when I was at the Joint Commission that was one of my biggest concerns always. This is all about the list. This is not about the appropriateness of the medications, and we haven't got in the health care system yet, although the discussions around the medical home might begin to address it, who's in charge of actually overseeing and monitoring the appropriateness of the medications.

But MedRec clearly helps to drive it a little bit, but you're right. It's kind of about the list right now, and we need to help look for ways within the safe practice to push it back to the appropriateness of medication as best as we can.

Your other comments, as I said, were germane, and we'll certainly take those into serious consideration.

Other comments from the panel? And then Chuck has a comment as well. Patrick.

DR. ROMANO: Well, I'm interested in thoughts about, you know, this information that you just passed around, and I've seen that, heard about that study previously, and as I mentioned earlier, I have a similar concern about the Leapfrog safe practices survey, and I can take that up with Leapfrog.

But I do wonder whether, I mean, in general there's no evidence to my knowledge that the domains particularly related to culture can be adequately assessed in a reliable and valid manner through a survey of the type that Leapfrog and MedStat do.

And there have been efforts to improve the validity of that survey in some areas, particularly in the CPOE area, by making things more specific and more validatable, but in general it's still a checkbox, and some of our hospitals, I'm part

of this Committee; you go through and we spend many hours going through and checking off and going through minutes and saying, "Well, did we do this? Did we do that? Do we do it annually? Oh, it was 18 months."

And I find it frustrating, and I think you do, too. So is there a way that we can put some type of disclaimer or somehow engage Leapfrog in some discussion about what we think some of the issues might be?

DR. ANGOOD: I met with Leah Binder and a couple of the other Leapfrog group staff recently, and we talked specifically about that. How can we continue to work better and to synchronize a little bit more smoothly?

Chuck has been heavily involved with Leapfrog for quite some time, and certainly we'll ask him to make his own comments on that.

I think that while Leapfrog has its own agendas and its own purposes, there is

intent to try and work a bit more together. Is it going to happen this summer? No, but I think as we move forward over the next iteration of this practice and the next one, it's certainly part of my intent to figure out how we can work more closely together on that, as well as other patient safety initiatives.

CO-CHAIR DENHAM: Yes, I'd like to just address this, you know, what Don has handed out, and this is one of the most important things, I think, that's happened in the last couple of years that has really, really concerned me, and that is that the co-authors of the JAMA report are developers of a competing measurement system.

The JAMA report addressed the 2003 safe practices measured in 2004. They've been upgraded twice by the time that report was written. That was not adequately addressed, and it leads my hospitals -- and I live in California where the author lives and where the competitive measurement system exists.

And I've been in meetings with anger generated by California providers who have a vested interest in defeating Leapfrog in public transparency for two reasons: one, because the measurement system by which they're measured. Number two is they have a competitive measurement system, and to miscarry science this way and to have a JAMA article that does not address the fact that the safe practices had been upgraded twice since then and have no similarity to what was published this year is just an abomination to me, and it's a miscarriage of science, and I think it's inappropriate.

And so, you know, I'm the first one to say we need to have evidence, but I'm also the first one to say let's have some integrity in what we're doing. And I do believe that that's why when we go around the table here and we say, we'll, we have no conflicts, anyone sitting on this Committee, you're measured by Leapfrog. You're measured

against the safe practices. That really is a conflict, isn't it?

Wouldn't it be in your best interest if you had somebody on Wall Street who sat here and said, "Well, your guys that are measuring yourselves are going to kind of defeat things that are hard to do, things that are not in your budget." I mean, that just is a no-brainer.

So I think we have to be very transparent. We have to be very, very careful, and I am very concerned about quasi critical thinking. I am very concerned about defeating practices because they don't have, quote, evidence, unquote, when there is so much face validity that it's just shameful. It's absolutely shameful.

And I've sat in these committee meetings where people are trying to vote down things that will save lives. It's a no-brainer. It doesn't take somebody to have an M.D. or an R.N. to know it, and yet we're

going to sit and debate it, and so that's where you'll find me cross swords with some of the what I would say pseudo critical thinking to defeat things that just have face validity.

And this is a complete miscarriage of science. The JAMA article was just absolutely -- and I guarantee you the reviewers looked at the statistical methods that were used, not the fact that they didn't even look at the '09 safe practices or the '06 state practices, and the fact that the headlines that came out were that the Leapfrog survey doesn't have any correlation with whether it's safer for patients or not, and so I'm dealing with hospitals out there.

So I think that this is a very clear example of the reverse of having evidence. It's when you have got a point to make. Never let the facts get between you and a good story, and the story here was let's get the Leapfrog.

So, you know, I mean, if we're

going to go on the evidence, if we're going to go on good science, if we're going to go on good work, let's really do it, and so I think it's really important that we have a little bit of common sense when we go through these, and I commend the Committee for defeating some of crazy critical thinking to put down something for evidence for which there will never be a study anyway.

That only makes sense, and it's just fundamental good medicine, and so I commend the Committee for doing that, but you know, I think that this kind of material, you know, it's just insanity because we have a JAMA article that doesn't even make reference to the practices that were only 20 percent override.

DR. ANGOOD: Yes, and you know, part of this next iteration of patient safety at NQF will be to monitor the literature. I was about ready to pull his balloon down, you know.

(Laughter.)

DR. ANGOOD: But I just want to have Don hear this. You know, we will monitor the literature and look for these kinds of things and be prepared to react to them and actually the letter to the editor that we wrote on that JAMA article was published two weeks ago, and unfortunately, there's a word count limit on letters to the editor, and you get capped off in terms of the dialogue that you can generate out of all of this, but it's an important part of this patient safety portfolio that we not just defend or react, but we actually promulgate the work and the critical strategies.

CO-CHAIR MEYER: So one request I think I would make at a future meeting is for us actually to get as a Committee from the folks that -- I know RAND has been working on this survey. I have gotten, you know, lots of phone calls about it and, you know, participate on focus groups for it and never

saw a finished product, and so I'd be anxious for us to as a Committee, for us all to hear from the folks that are developing the surveys and just getting a sense of what's going on out there. I think that would be a useful educational session.

DR. ROMANO: IU mean, I don't disagree with you at all, Chuck. I mean, I think this was poor science, but the point is not whether the safe practices make sense, not whether they have face validity. The point is whether this survey directed to administrators in this way can measure the performance of these safe practices in a reliable and valid manner. That's the issue that I'm concerned about, not the underlying merit of the practices.

DR. ANGOOD: Okay. Other comments? We've got the juices flowing again after dredging you all through 34 practices all day long.

David, is there any other tidbit?

Well, actually, I'm going to react to Gregg first for a moment. Part of our HHS work, as I made reference to in our opening comments, is to do a bit of environmental scan work, pre-work, assessment of the field, and will build into future meetings sort of the educational update and where we think the field is moving along. So thank you for challenging us with that.

But similarly then, David, any kind of crystal ball scoping from your perspective and where, again, you think we should head not just on the technology, but in general? And then we'll sort of finish it as we go around the table.

DR. HUNT: Yes, I'll commend the group because actually the trajectory that we're on, I think, is very consonant with where the Department of Health and Human Services is moving.

I also want to point out that other than the two or three opportunities

where there's immediate reference to where infirmation technology can plug right into the practices, I'll expect and I'm hoping that we'll be able to see over the course, once we release our full plans, not every practice but I would say 90 percent of the practices will have something relevant to our work in our office that can be linked into.

I saw obvious connections there and, to be honest, it will be our job to make sure that we make the obvious connections very, very plain. So I think those are the big things that I would say.

There was one other point that I would make. The kids down the hall had double stuffed Oreo cookies sitting out in the hall. They took them down? So while they're napping, I'm going to just suggest that -- no.

DR. ANGOOD: No, I like the double stuffed cookies, but I also noted that they had the nap room, you know. So we were almost heading in there for a while, but we got away.

Any other comments?

DR. McAULIFFE: I'd like to work with David on the technology piece. I think that would be a fun thing to do.

But we were talking a little bit ago about putting in central lines and the story about a resident who ran into difficulty, and I think that highlights a larger problem that we haven't really talked too much about, and that is trainees and the supervision of trainees as they learn to do things in hospitals, and it's not just a resident problem. It's across the board, all trainees, and I think it's something that we need to build into some of these safe practices. So I'd be interested in hearing more about that.

DR. ANGOOD: Good, good. Mary.

MS. MacDONALD: The only thing that I would add is as the consumer representative, I really appreciate the hard work that everyone has put in and the rigor

and also the idea that the patient remains the focus in the center of everything that we're talking about, not necessarily -- you know, you tend to think about your own problems and your own organization, but that the patient remains the center of it.

And just one other quick suggestion. Peter had suggested that David some up with some ideas for future standards. I think maybe something just on the implementation of electronic charting and electronic health records altogether kind of best practices in terms of patient safety, the kinds of training, you know, that's neither the recognition that there may be, you know, backfill needed as people are training and those kinds of things. It might be something to consider.

DR. ANGOOD: Thank you.

Patrick, other comments? Mike, any other comments? Gregg and Chuck, do you want to do some wrap-up comments or are there

any lingering agenda items that we didn't quite catch?

CO-CHAIR DENHAM: We just have a list of areas that were high interest areas that we put kind of on ice for the 2011 update, and they include areas like the rapid response teams, simulation, and the number that were on original tables and lists, and so because the decision was made to get these out in January, you know, we've curbed the enthusiasm, if you will, to add new practices.

But all of those will go through a thorough review, and we're looping back with a number of folks, and I think you'll be making a call for practices to get on a cycle so we can do a really good job and give the NQF staff enough time to do a really good job on their part to have them out by January 1 so that hospitals have a corridor before payers might start asking them to do thing and that kind of thing, and to get them synchronized.

And so we really appreciate NQF,

you know, taking the leadership role to do that because our hospitals out in the field really would appreciate that, and so there are some that we didn't address today that will be brought up, that already have been brought up, have some evidence and that kind of thing on the prior listed tables, but for time today we didn't go through them.

DR. ROMANO: Were you going to say something more about these complex matrices at the back end or is that for future discussion?

DR. ANGOOD: I made more of those comments at the front end. I can work with you through a further phone call or if we have a couple more minutes, by all means.

I guess before, Gregg, you make a comment, peter Pronovost, are you still on the line? I thought I heard him check off.

So Gregg, please go ahead.

CO-CHAIR MEYER: So thanks to the NQF staff and, as always, thanks to Hayley for holding all of this together and all your

support.

Peter, I think the vision that you place out there trying to pull the pieces together under patient safety and the quality forum is incredibly right-headed. It's not going to be easy, but I think you've got a good group of people here who are interested in working on it.

At times when you get into these discussions and you focus on the evidence, you can get a little bit lost in terms of the science here, and I got called out, as you saw here, to deal with a brother-in-law who has a methicillin-resistant Staph. aureus infection in his knee following knee surgery literally as we were talking about infection control, and so it was a little bit of an "O. Henryesque" moment, but it is a starkly important reminder why this work is really, really important.

So thank you for your time.

DR. ANGOOD: All right. With that

we actually met our mark by four minutes, and I don't have to rush to meet Janet.

So thank you all, and we will continue to work these. There will be E-mails. There might need to be a conference call, and then we'll continue to build up the program overall.

So thank you very much and we'll formally close the meeting. Thank you.

(Whereupon, at 3:27 p.m., the meeting was concluded.)

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