THE NATIONAL QUALITY FORUM

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MEETING OF THE HEALTHCARE ACQUIRED

CONDITIONS AND SERIOUS REPORTABLE EVENTS IN

HEALTHCARE STEERING COMMITTEE

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Wednesday, November 18, 2009

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The Steering Committee convened, at 9:00 a.m., in Salon A of the Park Ballroom of the Park Hyatt Washington, located at 1201 24th Street, N.W., Washington, D.C., Gregg Meyer and Sally Tyler, Co-Chairs, presiding.

PRESENT:

GREGG MEYER, MD, MSc, CO-CHAIR
SALLY TYLER, MPA, CO-CHAIR
LEAH BINDER, MEMBER

PATRICK BRENNAN, MD, MEMBER
TEJAL GANDHI, MD, MPH, MEMBER (via telephone)
CHRISTINE GOESCHEL, RN, MPA, MEMBER
CYNTHIA HOEN, ESQ., MPH, FACHE, MEMBER
HELEN LAU, RN, MHROD, BSN, BMus, MEMBER
(via telephone)
KATHRYN McDONAGH, PhD, RN, FACHE, MEMBER

JOHN MORLEY, MD, MEMBER
DEBORAH NADZAM, PhD, RN, FAAN, MEMBER
MARTHA RADFORD, MD, FACC, FAHA, MEMBER
(via telephone)
STANCEL RILEY, MD, MPA, MPH, MEMBER
DIANE RYDRYCH, MA, MEMBER
DORON SCHNEIDER, MD, MEMBER

PHILIP SCHNEIDER, FASHP, MS, MEMBER
ERIC TANGALOS, MD, FACP, AGSF, CMD, MEMBER
MICHAEL VICTOROFF, MD, MEMBER
PETER ANGOOD, MD, FACS, STAFF
HELEN BURSTIN, MD, STAFF

JENNIFER HURST, MHS, STAFF

LINDSEY TIGHE, STAFF

NOT PRESENT:

SUSAN GENTILLI, MBA, RHIA, CPHQ, MEMBER

KEVIN HIGH, MD, MS, MEMBER

A-G-E-N-D-A

A-G-E-N-D-A (CONTINUED)

P R O C E E D I N G S

(8:59 a.m.)

DR. ANGOOD: Well, welcome to each of you.

My name is Peter Angood. I am a Senior Advisor at the National Quality Forum in regards to patient safety.

I want to thank each of you for taking the time out of your busy schedules to join us. We have a busy couple of days.

The work of this project fits in well with a variety of other patient-oriented activities that we have within NQF. We will highlight some of that in the next sets of presentations.

We have NQF processes here. We have to open the meeting formally. So we will do that.

We have the meetings open to the public for comment and listening. That should not hinder your comments.

The meeting is recorded, so that

we have transcripts as well as a full record of all of the deliberations. That is part of not only our intent of trying to make sure we have accuracy in keeping track of all of the comments, but it is part of our open transparency approaches in terms of all of the NQF activities.

But, again, please don't have any hindrances in terms of your comments. We want open and productive dialog. And if there is agreement, great; if there is some disagreement, we need to hear those because we want to hear where the differences of opinions come from.

A couple of brief announcements, and then I am going to turn over the meeting to Sally and Gregg.

We have as well the need to have full disclosures from each of you as we go around doing the introductions. We need to make sure, as part of our processes, that we are aware of any potential conflicts that you

may have as a part of your activities.

We will make sure that the follow-up meetings include the reimbursement forms and all of the materials to get your finances back in order.

I think all of you have had a copy of the meeting materials forwarded to you. You have some hard copy on the table top. One is the agenda and copies of the PowerPoint slides. Then there's a short page that we will talk about a little bit more in terms of our Technical Advisory Panels, when we have that discussion tomorrow.

For those of you who may want a freshened-up thumb drive with all the materials, Lindsey has those in the back, but really none of the materials have changed, other than the PowerPoint slides, but we do have extra copies, if you would like that.

The Blackberry and iPhone services and all those things, as you can see if you have looked at your device, there is no

reception down here really. So keep your device turned off, please. But we will have breaks during the day, and you can scoot on upstairs and get caught up with your different emails, et cetera.

And, Chris, we are just getting started. Just pick any spot that is open.

The washrooms are out the hall and in the far left at the very end of the hall. We will leave it up to Sally and Gregg to put the breaks into place.

Then one last comment which I forgot to mention about NQF process. We do have in the agenda formal periods where those on the line or who choose to join us in the audience have the opportunity to provide comment on the information that they have heard and to provide inputs to our deliberations as well.

We have an interesting set of topics. It is generating a lot of interest on multiple levels, and the work that we do with

this Committee I think is going to have a significant impact for American healthcare and, to some degree, internationally as well. Because the activities around the serious reportable events and this new concept of healthcare-acquired conditions is certainly of strong interest for everyone. We will get into more details with that.

So, with those as my opening comments, I just wanted to also introduce Helen Burstin, who is Senior Vice President at the National Quality Forum in charge of performance measures. Helen has been instrumental in my getting oriented and acclimated to NQF. It is a pleasure to have Helen here as well.

With that, I will turn it over to Gregg and Sally for their introductions and to get the meeting formally started.

CO-CHAIR TYLER: Hi. Good morning.

I'm Sally Tyler. I am really happy to be here with you all this morning,

very happy to co-chair the Steering Committee with Gregg.

I have met a couple of you before, but most of you have not. My background is a little bit different from most of everybody else in the room. I'm a health policy analyst, and I work for a labor union.

I have previously served on another steering committee for NQF last year on the voluntary reporting standards for hospitals. That was a valuable process for me. I learned a lot, and I also learned a lot about the workings of NQF.

One of the things I did notice in that process, though, was that a lot of our discussions were just clinicians talking to clinicians. That would be natural because, generally, those were the people in the room. But I hope, in moving forward with this process -- and this is one of the reasons that I very much wanted to part of this project, because I think this project has such huge

implications for the public, for consumers, and for the healthcare workforce, that I hope we remember that we are talking to those people as well. Certainly in our report language, when that becomes final in 2011, but certainly even in our deliberations and discussions here, that we remember that.

From time to time I believe there will be members of the public in our discussions as well. But even when they are not in the room, I hope we can remember.

So I am not shy about interrupting when we get into much alphabet soup, and I will ask for, you know, "And in plain language that means what?" or "Why is this significant to our project?" So that everybody takes that in the spirit that it is meant, not just to slow down the deliberations, but to make it a little bit more accessible to consumers who are some of the people who are going to be impacted and have a lot to gain by this project. I also think it can really help them

gain confidence in our process and raise awareness of this process with the public.

So I am really look forward to working with all of you.

CO-CHAIR MEYER: Good morning.

I am Gregg Meyer, and thank you for participating on this Work Group. I am a general internist and the Senior Vice President for Quality and Safety at Mass General Hospital and the Mass General Physicians Organization.

I have had the privilege, actually, to be associated with this work, either directly or indirectly, really, I think, from the very beginning. I would actually draw the timeline back on the work on serious reporting events and the kind of complementary set of safe practices to a report that myself and colleagues had an opportunity to work on for President Clinton that came out of AHRQ. That was the "Doing What Counts" report.

Actually, if you go back to the original document from serious reportable events, you will see that that report is emphasized and referenced heavily there. The reason was because, when we were looking at the Institute of Medicine report and what the government ought to do at that time, there was a lot of tension between what ended up being two, again, I think complementary forces.

The first one was, what is it that we need to do nationally to improve? And, oh, by the way, we also have an obligation for accountability to the public.

The way that that was split was to work with the relatively nascent Quality Forum at that point in time and come up with what became the patient safety practices. And I have had the privilege of chairing that Committee over the last several years and being involved with that group from the beginning, and the complementary set of serious reportable events, which were at the

time very much focused in on the accountable side, with a recognition that you need both to move forward.

I think we are going to be revisiting some of those conversations over the next day and a half. I think I look forward to a lively discussion. Please speak freely and openly, because that is what will make, I think, this much more interesting.

This is going to be tough work. I think that, on the one hand, you can look and say, boy, 2011 seems so far away, but I think that the NQF staff who are with us here today recognize that that moves along very, very quickly. In fact, the task ahead of us I think is relatively formidable.

With that said, there is no doubt that this group is up to it. We will commence getting to work today.

I am going to be with you in person today. I am going to be, actually, one of those virtual voices on the phone tomorrow

because I need to be in Boston in the early afternoon, but I will be here to participate in your deliberations tomorrow. I look forward to that.

I am going to start by asking, I am going around and ask everyone to do their introductions. In addition to telling us who you are and where you are from, we also need to hear from you a little about your disclosures. In fact, we are required to hear about your disclosures.

So I will begin with that, and I will tell you that what I need to disclose in this forum is that, as mentioned earlier, I have been the Chair of the Patient Safety Practices Committee. I received no remuneration for that.

I am actually working on Peter Angood and Helen Burstin to try to fix that thing.

(Laughter.)

But I have failed so far, much to

all of our mutual chagrin.

And I also serve on a committee at RAND which is a Technical Advisory Panel, which is under contract to AHRQ to actually look at the evidentiary base in trying to create a grading system for patient safety practices.

And that is my disclosure.

So, please, if we can go around to the left here.

MEMBER GOESCHEL: Wonderful. I am Chris Goeschel. I am a registered nurse, have been a healthcare executive, am now a health services researcher at Johns Hopkins with Peter Pronovost.

I have to say that my links to the National Quality Forum started when I petitioned the Michigan Health and Hospital Association to join, and they would not when I was there because it was too expensive. They do now. Yes, they do. No thanks to me; I was gone after they made that decision.

(Laughter.)

But I would say that I am thrilled to be part of this. Certainly, Peter Pronovost and I have a number of grants through the Agency for Healthcare Research and Quality working on patient safety, specifically in the area of culture change and reducing infections, but I also speak frequently on the topics of quality and safety, both nationally and internationally. And I formerly a Senior Advisor to the World Health Organization Patient Safety Program.

I am thrilled to be here.

MEMBER NADZAM: I am Debbie Nadzam. I am the Practice Leader for Patient Safety at Joint Commission Resources, although I have also been recently designated the Director of International Quality Measurement. So I guess that is a little bit of a disclosure. We are part of the Joint Commission Enterprise.

I am a nurse by background. In

terms of my NQF days, my physician colleague at Cleveland Clinic, when I was there, and I convinced Cleveland Clinic to participate. They were one of the early providers. As their representative, I served as Vice Chair for the Research and Quality Council for the first four years.

Other disclosure, I am a member of the National Coordinating Council for Medication Error Reporting and Prevention. I don't know that that is relevant.

I am very happy and honored to be here. Thank you.

MEMBER BRENNAN: Good morning.

I am P.J. Brennan. I am the Chief Medical Officer and Senior Vice President of the University of Pennsylvania Health System.

My background is infectious diseases. This is my first professional activity with the National Quality Forum.

Peter and I worked together at the Joint Commission when I chaired the Sentinel

Event Advisory Group, and have been a member of that group for many years.

I have no commercial relationships. I currently Chair the Healthcare Infection Control Practices Advisory Committee, a federal advisory committee to HHS and CDC, and participate in a number of nonprofit healthcare boards. I am also a member of the SHEA Board, which is the Society for Healthcare Epidemiology of America. And I am a member of a physician advisory panel, uncompensated, for a local payer in Philadelphia.

MEMBER VICTOROFF: I am Michael Victoroff, representing the American Academy of Family Physicians. I am a family physician, but not an officer of that organization.

I am from Denver, where I am the Chief Medical Officer of a company called Lynxcare, which is a consumer-facing advocacy organization that does case management for

people with complex conditions.

I am also a risk management consultant for COPIC Insurance Company. In that role, in around 1992, I wrote one of the original taxonomies for coding errors in medicine, actually, before they were invented by the Institute of Medicine.

That taxonomy that we shared with just about everybody, including NQF, looks as though it was one of the germinal centers for classification systems and other event coding systems still in use today.

My research and work mostly at COPIC is involved in epidemiology of error, and specifically, research on errors attributable to electronic information systems.

I am also a member of the Rocky Mountain Patient Safety Organization, which is one of the PSOs chartered through AHRQ, and I belong to a number of other sort of consumer safety organizations in Colorado.

MEMBER RYDRYCH: I am Diane Rydrych, and like Sally, I bring a non-clinical perspective to the group. I also have a background in health policy analysis, and am the Patient Safety Director for the Minnesota Department of Health. So I have been working for the last few years with hospitals and other providers to help them understand and implement the serious reportable events.

I don't think I have anything to disclose. I do participate in a number of patient safety coalitions, including the Minnesota Alliance for Patient Safety and others, but none that I think are necessary to disclose here.

It is my first opportunity to be on an NQF committee, and I am very much looking forward to the discussion over the next two days.

MEMBER TANGALOS: I am Eric Tangalos, one of the three majority

Minnesotans here.

(Laughter.)

And former Chair of the Division of Medicine at Mayo Clinic and First Quality Officer for the Department of Medicine at Mayo.

I am here because I think I was nominated by the American Geriatrics Society, where I serve on their Foundation for Health in Aging.

I am Policy Chair for the American Medical Directors Association.

The disclosure would be that I am still active with NCQA on one of their technical panels, the Joint Commission on a couple of their panels, and have been very active with the MDS 3.0 rollout, which is a CMS project that at times has had contracts with RAND, RTI, and others, and I am still active with that.

MEMBER RILEY: Hi. I'm Stancel Riley. This is my first opportunity to serve

on an NQF committee, and I am very grateful and honored to be here.

For 23 years, I was a cardiac surgeon, and then sort of made a transition to a separate career in health policy and public health. In that role, I served as the Director of what we call the Patient Care Authority in Massachusetts, which basically takes in all the reports from hospitals and looks at them. In that capacity, I have also served on several patient work group committees in the State.

And the only other thing I think I might have to disclose is we also have been deemed holder of group causes for the Joint Commission for the entire State. So we work with the Joint Commission on those things.

MEMBER McDONAGH: Good morning.

My name is Kathy McDonagh. I am also happy to be here. This is my first NQF committee experience as well.

My clinical background is in

nursing, and I have been an CNO, a COO, and for over 20 years a CEO of hospital systems. I have also done a lot of work with governing boards. I have done some research on how governing board performance impacts hospital outcome. So the theme of all my variety of work has always been on quality and patient safety and how to improve patient care.

Currently, I am the Vice President for Executive Relations at Hospira. I made a big jump after 35 years in the world of hospitals to take a new position last year. Hospira is a global healthcare company that makes medical devices, generic pharmaceuticals. Really, all of our product line is focused on patient safety, improving productivity, and reducing costs of medical care.

So I am really excited to be able to work at a national level with my C-Suite colleagues, governing board folks, to help people see how we can improve quality and

patient safety. So I am glad to be here, and I don't know of any disclosures.

MEMBER DORON SCHNEIDER: Good morning. Hi.

My name is Doron Schneider, and I am an internist at Abington Memorial Hospital. That is eight miles north of Philadelphia. There I am the Medical Director for our Center for Patient Safety and Healthcare Quality.

This is my first NQF meeting. I was nominated by the ACP. For the ACP, I do a lot of activities relative to quality improvement, mostly in physician offices, through several of their programs.

I also work with the ABIM to help with some of the PIM activities, and SHM as well for some of their improvement activities.

In the past year, I have served on an advisory board for Novo Nordisk for helping them understand insulin safety in hospitals.

MEMBER PHILIP SCHNEIDER: And I am Phil Schneider, no relation, though we do a

lot alike.

(Laughter.)

I am a Clinical Professor and Associate Dean of the College of Pharmacy at the University of Arizona at the Phoenix Biomedical Campus. It is a brand-new campus, health sciences center, that has been established in Phoenix. As you know, the University of Arizona is in Tucson, but the State has decided to invest resources, which they have less of now than they did when I decided to go there, to build an academic health sciences program, with the aim of having Arizona serve as a place where biomedical industry would like to locate their companies.

I was nominated by the American Society of Health System Pharmacists. My background is pharmacy.

And I don't know what the statutes of limitation are for disclosures, because in my capacity at Ohio State University, I had a

lot more responsibility for scholarly activity and research and received grants from the Agency for Healthcare Research and Quality, but also did some work with the private sector, helping them evaluate patient safety technologies, including Hospira, but also Cardinal Health and Baxter. So we had a balanced portfolio when it came to our research funding from the private sector.

I currently am on scientific advisory boards for two companies. One is called Intelligent Hospital Systems, which is a company in Winnipeg, Canada, not a great place to go for advisory board meetings in the winter. They make a robot that produces IV solutions in hospitals.

And the other is a company called SEA Medical, which is producing some technology that helps identify the identity and concentration of medicines that are given through intravenous infusions.

MEMBER MORLEY: Good morning.

My name is John Morley. I am from New York, the New York State Department of Health. I have been in government for four years, just over four years.

Prior to that, as a clinician, my medical practice and experience was in anesthesia, internal medicine, pulmonary and critical care.

My role in the Health Department is the Medical Director of the regulatory side of the Department.

And to the best of my knowledge, I don't have any conflicts. I don't have enough influence, power, money, or anything.

(Laughter.)

Thank you.

MEMBER RADFORD: Hi. I'm Martha Radford, and I am calling in from New York City.

I am the Chief Quality Officer at NYU Langone Medical Center. I have been on at least one other NQF technical panel earlier

this year on outcomes. I think I was on one other prior to that, although I guess I am getting Alzheimer's.

I have been active on panels with NCQA as well and a long-term member of the ACC, American College of Cardiology/American Heart Association Task Force on Performance Measures and Data Standards. I think one or both of those organizations nominated me to be part of this group, which I am very honored to be.

I am a cardiologist, and have no remunerative conflicts of any type, which means that I am living below the Manhattan poverty line.

MEMBER LAU: Hi. My name is Helen Lau. I am calling you on the next two days from California on the West Coast.

My clinical background is in nursing. Currently, I am a National Program Leader in Quality from Kaiser Permanente.

My background, a lot of experience

in quality management and also operational background from the hospital to home care area.

I have served, from 2001 to 2003, served at the National Malcolm Baldrige Quality Award as an examiner.

As far as disclosure, currently, I am also a member on the NQF, the Common Format Expert Panel. Other than that, I have nothing else to disclose.

DR. ANGOOD: Is there anyone else on the phone?

(No response.)

Thanks, Martha and Helen, for jumping in like that.

MEMBER RADFORD: Hi. This is Martha again.

I just wondered if someone could send the slides to us that are out of the --

DR. ANGOOD: Sure. We will see what we can do. We are in kind of a low-frequency area in terms of wireless, but we

will ask Lindsey Tighe to pop up and send those in to both you, Martha, and Helen as well.

MEMBER RADFORD: I just wanted to say that I will be there tomorrow. I am sorry that I couldn't be there today.

DR. ANGOOD: No, that's not a problem at all. Thank you for piping up.

Jennifer?

MS. HURST: Hi. Good morning.

My name is Jennifer Hurst. I'm the Senior Project Manager on the Patient Safety Team.

I have no disclosures.

I would also like to take the opportunity to introduce you to Lindsey. She is in the back.

All of you have received a lot of emails from Lindsey. So thanks so much for your patience.

DR. ANGOOD: While Cynthia is getting organized, I will just sort of give a

little bit more brief background on my origins.

Unfortunately, I did grow up in Winnipeg.

(Laughter.)

And that's why I don't live there anymore.

(Laughter.)

MEMBER PHILIP SCHNEIDER: I bet it is nice there in the summer. Our last meeting was in February.

(Laughter.)

DR. ANGOOD: All two weeks, and it is a dry cold. That's what they always say, too.

I come from a surgery background, spent a lot of years doing trauma and critical care and a variety of academic backgrounds, and spent a number of years at the Joint Commission looking at the patient safety activities there, including the National Patient Safety Goals and the Sentinel Event

Reporting System.

I have been at NQF since the springtime, helping to consolidate and expand the patient safety portfolio.

Helen, do you want to do it? Then we will get Cynthia, once she is settled.

DR. BURSTIN: Sure. Hi.

Helen Burstin. I'm the Senior VP at NQF for Performance Measures for about the last almost three years. Before that, I was at AHRQ for about seven years; spent a fair amount of time with my colleague to my right here, together with John Eisenberg, and had a phenomenal opportunity to really think and build a lot of the patient safety and quality work that we did at AHRQ.

Before that, I was at the Brigham in Boston and was head of Quality Measurement and was also an investigator on the Harvard Medical Practice Study as well as the Utah/Colorado Study. So patient safety is sort of in my blood to a certain extent.

I also have a very strong interest in HIT.

DR. ANGOOD: Cynthia, we are just doing the introductions. Basically, if you could just give a short background on who you are and how you are here, and any disclosures, please.

MEMBER HOEN: Sure. I'm sorry I am late. I was doing the Acela taxi thing through the city, but I am glad to get here.

My background is in law. I got my JD about 20 years ago and practiced defense for 14 before going in-house with a hospital system. I have my master's in public health. I run risk management and claims management insurance programs. I am very involved with the medical staff as well as the Quality Director and Legislation.

CO-CHAIR MEYER: Anyone else join us on the phone who hasn't already had a chance to introduce themselves?

(No response.)

Okay. Hearing none, we will move forward.

What we would like to do is, at the onset of each of the sections that you see listed in your book here, we will try to be pretty explicit about what we want to try to get out of that session, so you can focus on that.

The first part of our day is going to be spent with an overview and orientation to this project, and also committee roles, and a bit about where we fit into the NQF framework, which is incredibly important. I think all of you know that the NQF is not just about the content of the products that it produces, but it is very much about the process and doing things the right way.

So, with that, I will turn it over to Helen and Peter.

DR. BURSTIN: Again, it is a pleasure to be here.

I want to run through this very

quickly. I think you may have had some of this orientation on your call.

What we wanted to do a little bit was give you an orientation to -- I will start out broad and Peter will get specific -- about our work, how it relates, and then specifically, how this particular piece fits into the broader safety portfolio at NQF, but also the broader piece of the more specifics of we are hoping to go.

So the next slide, please.

So, just to begin, the mission of NQF is something most of you probably know, all about improving healthcare quality. Obviously, over the last two years, really beginning to set the priorities and goals for the nation around performance measurement and improvement, endorsing National Consensus Standards. That is the piece we are sitting on today.

The hope is the current, for example, serious reportable events are

National Consensus Standards of the NQF. The question is going to be: should we expand, revise those, think about a broader set of those? And that will be the discussion for today.

And specifically, the idea is that the measures and other consensus standards, like serious reportable events, that are endorsed by NQF are important for measuring performance, and specifically, are considered appropriate for public reporting, to get at comparisons between providers.

And lastly, a modest education and outreach program, and probably soon to be a fourth goal, which is all focused around this issue of translation of what's currently happened to an HIT environment. So, for example, moving the measurement platform away from medical records, even some of the administrative data, to more of a focus on how we can use various electronic data sources to get at better measures.

Next, please.

So the goals for today will, as I mentioned, orient you to where we are currently, specifically thinking about your role and the TAPs that will follow. We will talk a little bit about the safety work. Then Peter will get into the details around some of the specific questions, the scope of this project; definitions, which is going to be -- I think if we come out with nothing today other than with a set of workable definitions to define the next phase of work, we would be very, very pleased. Then, ultimately, thinking about how we would review and update the criteria reviews for SREs, and then create what those criteria might be for a broader set of events.

Next.

So NQF is a private nonprofit. It is a voluntary consensus standard-setting organization. The standard-setting organization is particularly because of a

national act called the National Technology Transfer and Advancement Act that essentially deems NQF as the standards-setting organization for healthcare quality.

This is important because, when the federal government is seeking to use healthcare quality standards, they need to use standards that are NQF-endorsed. So that is the reason we try to really bring together these multi-stakeholder groups and try to get the best of standards we all feel comfortable with.

Very explicitly, around the table, as you will see, steering committees are always constructed to be multi-stakeholder, to try to get the full range of voices, as Sally mentioned earlier.

Over 400 members currently, a broad set of stakeholders across of a variety of councils.

Go to the next one. Sorry, that's in there twice. Next. We must be going the

wrong way.

For those of you who haven't seen our website recently, I would recommend you take a look. It has been revamped and, actually, much easier to use than the old one was, which I could never find anything on. Although after three years, I kind of could find anything, and now I can find nothing because I used all my workarounds. I am handling the new IT.

But the thing about having an account there, it is very easy. Anybody can go on and just get so you can track projects, for example. You could easily go on as a member of the Steering Committee, enroll, and then say you want to track this particular Committee, and then easily just go to the website and pull up any of the documents as they come up, just one easier-step shopping for you.

Next.

So where do you fit? This is the

way we organize our projects. We have specific project areas, and we convene a multi-stakeholder steering committee.

Then we use technical advisors or work groups or technical panels to do more of the detailed evaluation that feeds into the steering committee. The steering committee is the ultimate deciding group that makes the recommendations to the NQF membership and the public prior to commenting.

We will then have a set of draft recommendations, draft consensus standards. We will then have a public comment period, which is remarkably robust. I mean, in our most recent project we did on clinically-enriched administrative measures, we had 800 comments.

So we consider that a positive sign that the membership and the public are engaged. It makes it a pretty hard job for all of you because you get to look through all of those comments and make a set of your

recommendations based on the comments, as to whether or not you want to modify what you would like to do.

Ultimately, we will then put those standards out for member voting. It will go to the Consensus Standards Approval Committee and the Board. We always, as is required for all consensus standards organizations, have a 30-day appeals period.

Next.

So, as I mentioned, we have a very formal consensus development process, which we really must adhere to for the sake of maintaining our status. We really try to always, as I mentioned, have multi-stakeholder input, and we always have public and private sector representation.

We really are increasingly trying to move, as I will tell you in a moment, moving towards thinking about this full continuum of care. So many of our measures are very siloed into this is a hospital

measure; this is an ambulatory measure, and trying to move much sort of care across the continuum.

Some of our current safety measures, for example, like surgical site infections, are one example of where that already happens. It goes out 30 days beyond the surgery to begin looking for SSIs.

Next.

So your role? You, essentially, serve as a proxy for the broad multi-stakeholder group within NQF. You are serving as individuals, though. So, although you have been nominated by others, you are here because of your expertise. We expect you will bring that stakeholder perspective to the table, which we think is very important. Work with us to make sure we do it right.

We will have you think about, once we figure out what the criteria are, whether we are going to modify the SRE criteria for this project. You will help us look to ensure

that we are, in fact, applying the criteria appropriately, make recommendations to the membership, respond to comments, as I mentioned. The Co-Chairs will actually represent you at the Consensus Standards Approval Committee, and any further directions to the CSAC will come back to you.

Next.

The role of the TAPs. In this particular project, we are envisioning probably, as Peter will go over with you, to have three Technical Advisory Panels, to allow us to think through the expansion of the serious events, whatever they may be called, to other settings. So perhaps you have been thinking of an ambulatory-oriented group, nursing homes, home health, groups like that. So we will want your thinking in helping us think that through.

They will advise you, essentially. They will do the deeper dive in terms of the draft review of the events. They will respond

to any questions you may have.

Our plan is we would like to try to pull a Chair for each of those panels from this group, so that we can actually have some cohesion between the work of the Steering Committee and the work of the TAPs.

Next.

Our job? In terms of staff, we will again, as I mentioned, make sure we are adhering to the process. We will organize the meetings to the best of our ability in conference calls; guide you through the steps of the process. We will work to respond to any queries that are out there; maintain documentation on the website and to the public.

Really, one of the core features of NQF is transparency. Everything we do, every deliberation of every committee is completely transparent, and that is quite intentional.

The person in the back who is

taking notes will do, literally, a transcript for us, a legal kind of transcript, which we will have. You will feel comfortable with that.

It will get posted on our website, as will a summary of all the Steering Committee deliberations. The reviews of all of our events that you do will all be posted on the website. So, when people come to really make an assessment, they will have all of the information you had to make that determination.

Then we will work to make sure you have all the information you need from any submitters of any of these events.

Next.

So just a tiny bit about where we are moving to in terms of NQF. There's no doubt that performance measurement in general is clearly an evolution, in a lot of different ways. There is definitely a drive towards higher performance.

Many of the measures that came in, I think, over the last few years, people have thought perhaps didn't represent the highest level of performance, but perhaps the base level of performance. We are trying to move that bar a bit; seeing more and more of a shift and an interest, especially from our consumer and purchaser colleagues, to get towards composites, to get to a more comprehensive view of what we do. Always trying to remember to ensure that we measure disparities in all we do, as opposed to the after-thought that it often is.

NQF has done some work determining a set of criteria that we use for determining which standards should be stratified. This will be something interesting for this group to think about, perhaps not at this meeting, but perhaps at the next one, whether some of those events really are ones where we know there are known disparities, and you would want to make sure you look for stratification.

As I mentioned, trying to get more of a cross-site, cross-sectional view of healthcare quality. So thinking about harmonizing measures across sites and providers. Really a struggle, remarkably, because people tend to have fairly entrenched measurement systems within our silos, and breaking those is a pretty significant task, but I think a really important one at the end of day, to make more sense of where we are going.

And lastly, trying to promote this sense of shared accountability. This is probably the biggest struggle I think we have in talking to folks who live on the frontlines of healthcare, which is that it is very easy for us to say let's pick the best possible measures we can to get from a very patient-focused viewpoint healthcare quality. But it is inevitable that we come back to this question, "but I can't be solely accountable for that outcome."

So the classic example here would be re-admissions. You know, hospitals will say, "I can't own this. You know, there are community providers for whom I need to do a hand off." But, yet, there is no question that measuring re-admissions is the right thing to do.

So we are struggling with that, but I think we really, at the end of the day, want to try to get a set of measures that allow us to see that patient-focused view of the world.

Increasingly, a focus on outcome measures. We are doing a project currently on outcomes across the top 20 Medicare conditions, as well as a steering committee focused on child health outcomes and mental health outcomes. So we are really trying to move the needle there.

We are planning to do a great deal of work on appropriateness and overuse as we go forward.

And then, also, launching a project very soon, in the next month or so, for the first time beginning to look at cost and resource use, as coupled with quality measures. It will be a real interesting challenge, I think, for us going forward to begin knitting together what are the appropriate measurement sets across some of these conditions, when you have outcomes, resource use, safety measures, patient satisfaction, patient shared decision making into a real measurement set that would add value from all stakeholders.

Next.

Actually, I will skip this.

We have updated our endorsement criteria last August. Again, they are not directly applicable to these events, but I think they are many of the same concepts that we want you to think about as you are developing or expanding the criteria that we are using for SREs and perhaps this broader

category of HACs.

We very much tried to strengthen the criteria so that we had a stronger link to the National Priorities that I will mention shortly, higher-level performance measures, greater harmonization as much as possible across sites of care.

So perhaps, as you are thinking through SREs or HACs across site-specific, are there opportunities to think about events that would cross sites of care, for example, rather than just be siloed?

A greater emphasis on thinking about outcomes of care. And then, if there are more process measures, ensuring there is a fairly tight process-to-outcomes link.

Next.

These are the criteria that we have currently. Again, you will need to think about how these fit within the context of SREs and HACs.

We have now a must-pass criterion

of importance to measure and report, which was a change for us. The idea here was, really to put it in the simplest terms, is the juice worth the squeeze? Is it really worth collecting the data? Because at the end of the day there is a known performance gap; there is clear evidence that this measurement focus is important.

Then, lastly, there is an opportunity for improvement. There is a gap here. There is a real problem.

So, for example, identifying events for which there is a very small number, and perhaps not a great impact on the overall healthcare system, may not be where we want to go, just to think about it in this context.

We want to, as much as possible, drive toward high levels of a scientific acceptability of the measurement properties, the reliability and the validity of the measures, and in this case the events. Can you set up specifications for these events in

a way that they are replicable across hospitals, across health system, across different pairs and data sources?

Usability, ultimately, can the intended end-users of that, whether that is consumers, purchasers, clinicians, whoever it may be, understand and use those results for decision making.

Peter will tell you about a parallel effort that is happening in just a couple of weeks, which is a steering committee that will think through a framework for reporting on these kind of events, which we will, obviously, make sure you guys stay connected.

And then lastly, feasibility, can we logically implement these measures without undue burden? So that is where we have a great deal of shift toward electronic data collection and EHRs.

A real question would be, how much of this kind of work can begin to be built off

that platform? It is still unclear, I think.

Next.

I mentioned disparities. I think a last point here, just to make the point that we have been trying to think about how to make disparities assessment a routine part of measurement, working closely with lots of other stakeholders to think about both the direct methods in terms of how do we ensure, for example, an EHR environment. If you're collecting race, ethnicity, language data, how does that data flow through so that you can, in fact, always have it to marry it to your quality measures, to be able to stratify for disparities, thinking through some of the indirect methods that are currently being used with geographic information systems, for example, to do that.

Then, lastly, this concept that we have developed called disparity-sensitive measures, where we have come up with a set of criteria around prevalence, the impact of the

condition, the impact of the quality process to narrow the gap, and then, ultimately, the size of the gap as being the ones, in particular, we should always stratify, something for you to think about as you go through the events.

Next.

This is just a framework we have been thinking through, as we start thinking about care across an episode. These are episodes as we have developed them from the patient perspective, not necessarily from the billing perspective, a billing-free time period when there's no bills.

Now this is really from a patient's viewpoint. We have developed these now across multiple conditions. This is the example for acute MI, just trying to think about how care begins to cross the bubbles here of various phases of care, understanding and trying to think about the population at risk, for example, and prevention,

understanding patient preferences, as they play in here, and, ultimately, recognizing that there are different outcomes for patients, depending on different trajectories of their care.

A patient who has an acute MI and winds up with PCI could wind up for whom really secondary prevention is most important. The patient has a pretty significant hit on their myocardium, a whole different set of outcomes that are going to be especially important that we consider for them.

Next.

And lastly, I just want to end with a bit of a discussion on the National Priorities before I turn it over to Peter. We have been trying to think through what are the highest leverage areas where we think, if we really work together, we could really make a significant change and drive change and improvement in the healthcare system.

Next.

So the National Priorities Partnership was established a couple of years ago to specifically set up this goal. There are now 32 leadership organizations. Pretty much all of the major effector arms in healthcare are represented at some macro-level. It is chaired by Don Berwick and Peggy O'Kane.

Next.

And these are the six National Priorities and Goals on these two slides. I am not surprised on this slide to highlight patient safety, since it was one of the six. But the others are directly relevant, I think, as you think through the kind of events you want to be thinking about.

The first is that patients receive well-coordinated care across provider settings and levels of care with a specific focus on some of the issues around medication reconciliation, hospital re-admissions, and perhaps preventable and emergency department

visits.

The second is a more population health lens to the healthcare system, focusing on ensuring that 100 percent of patients get what is indicated in terms of preventive services, ensuring access to the healthy lifestyle behavior interventions we can do, and then moving towards this concept of more of a population-level health index, which is more of a community-oriented measurement. We don't have very many of those, except for the AHRQ prevention quality indicators, which look at preventable admissions in a community.

The safety one is interesting and fits directly into this work. A strong focus here on improving the safety and reliability of the healthcare system with a focus on hospital-level mortality rate. They called it serious adverse events to keep it quite broad, as part of that initial rating group. This was initial.

Then, lastly, healthcare-

associated infections. Peter will say more about that.

Next.

These are the remaining three. Engaging patients and families on managing health and making decisions about care. Strong import here around shared decision making. Patient experience of care at every setting.

Patient self-management. Guaranteeing appropriate and compassionate care for end-of-life is a particularly important one that has had very little attention to date.

And lastly, eliminating waste while ensuring the delivery of appropriate care, which has nine focused areas of overuse that we will be working through over the next year to two.

Next.

So, just putting it together, thinking about that lens across episodes, and

then overlaying in yellow the National Priorities, this is really the vision of where we see our portfolio moving to. We want to see it as sort of a two-dimensional matrix across the high-level, high-impact conditions, as well as these cross-cutting National Priorities and Goals to begin giving us a broad picture as to where we think we need to go to, hopefully, make some significant improvements in the healthcare system.

Next.

And lastly, just hard to not mention HIT, since I think it is so relevant to where we are at the moment. ARRA, the American Recovery and Reinvestment Act, had a significant amount of dollars at stake, I am sure you all know, $40 billion, around the use of electronic health records.

One of the key capacities that they are going to be assessing is the ability to capture and query information relevant to healthcare quality. So just something to

think about as you, again, consider what kind of events can be captured from different data sources.

Next.

And lastly, this is a great slide that the RWJ Aligning Forces for Quality group came up with that I think just makes the case specifically, as we are thinking about a very broad set of events across a broad set of settings, begin thinking about how we may need to bring together data across a whole range of different settings and information systems, to get at what we want, to get at the data aggregation, to again try to be more patient-centered into what I think they need.

I think that is it. Peter, I think it is yours, yes, next.

Lastly, NQF just released the quality dataset, which we have been working on over the last year, of those key data types and data elements that should be embedded into EHRs to allow for quality measurement.

Next. And I think that's it. There you go. I will turn it over to Peter.

CO-CHAIR MEYER: Actually, before you turn it over to Peter, any clarifying questions for Helen? I think the most important thing I want you to focus on is, as I said before, is the importance to process.

DR. BURSTIN: Yes.

CO-CHAIR MEYER: One of the things that we will be counting on the NQF staff, both Sally and I will be regularly asking to make sure, are we on track; are we going through all of the right steps? Process really matters here.

Any questions for Helen at this point?

(No response.)

Any from the folks on the phone?

MEMBER RADFORD: No. Very clear. But thank you.

CO-CHAIR MEYER: Peter?

DR. ANGOOD: All right, thanks,

Gregg. Thanks, Helen.

Each time I hear Helen's talk, I continue to learn more. I think, from your perspective, NQF is complicated to learn because it has really got these tight processes, but it is, obviously, also expanding its whole scope of activity on a lot of different fronts. That is an exciting part to be a part of.

What I will do in the next couple of minutes is just sort of review some of the aspects of safety, and then we will start to hone this all down into this Committee's work overall.

As you can see, the roles of NQF so far in safety, this serious reportable events, a very early program, got a lot of national and international notoriety. The first release was in '03. There was an update in '06. Even before our current contractual work with the Department of Health and Human Services, we were scheduling in to have the

serious reportable events updated for 2009, but we have rolled it into this particular scope of work.

These 28 SREs really, I think, have taken hold in many, many different ways. It is on the national level. It is in the state levels. It is in regional levels. It is certainly within healthcare systems, and, obviously CMS has taken up some of these as concepts in terms of the payment strategies. So NQF I think had a lot of foresight in terms of bringing these into play.

The cross-cutting safety measures, there's about 550-or-so measures within the NQF measures database now. About 20 percent of them are safety-related. That is mostly oriented towards the safe practices and the serious reportable events, but a number of them are oriented as well to specific areas, healthcare-acquired conditions, I'm sorry, infections, and a couple of other focus areas.

But there's some incongruities in

there as well. We have some gap areas. As we move forward, one of the other pieces of work that we will be doing is to look at expanding the patient safety measures and filling in some of those holes. I will talk more about that in a moment.

NQF's safe practices are also a very well-established program now. They have been recently updated for the third time. Those were released in 2009.

We have moved into an annual maintenance cycle for these. We recognize that the evidence on the safe practices evolves rapidly enough, and the topics themselves continue to evolve, that the annual maintenance process is important.

So we have already done a fairly light but I think thorough review of the just-released 2009 safe practices for 2010. Those will be under final approval by the Board toward the end of the month. Then they will be released at the end of the year, or

certainly by January.

Then we will do a deeper review of the safe practices again during 2010 for release in 2011. We will probably move to this sort of light year, heavy year, light year, heavy year, to make sure that we are keeping abreast of the field.

One of the things I learnt, and many of you have felt it, is with the Patient Safety Goals Program at the Joint Commission, if you tweak them too much too often, you just confuse the field. We want to make sure that we don't do that with the safe practices as well.

They have been taken up very well, but what we need to do is really learn how to better at NQF bring the safe practices in with the serious reportable events, in with the measures, so they all weave better together.

They kind of sit there as three separate programs, some overlaps, and I think the evolution of NQF is just reflective of how

these programs came to be. But there will be a concerted effort on our parts to really weave those three programs together.

That also fits in with the National Priorities patient safety activity that Helen mentioned in there. Some early work with NPP is we are going to be focusing on the perioperative environment, specifically looking at, how do we decrease the healthcare-acquired infections in that perioperative environment, as well, how do we decrease the serious reportable events in that perioperative environment? It is not just cutting off the wrong leg. It is the pressure ulcers. It is all those other things.

Then, how do we improve or augment the cross-disciplinary team activities in the perioperative environment? We got to that point by looking at the safe practices or the practices of each of the member organizations within NPP and realizing that those were common themes across all of the member

organizations.

The perioperative environment is just chosen as an initial start point because it is relatively contained in terms of the environment, in terms of the number of disciplines, and the definable types of conditions that are in there.

But, as we learn from that, we will be looking, again, for ways to, within the NPP activity, cross over that to the serious reportable events, to the safe practices, to the measures. Then we will move beyond the perioperative environment with NPP there, obviously. But that is just a starting point.

The common formats for the patient safety organizations, we have been overseeing the Steering Committee activity in developing those common formats. The first iteration of those common formats are out there. They are still open for public comment. So, if you have interest in these, by all means, seek

those out.

The development of the common formats has, I think, been important work because it really is trying to make sure the commonality of terms, the approaches, the data is as uniform as it can be, as they go into the reporting structures of the patient safety organizations.

There's about 70 PSOs out there now. They are just getting started on their reporting activities. We will be following along with the Agency for Healthcare Research and Quality to see how that evolves.

That, too, ties into some of the IT work that Helen just mentioned. I am not going to go into that further, but, obviously, the focus on the national level with electronic health records and HIT overall, clearly, is an important facet in all of this. It, to some degree, will help us with driving these commonalities across these programs as best as we can.

Now, having said all of that, the serious reportable events are clear and distinct by themselves. The safe practices are also clear and distinct by themselves, as are the measures. They have different focuses, but we need to just get them to come together more closely.

Next slide, please.

The Health and Human Services contract is a four-year contract that HHS approached NQF for in January of this year. It is a multi-faceted contract. It has got numerous components to it.

We have been rapidly ramping up as an organization in order to get all of these projects off of the ground. Eddie Garcia is a part of that project's work. He is sitting there in the back. So, if you have more ideas from their perspective, don't hesitate to approach Eddie -- he is a very approachable guy -- during the course of the day.

The three specific areas for the

patient safety component of this large contract are expanding the healthcare-acquired conditions into other environments of care beyond the hospital setting. As we will discuss more, this term, healthcare-acquired condition, is actually undefined. We have opportunity to define that.

There's been a lot of discussion, a lot of email traffic, between ourselves and HHS and CMS about this term, but I think we have, to some degree, a clean piece of paper to start with, but there will be context as a result of the serious reportable events, and as well from the HAI world and CMS's hospital-acquired conditions. But we need to make sure that we don't confuse the field as we define this, because there already is some confusion out there.

So expanding into non-hospital environments for these so-called HACs, and we need to be careful, and HHS is certainly in agreement with this, that the NQF serious

reportable events don't get lost in this process. You can think about them as a subset of the HACs. You can think about them as a slight parallel set, if you would like. But the serious reportable events from NQF carry a lot of value to the healthcare industry. There is general agreement that that program should not be subsumed by these HACs, but more as we discuss through that.

The second deliverable is, as I briefly mentioned, the expansion of patient safety measures across a variety of environments of care as well. As we define those environments, then this second deliverable will follow along with those same environments, as we begin that activity in January. That deliverable has not begun as yet, because, in part, we wanted to see how this group's activities came together as well. We will certainly keep you apprised of that work overall.

The third deliverable is what

Helen briefly mentioned. That is the development of a framework report on all of the issues related to the measurement, the evaluation, and the public reporting of these so-called healthcare-acquired conditions.

That is a framework, and NQF does these framework reports from time to time to sort of set out what the issues are and where the field should follow, as we put these things through our consensus development process.

A couple of you, John and Diane, were involved in one of our early environmental assessments as part of this third deliverable. That was recognizing that the 27 states and the District of Columbia state-based reporting systems have never really been brought together into the same room to talk about the issues. So we had these folks together -- what? -- just three weeks ago, or thereabouts.

We have provided some of the

output from that meeting in your materials. Through a fairly busy day of activity, we had some presentations from six of the individual states. We had some breakout sessions with some very focused activity on reporting and the issues related to that.

We also had them spend some specific focus time on the serious reportable events. That is some of the information you have got in your packets.

So those three deliverables are fairly robust. We've got a set of timelines to, hopefully, wrap up most of the hard-core work by the end of 2010 and the reports by first or perhaps second quarter of 2011.

With all of what I have described so far between our NQF-specific safety activities, the NPP, and these three deliverables, we have set up with a Patient Safety Advisory Committee at NQF to just help get some broad-based overview and make sure that we are targeting these programs

appropriately and reasonably.

May I have the next slide, please?

Then the three proposed settings that we have here -- and we will talk more about them -- as we looked at the HHS contract, and trying to get focus for this, we said, well, there's a number of conditions that are out there. You can start with the top 20 CMS conditions. There are a number of environments in which those conditions are taken care of. CMS has the 10 environments that they usually have, but we don't have resources available to run 10 focused Technical Advisory Panels. So we look for ways to bring these environments into similar areas, recognizing that it is far from perfect, but it is certainly a good starting point.

So the ambulatory home health environment, the inpatient hospital settings, as it is aggregated, and then the whole issue of sort of extended care with the nursing we

have in long-term care facilities, those are the three environments that we are going to try to use for both this first deliverable, this group's activities, as well as for that development and expansion -- not the development, but the expansion. Helen always slaps my wrist when I say, "development", because I have to be clear, NQF does not develop measures, but we expand them and we have the field nudge them along. I have to just delete that one off my lexicon.

But the next slide, please.

So, in terms of our scope, it is fairly robust. Maintenance review of the existing serious reportable events. That is an important component, and that will be the early part of our work. Then the developing of the definitions and the criteria for these broader-based events. How will we define the healthcare-acquired conditions or the healthcare-associated conditions, and then how does that impact or overlap with the serious

reportable events? Then how do we do this in a meaningful way for the field into other environments beyond a hospital setting?

As many of you know, the SREs themselves are meant to be fairly generalizable, but we need to review them in terms of the context to specific environments and settings. So, as Gregg said -- next slide, please -- we will have a fair amount of work for us.

So, just very briefly, review the criteria of the prior SRE work, clarify the definitions. We will be doing a call for update and maintenance around the SREs, and potentially around the HACs, depending on how that conversation goes.

Certainly, as part of the SRE update, we will want to do a call, so that we get the opportunity from the field to also comment on the existing serious reportable events and also have the field with opportunity to input for other new serious

reportable events or the opportunity to suggest where some of the serious reportable events should be deleted or removed from the list. That is an important part of the maintenance and update process.

The Technical Advisory Panels, we will talk more about those. That is most of tomorrow's discussion. We will get into a bit more detail on that.

Next slide, please.

Then the applicability to these environments, both for the serious reportable events themselves, but the healthcare-acquired conditions. In fact, a little bit about the TAPs already, and then the evidence around the level of preventability and endorsement of the existing SREs I mentioned briefly, and the additional ones, all for discussion.

I will close up with a few comments about the definitions, and then we will come back to them and let ourselves get into the work.

So next slide, please.

So the current definition is preventable, serious, and unambiguous. These are the types of events that should never occur.

Next slide, please.

Now, just to refresh everybody, the current listing of these SREs, it is not intended to capture all events that are out there. It is really meant to be those highly-significant events that are of concern to the public, to the healthcare professionals, and to the providers overall. They are meant to be clearly identifiable, clearly measurable, and therefore, feasible to be reported in some type of a reporting system, and the risk of their occurrence is significantly influenced by the policies or the procedures of a particular facility.

As we know, that is sometimes difficult in itself because these are uncommon events, but should they occur, there needs to

be a lot of focused activity around them. There is an awful lot of discussion out there, well, shouldn't we focus more on the more common things, so that organizations can move towards managing those, as opposed to these rare birds that don't happen?

Unfortunately, some of you who are in reporting systems know that these, quote, "rare birds" happen more frequently than we like them to still. It is jut an unfortunate part of where we are at as a healthcare system overall.

The criteria -- the next slide -- is really, as I mentioned, preventable serious, unambiguous, and any of these following. They are adverse. They are indicative of a healthcare safety problem in their system. They are important for the public and the private, and it is usually preventable. These are not always truly avoidable instances because healthcare is complex overall.

The next slide.

I am not going to take us through each of these, but we will review them during our further discussions. These are up for, I think, us to -- you know, if we are happy with them, that is fine. If they need to be cleaned up or modified, that is fine, too. We don't have to do all of that this meeting, but it is certainly something that we have to stop and review for ourselves.

I think we are close to the last couple of slides.

Do you want to stop for a moment?

CO-CHAIR MEYER: Yes, one point there of clarification is, actually, my sense is that, if we are going to go out to the field and ask for a call for events, then, actually, we do have to leave this meeting with a pretty clear definition here.

DR. ANGOOD: Okay. That is a good technical point. Thanks.

CO-CHAIR MEYER: That is going to

be a deliverable for us, and, actually, in the not-too-distant future.

DR. ANGOOD: No, thank you for that.

All right. Next slide then, please.

Hospital-acquired conditions, this is the CMS term. Okay? This refers to those conditions deemed reasonably preventable with implementation with evidence-based guidelines. We just have this here. We are not married or wedded to this. This is not our term. But we just wanted to make sure that you were aware of that CMS term.

And we do need to make sure that we don't further confuse the field overall, as we move forward with this other version of HACs.

Go ahead, Helen.

DR. BURSTIN: One point of clarification, if I could. So the HACs are currently a term CMS uses which is attached to

a payment issue. I think it is just important to remember that NQF does not engage -- you know, our line stops at implementation. There's no NQF issues around the payment or non-payment. That is for CMS to decide.

The reason this definition is important, and the reason CMS just came to us with part of this task, was the idea that the SREs seem -- and feel free, Eddie, to hop up at any time -- that the SREs seem too narrow, and there seemed to be a desire to potentially widen that group of potential events that we would want to be able to report on and consider. So that was the idea.

So, starting with the definition of HACs that CMS uses just seems like a good, logical place to begin to understand, and there is a whole series of like terms in both of those: what is preventable? What is largely preventable? What is serious? What is not so serious? So these are the kind of terms we think you will grapple with today.

Sorry.

DR. ANGOOD: No, that's good. Thanks. I appreciate your making that comment.

So the next slide, please.

So, as we were putting the work plan together, we felt it was important to at least get some preliminary concepts into place. This language was comfortable for the folks at HHS who reviewed our work plan proposal.

I have reread this a number of times. I think it is good guidance, but we need to look for, how do we make this much more in a way of a crisp definition?

So "untoward conditions or complications that are acquired by patients during the processes of their care for any given illness that is being managed across a variety of environments of care". That is kind of a lot of words, but I think the concept is in there.

They can be across the spectrum from rare to uncommon to common. They may or may not require formalized reporting to different external agencies, but they should, as a minimum, be reviewed internally as part of the QI processes of an organization.

We can come back to this. Between Helen and I, we have been talking too much.

But take a moment and reflect on this particular slide, as we go through the day, though, and as we try to delineate the differences between the SREs and what this expanded term of HACs is.

So some questions that we want you to be thinking about. Are there changes or adjustments to the definitions and criteria for the SREs? The SREs themselves, do we need to change that list? Can we consolidate it and omit, add, those sorts of things?

Next slide.

Then, sort of the framing questions around the HACs: what is the scope

that this definition should encapsulate? What are those differences, as we have mentioned?

Then there is this whole set of discussion around acquired versus associated. Acquired has a connotation that there is something related to the processes of care; whereas, associated could be any number of different reasons why a condition shows up. So we need to tease on that one.

The folks at HHS don't have a bias at this point in time. I think it is important for us to have open discussion about this nuance because it has huge ramifications, depending on which direction you go towards.

Then, while Helen mentioned we don't concern ourselves with the payment strategies, we do need to consider the ramifications on the potential uses of these HACs. As we have felt, and as we made comment, the SREs have been uptaken -- that's not the right word; taken up is the right word -- in a number of venues. There's a lot of

infrastructure already in place across the country related to the SREs. So, while we can't predict where those HACs go, it is certainly something that we need to think about.

Then the last slide I believe is the relevance related to the CMS top 20 conditions. There's other types of conditions, other patient populations in the CMS populations, obviously, pediatrics being an obvious one.

Then what are these different types of settings, and how do we consolidate them, as we mentioned? Then the topics could also be expanded potentially into not just conditions and environments, but the procedures related to some of these conditions or whether or not teams of care or individual disciplines of care should have some of these topics related to them.

That is a lot more contentious and a lot more sensitive, obviously, but over the

course of time, these things have a habit of creeping, and we need to think through some of those ramifications.

All right, I think I am done.

We have a listing of all of the current SREs, but we are not going to go through that just right now.

CO-CHAIR MEYER: Before we move on to questions from the group, have you had any comments from the CMS perspective?

DR. BURSTIN: It seems like you should sing with that kind of microphone.

(Laughter.)

MEMBER RADFORD: If there was a question, then we couldn't hear it. So, if someone could repeat it, that would be great.

DR. ANGOOD: There hasn't been a question yet. We are just setting up with another microphone, but we will get it right away.

MEMBER RADFORD: Thank you.

MR. GARCIA: This is Eddie Garcia

from CMS.

I think Helen and Peter did a good job of capturing our thinking on HACs. We have hospital-acquired conditions now. Our thinking was to expand the SRE list initially into other settings of care, but then, also, to look at things that are potentially occurring more often and frequently. That could be captured.

So we just take this term "healthcare-acquired" to capture different settings of care outside of the hospital and to also gather information on events that are occurring frequently.

So I am really glad that the meeting is going on, and we can, hopefully, get to definitions that are useful.

Another thing to not complicate this work with is our HAI initiative at the Department, which is looking at healthcare-associated infections, which I am hoping that this HAC term can also be encapsulated

underneath as well, with the SRE list.

So that is all I have to say.

DR. ANGOOD: Yes, and on that last point, I forgot to mention that on that second deliverable, where we are expanding the patient safety-related measures, there will be very specific focused efforts on the HAI as well. That is a part of where we are heading, so, again, helping to bring that harmonization of the HHS's HAI action plan and the scope of activity related to that with the measures, et cetera.

MEMBER BRENNAN: Peter, will that be part of the work of one of our Technical Advisory Panels?

DR. ANGOOD: No, P.J., we will formally have another steering committee that will begin in January on the measures, and they will have their own Technical Advisory Panels as well.

We need, obviously, to keep bringing the information into both groups or

all three groups.

MEMBER TANGALOS: Yes, well, since we are a steering committee, let me float around at 30,000 feet for just a couple of minutes. Because our task may be much more difficult than the hospital-acquired activities. So a few random thoughts from both discussions, if you will, and then maybe a little bit of a philosophical discourse as well.

But, you know, in the hospital we can call people "patients". But when we get into the other environments, it gets very, very difficult to use that term. And not being politically correct, I am actually thinking about how people, individuals, interact with their environments, and where that safety-versus-autonomy question comes up; also, where the question between populations and what is best for a population versus what is best for an individual comes up. I have heard a fair amount of that.

I think it is going to be a struggle. I don't have to go back but 24 hours to look at the maelstrom that we have right now in front of us regarding breast cancer screening.

It really is an issue of population, which is where you want to go with a lot of NQF things, and the individual. We have heard from the individual repeatedly last night with anecdotal stories. We see the patient listed a number of times, the individual here.

So I struggle with where this group is going to go in this expanded environment, where it is less clear that we are dealing with a patient as much as we are with an individual, and where they have an autonomy of their own.

Of course, my own background, it is expansive, but it is long-term care as well. We will get to one of the reportable events, which is falls, which happens to be in

Minnesota right now a huge expos,. It is an incredibly complicated issue between autonomy and safety and where we are with that.

So I am sure that NQF has struggled with these things, but it is going to influence all that we do until we finish our work.

CO-CHAIR MEYER: Other questions? We apparently have one from the phone.

(No response.)

Yes, please.

MEMBER NADZAM: One of the things that struck me with the transition from hospital to healthcare is that a hospital is a provider setting; healthcare is everything we do. I think that will have an impact on whether acquired or associated is used. Healthcare-associated doesn't attribute any accountability to the provider, whether it is an organization or a clinician. It can be, you know, I am at risk for developing an infection. So I don't know what the right

words are, but I am not sure healthcare is the right transition term.

DR. BURSTIN: Also, in addition to that, I think it would also be helpful for us to define associated versus acquired, which we didn't do, just to get a better sense of what people's thinking is.

The reason this really jumped to me is I was looking at CDC stuff just a couple of days ago and realized that, although some of us still call them healthcare-acquired infections, it is, clearly, healthcare-associated infections, is the preferred CDC term. Yet, it is hospital-acquired conditions on the CMS side.

So it just seemed like it was an opportunity to reconcile, and it is a really very different term. So I just think it is one of those other sort of concepts we need to grapple with.

CO-CHAIR MEYER: I think that would be a good part of our discussion, that

mission later on.

Christine?

MEMBER GOESCHEL: Chris Goeschel. I have a comment as well.

I think, agreeing with everyone in terms of the magnitude of the challenge that is in front of us, I have to applaud the fact that we are having the conversation. Because, as I look at what is on the plate, I have seen many of these dishes in other settings, be it CDC or other settings that we are working in.

The real risk to any of this, in my estimation, is that well-intentioned people go down parallel paths and we end up with a duplicity of wisdom at the end of the day that only serves to confuse consumers and CMS and others for whom important decisions are really our responsibility.

So I am a bit overwhelmed at the challenge, but glad that all the things that are listed here today are in front of us. I think we have an accountability. So thank

you.

CO-CHAIR MEYER: Well said. I think one of the things that Peter mentioned, and I think it is worth reflecting on for a moment, is this notion of harmonization and trying to provide what is a relatively clear message to the field, to the people on the frontline in a variety of settings trying to do this work.

I am a huge fan of that effort. On the other hand, we want to harmonize, but we don't want to necessarily homogenize these things. That really will be our challenge, I think, over the next day and a half.

Other comments? Please, Michael.

MEMBER VICTOROFF: I don't know if this is timely, but I have a pedantic, annoying bias. When we begin to parse out nuances of words, there's two ways to express what we mean precisely in general.

One is to spend a huge amount of time getting the poetry of the exact selected

word for the exact selected concept agreed in the room, but I find that, usually, when you choose the perfect word in the room, it is no longer perfect when it falls into the community. You have a bunch of interpreters and other critics and poets and people performing exegesis on the perfectly-selected word. I think that is self-defeating.

So my bias, when we are talking about associated versus acquired versus caused by or resulting from, I can see us getting into -- I will also introduce another bias pretty soon, which is the legalistic prejudice about there's an undercurrent here that we need to be aware of about liability.

So my preference for solving the choose-the-perfect-word problem is usually to attach enough footnotes or explanatory material to clumsily and brutally, but clearly, explain what the word discussion is about, rather than just being happy with putting up a perfect piece of poetry.

CO-CHAIR MEYER: I think one of the things that is useful, when you look, going back to the 2002 report, you will see that not only did they define the serious reportable events, but they actually defined the words within the definition. I consider that part of the work for us to consider taking on today, is looking at that as well.

Any comments? Please, P.J.

MEMBER BRENNAN: A question for Helen or Gregg. There are events, I think, that are not outcomes, but process measures that could be good surrogates for outcomes that are very difficult to measure. You know, an action that is clearly proven to prevent an event that may be manifest post-discharge or in another setting of care that would fly in the face of SREs as they are currently defined, without giving examples, would such process measures be suitable or is an event always an outcome?

CO-CHAIR MEYER: I will just

speak. This is not in my role here as the Chair. This is actually reflecting back on my work on state practices.

That is where I think, something like that is where we would fold that into the work on the state practices group. But, again, as Peter was trying to say, we want the two to complement each other, but they won't necessarily 100 percent overlap.

I do think that that may be one way to start to parse them out, as folks see processes in the state practices and more on the accountability for the actual outcomes of events in this Committee.

DR. BURSTIN: And also, on the measures side, I mean, in some ways, if you looked upon the SREs as being the outcome, it would be very logical to think of what are the linked process measures that you could associate that. Ultimately, as you begin thinking about a measurement set around falls, or whatever the case may be, these would be

the sort of interventions that might be well-laid-out in exquisite detail implementation-wise and safe practices. This is how you would measure those processes, and these are the events we are trying to prevent. So I think it actually winds up being a nice, logical procession -- I hope.

DR. ANGOOD: Well, yes, just to tie the bow on the box here, so it is the reportable event, it is the practices, and it is the measures, and how do we build that continuum, if you will, because they are needing to be related, but they are separate and distinct.

I think, as we deliberate through this group and move through the next year or so, it will help us in those other venues to really move toward how to make these overlap and flow together.

MEMBER DORON SCHNEIDER: Just a comment: the tight coupling that occurs in the hospital environment is what I am thinking

about, and it is not seen in private care offices. I am not sure how to really phrase it, but I worry a little bit about us defining an event and where it initiated, and some of these events may really span many encounters. Thinking that through is going to be difficult.

DR. BURSTIN: Actually, just one thing to add: another incredibly important role of the Steering Committee is to define what is not there and what needs to be developed. So, in fact, you may define events in primary care and then the need to identify the set of processes that go along with them that could be built into linked process measures or safe practices; you're absolutely right.

CO-CHAIR MEYER: Other comments or questions?

(No response.)

I will just make one final comment because it came up today, and it just forced

me to reflect back on discussions that we had literally eight or nine years ago now. That was this issue of rare bird, and that some of these are very unusual events. That was always a struggle when we initially thought about really moving this contracted work from AHRQ over to the National Quality Forum.

One of the things I would ask us to think about broadly is that we can look at many of these and say these are extraordinarily rare. So, as mine and Helen's former boss, John Eisenberg, was often wont to say is he would note that we could get rid of most of these serious reportable events from American hospitals and healthcare settings next week, and would we really be safer because they are so rare?

I think it is a provocative question, but I think the other thing for us to think about is that sometimes what we need to do to address what is a relatively rare event gives us organizational capacity to

indirectly impact many other events.

So it is a bit of a struggle here. I think it is one that I just want us to keep in mind as we move forward.

Please do.

MEMBER GOESCHEL: Again, Chris Goeschel.

I think, to that end, I agree with you completely. Yet, I think -- and I know it is not the work of the National Quality Forum -- but we nodded earlier, the things that seem to be rare events in our individual organizations or the U.S. health system often are not rare when we look at global healthcare.

The world is small, and hospitals and healthcare organizations increasingly are looking at what is happening in the U.S. through organizations like NQF to learn from and not make mistakes. So I think, with that WHO hat on that I wear, I think it is really important and valuable to hold onto this

because, you know, Peter talked about the insurers are people that latched onto the serious reportable event list. That list has legs around the world. It may not be our primary focus, but we can't forget it.

CO-CHAIR MEYER: So, with that, now I have that we are almost at about 10:30. I think we should restart at 10:45. So we will take that 15-minute break. I think we will need the extra time that we will have by starting a bit earlier. So we will convene again at 10:45. And for those on the phone, again, we will restart at 10:45.

Thank you.

(Whereupon, the foregoing matter went off the record at 10:29 a.m. and resumed at 10:52 a.m.)

CO-CHAIR MEYER: We will go ahead and reconvene now.

For those that are the phone, if you, again, could just identify yourselves to us, the Committee members, that would be

helpful.

MEMBER RADFORD: Hi. This is Martha Radford. I'm here.

CO-CHAIR MEYER: Welcome back, Martha.

MEMBER RADFORD: Thank you.

MS. CANNON: This is Marge Cannon. I'm from CMS, and I work with Eddie.

CO-CHAIR MEYER: Okay, thank you.

And Helen?

MEMBER GANDHI: Gregg, it is Tejal calling in.

CO-CHAIR MEYER: Tejal Gandhi. Thank you. Welcome, Tejal.

MS. MURPHY: Melinda Murphy, NQF.

CO-CHAIR MEYER: Welcome, Melinda.

And Helen, are you still on? Okay, I think we lost Helen over the break, but, hopefully, she will rejoin us.

As I said before, before each session, we are going to try to be pretty explicit about what we are looking to be able

to have as a goal for that discussion. This one is relatively clear.

So, from now until around noontime, what we would like to do is we would like to come out of this discussion with either an endorsement of the current or a vision of the current definition of serious reportable events, and have that to the point where, after we hear some public comment, that we will actually be able to take a vote for the sense of the Committee.

So this will be a little bit of wordsmithing in real time, and I think we are going to rely on Jennifer to help us keep track of that in real time as we move forward.

But, very concretely, we want to come out of this next hour and 15 minutes or so with a clear sense of what this definition will be.

Now, as you recognize, there are more than one bites at the apple in the process that Helen and Peter reviewed with

you. So, if we don't get something perfectly right or, in retrospect, we think we need to tweak it a bit, there will be opportunities for that built into the process. But this will be what goes out to the field in terms of the call for events.

So I would like to begin by, again, calling your attention to a slide that Peter reviewed for us. You will also find that slide in your hard copy in front of you here, and it is labeled as page 11 and it is Slide No. 33.

This is the definition of serious reportable events, defined as: "Preventable, serious, and unambiguous adverse events that should never occur."

So I would actually like it if we could be reductionist about this, to actually pick off each bit of this as we go along, and begin first by acknowledging that first piece of it, and that is preventable.

One of the things I think that is

important is that you will see, again, going to your hard copy on page 12 at the bottom, that the slide there defines the definitions of the terms actually used in the serious reportable event definition. And there, you will see the definition of preventable is described as an event that "could have been anticipated and prepared for, but it occurs because of an error or other system failure".

One, if you read the report closely, you will actually see that they go on further to use the term "usually preventable". That may, in fact, be something that we want to think about.

So I am going to stop there and ask people to begin the conversation here. If you think that this is not the right way to tackle it, please speak up on that first and foremost.

MEMBER RADFORD: Hi. This is Martha Radford. I am going to jump in here.

This is a huge issue around

preventability and an intense gray area for many adverse events that happen. It really has to do with a gradient of contribution to the event from patient risk criteria versus care criteria.

There are going to be patients for whom every conceivable prophylactic measure against the anticipatable event is taken who will get it anyway. I think this is the most clearly manifest in VTE prevention, where all of the studies have shown reductions, but never elimination of a hospital-acquired VTE in high-risk groups.

So I just want to toss that out there as a remark, which is not to say that we should avoid these types of events. I think we have to deal with it, but just to acknowledge that preventability is never black and white almost.

MEMBER PHILIP SCHNEIDER: I think that is probably true. I think there are some adverse drug events that are clearly

preventable, like patients getting a drug to which they have a known allergy.

And I think about infections and some of the work that I did with the Nutrition Support Service. We tried to minimize central venous catheter infections. But I guess your aim should always be zero, but, you know, the fact is some people will get them.

So is it potentially preventable? Would that be an enhancement that would get at this issue that many adverse events will happen, no matter how rigorous or serious our intent is?

CO-CHAIR MEYER: I think, just in terms of process, if you could, I will try to keep track of everybody and periodically also pause and go to the phones, but if you could raise your hand, and if that is not working, we will move to the flipping up the cards. But I will try to get folks in order here.

Please.

MEMBER RYDRYCH: Yes, I would

agree with the comment that not all of these events are preventable. We see it mostly with pressure ulcers and falls, where there is that issue of patient autonomy or there might be co-morbidities. We have had very serious trauma patients that developed pressure ulcers, despite best efforts.

I do like the idea of potentially preventable because it is a bit more aspirational. There may be events that are not preventable right now with what we know right now, but that may be in the future, as best practices evolve. So getting that idea in there might be a good idea.

CO-CHAIR MEYER: Please, Michael.

MEMBER VICTOROFF: I will third, pile on.

I am congenitally opposed to zero tolerance philosophies because they are not realistic.

Also, I am going to interject what may get tiresome later, a liability risk

management viewpoint that puts anyone in the position of being associated with an allegedly preventable event, you know, at least one strike and you're out situation in terms of trying to defend it.

So I guess I would like to find the language. I don't have it right immediately. But I think, for me, the approach is going to be to qualify the word "preventable" by saying something like under the usual conditions of care or under the best conditions of care, best obtainable, best feasible conditions of care.

What I am trying to allow with that language is that sometimes you are not operating under the best possible conditions. I am thinking about times in the clinic when the power has gone out and floods and swarms of attacking killer bees. There's all sorts of less-than-optimal conditions. Maybe optimal, maybe the word "under optimal" conditions, something like that. But I need

to see that word "preventable" qualified.

CO-CHAIR MEYER: So, so far, we have a call at least to qualify this.

We will go to Cynthia and then Doron.

MEMBER HOEN: Yes, I think one of the frustrations of the people in the field with dealing with this term is that it somehow needs to be linked to proven best practices. So that, if I implement as a nurse those practices which have been proven to reduce or to prevent that event, that it won't happen unless there's outside influences such that the other members are talking about, the conditions of the environment which would cause it.

So, right now, the people that I talk to, there's not a lot credibility to the preventable part of this definition because it is not linked to what can we do to prevent it in the first instance.

CO-CHAIR MEYER: Doron?

MEMBER DORON SCHNEIDER: I was going to say the same. I think that if we use "potentially", which I like a lot, then we would need a definition of what that is. We can subsume all of these comments into that.

Do you see what I'm saying? To have "potentially" be defined as such, under "usual conditions", et cetera, et cetera, with the implementation of appropriate evidence-based care measures, et cetera, et cetera. That is what we are trying to capture with "potentially".

MEMBER RADFORD: I do like the "potentially" term, and I will agree that tying potentially into the evidence base might be a good way to proceed.

I would hope that perhaps you could share with the Committee the recent evidence base that was referred to in the introduction, the evidence-based review, I should say.

MEMBER TANGALOS: All right.

Well, I would say that I like the original three words. They have strong cache. They have been used a lot.

I think "potentially" will be just an argument in balls and strikes. I would suggest that, if we want to get at this end of it, though, maybe "never" should come out because the never event has its own cache.

CO-CHAIR MEYER: We will certainly get to that.

MEMBER TANGALOS: No, no, but that is the point, that that is an incredibly important concept right now. If we are talking about some wiggle room, then I would go after the never in that elimination, rather than preventable, serious, and unambiguous, because they have been in play for so long.

CO-CHAIR MEYER: Stan?

MEMBER RILEY: I guess I am going to argue again for different words here. I think "potentially" opens things up in an incredible way for all kinds of exactly as

Eric and I probably are going to say for arguments about it, you know. So exactly what is preventable or not?

I think the other problem is I am not sure that we have the tools to say something is potentially preventable, even something as terrible as retained foreign bodies. I mean, you know, there is a huge debate and pages and pages of articles written about, what can you do to prevent them? You know, x-rays don't work. Counts don't work.

So everybody has to have some real good tools to be able to do it to make it a preventable event.

CO-CHAIR MEYER: I have Philip, Diane, and then P.J.

MEMBER PHILIP SCHNEIDER: I guess, as I remember reading about serious reportable events, the "never" part really defines the scope of what is a serious reportable event in a very narrow way. By taking it out or diluting it, you really widely increase the

number of events that could be potentially reported.

I think of a "never" event as wrong site surgery. I can't think of any, no matter how inevitable it is because of the limits of human performance and human factors, it still should never happen, and we should constantly strive for no wrong site surgery. You should always strive for not leaving foreign bodies in patients after a surgical procedure.

So I think we need to be careful. I don't have any objections to "never" being in or out. But if you take it out, you are going to really increase the scope of events that would fall under this definition.

And I think there's some value in identifying a number of things, be it a relatively short list, 28 or whatever, that really should never happen, and for people to think about healthcare in a much more vigilant way than they have historically.

CO-CHAIR MEYER: Diane?

MEMBER RYDRYCH: I think we have to make sure we are thinking about what the purpose of this definition is and what the implications are of making a change to it.

My understanding of the reason why the serious reportable events list was adopted was in the hope that states, that other bodies, would begin doing public reporting based on these measures, and that it was an important accountability measure.

For us in Minnesota, it probably doesn't matter how we define this because we make it very clear that these are reportable events, whether a facility considers them to be preventable or not. So, whether we say it is potentially preventable, may be preventable, often preventable, it is a never event, it is not a never event, it is still something that we expect to be reported. We still expect for cause analyses. We still expect corrected actions. The facility may

determine that it wasn't preventable in their case.

But it feels a little bit like when we are talking about the definition here, we are saying that there might be implications to what is reportable if we change this definition. I think we need to be clear on that.

CO-CHAIR MEYER: Just one point of clarification before I move on to P.J. and then John.

That is that our job here is twofold in terms of the SREs. First of all, it is to look at this definition, but it also is to define the list. So those two go hand-in-hand with each other. So I would argue that this is not necessarily expanding this to 5,000 things or reducing it to one or two.

MEMBER RYDRYCH: Right. And I think as long as we deal with that as two separate topics or two separate tasks for this group, defining the definition and then

defining the list, we are okay. But if we start thinking of changes to this definition, potentially opening up the list to other types of events, then I think we are blurring the areas a little bit more than we probably want to.

CO-CHAIR MEYER: P.J.?

MEMBER BRENNAN: Gregg, I find it very ambiguous, a very ambiguous definition. And I want to agree with Eric's comments. The ambiguity is created by the fine detail in "preventable", "usually preventable", but then going on to say that they should never occur. So which is it?

I worry about setting the bar too low by introducing too many qualifiers in it. So I would prefer to have the fine print and say that it is preventable, it is unambiguous, and it is serious, but take out the language on "never".

I mean I agree that it doesn't matter whether it is never or not. It should

be reported. It is serious. In fact, I think if you take as an example central-line-associated bloodstream infections versus catheter-related bloodstream infections, as somebody who practices in this field, I think that really all the catheter-related bloodstream infections can be prevented. The central-line-associated is different. Not all of those can be prevented, frankly, because some of those don't come from the line; they come from the intestines of neutropenic patients, for example, and there is not much you can do about that.

So I would try to avoid the qualifiers on this.

CO-CHAIR MEYER: I think I had John next, and then Deborah and then Christine.

Before I do that, just one point of clarification. So, just so everyone is on the same page, so when you were referring to the fine print, what you were referring to is

the fact that preventable, if you go to the fine print, actually says "usually preventable" --

MEMBER BRENNAN: "Usually", yes.

CO-CHAIR MEYER: -- in the current definition?

MEMBER BRENNAN: Right. Right.

CO-CHAIR MEYER: Okay. John?

MEMBER MORLEY: John Morley.

I don't disagree with anything that has been said so far. I think there's been some excellent points made.

One of the things that caught my attention, particularly Diane's comment about thinking about the goal of this, clearly, the ultimate goal is that this is a tool for safety and for collecting information and for change.

But, in the shorter-term, I think this definition is what we use, then, to revise that list of 28 things that is at the end. I am looking at the list now. As I look

at the list, I could live with any of these things.

I particularly agree with what Diane said about, regardless of what is up here, in New York State we are going to set a bar about what is going to be required to be reported, whether it is potentially preventable or not. We are going to get those reports.

But, as I look at this list, I see some things in here that I don't think are 100 percent preventable, but I would like to know 100 percent of the time that they happen.

CO-CHAIR MEYER: Deborah?

MEMBER NADZAM: Yes, I was going to say the same thing. I like what Diane said. It makes me think, why should we even have "preventable" in there?

I wondered if you might give us some background about how it got in there in the first place.

CO-CHAIR MEYER: Boy, I am not

sure if my institutional memory on that exact one is clear. I do know that there was a lot of discussion around the "usually", and it was very much along the lines that we have had this morning now, is that there are some things -- I particularly remember one of the examples that came up was around pressure ulcers and the notion that some pressure ulcers in some patients, it stretches the imagination about how it will be potentially preventable.

So I can't really say anything more beyond that, though, in terms of the background.

DR. ANGOOD: Gregg, if I could just jump in, Melinda Murphy is on the phone. Melinda was involved in the early stages of this.

So, Melinda, do you have some institutional memory on the term "preventable", by chance?

MS. MURPHY: Well, I was just

looking back at the original report. I was not involved in the original report.

But there is a section in the commentary that added to the original report about the evidence for preventable that acknowledges that there was not an exhaustive review of the literature on preventability prior to selection of the events.

DR. ANGOOD: Thanks. That helps.

CO-CHAIR MEYER: Okay. Christine?

MEMBER GOESCHEL: Great. Thank you.

I would suggest and believe that the list needs to be as it was written, "preventable, serious, unambiguous". As I look at our definition of preventable, having had many discussions around this with organizations, the current definition says, "Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure."

As Diane said, there may be things

that are on the list that occur, but not because of an error or a system failure, that could have been alluded to.

I think the other thing, building on what John said, it seems as though our choice is to tighten the definitions, quote, "shorten the list" or expand the definitions, and see what happens with those. I don't think we want to go there.

I think people understand preventable, unambiguous, and serious. I think the opportunity to clarify what is on the list is useful. Beyond that, I think one of the opportunities that we have, as I understand it, is to make certain that, ultimately, reporting is important.

But, going back to where we started, the goal isn't reporting. The goal is eliminating these events.

So preventable helps me at an organizational level to know where I should focus my efforts. We could go after a lot of

things that are serious and reportable, but are not preventable. So I think "preventable" is a very important word.

CO-CHAIR MEYER: Sally?

CO-CHAIR TYLER: Yes. I think also that "preventable" is an important word. To me, one of the reasons it is important is that it really links back and reminds us of evidence-based care and brings the whole evidence-based process into it.

There are things we know to be effective, to make a difference, that should be done. That is something I think that is very important in the public accountability concept, that this should link back to evidence-based care.

I also very much agree with -- I hadn't thought about it until Eric brought it up, but the concepts of "preventable" and "never" work at this from different sides. If we modify it to "potentially preventable", then it does certainly -- it is hard for us to

say it should never occur. So I think it is a very good point.

CO-CHAIR MEYER: Helen?

DR. BURSTIN: I was just going to say I did grab the 2002 report yesterday before I left the office, thinking it might come in handy.

Just a brief paragraph here about they actually struggled with "unintended" versus "preventable", interestingly enough, in the initial report. They tried to make a distinction between "unintended" and "preventable" as a criterion for events, because "unintended" was considered to be less associated with the implication that someone was to blame for an event, and was also considered to have the advantage of capturing the events that, upon analysis, suggest methods of prevention that would otherwise be unknown.

"On the other hand, there was concern that many unintended events are truly

not preventable, given current knowledge. Reporting such events to an external body, particularly if the data were eventually summarized for the public, would lead to misunderstanding.

"Ultimately, the Steering Committee agreed that `preventable' was the more relevant concept for the intended purpose, but because few classes of events are always preventable, the Steering Committee concluded that an event be judged `usually preventable' to qualify for the list.

So they certainly make many of their own qualifications in their determination of words as well.

CO-CHAIR MEYER: Eric?

MEMBER TANGALOS: When you go back to the 2002, I had a flashback of working on a mission statement, any mission statement. I mean tread carefully when you start to revise mission statements. Essentially, that is almost what we are looking at here.

CO-CHAIR MEYER: Michael, and then I am going to take the Chairman's prerogative and try to move this --

MEMBER VICTOROFF: I think the point about mission statements is very good. I think it is important for me to make sure that we have a very clear slogan expressed in unambiguous terms.

The first three adjectives are fine for me with these qualifications in the fine print; I really think the fine print is important when we talk about preventability because preventability is a very large concept. There is a lot packed into it.

But I really feel it is important for me to remove the word "never" because not only is it used as a bludgeon by people who are more interested in blame than in problem-solving and in litigation, it is a bludgeon potentially.

But it is a trivializer because anything that happens that somebody doesn't

like should never happen or never had happened or never did or never could or never might or never should. No one should have their parking ticket not stamped when they leave the hospital. There's all kinds of "nevers".

So it ruins the force of the slogan for me by attaching that caboose to it.

CO-CHAIR MEYER: I think we have actually heard from just everyone at this point.

What I would like to do is just put a proposal just for us to chew on. That is, I think that one of the things that is important here is that there is the existing fine print.

Just to remind people, that fine print, again, is on page 12 of your hard copy. It says, "Use of the term `usually preventable' recognizes that some of these events are not always avoidable, given the complexity of healthcare."

I think that that is quite

consistent with what we have heard around the table here.

To that end, and again, I do think there is a conflict between "preventable" and "never", "potentially preventable" and "never" that we would introduce here.

So, if we left it as preventable, but kept the footnote, kept the clarification, would that work for people? Or do people feel that we need to pull the word "usually" right up into the definition, rather than have it down in the footnote?

MEMBER BRENNAN: Gregg, you would leave in the final clause on "never"?

CO-CHAIR MEYER: I would not.

MEMBER BRENNAN: Okay.

CO-CHAIR MEYER: Let me just, if I can jump ahead here, what I would say is, "Serious reportable events" -- by the way, we can't change serious reportable events; we are given that -- "defined as preventable," with the footnote "serious" -- I don't think there

is going to be any argument about the "serious" -- "and unambiguous adverse events." Full stop.

MEMBER BRENNAN: I'm okay with that.

MEMBER RYDRYCH: Just a comment. We have really been trying to move away from talking about never events in our State, for all the reasons that people have talked about.

But I do wonder, and I don't want to quite be devil's advocate on this. But one of the downsides of talking about "never" is what we have said, that these are not always preventable. I think it is that fear of being labeled publicly, because we have a public report. The fear of a lot of hospitals is, you know, your name shows up in a report; this is something that never should have happened. That anxiety drives a lot of the dynamics in our State. So that is part of why we have moved away from it.

But the one silver lining of it is

that I think it has also driven a lot of urgency around change for these events. So I do wonder, do we lose some of that urgency of the serious reportable events or some of that sense of priority for them if we take out that clause entirely? Is there a way to modify it that still gets at the importance of reducing the numbers of these events, but still acknowledges that they in many cases should not occur?

I would agree that there are some that are "nevers", there are some that are not. I am not sure that that nuance can be captured in one phrase, but I just wanted to make that observation.

CO-CHAIR MEYER: I have a response to Diane, but before I do, do others have a response to her comment about just removing --

MEMBER GANDHI: Gregg, this is Tejal on the phone.

CO-CHAIR MEYER: Yes, please.

MEMBER GANDHI: So I still worry

about the falls and the pressure ulcers and this issue of preventability really. You know, people at the hospitals who are trying to report, the preventable thing ends up being a real sticking point for many.

I just wonder about -- I didn't think "potentially preventable" was going to be good because I think that is just opening it up to way too many things. But I wonder if -- I know there is a footnote, but I just wonder if, instead of having it in the footnote, if the word "usually" was up in the main definition, that might just help quell many of these debates that happen in the hospital about, "Oh, that fall wasn't preventable because...." You know, there is so much debate about that unnecessarily sometimes, I think.

I wonder if people will really get to the footnote versus if it was just in the main definition to use the word "usually".

MS. CANNON: This is Marge Cannon

from CMS. I am one of the medical officers at CMS.

I really like "preventable" in there kind of as a standalone, only because it kind of really packs a punch, so that you know that your hospital system is going to go back and look through that case specifically and highlight that case and say, "What did we do or did not do that could have prevented this outcome?"

Of course, they will do their own investigation. As a clinician, we all know that there are going to be one or two cases that there is nothing you could have done to prevent it. But I really think that the stronger language -- I agree with taking the "never" out, but I really think the stronger language and the power that prevention packs in highlighting the incident is really valuable and useful in retaining, and maybe not doing a caveat except as a footnote.

Just my thought.

CO-CHAIR MEYER: I don't think anyone has proposed removing the word "preventable" in total. I think it is a question as to whether or not we qualify it further.

MS. CANNON: No, but my thing is I think that it should -- I really like it in there without qualifying it in the main body.

CO-CHAIR MEYER: Please, Christine.

MEMBER GOESCHEL: Just a quick comment. I would agree with you wholeheartedly. Although I know organizations struggle with this, being perfectly candid, many organizations look and, with any sort of qualifier that says "usually", they will discern that they are different and that theirs were not preventable.

I think, for people that are alarmed by the word "preventable", the opportunity to read the footnote is a small amount of effort to begin to look at their own

events more systematically perhaps.

I think "preventable" to stay the way it is without a qualifier in the definition.

CO-CHAIR MEYER: I just did want to respond to Diane, because I think your point is well-taken that we don't want to lose the urgency that is implied by the final tagline there of that should never occur.

On the other hand, what I would argue is that the world is a different place in 2009 than it was in 2000 or 2002, in that you and a number of the folks represented around the table here are in states where the reportability piece is there. The reality of it is that these things are not going to go, the urgency is not going to go away, by definition, because of what you are doing.

In fact, that is exactly what the original intent of creating this list was, was that states would pick this up and ask people to report on it.

So I am not sure that we are going to lose any urgency here. I think that urgency is almost hardwired at this point.

MEMBER RYDRYCH: I would say yes and no. And again, I want to say I don't like the "never" term, and we don't use it. But I think we do face in our State a loss of urgency around this in some ways because we have been doing it for a number of years, and because the coverage of our report and our learnings has almost become routine now. It is like, "Oh, here's another report from the Health Department. Look, more of these things happened."

Because we have been so successful at giving the message that they are not always preventable and that there is going to always be some level of these events, I think it has ended up sometimes coming back to bite us, and reinforce the idea that there's a level, maybe higher than what it should be, that is okay of these events.

So I don't know what the answer is on that clause because I don't like the "should never occur" clause, but I do think that thinking of them all as "nevers", thinking of them all as "preventable" has led to more aggressive action in our State and more aggressive change in our State, especially in the early years, because it was sort of a goal, one we knew we would never achieve, to prevent all of these, but a goal, nonetheless.

There may not be any way of putting that into a definition, and it may not be necessary to be in a definition. It may be just one of the caveats that is part of this.

But it is certainly a tension that we have experienced. I don't know if other states have as well.

MEMBER GANDHI: This is Tejal Gandhi again from Partners.

I actually agree with you in the sense that, you know, in the State of

Massachusetts or at Partners, about 60 or 70 percent of the events reported are falls. Then a large percentage of those after -- I mean everybody does root-cause analysis on all of these, and so on. Many of those are deemed not preventable.

I think the message ends up getting blurred because that is sort of the message of, oh, you know, here are the SRE rates, but most of these were falls; many of those were not preventable. Then they lose sight of the retained foreign bodies and the wrong site surgeries, or whatever, because they got diluted by that 70 percent falls issue.

So part of me wonders about being inclusive of these events, where I know we want to know about falls, but include things like the falls and pressure ulcers, where there is so much debate about preventability; I think some of the ones that we truly think really should not happen, like the wrong site

surgeries, kind of get lost.

CO-CHAIR MEYER: We will have an opportunity to talk about specifics on the list, to do that later on this afternoon.

MS. MURPHY: Gregg, may I make a comment? This is Melinda.

CO-CHAIR MEYER: Please do, Melinda.

MS. MURPHY: I looked back in the 2002 report and the 2006 report. The term "never" is used in the document. It is, however, used outside of the criteria for identifying the event.

So, in 2002, it says, "a serious preventable adverse event sometimes called `never event'", and that is just in the introduction to the document.

In 2006, in the criteria for inclusion verbiage, outside the criteria itself, it says, "The listed events described in this report that meet those criteria is not intended to include all events that might

possibly be useful to the report and that do not include all events that should never occur."

But the term itself is not used inside the criteria.

CO-CHAIR MEYER: I think that point is well-taken. I think that one of the things that we will do, after we review the definition here, is go through those criteria.

But operationalizing this, in fact, it was not part of the language. So it really calls into question why it was there at all. Again, there are some historical reasons why it was there. Perhaps those have faded.

Deborah, and then I am going to try to move this along a bit.

MEMBER NADZAM: Yes, I am just recalling that, when this group first got started back in 2001 or 2002, it was called the Never Events Committee, wasn't it? Didn't you all purposely change it, as I recall from Dr. Scheibe's participation on that, I think

hearing about it?

CO-CHAIR MEYER: The history of the term "never events" is that it actually came out of an early discussion around the contract to create this Committee. At that point, it was Dr. Kaiser's interpretation. He was the one who coined that phrase at that point in time.

CO-CHAIR TYLER: I just had a question. I guess I had always been taught that, in coming up with a definition, that you don't use within the definition itself a word that is in the word to be defined. So I am wondering why "serious". It is "serious reportable events", and then we say, "What's a serious reportable event?" "Well, it's serious."

I mean that is a bit circular. You know, there is a reason it is not done. It leads to sloppy thinking in some ways. So I am wondering.

I know that we actually define now

"serious" as well. But I am wondering if that is necessary and if that is the best way to do it.

DR. BURSTIN: I just think it would also be helpful that I think it is important to remember that we are going to come back to this after you try to nail down what HACs, whatever this broader term is.

I think, again, it would be helpful to sort of think about how these come together logically. So I think it would be a good place to start, but don't forget you will have, I think, another chance at it, once you get the bigger sense of it.

CO-CHAIR MEYER: John?

MEMBER MORLEY: As I listen and go around in circles in my own mind on the thoughts that go back, I still end up back with what I had said before. The importance of this, even more clearly now to me than five minutes ago, is just that this is a definition that will help me to define that list.

The purpose of putting this out there is for transparency, so that the public sees what this Committee was thinking.

I don't think that that is something that I am going to use in terms of an argument with an institution about what is reportable or not. It is a serious reportable event. Here's the list. It's reportable. That is it.

Whether I am using my old CMO hat or my new regulator hat, I am going to be going with the list and saying: this was what was used to create the list.

CO-CHAIR MEYER: I think that is the reality there.

So what I would like to do is I would like to try to move us on to actually start to take a look at the criteria here.

There are a couple of questions that I think are kind of left on the table on that. Actually, I am going to ask for folks in the room here to go for a hand vote. What

I would like to do with those of you on the phone is I will call on you at the end, and we may vote by exception, just to make it easier.

The first issue I would just get a sense of the group on is whether or not folks are comfortable with leaving "preventable" with the existing footnotes and definition in unqualified. So it would say, "Defined as preventable".

Again, I would ask just for a raise of hands of those who are comfortable with leaving that as is.

(Show of hands.)

Okay. That is the vast majority here.

And those on the phone, do any of you feel that it needs to be qualified?

MEMBER GANDHI: Do you mean in the footnote or do you mean in the body?

CO-CHAIR MEYER: No, I mean in the definition. No one, I think, has suggested the footnote would change, and I think the

footnote is very consistent with the conversation.

MEMBER GANDHI: Okay.

(No response from those on the phone regarding the vote.)

Okay. So I think we have a pretty clear sense there.

The next is well-taken. That is Sally's about, is the "serious" redundant? I think probably, if there are any English teachers here, I think they probably would say yes. On the other hand, one could say, boy, it really hammers it home.

And, P.J., you have a quick comment on that particular issue before we --

MEMBER BRENNAN: Yes. Gregg, in the electronic version of the document that I am looking at, in the Executive Summary, "serious" is defined, and it is unambiguously defined.

CO-CHAIR MEYER: It is. It is.

MEMBER BRENNAN: If you read that

fine print, it is pretty clear, yes.

CO-CHAIR MEYER: Deborah, are you wearing your English teacher hat?

MEMBER NADZAM: No, I'm not, although when I saw that definition, too, as long as you have it up, I am looking at your screen, that last clause "an event, the occurrence of which is not trivial", it is kind of awkwardly stated. Then we run into what is "trivial".

CO-CHAIR MEYER: And just to call that out to people, that is on the bottom of page 12. You will see that that is a definition, using necessary criteria.

Sally, please.

CO-CHAIR TYLER: Yes, and I guess "serious" bumps up against "adverse", how they differ, how they overlap. Do they replicate each other?

"Adverse" is described as a negative consequence of care that results in unintended injury or illness which may or may

not have been preventable.

CO-CHAIR MEYER: Michael, and then Philip.

MEMBER VICTOROFF: Well, just speaking very quickly in favor of not changing it, although I think technically there is a slight pedagogical problem with redundancy. But the use of this, the point of this, I think, going back to what John was saying, why do we care?

These are things about which there are actions that could be taken to reduce the rates, not maybe make them vanish from earth, but to reduce the rates because we care about rates. And they are important because they are more important than other things that we could also be working on. So we should prioritize these things because they will, either in magnitude or in quantity, impact the experience of our patients more than the things that we would say are trivial.

So, for those kinds of reasons,

qualitative reasons, I would just leave it alone.

CO-CHAIR MEYER: Okay. Philip?

MEMBER PHILIP SCHNEIDER: Well, you know, my sister's a PhD in English. So I am steeped in this stuff.

I agree it has a redundancy to it, but if I take it out of either the title or the definition, it bothers me; it is not complete enough.

So I am wondering whether we could --

CO-CHAIR MEYER: It can't be taken out of the title. We don't have that leisure.

MEMBER PHILIP SCHNEIDER: Right. So, therefore, I will just focus on the definition then.

One option would be to change "serious" to another word. "Significant" would be one that comes to my mind. Then maybe you would define "significant" in the way that "serious" is defined on page 12.

CO-CHAIR TYLER: That was, actually, what I was just going to suggest. I think that would make a good --

CO-CHAIR MEYER: Well, how about that?

So further comments on that? Okay, I see some head nods around the table on that.

Yes, I'm sorry. Please.

MEMBER HOEN: From a legal perspective, which I can't leave behind here, I really do not need another word to define in that definition. So to have "serious" in both places, I agree is not the perfect model. I would rather leave it out of the title and have it in the body defined. But to put in another fourth word, which then becomes the subject of definitions, from a legal action, is problematic.

CO-CHAIR MEYER: I think the suggestion was that it would say -- "serious reportable events", again, we can't change

that piece.

MEMBER HOEN: Right.

CO-CHAIR MEYER: Defined as "preventable, significant, and unambiguous".

MEMBER HOEN: But now I have got to define "significant" and then "serious". That could become debate.

CO-CHAIR TYLER: But I think what Philip was suggesting -- and correct me if I am wrong -- that "significant" would be defined as "serious" is defined in our breakout. Right?

MEMBER PHILIP SCHNEIDER: That is right. I wouldn't define "serious" anymore. I would change the word "serious" in the definition of terms used to "significant". So there wouldn't be a fourth term. There would only be three.

MEMBER DORON SCHNEIDER: Reporting near-misses is important. I just worry about, when we use "significant", you know, it, to me, kind of opens it up to who is it

significant for. I need to know, as a safety officer in my institution in the State, that other things are occurring. And "significant" I think opens it up to further problems.

MEMBER GANDHI: I would just comment that in the adverse event literature there is often severity classifications, and the classifications are significant, serious, and life-threatening. So "significant" and "serious" are two different classifications in much of the literature around adverse events, particularly adverse drug events. So I think that would lead to some confusion.

CO-CHAIR MEYER: Thank you, Dr. Gandhi.

Diane?

MEMBER RYDRYCH: We might be getting into the territory that Michael talked about before, where we are trying to find the perfect term when we really need to look at how we describe it in our definitions.

I think whether we choose

"serious" or "significant", it is going to be ambiguous. For events that we are describing as unambiguous, our definitions are always going to be ambiguous on the ground in some sense.

I know that we get pushed back sometimes on "serious". Because people don't understand that "which is not trivial" clause, we get pushed back when there is no patient harm. There are cases where people think that should not be a reportable event or something that needs to be learned from if it didn't involve patient harm. So I think we will run into that problem either way.

So, despite the redundancy in the definition -- and I will play the English card, too, and say I used to be an English teacher -- despite the redundancy, I would keep the "serious" in there.

CO-CHAIR MEYER: I would, again trying to move us to a decision here, I think that Dr. Gandhi's note that "serious" and

"significant" are defined very differently in an important way in the safety science literature I think is well-taken.

So, with that, what I would put on the table is, basically, a vote, those in favor of leaving serious in as it stands -- we will, actually, look at the specific definitions, by the way. This is the first part. We've got so more work to do after this.

So those in favor of leaving "serious" in? And a vote to the no is actually that we would take "serious" out. So those in favor of leaving "serious" in?

(Show of hands.)

Okay. All right, and again, those on the phone, is there anyone strongly in favor of taking "serious" out, since the majority of folks here in the room voted in favor of leaving it in?

MEMBER RADFORD: I would leave it in.

CO-CHAIR MEYER: Okay. So we now are left, the next term we have is "unambiguous". Again, I would call to you, on page 12, "unambiguous" is defined as "refers to event that is clearly defined and easily identified".

I would say "unambiguous" is an aspirational term for those of us on the frontline trying to figure this out every day, but it did seem to carry some import.

MEMBER TANGALOS: I would leave it in. I think it will be a term that will be retired in the next decade. It is an overused -- it is one of those words that gets overused. But I wouldn't change it.

CO-CHAIR MEYER: So you are suggesting that we punt this to the 2020 update?

(Laughter.)

MEMBER TANGALOS: Yes. Yes. That's a good idea.

CO-CHAIR MEYER: Hard to argue

against that.

(Laughter.)

Stan?

MEMBER RILEY: In a way, I guess I agree, but at the same time, being on the frontlines, you know, we get a lot of pushback about "unambiguous". You know, what exactly does that mean?

You tell people the definition here, and it still is like there is just a lot of controversy, at least out in the frontline, about "unambiguous".

And it is hard to counter arguments about it. Although I have to tell you the truth, I think it should be in there. It just is one of those things that you can expect a lot of pushback from.

CO-CHAIR MEYER: Philip?

MEMBER PHILIP SCHNEIDER: I think "unambiguous" refers to the event itself rather than the causality, right? Is that right? Because causality is highly ambiguous,

but the event itself is usually -- I am not too uncomfortable with --

CO-CHAIR MEYER: It refers, specifically in the definition, it refers to the event. To the event.

MEMBER PHILIP SCHNEIDER: I am okay with it.

CO-CHAIR MEYER: Diane?

MEMBER RYDRYCH: Yes, and I would just note I am fine with it, too. But I think part of this comes down to the guidance that is part of the definition of each of the individual 28 events, right? So, if we are looking at potentially modifying the list of the 28, I am assuming modifications of that definitional guidance might be part of that as well, which helps to make them a little bit less ambiguous.

CO-CHAIR MEYER: Absolutely. Absolutely.

Anyone in favor, again, just a quick vote, anyone in favor of removing the

term "unambiguous"?

(No response.)

Okay. Seeing none.

Anyone on the phone in favor of removing the term "unambiguous"?

(No response.)

CO-CHAIR MEYER: Hearing none --

MEMBER GANDHI: I'm good.

CO-CHAIR MEYER: Okay. So we will leave it in.

And the final point here before we can move on is -- and I will, again, put this in terms that we have had a fair amount of discussion -- is anyone in favor of leaving the clause "that should never occur" as part of this definition?

Philip?

MEMBER PHILIP SCHNEIDER: I am not opposed to it, but I will say that it kind of reduces the impact factor to the public. If there is an interest, and the issue of urgency comes to my mind, and when you see things that

are reported, that catch phrase "never events" establishes a sense that healthcare providers are really interested in making sure that some things really don't happen. I think there is some public relations elements to that statement that we will lose.

Having said that, given the nature of what we are going to try to do, the fact that it is almost impossible to make sure that something never happens, I probably would support taking it out. But I do think we are going to lose some of the top spin that is embedded within this definition.

CO-CHAIR MEYER: I do think one of the things that we can, as a Committee, really provide a sense of the Committee to the Quality Forum staff is that folks did identify this issue of urgency and the idea that we want to keep the spotlight on this. That is actual work for the NQF to do, to help ensure that that continues.

John?

MEMBER MORLEY: Right now, I am hearing that there's two choices, essentially; you know, either keep it in or eliminate it entirely.

I agree with the comments that were made that it does de-emphasize the statement a bit. Is there a third opportunity to say something along the lines of "that should not occur"? The heat is really attached to that word "never" for lots of reasons. Can it be a third one? And I offer as the third possibility "that should not occur".

MEMBER RADFORD: I would also like to see perhaps a little bit of discussion in the document that comes out of this about, you know, the tension in using the term "never events", whichever way we decide, to take it out or leave it in, around this issue of the urgency versus the bludgeon. I think that was well-put.

CO-CHAIR MEYER: If I could, we

are just going to pause for one moment to welcome Leah Binder.

Leah, welcome to our conversation. If you can, Leah, just quickly share your background, and also your conflicts, with the group. Then we can move on in the discussion.

I would just remind folks to use the microphone because that is the only way the folks on the phone can hear us.

MEMBER BINDER: Okay. I am Leah Binder, and I am CEO of the Leapfrog Group, which represents purchasers of care. We focus on hospital care quality.

Conflicts, I am not sure we have conflicts. I don't believe we have any, but we have a strong interest in never events. We did have a major policy on never events that we were the first national organization to issue, which identified the 28 serious adverse events from NQF back in 2006.

CO-CHAIR MEYER: Other comments on this? So further discussion on this notion of

"that should not occur" versus "that should never occur"?

MR. GARCIA: Can I just make a statement on that?

CO-CHAIR MEYER: Please do.

MR. GARCIA: I would support this change away from "never", the word "never" and changing it to "not", to maintain that urgency on this list of SREs.

Then, looking to the next definition on the HACs, to have a broader, expanded list, maybe events that aren't as rare or potentially could occur.

I think that is something we need to look at in the discussion. I really think the SRE list is good the way it is. I think we should maintain that urgency with it.

CO-CHAIR MEYER: And you feel that using the word "not" would continue to do that --

MR. GARCIA: I think so.

CO-CHAIR MEYER: -- in a way that

would be helpful to it? Okay.

Christine?

MEMBER GOESCHEL: I don't want to belabor this, but I think, if it helps, for those who do a quick read, to have "not" in there, it is fine. But at my core, and as leaders in this field, the fact is that anything that is adverse and preventable brings with it that it should not occur.

So, I mean, I think we don't want to lose sight of the fact that we also need to have NQF staff, as they write the report, make certain that the broader meaning of all of this is not lost.

CO-CHAIR MEYER: Okay. Further comments? Leah?

MEMBER BINDER: I guess I am jumping right in. So apologies if this is out of context.

The term "never" is very important. I know to our constituent the term "never" actually really does matter, has a lot

of resonance.

If I had to name one thing, one issue in the Leapfrog survey that is of most importance to purchasers, it is the never events policy. The word "never" is a powerful word, and it states that these events are just so catastrophic that they should never occur. I mean it just has a resonance and importance.

So removing "never" from the definition, if that is what we are talking about, would have very serious -- it would be a statement, in and of itself, that we have removed the word "never" from something that has had such a powerful impact in the field.

CO-CHAIR MEYER: So, just to catch you up, we have actually had a fair amount of discussion around whether that "never" needs to be in there. I think that folks have come to a place where at this point what I would like to do is I would like to move us to making a decision on this, unless people have further discussion.

Anyone on the phone have any further comments before we start to get a sense of where the Committee stands?

Yes, please, Cynthia.

MEMBER HOEN: Just one comment. I think I heard a different opinion on whether that terminology stays in there if we remove pressure ulcers and falls from the list than I do when they are on there. So maybe this is an issue we should leave right now -- I don't know how the rest of the Committee feels -- and move on and maybe look at some of those other things.

CO-CHAIR MEYER: So I would propose, actually, I think that is an excellent point. I do think that what we ought to do is, at the end of the afternoon, hopefully, if we get through the list, go back and circle back and see if this works. But I would like to still get a sense of the Committee now, just because I think that that is one of the deliverables that we have been

asked to work on today.

So, if I could call the vote, the first vote is for those who feel that the phrase "that should never occur" should remain in. So that would be keeping the phrase "should never occur".

(Show of hands.)

Anyone on the phone feel that the term "should never occur" should remain in?

(No response.)

The second question would be, do those who feel that the term "that should not occur" should be in the definition -- "that should not occur"?

(Show of hands.)

So we have a bit of a split here. So one, two, three, four, five, six, seven.

And on the phone, if you could please let us know if you feel that the term "that should not occur" should remain in?

MEMBER GANDHI: This is Tejal.

I would be okay with it.

MEMBER RADFORD: I would agree with that.

CO-CHAIR MEYER: Okay. So let me do this a little bit more formally.

So, Martha, "that should not occur", should that be in our out of the definition?

MEMBER RADFORD: I have no problem with it being in the definition, but I would like to see a short paragraph of discussion about it.

CO-CHAIR MEYER: Okay. Helen, are you with us?

(No response.)

Okay. And Tejal?

MEMBER GANDHI: "That should not occur" is fine with me.

CO-CHAIR MEYER: Okay. And any other voting members on the phone?

(No response.)

Okay. Again, anyone, just so I can clear it up completely here, anyone who

feels that that term "that should not occur" should not be in the definition?

(Show of hands.)

Okay. So one, two, three, four, five.

Okay. So, for those on the phones here, the majority are in favor of adding the term "that should not occur". With that said, there was a split vote, and that is something that we try to avoid, whenever possible.

I am not sure at this point in time that further discussion of this out of the context of the list itself is going to move us across the finish line.

So what I would like to do is I would like us to leave this stand as it currently states here.

And for those on the phone, the current definition is: "Serious reportable events defined as preventable, serious, and unambiguous adverse events that should not occur."

What I would propose is that, at the end of the day when we review the list, we go back to this and see if this is still working for the group.

Okay. The next step, that is great. We have made some progress there. So congratulations to us on that. You know, that works. That works, yes. Okay.

If you could just move to the next slide, please, Jennifer?

Just to remind you that behind this are the criteria. I do think we should spend a moment and reflect on whether or not there are any changes.

It looks like we skipped some there, Jennifer. If you can go back up, just do the PageUp function; it will be easier. Yes. So if you can leave it there?

So an event must be unambiguous, usually preventable, serious, and any of the following. So these are the criteria that are up there.

If we can go back to that, please? Leave it there for now.

So, if people can take a look, again, for those of you with hard copy, this is on page 12, the middle slide there.

And the question is, does anybody feel that we need to make any changes to the criteria? These are the criteria that we will use this afternoon to look at the current list and to consider additions or deletions.

MEMBER TANGALOS: This is Eric again.

Now this "usually" gets in there. I would have to say that is ambiguous.

DR. BURSTIN: Just one point of clarification. I underlined "usually preventable". It is not in the book, just for point of discussion. So it is not underlined in the actual SREs, but it is there.

MEMBER TANGALOS: But it says, "usually". And I am glad you underlined it. I mean I don't think you needed to; we would

have caught it anyway.

CO-CHAIR MEYER: And so, Eric, what you are saying is you're saying that, if it said the use of the term "preventable" recognizes that some of these events are not always avoidable, given the complexity of healthcare --

MEMBER TANGALOS: Well, that is enough.

CO-CHAIR MEYER: That is enough?

MEMBER TANGALOS: I mean, for me, the less said, the better. I don't like arguing balls and strikes.

CO-CHAIR MEYER: That is a fair statement. It would have to come out from both sides, yes. Yes. Yes, I think that that is fair.

Diane?

MEMBER RYDRYCH: Just a small grammar comment. Are those really "and/or's" or should they just be "and's"? Because the way we have it written here, it could be

adverse or it might not be adverse, but indicative of a problem, or it might not be either one of those, but important for public credibility. I would argue they should probably be "and's".

CO-CHAIR MEYER: I think they are. I agree with that. But, with that said, I am interested if other people, you know, different people read it and have different interpretations. Do people look at that differently?

So we've got Michael.

MEMBER VICTOROFF: I am not quite clear what this slide means. If this were the typical PowerPoint, non-grammatical, typographically illiterate slide that I often use, it is fine. But if this actually is language for a report, then it is illogical, and the fourth bullet doesn't parse with the verb of the subject. So it really needs to be rewritten.

This is not an English teacher

because I barely speak English, but I was a philosophy major. So this is a logic issue.

MEMBER RYDRYCH: I think the fourth one is not intended to be part of the definition. It is more an elaboration of --

MEMBER VICTOROFF: Well, okay. So, now looking at the fourth bullet itself, you see the glaring problem logically with it? On the slide, it looks like a bullet. But in the text --

CO-CHAIR MEYER: So Helen?

DR. BURSTIN: Just to clarify that, it actually is A, B, and C. Then, underneath it, they define usually preventable outside of the scope of the criteria.

MEMBER VICTOROFF: Okay. So that problem is solved. But the "and/or" needs to be --

CO-CHAIR MEYER: And just to help to orient folks, if you look at your briefing document, under the section on definitions, it states, "To qualify for the SRE list, an event

must be unambiguous, usually preventable, serious, and any of the following adverse and/or indicative of a problem in healthcare facilities, safety systems and/or important for public credibility or public accountability."

That is where it does stop there. The "usually" is in the paragraph beneath.

Please, Cynthia.

MEMBER HOEN: Yes, I think that the "and/or" is very important because I think that allows a broader group of conditions to be listed, based upon those criteria. If you say, "and", "and", "and", it is going to be very difficult to define anything that will go into there.

MEMBER VICTOROFF: Let me clarify. You can't have "and" alone and you can't have "or" alone. So, if you insist on having a conjunction, it's got to be "and/or". But, in fact, having a conjunction there is not necessary since you have already said that

these things are inclusive above.

So now, really, that settles my objections. If you are going to put a conjunction at all, it needs to be "and/or", and I could live with that, if we have to. It is not vital.

MEMBER RYDRYCH: Is it any of the following or is it all of the following?

MEMBER VICTOROFF: Any means "and/or".

CO-CHAIR MEYER: Yes, what this says is, just to remind you, the wording here says, "To qualify for the SRE list, an event must be...." Now one could argue to say we, as a Committee, would say that it pretty much ought to be all three of them. With that said, what the criterion says specifically, it says, if it not one of these three, then it can't be on the list. So the current language leaves it open a little bit.

And actually, if you could, Jennifer, if you would go to the background

document quickly, just to pull that one up? It is a Word document. Let's put that up, and then we will get people to look at that, and I think maybe we can solve this relatively quickly.

Maybe not so quickly. So maybe we will go to Deborah, if you can --

MEMBER NADZAM: Yes. I think, if it says it can be any of the following, you just need commas in between or nothing. Because something can be adverse, but not indicative of a problem in the healthcare facility.

I mean we just went through all that "preventable" and "never" discussion. So I would be for leaving it "any" and dropping the "and/or's". I mean it is almost redundant.

CO-CHAIR MEYER: And again, just to remind the group that what we are producing is an NQF consensus-based list. So, to those of you that may have a visceral reaction to

say, boy, we are really opening things up by saying you just need one of these three, the reality of it is that the work of this Committee is to decide what is on the list and what is not on the list. So, to me, that is relatively clear.

DR. ANGOOD: So, while we are fussing on that, while we are fussing on the technical side, in the briefing document, on page 4 of that in the .pdf, is where --

CO-CHAIR MEYER: Right.

DR. ANGOOD: -- Gregg is making mention of this.

CO-CHAIR MEYER: So I guess I will put the question on the table, is the "and/or" necessary? On that, I am getting a bunch of heads saying, no, they don't really feel it is. But let's project it up here, so everybody is on the same page and we know where we are.

Right there. Right there in the middle.

So "to qualify for the SRE list".

So the question on the table is, do we leave the "and/or" in or out?

MEMBER TANGALOS: Again, we have been discussing proper English. My understanding is that that isn't proper English anymore; "and/or" doesn't fit.

CO-CHAIR MEYER: Who wants to leave "and/or" in? Raise your hand.

(No response.)

Seeing none, we will remove "and/or". It will be the bulleted list.

I'm sorry. For those on the phone, does anyone feel showing that the term "and/or" -- this is on page 4 of your briefing document, is the paragraph in question. Does anyone feel strongly that we need to leave the term "and/or" in?

MEMBER GANDHI: I don't feel strongly either way.

CO-CHAIR MEYER: And Helen?

DR. BURSTIN: And just for

clarity, at the end of the day, I want to be sure you have also grappled with the question of, do you think they should be "and's"? Now that you've gotten past "and/or's", just to be clear, is there any reason for "and's"?

MEMBER RYDRYCH: Although, as the person who suggested that, I am going to take that off the table, as I think a little further.

CO-CHAIR MEYER: I think that that would in some ways maybe hamstring us a little bit in the future in terms of what we could consider.

DR. BURSTIN: I just know we are going to get asked that question. So I was trying to preempt it. Thank you.

CO-CHAIR MEYER: It allows it to be open, I think.

DR. BURSTIN: Yes.

MEMBER PHILIP SCHNEIDER: You know, if you look at page 4, it says, "any of the following". So "any" is inconsistent with

"and/or" in a way.

CO-CHAIR MEYER: We are making progress. We will move on, if we could.

Boy, I am really going to test your skills here, Jennifer, because I am going to ask you -- actually, let's move to the next slide here. PageDown. Yes.

So these are the definitions of the terms that are used in the SRE criteria, and some of them are also used in the SRE definition.

And again, if people could take a moment to look at these, just to orient folks, it is the last slide on page 12 of your hard-copy handout. There are five terms that are identified here: event, adverse, preventable, serious, and unambiguous.

We have had a little bit of a discussion about the term "serious", but let's takes these in turn.

Anyone have any objections to the current wording of "event" or suggestions for

modifying it?

Deborah?

MEMBER NADZAM: The way it is currently defined, it does not say it has to be a patient outcome. I am thinking of what you said earlier, P.J., about, could a process be an event? So I just put that on the table. Is that the way we still want it?

CO-CHAIR MEYER: No, I think that that is okay to put it on the table.

Any reactions?

MEMBER NADZAM: And actually, some of the criminal --

CO-CHAIR MEYER: One could argue that these leaves it open broadly.

MEMBER NADZAM: It leaves it open.

CO-CHAIR MEYER: And again, at the end of the day, this Committee and its predecessors will be the ones that have to sort out what is and isn't on the list, but it doesn't limit necessarily.

Yes, Michael, and then Philip.

MEMBER VICTOROFF: Is this the right time to talk about "usually" under the third bullet "preventable"?

CO-CHAIR MEYER: We are going to take these in turn.

MEMBER VICTOROFF: Okay.

CO-CHAIR MEYER: Hold your fire.

Philip, anything on "event"?

MEMBER PHILIP SCHNEIDER: Yes, my brother here, Doron, mentioned the issue of near-misses. I am wondering, there could be a near-miss that would have really been a disaster.

I am wondering, in the context of our overall discussion as it relates to an event, whether an occurrence is something that is a clinical event or whether it is something that could be a near-miss, that was an event, an error that was caught? And where are we going to get that?

CO-CHAIR MEYER: So I will hear from Michael on that, and then I have a

comment to respond as well.

MEMBER VICTOROFF: In our culture in Colorado, we have a practice of occurrence reporting. We require all the doctors insured by our company in Colorado to report occurrences, even those that do not continue trajectory to harm.

So, at least in some cultures, those I am familiar with, occurrences comprise near-misses and events for which the normal safety procedures operated properly; nevertheless, something happened that needs to be considered instead.

CO-CHAIR MEYER: And just to follow on that comment, I think kind of in the safety science literature, I think the term "occurrence" would be broad enough to include events that did not result in patient harm. So there are no-harm events that you would call an occurrence.

So, again, this leaves it very broad still. This allows this to be open to

perhaps a broader range of issues to be considered on the SREs.

MEMBER BINDER: I just would echo the comments, but I would think an event is serious if it is a near-miss that could have resulted in the things on those lists. That is that serious, in my mind.

CO-CHAIR MEYER: So, as currently written, this would allow this Committee and its predecessors to continue to consider those for lists, to be included on the list.

MEMBER BINDER: The way the definition is written here for serious, it has to result in death or --

CO-CHAIR MEYER: Deborah?

MEMBER NADZAM: Yes, I don't know that this is a discussion for right now, but I want to say it and maybe put it on the parking lot, to have a discussion about the term "near-miss".

CO-CHAIR MEYER: Close call. Yes, we will have that discussion.

DR. ANGOOD: Gregg, if I may, just for context for the group, the third deliverable, which is this framework report on measuring, evaluating, and publicly reporting these healthcare-acquired conditions, as part of our background work, we are certainly discussing the issue of near-misses, close calls, however they want to be framed up. So that will be in there as well.

And as we get to the definitions of healthcare-acquired conditions, I think there is need to keep this concept in there as well. I think what I am trying to drive through is this is one of those differentiator points sort of between the NQF SREs as opposed to the whole field of trying to report and create change around these healthcare-acquired conditions.

CO-CHAIR MEYER: Any further comments on the term "event"?

(No response.)

"Adverse", any comments on that?

Deborah?

MEMBER NADZAM: I am wondering if we need that last clause, "which may or may not have been preventable".

CO-CHAIR MEYER: Yes, please.

MEMBER McDONAGH: I was going to comment that I think it is important that "which may or may not have been preventable" is in there because we deleted that whole other section of -- what was it? -- "potentially" or that we deleted in the previous slide.

But, at any rate, we later describe "preventable", which I think is different from "adverse" because "adverse" may or may not have been preventable.

What I am arguing is to leave it in.

CO-CHAIR MEYER: You are arguing to leave it in.

Michael, and then I am going to try to move us along quickly.

MEMBER VICTOROFF: Sorry. To me, it doesn't make sense to have "preventable" in two places, but I have always interpreted this to need the word "actual". If the word "potential" versus "actual" had any place in the entire definition, it would be here because there are near-miss events or psychological harms or other really scary things that almost happened that are very adverse, but they might not actually have occurred.

I don't argue strongly for including that, but, to me, that would be much more valuable than to duplicate the language of prevention in this bullet.

CO-CHAIR MEYER: Do you have a specific proposal for a qualifier to put on the end there, Michael, or is that --

MEMBER VICTOROFF: Not unless there is a strong feeling. I think we could tinker with this all day, but I don't think I can significantly improve it.

CO-CHAIR MEYER: Christine?

MEMBER GOESCHEL: I need someone to clarify for me why we need unintended injury or illness, since the consequence of care that results in injury or illness is never intended. We never intend to cause injury or illness. Is that an injury? I don't know. I mean I am asking for clarification.

CO-CHAIR MEYER: Yes, I think that's a --

MEMBER GOESCHEL: Unintended versus intended.

MEMBER DORON SCHNEIDER: But doesn't the word "harm" fit there? Describe the "results and harm"?

MEMBER RYDRYCH: Except that not all of these events result in harm, though.

CO-CHAIR MEYER: Right, not all of these will result in harm.

MEMBER RYDRYCH: Right, right.

CO-CHAIR MEYER: I think that that

is important.

Help me out here.

MEMBER GOESCHEL: Yes, I just need someone to explain that to me. I trip on that.

CO-CHAIR TYLER: I have to add something that may or may not add to the murkiness of that unintended. At another point, we are going to be talking about our list of conditions includes criminal actions. Certainly, there is intended injury in some of those. So that may bring it under the big tent there. At least that would be an exception that would be included.

CO-CHAIR MEYER: P.J.?

MEMBER BRENNAN: Gregg, I think there are surgical procedures that clearly result in injury that is an unavoidable and even an intended consequence of the surgery, in part to create some desired effect. So I would argue to leave "unintended" in, "unintended injury".

CO-CHAIR MEYER: Cynthia?

MEMBER HOEN: Yes, just back to the "usually preventable" or "not preventable", the criteria initially starts out with "usually preventable, serious, and any one of the following adverse...." So, by putting in the definition of "adverse", which may or may not have been preventable, we seem to undermine the initial definition that we were working with.

CO-CHAIR MEYER: I do think I am anxious to move us -- this is the slide between us and lunch. That is a good sign.

(Laughter.)

Public comment as well, though, just so you know, to remind us.

So the current definition is described as a "negative consequence of care that results in unintended injury or illness which may or may not have been preventable". And the question is, I would like to call the question on whether or not we include the

"which may or may not have been preventable", and let's see where we are.

So who feels strongly that "which may or may not have been preventable" needs to stay in that definition?

(Show of hands.)

Okay. So P.J., Philip and -- okay, so four.

And on the phone, if I can take a quick roll?

Martha, do we leave "which may or may not have been preventable" in the definition of "adverse"?

(No response.)

Tejal?

(No response.)

Oh, they're gone.

Okay. So what I am taking from that is that -- so just to clarify, how many folks think that that final term "which may or may not have been preventable", that we should strike it from this?

(Show of hands.)

So what I would propose that this is an issue, again, that I would like to, at the end of the day, after we go through the list, let's go back and revisit this and make sure that we are consistent.

What we are tripping up against here is that in the past there have been inconsistencies. There have been inconsistencies between what is on the list and the criterion here, and we will try to clean it up as best we can.

So we will strike it for now, based on the sense of the Committee, but we will revisit this one as well, just to make sure we are making them consistent.

"Preventable". Let go. Let's hear.

(Laughter.)

We have had a fair amount of discussion on this already.

Please, what I would like you to

do is, also, to suggest some wordsmithing for us, if you can.

So, Michael?

MEMBER VICTOROFF: Let's see, the shortest way I can probably help this is to say there are other causes for events besides error and system failure. To list them all, I am not sure I could.

So what I would probably substitute, I would leave the words "but that occurs" and then say, substitute something like "despite the presence of preventive mechanisms", "in the course of optimal care", or "despite adherence to best available guidelines".

MEMBER DORON SCHNEIDER: I'm not sure we want to --

CO-CHAIR MEYER: Doron, if you can help us with that, please?

MEMBER DORON SCHNEIDER: I am not sure we want to bring it down to the level of the event. I mean you are trying to define

"preventable". So isn't it that it should capture something about reducing the likelihood of an event due to the application of evidence-based care, you know, some language like that, that really brings the evidence-based medicine into that, as opposed to describing an event?

Because you really want to describe here, define the word "preventable". So "preventable" means that, through the application of evidence-based practice, there is reduction in risk for that patient, something like that. That is what "preventable" is.

CO-CHAIR MEYER: So, just to follow up on Doron's comment, I call your attention, as Helen pointed out to me, on page 13, the top slide there, under the proposed definition for HAC, it says, "Refer to conditions being reasonably preventable with the implementation of evidence-based guidelines."

So is there something we can work from that?

MEMBER DORON SCHNEIDER: And that is the CMS definition of a hospital-acquired condition.

CO-CHAIR MEYER: So that would leave us with "preventable" describes an event that could have been anticipated and prepared for through adherence to -- or through implementation of evidence-based guidelines or evidence-based -- I think "guidelines" is a little reductionist. Evidence-based practice?

I know. Let's work on it. I don't think we're there.

Cynthia?

MEMBER HOEN: Yes, I think I would like to leave what we have and add the evidence-based guidelines. So it would read, "been anticipated and prepared for". Those are the obvious things that we may put on the list that you should have done something about. Or use the HAC language that you just

read that I can't see without my glasses.

CO-CHAIR MEYER: So what I said was, I said, "Preventable describes an event that could have been anticipated and prepared for through adherence of evidence-based practice."

Eric, please help us.

MEMBER TANGALOS: Yes, I actually have trouble with that.

CO-CHAIR MEYER: Good. Help us out.

MEMBER TANGALOS: Well, again, that gives another out there because a lot of bad things can happen where there's no guideline around it. Yet, you know it is a bad thing that happened.

CO-CHAIR MEYER: Yes.

MEMBER TANGALOS: So I would be a little bit careful. Again, I think the less words, the better, not the more.

I am a little surprised on page 13, although we are not discussing it right

now --

CO-CHAIR MEYER: We will get there.

MEMBER TANGALOS: Yes, but we have added another word "reasonable".

CO-CHAIR MEYER: Yes. Yes. We'll get there. We will get there.

So, Eric, help me out. How can we make this --

MEMBER TANGALOS: Well, we are in Washington, D.C., and our Founding Fathers created the Constitution, and we have left it alone for the most part.

CO-CHAIR MEYER: Yes. So what do you say?

MEMBER TANGALOS: Leave it alone.

CO-CHAIR MEYER: Leave it alone? Okay.

MEMBER PHILIP SCHNEIDER: Is it possible to have an event that could be anticipated and prepared for without having evidence-based practices defined?

CO-CHAIR MEYER: Yes, I think that was the point.

MEMBER PHILIP SCHNEIDER: Yes. So, in that, I agree with that comment, Eric's comment then.

CO-CHAIR MEYER: If I can, again, to move us on, I am going to call the question. So the question here is, those in favor of leaving the definition of "preventable" as it was, as it was stated originally -- so that was Eric's proposal.

And again, "Preventable describes an event that could have been anticipated and prepared for but it occurs because of an error or other system failure."

I do think we could, in the text of the report, we will have the opportunity to note that there are other things besides an error or system failure -- I think the point well-taken -- other things potentially that could, but I think for this report that is what we will largely concentrate on.

So those in favor of leaving it as is, if we can see a show of hands?

Okay. And on the phone, Martha?

(No response.)

Tejal?

(No response.)

Okay. And those in favor of making some change to it, again, if I could just get a quick show of hands?

So, again, we will leave it as is.

"Serious", the definition of "serious" is in front of you.

Deborah, get us going.

MEMBER NADZAM: I just want to point out that, in the 2006 monograph, it is a different definition.

CO-CHAIR MEYER: Oh, we don't want that.

MEMBER NADZAM: It says, "An event whose occurrence is grave", not trivial, which I like better, but --

CO-CHAIR MEYER: I don't know if

we can pull up that 2006 language.

MEMBER NADZAM: It was in the materials you sent us.

CO-CHAIR MEYER: Okay.

MEMBER RADFORD: This is Martha here. I am going to have to leave for a bit to go to the meeting that I had to stay back for. I will join up again.

CO-CHAIR MEYER: All right.

MEMBER RADFORD: Thank you.

CO-CHAIR MEYER: Thank you very much.

So you are looking --

MEMBER NADZAM: It is C2 in the glossary.

CO-CHAIR MEYER: C2 in the glossary. That actually is, I believe that is, what you are looking at probably is the 2002 report.

Let me just look here very quickly because it is important.

Yes, it is the 2002 report. So

the 2002 report -- yes. Yes, so it changed between 2002 and 2006. In the 2002 report, it says, the final sentence is "An event whose occurrence is grave." Here it says, "An event the occurrence of which is not trivial."

MEMBER NADZAM: It conflicts with itself, the monograph, because on page 3 --

CO-CHAIR MEYER: You're right.

MEMBER NADZAM: -- it has your definition.

CO-CHAIR MEYER: At the head of the table, we have just discovered that. Another contribution.

But let's talk about that because I do think that, if we can go back and pull up the slide -- yes. So we have had some discussion, but --

MEMBER TANGALOS: You get the OCD award of the day.

(Laughter.)

Actually, it is; it is spectacular.

CO-CHAIR MEYER: Let the record reflect that Deborah won that award.

(Laughter.)

Okay. So the question here is I think the good news is that we have a choice, and that choice is, do we have nothing there at all or do we put in "grave" or do we say, "which is not trivial"? Boy, those are very, very -- I mean it strikes me that they really are really very distant goal posts, those two.

Diane?

MEMBER RYDRYCH: So, just to clarify, is the intent of that final clause to capture events that we deem serious, but that don't cause patient harm? Because I have always found that last clause to be rather confusing.

"When referring to other than an adverse event, an event the occurrence of which is not trivial."

And there are some of these events that aren't related to patient harm that

wouldn't otherwise be captured in the first part of this definition because they don't involve death or serious disability?

So I am assuming that is the intent. But there is a way of talking about it that is a little bit less ambiguous?

CO-CHAIR MEYER: Anyone help us out here? Michael?

MEMBER VICTOROFF: I am always hesitant here. But this looks like we are debating synonyms for the word "serious". If you go to the dictionary, which I just did, and you look for synonyms for "serious", you get things like "not trivial" or "grave" -- (laughter) -- or appealing to the sensibilities of a connoisseur, which probably isn't what we want.

(Laughter.)

CO-CHAIR MEYER: I do like it.

(Laughter.)

MEMBER VICTOROFF: Well, you could use it, but I am not proposing it.

So we are dickering here over which synonym for "serious". Do we want to redundantly say "serious" means, yes, serious, we really mean serious; we seriously mean really seriously serious?

However, the important part of this clause it means for me is for things other than adverse events. So I would almost propose here to just forget the synonymizing, which is a new verb -- (laughter) -- and say, "which entail important consequences for the patient" or "the participants" or "the institution", or something.

CO-CHAIR MEYER: It is the "something", that is probably broader than that. Because, again, these criteria and these definitions are putting guardrails around what we can possibly consider.

So, to my mind, leaving that broad, with the notion being that, yes, a significant close call is something that we still want to maybe be able to consider here.

I think it would be difficult to say it has a consequence to the patient.

Diane, you look like you want to -- can you help us out?

MEMBER RYDRYCH: Well, I don't know that I have a suggestion. Because I think it is possible to have something that is an adverse event, but that still doesn't involve harm to a patient. It can be a negative consequence of care, but it can be something that is easily addressed and has no harm to the patient.

So it almost seems like the clause needs to take out that, when referring to other than an adverse event, and somehow get at -- it describes an event that results in death or serious disability or an event whose occurrence is whatever synonym we choose to use, even when no harm occurs to the patient, which seems to be the intent of it, right? I don't think that is quite right.

MEMBER DORON SCHNEIDER: I mean,

aren't we trying to model the sentinel event verbiage from the Joint Commission? I mean the sentinel event verbiage really does have that. It is the risk thereof that is clear, I think, that helps you figure out --

CO-CHAIR MEYER: So can you help us? Doron, can you help us work through to something that we can react to?

P.J.?

MEMBER BRENNAN: I think this definition is too long. I would suggest ending it at "loss of bodily function or the risk thereof".

CO-CHAIR MEYER: "Loss of bodily function" --

MEMBER BRENNAN: "Describes an event that results in death or loss of a body part, disability, or loss of bodily function, or the risk thereof."

Now we are getting very close to the sentinel event definition, yes.

But why limit it to seven days?

Events beyond seven days or --

CO-CHAIR MEYER: Eric, and I would like to hear from some of the -- Stan and John and Diane, I am going to cold-call you on that because I do think that that is an issue that you struggle with in terms of the --

MEMBER TANGALOS: We could still argue trivial, but I think the bigger issue is above that, because we can't use this definition in the universe that we are expanding into.

CO-CHAIR MEYER: That is true.

MEMBER TANGALOS: It can't.

CO-CHAIR MEYER: That is absolutely true.

MEMBER TANGALOS: Setting a time limit is one thing, but discharge from an inpatient facility makes no sense at all.

So, if we are to bring this forward into the expanding universe, we have to end it sooner.

CO-CHAIR MEYER: So we have to end

it sooner, and I am getting a nod of agreement from our CMS colleagues here.

I think what that will leave us with, of course, is going to be ongoing, robust discussions with our colleagues to whom we report.

So, Stan, you look like you are ready to jump in.

MEMBER RILEY: Yes, you know, I guess I agree completely that we need to scratch the time limit there. But I also agree that loss of bodily function, okay, or risk thereof.

CO-CHAIR MEYER: Period.

MEMBER RILEY: Period, yes. I think that does it all for me.

CO-CHAIR MEYER: I think the point is very well-taken.

I would like to, if we can, any further comments or wordsmithing on this?

(No response.)

Please, Sally?

CO-CHAIR TYLER: I just have a question because I don't know if that goes enough. Does disability, are you all thinking that that would include psychological harm --

CO-CHAIR MEYER: Oh, yes.

CO-CHAIR TYLER: -- trauma? So that is inclusive in this definition, right?

CO-CHAIR MEYER: Absolutely. Absolutely. That is a nice footnote, but I think we considered that in the very beginning.

DR. BURSTIN: That was a footnote.

CO-CHAIR MEYER: Yes.

DR. BURSTIN: There actually is a definition as well, which we should have included in the original report as well, for disability. So, since disability is in this title, not to footnote the footnotes, but it does specifically say, "Disability means a physical or mental impairment that substantially limits one or more of the major life activities of an individual."

So I think that is encompassed.

CO-CHAIR MEYER: So I would like to move us to -- those in favor of this language? "Serious describes an event that results in death or loss of a body part, disability, or loss of bodily function, or risk thereof." Full stop. Those in favor of that change?

(Show of hands.)

Okay. And anyone on the phone?

(No response.)

Okay. We will leave that as is.

We are left with "Ambiguous refers to an event that is clearly defined and easily identified."

Any recommendations for a change here?

(No response.)

Seeing none, those in favor of continuing it?

Mike?

MEMBER VICTOROFF: No, that's it.

CO-CHAIR MEYER: Those in favor of continuing it as is?

(Show of hands.)

Okay. We have now updated the definition of serious reportable events.

We will move briefly to a few moments for public comment. There are no public members here.

Anyone on the phone?

(No response.)

No public members on the phone.

DR. BURSTIN: Operator, are all the lines open for the public?

THE OPERATOR: Yes, ma'am.

DR. BURSTIN: Okay. And if there's any public comment, this would be the time.

(No response.)

Hearing none --

CO-CHAIR MEYER: Right. Hearing none, we have voted through the changes. Again, I think we will want to revisit these

at the end of the day or perhaps even at some point tomorrow.

And thank you, actually, to those of you who reminded us that we have got to also do the healthcare-acquired conditions work, and we've got to make sure these fit and mesh well there.

With that, we are a bit late, 15 minutes. It is time for lunch.

We will reconvene at 1:00 p.m.

Thank you. That was a terrific discussion. Language matters, and clearing up some of the conflicts in the earlier reports alone will be a good contribution from the Committee.

So thank you.

DR. ANGOOD: Yes, I just want to say thank you as well. That was strong work. Many of us don't naturally gravitate to word-by-word dissections, but this has helped streamline this tremendously.

So thank you, and let's enjoy some

lunch.

(Whereupon, the foregoing matter went off the record at 12:32 p.m. for lunch and resumed at 1:10 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

1:10 p.m.

CO-CHAIR MEYER: Actually, can I do a quick roll call? If you are on the phone, please identify yourself.

MEMBER LAU: Yes, this is Helen Lau from California.

CO-CHAIR MEYER: Welcome back, Helen.

MEMBER LAU: Yes, thank you.

CO-CHAIR MEYER: Anyone else on the phone other than Helen at this point?

(No response.)

Okay. Hopefully, we will get Martha and Tejal back at some point.

We are going to go ahead and get started on the work of the afternoon. But, before we begin the formal work, let me just let people know that, for those that are interested in joining colleagues for dinner, there is going to be a plan to make a reservation here at the Blue Duck Tavern,

which apparently, I heard on good authority, is quite good. That would be for around 6:30 p.m. this evening. So, if you are interested in joining others for dinner, let Jennifer know during the break, and she will go ahead and get the proper reservation set up for you.

Actually, a very quick show of hands right now would be helpful, if you are interested.

(Show of hands.)

Very nice.

By the way, orientation for the afternoon, I am actually going to ask Jennifer to go back to the slide set and remind folks that, under this contract from HHS, the National Quality Forum is not only asking us to work on the serious reportable events, but they are also asking us to work on HACs. I specifically use the term "HAC" rather than say, "acquired/associated" at this point in time.

So, if we can get the slides up in

a minute, and actually just go to the HAC definition, the goal of the next conversation, just to orient folks to the hard copy, we are now on page 13. So, beginning on page 13, the goal of the next conversation is for us to actually try to define HACs.

Some if you were sitting here during that last conversation and saying, boy, I wish we had a blank slate; we could do so much of a better job, my advice to you is be careful what you wish for because that is what you have right now with healthcare-associated or -acquired conditions, that there is not a definition in place. This group is being asked to develop that. That is our task over the beginning of the afternoon here.

With that said, we made some great progress this morning and in some ways may have opened up some opportunities to try to come to some clarity about the way that HACs and SREs can relate to one another.

With that, I am going to turn it

over to Helen Burstin.

DR. BURSTIN: So several of us were sitting here thinking, okay, you guys have now clarified this definition sufficiently that the question is, is there really a need for a second term? I actually did have a brief conversation with Eddie Garcia from CMS.

Obviously, one, we understand they are a big, complicated organization. But he has very similar thinking.

I mean, really, their major objections to SREs was that they were so, the implication of them being never events meant that you couldn't have a broader set of events potentially that they could use. We have already indicated we are going to expand the SREs beyond the hospital setting.

So I guess I would just, before we even sort of jump into trying to divine this thing, can we take a look at this definition with reference to the great work you did this

morning, and think about, in fact, whether a second definition is actually needed?

MEMBER PHILIP SCHNEIDER: I think I kind of mentioned this earlier, as we were tweaking the definition for serious reportable events, to some extent it dealt with the scope. If you look at the proposed definition for hospital HAC, it seems like that could be an awful lot of events.

Can you go back to that hospital-acquired/associated?

Because there are many things that are reasonably preventable. I mean you could look at fevers or a lot of things.

Again, this gets into the issue of process variation versus really focusing on really serious events in-depth. It may be desirable to look at very frequently-occurring events that shouldn't happen as a measure of variation that should be taken out of healthcare. It is an entirely different approach than looking at serious events that

involve root-cause analysis and looking for system causes.

So I look at the universe of events that are encompassed by this definition as being huge, even with our new definition for serious events being relatively small. When I get into debates with human factors folks, they have said: I would rather analyze one serious event in some depth to find out where we can make improvements than have databases with a million events, finding out where the errors are most common. We know that heparin errors happen a lot, but let's look at a few of them and find out what the root causes are.

So this takes me to an issue that I have debated for my entire life in this safety science area, which is, when do you look at granularity versus when do you look at trends?

But the two definitions, as they are currently structured, deal with small

numbers of serious events versus large numbers of relatively-common events.

CO-CHAIR MEYER: Stan?

MEMBER RILEY: I guess, for me, it gives us the opportunity to look at all the rest of the events that actually happen. Serious reportable events, at least in Massachusetts, comprise about 20 percent of the reports that we get. The other 80 percent are these kinds of things.

So, without this ability, you know, I think we would be missing a lot. Probably the same thing is true in Minnesota. You know, the SREs are just sort of a small slice of the pie.

So I think this gives us a really good opportunity to look at some of the other things that are happening out there. Some of them are really terrible that are going on.

So I think, even though it expands the universe a lot, it does give us an opportunity to actually see the kinds of

things that are happening out there that we would miss without a broader definition.

CO-CHAIR MEYER: Before we go to Michael, I just want to make sure one thing is crystal-clear for everybody, that we have two highly-related but separate tasks with regard to the SREs.

The first one was to do the work of this morning. That is, to define the SREs. But also, recognize that within what I think we created were relatively broad definitions. There is the specific list of things that are reportable. Following kind of the spirit of this project from its beginnings, the hope was that states would then take up this list and require reporting on that basis.

So the two are separate, highly-related, and then there is this third nuance. I think that Helen kind of begs the provocative question; that is to say, can we kind of within the definition for serious reportable events, you know, consider a

broader range of issues that would allow us to accomplish what was being asked here?

So, with that clarification, I am going to go to Michael and then Deborah.

MEMBER VICTOROFF: To begin to untangle this, a couple of threads I see dangling are that conditions for me are totally different things than events. If we were to honor that difference, which we could, I would leave the events as they are. They have to do with sort of events or things that transpire in the world, whatever processes.

Whereas, conditions, to me, I am fairly narrowly trying to understand these as diseases or disabilities or disorders that a human being acquires as a result of a healthcare process. So they are completely different things.

I think I like the idea of a parallel list of acquired conditions that a person got because of something that we did to them in the healthcare system. But that,

then, opens up two more threads that we didn't have with the reportable events thing.

No. 1, we are going to have to grade them for severity again, because nausea is a healthcare-acquired condition when you get chemotherapy, and stomachache is something you get from aspirin. You know, where do we want to go? We need to put some kind of a scale with this, like serious or something equal.

But the other one is the big gorilla for me. That is that I understood that CMS wanted this list, or something, to be the foundation of an intervention, something we haven't talked about, which is the non-reimbursable aspect of some of these things, which I also support, the idea that if the hospital or the doctor or the system imposes a condition wrongly on someone that was avoidable, then we ought to stimulate their quality improvement system by not paying them, or whatever, burning the place to the ground,

doing some kind of an intervention.

So those are threads that we didn't see in the SREs. I like them, but I have a lot of problems with this phrasing.

CO-CHAIR MEYER: Let me, before we move to Deborah, just again I think some additional points: one of them is that, for the serious reportable events, one of the things that we have learned over time is, when someone says they want to measure something, the right question to always ask is, for what purpose?

The purpose for the serious reportable events is very clear. It is stated in the prior reports. That is to come up with -- it is for accountability, and it is to come up with a list that states would implement for public reporting.

There is a lot of ambiguity, I think, right here. I am going to call on our colleague from CMS to see if he can help us out at all. Because I do think, if he can

help us frame this consideration by knowing for what purpose they are likely to be used, it will make a difference for us.

So any help you can give us, and I don't want to put you on the spot, but I do want to put you on the spot.

(Laughter.)

MR. GARCIA: I think, originally, you are encompassing what we had hoped for, which is an extension of the SRE list. I think the definition that you have come up with does do that. So you have taken out the inpatient hospital portion and you have taken out this reference to never events, which was politically not feasible for us to use. So you have done away with those references.

In parallel to this list now that could be expanded across settings of care and could be expanded to encompass more events potentially, we have this thing called healthcare-acquired conditions, which look at things that are potentially of less -- that

are not as rare, that maybe aren't as serious as the serious reportable events.

So I think this has taken us down another track that I think we hadn't thought of before and that is just as useful. The HACs, then, would be used for, as you are saying, quality improvement. We could put quality measures off of those. The SREs tend to be, as you know, counts. So I think both are useful. One is for reporting; the other possibly for reporting and for QI.

I am not sure if that is helpful or if you have --

CO-CHAIR MEYER: For QI and for payment purposes are two different things. So I guess I am, again, putting it kind of back to you in terms of, you know, Michael's statements in terms of, well, it depends a little bit on what it is going to be used for.

MR. GARCIA: Sure. Right. I'm sorry, I really shouldn't comment on that.

CO-CHAIR MEYER: You have a future

in government.

(Laughter.)

Congratulations.

MR. GARCIA: Right.

CO-CHAIR MEYER: Speaking from one who knows.

(Laughter.)

MR. GARCIA: I know that with the healthcare-acquired conditions, they are using that for something like determination. Right now, there aren't discussions to expand that.

On the quality improvement side or through our QIO programs, we would look to the evidence base and quality measures that could be generating from this list of HACs in other settings of care.

CO-CHAIR MEYER: Deborah, and then I am going to come back to Helen.

MEMBER NADZAM: Yes, I was having similar concerns about how are they different and how are they the same, and for what purpose are these lists being developed?

On that list of conditions are a variety of hospital-acquired infections currently from SSI to bloodstream, UTIs, et cetera. So they are different, and it doesn't sound like we are willing to move to the point where we would say those HAIs are serious reportable events completely, but they are.

It is a slippery slope, I think, for when is a condition, you know it shouldn't have happened and we're not paying for it. I mean it is a slippery --

MEMBER VICTOROFF: And if I could just respond, I think this is the nugget of the problem. If we open-endedly define anything you acquired from healthcare, which would mean any iatrogenic effect or any side effect, or even any intended effect like, "What is your condition?"

"I've got one leg."

"How did you get that?"

"Well, you see, I stepped on a landmine and then they sawed it off to prevent

the gangrene, and now I have one leg. My healthcare-acquired condition is I've got one leg."

So there are some healthcare-acquired conditions that are deliberate, intentional, in fact, beneficial, the best we could do, or a trivial, minor, not important, or expected and anticipated. You are going to get nauseated from your chemo; we are sorry. Your hair is going to fall out. That is an acquired condition. We're sorry.

Now, on the one hand, I think it might be very good for quality and for science, for other reasons, to know who's got no hair because of healthcare and who's got no hair because of the wrong genes. That could be important. You know, who's got one leg now because of healthcare? You know, okay.

But that is not really a quality measure yet. It is just sort of epidemiology.

But if we were, at the same time, to say, healthcare-acquired conditions,

inadvertent bad conditions, that we didn't mean them to have that we should have tried to prevent, and we did our best, but now they are all screwed up, and it is our fault, those kind of conditions, for which maybe it is very fair and valid to not to pay us because, okay, you're right, you know, we shouldn't have done that. And we shouldn't make you pay for undoing the error we shouldn't have made anyway. That bunch of things.

We really do have a mixed bag here. There's two colored jelly beans in the bag. That is where I don't think we can use the same definition.

First of all, this definition is too bland. Healthcare- or hospital-acquired conditions, that won't do it for me. All the jelly beans in the world are in there. And if we just mean bad stuff that we didn't mean to do that we hurt people with inadvertently, and we are really sorry kind of things, this definition doesn't capture that. I think that

is in a whole other gang of things that we ought to be thinking about.

They are not necessarily events, right? Like there's a fire in a trash can, and that is an event, and that shouldn't have happened. That's maybe reportable. But there's no condition there.

Whereas, myocardial toxicity, maybe that is a condition. But the event is tricky.

So there really is room for me for two lists, but we've got to be clear what we are doing. Okay?

CO-CHAIR MEYER: Helen, you wanted to jump in?

DR. BURSTIN: Yes, I was just going to make a point that, first of all, I think it is important to remember that payment issues are outside our scope, really outside our scope. How these get used is really not an issue.

The real issue for this group

should be, is there a need for a second set of events, whatever we call them, whatever it is, that is potentially reportable or not reportable, serious or perhaps maybe not as serious?

But I do think it is important to note, and I just pulled up the list from last year, and I think you added one more SSI. You know, of the current one, two, three, four, five, six, seven, eight HACs, four of them are SREs. So there is already blurriness. So we shouldn't pretend that they are separate. Four of them are SREs. The remaining ones are bloodstream infections, urinary tract infections, a couple of SSIs, and falls.

So I guess my question would be, is there an opportunity to think -- I am a lumper by nature; I'll admit that -- you know, is there an opportunity to think about whether there are serious reportable events? And perhaps there are some of those events that get into this issue of always reportable

versus events for which there are known strategies to reduce care.

I just think there might be an opportunity to think about something, as you think about it from where you sit, Stan: what are the events that are important, 20 percent of which get to you? How many of that remaining 80 percent are the kind of thing that would be important to have a standard definition for, however it may be used in healthcare?

CO-CHAIR MEYER: So I am going to go ahead and go to Doron and then to John.

MEMBER DORON SCHNEIDER: So the term "hospital-acquired conditions" is being used, to my understanding, by CMS to look at payment withholding. The way I am thinking about it, these hospital-acquired conditions, you know, should be used by the National Quality Forum differently, which really are unintended conditions that are a cause of healthcare, of which the SREs are a subset and

I think, you know, HAIs may be a subset of.

Because we do want to have reporting of these other events. By definition, if you have a list of things which are serious, then you have a list of things which are not serious. Those are hospital-acquired or -associated, whatever we come up with, conditions.

Because, to your point, we are not supposed to be thinking today about payment. We are supposed to be thinking about reporting. So, if we are thinking about reporting and accountability, then it is SREs are serious; these other events are other events. We want near-misses and we want the minor events, and we need to learn from them.

DR. ANGOOD: If I may, just on that point -- sorry, Gregg -- we don't have the full context from all of CMS here. Eddie is doing a formidable job of sort of fingering in the dike while we pepper them all morning and afternoon.

But the hospital-acquired conditions is not just about money. It actually is part of CMS's incentive strategies to improve quality of care. We just have to help tease that out for perhaps bringing the term back to what its true purposes are, and that is to help improve the safety of quality in healthcare.

If this, then, comes back to CMS and they reconfigure, that would be a good outcome. My point being is I don't think we are necessarily beholden by rigidity in CMS, and they are just taking a focus on payment, because we are really trying to improve quality.

CO-CHAIR MEYER: John?

MEMBER MORLEY: Harmony was never my forte, but I would like to comment in terms of harmony.

The first comment is I think how we got to this point, to some significant degree, started with the IOM report 10 years

ago. I think this really is about what Peter was talking about in terms of quality and safety.

I think reporting for the sake of reporting is of zero value to me. I try to convince the reporters that yell at us, "Why aren't you whacking the hospitals more for not reporting?" that the value in the information that we collect, as we were just hearing a little while ago about collecting information for analysis, is my concern.

Now let me go someplace else and come back to there. When I was on the hospital side, one of the struggles that I had was that there was a list that came from the Joint Commission. There was a list, even then, from the NQF. There was a list from the health department. There was a list from our friends at CMS. I needed a list to keep track of the lists.

And one of the great things that I see about NQF is that there is an appreciation

that we need to have a little more unity, a little more harmony, and less of these lists.

The list, actually, is far -- it is easier for me to handle one list of 40 things than four lists of 10 things. I would just rather have it all in one.

Now, to respond to something that Mike had said, clearly, there is a major difference between events and conditions, but for our purposes today, an event is an event that we care about, unless there is a condition associated with it.

So I think the two merge in that respect. I would just as soon have a single list issue that, once again, is very important to me, it is not about just collecting notches on a gun belt, that there was another wrong-sited surgery. I want to know how it happened, why it happened, to try to prevent it from happening again.

And those fewer lists that we can have, I think there is a very limited number

of resources we all have. When the topic comes up in the press, what has been accomplished in the last 10 years, the answer has been given, well, we really haven't accomplished very much.

I would differ a little bit and say that there are clear pockets that we can identify improvement, but they get diluted in the bigger picture. One of the things that I think has been a downside in terms of the last 10 years is the variation in what our responses have been, the different things that have been attempted.

If there had been more focus on a single list with similar issues being driven from NQF, from the Joint Commission, from the state health departments, from Leapfrog, and from many of the other quality improvement organizations that are out there, I think we would have accomplished more.

It is sad to me that something as important as retained foreign bodies or wrong-

sited surgeries, that we haven't made more of a dent in those topics in the last 10 years. Maybe Minnesota made a difference in retained foreign bodies; I am not sure. And Pennsylvania is starting to hint at improvement in wrong-sited surgeries, but it has been 10 years on those two topics.

Again, from my perspective, I would like to see a simpler list. I am a huge believer in the KISS philosophy, keep it simple; for political correctness, I will say SILLY. But whichever it is, you know, the simpler we can make it, the better, and the more focused we can make it, the better.

CO-CHAIR MEYER: P.J.?

MEMBER BRENNAN: I am looking at the slide deck that was provided to us from the state meeting, the state-based reporting meeting perspectives on SREs and HACs. Looking at the tables, it makes me ask the question, serious to whom?

This strikes me as a matter of

degree. I am really struggling with the distinction between conditions and events.

So, unless I am reading this list incorrectly, there's a table -- I am not sure which slide it is -- but it was hospital-acquired conditions and it has got HAIs. They seem to be hospital-acquired conditions rather than SREs, but, boy, those are serious conditions. Those are really serious events.

You know, 15 to 40 percent of people die of vascular catheter-associated infections. Mediastinitis after a CABG is a horrendous event. Orthopedic procedures with infections are potentially fatal, not because of the infection, but because of the disability that ensues. DVTs and PEs are self-explanatory. Infections after bariatric surgery are catastrophic.

So I would like one list, to be honest with you. I am really struggling with the distinction here, and I think it is more a matter of degree than reality.

CO-CHAIR MEYER: Let me, just before I jump to others, if I could, I just want to make sure I am hearing this right. So what I am hearing from John and from P.J. is keep one definition and generate one list. That list would include some things that states would be asked for public reporting on, and it would include an additional list of conditions or events, and we can work on that as time goes on, that would be used for other purposes.

Is that what I am hearing from you?

MEMBER BRENNAN: Yes, yes.

CO-CHAIR MEYER: Okay. One of the things I just want to let people know about, and this is not good nor bad; this is just reality. The reality of it is that neither this Committee nor the Quality Forum, nor any of us in our other roles, have the ability to control what is going to be done with these lists.

At AHRQ, we used to coin this term called "off-label use". However, we would say, boy, we want to put out these indicators for quality improvement purposes, and that is what they are best suited for, and that is all well and good. The reality is someone can pick them up tomorrow -- they are in the public domain -- and use them for payment purposes. That is America, and I don't think we can change that. So I think it is something just to keep in mind as we work through this.

John, I am going to go to you, and then I want to move on to Christine.

MEMBER MORLEY: On that very issue about information or the product of this Committee and this work being used for other purposes, it seems pretty clear to me at least, and I am not on the inside on CMS, but they didn't decide not to pay for these things because they wanted to save a ton of money. They didn't save a ton of money. I have seen

in some place in writing some of the numbers, and the numbers relative to the budget are incredibly small.

They wanted to send a message. What we are about today, and all of this work, is toward changing our culture to say quality isn't an afterthought, a "one more thing". Quality is job one, not that I am a big fan of certain car companies, but there's something to be said about that is our priority. We are changing the culture.

That is the message that I got from CMS, is intent to change. There will be multiple other ways that we haven't even thought of yet that people will use this, and I appreciate that, as long as the goal, hopefully, is to drive change, improvement, culture, safety.

CO-CHAIR MEYER: Okay. Christine, and then Deborah.

MEMBER GOESCHEL: Great. Thank you.

First, I need to apologize because I am going to sneak out a little early for something I could not get out of that was preordained.

But I need and want to weigh-in strongly on the value of a single list. I agree. I mean we have talked about the need to figure out what other entities are doing above and beyond NQF. For every additional list that we have, it just complicates the challenge.

I think the other thing, agreeing particularly with what P.J. and John said, it is that I would hope, as we go after these conditions, or whatever we are looking at, that we start with where evidence lives; that we don't start with the conditions, and then try to find evidence. Because part of the challenge that I think many of us face every day is we identify serious, important issues for which there is not evidence on how to improve, but we make it a top priority.

I think somewhere within, although we don't develop measures, I think it gets to part of the linkage that you talked about earlier with the measurement group to make sure that we understand where strong evidence lives, where perhaps the focus for gaps could start there, if that makes any sense at all.

I really feel strongly that part of the challenge we face is by identifying things for which there is not evidence. I will use UTIs as a perfect example of what do you measure. There's great debate on that right now.

CO-CHAIR MEYER: Deborah?

MEMBER NADZAM: Yes, something you said, John, sparked a thought related to the two lists. The SREs are single events. The others are conditions. And are they the same?

If you look at the conditions those events describe, it is death or permanent disability, except for the criminal ones perhaps and pressure ulcers, I think.

So, again, we have to go to the purpose. They are both for improvement purposes, but is each individual occurrence to be reported for every SSI or for patients who died as a result of an SSI?

I know you said something earlier about infections being considered on the SRE list and not included. I would like to see one list, too, but I think they do describe different groups of bad things that happen.

CO-CHAIR MEYER: P.J.?

MEMBER BRENNAN: I just wanted to respond to something that John said regarding CMS, and perhaps you can speak to this better than I.

But value-based purchasing is really part of the Deficit Reduction Act. So we shouldn't be mistaken in thinking that this is -- I don't mean to suggest you were mistaken, but the issue is not just culture change, but cost was clearly a part of that. I realize that this isn't part of our purview,

but that is certainly something that has driven CMS's activity I think.

I think there is a lot of congressional frustration that they have been able to find so few evidence-based conditions on which to develop a value-based purchasing program. I think there is a lot of impatience to push it in that direction.

CO-CHAIR MEYER: Before we move to Leah, just one, again, potentially qualifying issue, that in some ways the choice of term of condition versus event, which I think is one that we are hung on. Yet, when you look at the lists, there seemed to be a fair amount of blend there. I mean it begs the question.

Now what we don't have is I don't know the ICD-9 code for a rape on the campus of Mass General. It doesn't exist. I do know there is an ICD-9 code for every single one of CMS's HACs. There is an ICD-9 code for mediastinitis.

So to what extent did the coding

drive the use of the word "condition" is what I am wondering, because that seems like a pretty logical follow-on. Is that part of this? It may be ancient history.

I mean, clearly, to affect it in payment, you need to tie it to codes. It is impossible to do otherwise. But you just wonder how artificial this distinction is or how much it is a product of the use of the list as opposed to some kind of underlying philosophical approach about what makes sense.

I am going to go to Leah, and then I will come back to you, Mike.

MEMBER BINDER: I would agree with your comments. Actually, that was the point I wanted to raise.

I like the idea philosophically of one list. Leapfrog is a very strong proponent of harmonization and reducing the number of measures that hospitals have to collect, so they spend more time actually addressing the issues that are raised by the measures than

just collecting a lot of data. So having one list does have an appeal.

I also like it philosophically because it focuses on the harm to the patient. A condition or an event makes the list because a patient has suffered terribly in some way. So, therefore, it makes that list. It is a patient-centered approach, I think, to what we are trying to do. So I like that.

But I would add, and the next point is very important, these need to be reportable. So we need to make sure that it is pragmatic and feasible to report.

CO-CHAIR MEYER: I have Michael and then Doron.

MEMBER VICTOROFF: You are touching on something that I thought we would probably get to tomorrow, which involves the reporting systems. I think you are exactly right. My empiric observation is that the reason that we have so-called conditions from CMS is because that is all that they can

traffic in really. There is no procedure for let's go hand the baby to the wrong person. Again, there's no CPT for that.

There are ICDs for some of these conditions, although the ICDs are neutral with regard to whether they were intentional or they are complications, or whatever.

CO-CHAIR MEYER: Right, acquired on admission, yes.

MEMBER VICTOROFF: In essence, my global thought about reporting systems is that we don't have an adequate vocabulary, taxonomy, classification within either the CPT or the ICD that is suitable for reporting the kind of events we are talking. So we really need to be thinking about stepping outside of that or using some adjunct codes to the ICD, if we can come up with some, or G codes, or God knows what.

But, that being said, I am neutral on the subject of whether we should merge the lists or keep them separate. I don't much

care, although I am not a reporter. So, if the reporting faction in here really authoritatively says that, yes, that would really help enormously, then I will defer.

But what that simply means to me is that we have to take these conditions and rephrase them rhetorically to say a case in which a patient-acquired condition in the course of medical care, something, something, something. We can do it. It is a little wordsmithing problem.

But, then, what that means is we are still going to have to say that the condition was serious because we simply can't create another index of side effects and adverse events with complications in all of healthcare because that would be self-defeating. We have got to retain the fact that we are just talking about the top of a pyramid for now for a pragmatic reason.

CO-CHAIR MEYER: Doron?

MEMBER DORON SCHNEIDER: So the

one thing that we decided on this morning that is relevant to this is the words "the risk thereof". If we think from a reporting standpoint, and we would like to know about these events because that patient almost had a major problem, then that is one angle that that report would go. But CMS is not going to care because it didn't meet that definition of harm to the patient from a patient-centered approach.

So I think whatever we come up with here at the end has got to satisfy both of those. It is both the patient-centered approach, that there was harm, or the risk thereof, and there is where the learning is for the organization itself to protect the next patient.

CO-CHAIR MEYER: We will go to Philip.

MEMBER PHILIP SCHNEIDER: I am trying to get a sense of what we need to do here because I think we would probably agree,

from what I have heard, that if you had a Venn diagram method, the big circle is hospital-acquired conditions and then inside that --

CO-CHAIR MEYER: Healthcare.

MEMBER PHILIP SCHNEIDER: -- yes, the healthcare-associated, HACs, and inside, not outside at all like the ADE ones. The inside is serious reportable events.

So, by definition, a hospital-acquired or healthcare-associated condition is a different definition than a serious reportable event.

So, then, you are getting into this list and harmonization, and I certainly agree with the frustration that you have with having all these things, but do we have to do that? Or do we simply have to state for the fact that there are preventable negative, adverse events that happen in the healthcare system that people have, some of which are serious reportable events?

CO-CHAIR MEYER: Let me just

suggest --

MEMBER PHILIP SCHNEIDER: So I am trying to get a sense at the end game what we really need to do.

CO-CHAIR MEYER: So I think in terms of the Venn diagram that you propose, that sounds like what people are talking about, that HACs are more all-encompassing, and within the HAC is embedded a small circle of SREs.

To me, as I think about, well, what's the differentiator, what is defining that smaller circle, to me, it gets back to the purpose. That is, those are the things that we are going to ask states to have public reporting on, doing that.

And that is not to say that states won't ask us to report HACs or CMS won't ask us, but in terms of publicly reporting, that it is the smaller circle. I may be off there, and if I am, I want get folks to jump in.

Actually, Doron, and I want to go

to Christine afterwards because I want to catch her before she has to go.

MEMBER DORON SCHNEIDER: I think I am confused. I think that the Venn diagram is very critical. I am sort of with you, but then I am not.

Hospital-acquired conditions are everything. If we go down that line, all right, of which the serious stuff is one circle, all right, which is serious reportable events, I see two circles within the whole of these. You've got CMS's list, whatever you want to call it. Right now, it happens to be called healthcare-acquired conditions, right? Then you've got serious reportable events, of which there is, within that Venn diagram of those two, an intersection which now there are only four of the conditions, right?

Then the bigger Venn diagram, the bigger circle, is hospital-acquired conditions. So we probably need a different term, so that we don't keep stumbling up

against that for all reportable events.

So you've got reportable events. Let's just call it that. Then you've got the serious reportable events and CMS's list. That is where I think we have to have the discussion about bringing those two together and creating one. And, at the end of day, we don't have, to your point, control over what CMS does with the list, as far as from a payment perspective.

MEMBER LAU: This is Helen on the phone.

CO-CHAIR MEYER: Yes?

MEMBER LAU: I have been listening to this. I think it is fascinating with the Venn diagram. As you folks are talking, I start seeing more a tree diagram. The healthcare-associated condition is really the top of this tree. Then, there it depends on what setting the serious reportable event is. In the hospital setting, there are certain serious reportable events, and if you talk

about nursing homes or home care, the serious reportable event is of a different level. You know, it depends on the perspective.

I think, within that level, there are some cross-cutting, you know, an interchange arrow going back and forth. So, for example, aspiration. Aspiration could potentially be a hospital-acquired, a healthcare-acquired condition. Then, because of the aspiration, now the patient could have aspiration pneumonia, and then end up with septic shock, and maybe something else, and die.

So kind of start looking at that, okay, so aspiration itself is not an event. It is more like a condition.

So, in different care settings, you have a different seriousness of how, if you grade them, you know, different levels. So maybe I am thinking too much. So I think this is what you guys are talking about.

I also like the idea of one single

list, but how can we have a single list that can cross all care settings? I think that is also the challenge, but maybe there is some common area that can touch different care settings.

CO-CHAIR MEYER: Let's go to Christine.

MEMBER GOESCHEL: I actually need to listen at this point. Thank you.

CO-CHAIR MEYER: Okay. Cynthia?

MEMBER HOEN: Yes, picking up on what Doron was saying, if we have the universe of all bad things that happen to people in the hospital, and then the two subsets he was talking about, in my mind, I am now starting to think that one is sort of like criminal policy violations as opposed to those things, almost like Red Rules that we put in place because the Joint Commission says they shouldn't happen.

Then there is another subgroup of the sort of clinically-acquired bads that we

want to have best practices in place to prevent -- clinical best practices which are scientifically proven. Then, somewhere in the middle, there is the intersection which you were talking about, which may be they don't fall -- the falls, the pressure ulcers, where we are not quite sure what the clinical pathway is, but we also know that we don't want them.

CO-CHAIR MEYER: Okay. We are going to go to John and then to Deborah.

MEMBER MORLEY: I have to confess that I come to the table here with a very, very clear bias, and I am not sure how accurate it is. But all of the comments that I have had heard pretty clearly have been in terms of the goal is to improve healthcare, to reduce these events from happening.

I think there is a clear reason for having two different lists if there are two different goals. So I go back to what was said before, and you were asking CMS, and I am

not sure I heard a clear answer. But, if there is a different goal of the two lists, then, clearly, that would be the reason to have the second list.

Other than that, for my own purpose, if there is one goal, and I appreciate what the previous speaker on the phone was just saying, Helen, about -- who was on the phone, Helen?

CO-CHAIR MEYER: Helen, yes.

MEMBER MORLEY: So, in terms of potentially needing something else that addresses the specific issues of home care that may not overlap with hospital care and long-term care and hospice, and the rest of it.

But, if the goal is about tracking these cases, in the hope that somebody is actually making changes that reduce the events from happening, then a single list is still what I would like to see.

CO-CHAIR MEYER: Deborah?

MEMBER NADZAM: I am going to go back to the Venn diagram again, too. I think you could actually start with the circle of all HACs. I mean you could start with everything that is reportable, too, but you could start with all HACs, whatever the "H" and the "A" stand for, a subset of which are so egregious that every single time they occur they must be reported to somebody, if the state so deems that is the law.

But it would suggest going back to the definition of SRE and calling it perhaps an HAC that is preventable, serious, unambiguous, and has egregious results, or something like that, making the definition clear, that it is a subset of this larger group of things that can happen that shouldn't.

CO-CHAIR MEYER: Peter and then Michael.

DR. ANGOOD: Yes, I wanted to address Michael's plea for some type of

taxonomy or terminology. That is evolving through a lot of the work at WHO, and there is an existing taxonomy that we have endorsed, et cetera, et cetera, not the least of which is AHRQ's work with the common formats for the PSO reporting strategies. That remains to be seen.

So that is not our job, is to sort of get into that. But clarifying the definitions I think is important.

Unfortunately, part of what the struggle here is is the confusion that CMS has created by having this little list. Depending, actually, on how you tease it out, it is six out of the ten are true SREs in the CMS list.

Then what confuses the folks in a variety of environments is the HAI focus because it is healthcare-associated as well. And yet, actually, a lot of this is from P.J.'s work and others, that the HAI harmonization, actually, has been one of the

strongest activities that has occurred and is a good role model, I think, for a lot of activities in healthcare. Because you've got the Joint Committee, you've got NQF, you've got CDC, et cetera, all focusing on this one thing.

So, as we look at Venn diagrams or think about them, you can actually put the SREs, the CMS, and the HAIs all inside of that bigger bubble, which is the HACs.

To some degree, having said all of this, I think that the CMS and the HAI are kind of distractors in here. We can fit them in over time, but the single list or gradings on a single list, so that you get the really, really serious bad stuff versus all the other things, I think that is partly where we need to try to move.

If we create and get a fourth list, CMS, SREs, HAI, and now the HACs, and we are going to add a whole bunch of different environments, we have just created more

confusion in the field. So the more simplification, the better off we are, I think.

CO-CHAIR MEYER: Michael, and then I want to take stock and see where we are left.

MEMBER VICTOROFF: I am very sympathetic with the idea of having one list of bad things. I sense there is a movement toward the list of bad things. So we will call it the BT list.

(Laughter.)

But we are talking now proposing this new language.

But, in the list of bad things, not all mammals are dogs, and I can't make the Venn diagrams work and comprise things including such things as outcomes, diseases and disabilities, latent hazard situations, administrative or behavioral events which may or may not have created harm, like a guy comes into the ER firing a pistol, didn't hurt

anybody. So I guess there is no need to report it. I said we discharged a baby to the wrong person who showed up with a court order.

So there are a lot of things where it is hard to describe -- now so think about taxonomies and capturing reporting systems. I don't think that you are going to be able to get a good collection of all which we are interested in by saying let's just find a way to screw them into the category of diseases, disorders, and conditions and diagnoses. So every time we see streptococcus, we will know something bad happened. I don't see any way to do that with any of these, even murder, you know, if you are saying murder.

So I just think, on my one big master list of every bad thing, there is going to end up being -- there is going to be a spectrum of severity, and there are going to be at least a few, I don't quite know how many, boxes in which there are going to be some near-miss things that are really so

terrible we ought to tell everyone, and hazardous conditions, like this EEG machine always read it wrong whenever you set it this way. You know, luckily, it hasn't hurt anyone yet. And this provider is schizophrenic, and we don't have a system in our hospital to identify schizophrenic providers, but we think we should tell you.

So I guess I would be open to an unenumerated set of categories within these. I think that is my solution to, yes, some are processes; some are outcomes; some are conditions; some are hazards.

I think I would be more open to expanding the categories as we collapse the list.

CO-CHAIR MEYER: I just want to take stock for a second. The good news is we have the time for the discussion. Because, actually, the goal of the first two sessions this afternoon that take us up to three o'clock is to help define the healthcare-

acquired conditions, and then to discuss the interface between healthcare-acquired definitions and SREs. We are right in the middle of that, so we have got the time to chew on this.

With that said, one of the things that I would like to do, though, is to start to try to get us to the point where maybe we can start to come to some agreements around how to proceed.

One way to try to capture, to synthesize what people are saying, it is very clear what you hear over again, there is, by and large, with some exceptions, by and large, people think one list is a good thing. People also recognize that this distinction between event and condition is problematic.

We also hear that, if there is one list, there may be parts of that list that you would stratify to the here are things that every state ought to do public reporting on; here are things that we all ought to be

learning from and know about.

Then there are some outliers, and the outliers I think you have defined well. So some of the criminal acts and such just don't seem to fit well with any of these. It begs the question of, you know, we have a chance. We have two tasks. We have to do these definitions, and we have to come up with a list. That list may or may not need to contain those things. Maybe we should think about some other way to handle those, if they are outside of it.

But, if we started and said let's look at all events, and I am staring at Helen's keyboard here, but if you say, all events, that they are discrete, auditable, and clearly-defined occurrences, knowing that an occurrence could be a close call, and that you look at those that are adverse, that are preventable, that are unambiguous. So you have events that are adverse, preventable, unambiguous, with the definitions we had

earlier.

You could then say, from that list, you would say that some of these are so serious, that some of these will be very serious, and of those, some of them ought to be reported.

I am trying to see if we can work through a tiered list. I am not sure it is going to be possible. What I do think is points well-taken; if we take the current list of both serious reportable events as it exists from 2006, and then you look at the CMS list of hospital-acquired conditions, and you try to put it into Venn diagrams, not everything fits and not everything overlaps. It doesn't work. So we have to go back and look maybe at the lists, content, in addition to defining the process.

Is that congruent with the way people are thinking, or are you saying, wow, we are so far off the ranch, that we've got to reel folks back in?

MEMBER LAU: Yes, I agree.

MEMBER TANGALOS: Let me just ask, to what end you wish to accomplish this?

CO-CHAIR MEYER: Yes, for what purpose?

MEMBER TANGALOS: To what ends? If we take John's words about what has happened over the last decade as being not much, selecting out the individual events and then reporting them hasn't taken us very far.

CO-CHAIR MEYER: Unless you took a step back and you said -- and I am just going back to 2002, 2001, and the birth of this Committee. The counter-argument is to say, you know something; there are some things that there is an intangible value of accountability that you just need to have it out there, just because you have to.

MEMBER TANGALOS: Be that as it may, and I won't argue that point, if we are going to go forward, maybe we are stuck in that world of reporting those events and

trying to fix them and prevent them from ever happening. But it doesn't move the field very far forward.

CO-CHAIR MEYER: Yes.

MEMBER TANGALOS: So, as we look to the future, as we look to what we want to accomplish, can we select targets that really lift all of the ships, that get us to where we want to go, instead of continuing to focus on moments in time that are easily defensible that we have said amongst ourselves, "Yes, this is really bad."?

But, other than just fixing that really bad thing, what have we really done for the universe of healthcare? So I would kind of like to have us refocus along that line, if at all possible, as we look at what we want to report.

I am not so excited about looking at the individual events that the court system or somebody else is going to pull forward. I want to move everything.

CO-CHAIR MEYER: Leah?

MEMBER BINDER: I think it is a really interesting point, and I think it is worth reflecting on.

What comes to mind is the airline industry. It always comes to mind as sort of an analogy that we face in healthcare. And I am thinking about what the airline industry does with serious reportable events. That is they report them to all of the airlines. So, if there is one event in one airline, everybody knows about it.

So that it isn't just one hospital that is learning from an event. It is all the hospitals potentially could learn from the event. Maybe that is an area that we should be looking toward as well.

I think you are raising a really important point: how do we move beyond just reporting for the sake of reporting?

MR. GARCIA: I need to go, but I am going to be coming back in. I just want to

say I really appreciate this conversation that is going on. I will be coming back in to hear where you end up.

Thank you.

CO-CHAIR MEYER: Thank you.

Doron?

MEMBER DORON SCHNEIDER: So Pennsylvania has one of the oldest public reporting in the country. It would be interesting to see what P.J. thinks about it, but we have routine lessons learned that are sent down in the form of Patient Safety Authority bulletins. A lot of these are off of near-misses.

So I think that we do have an opportunity to enhance reporting in a meaningful way, and it is really up to the states to make or not make the learnings occur.

I would just say that, the way you led off this session, I would just make sure that in your diagram there on your computer

that, if you have adverse events as the whole, then you are going to miss near-misses. Then we have to then include the risk thereof as well.

CO-CHAIR MEYER: Yes, I agree. I agree.

P.J.?

MEMBER BRENNAN: To just follow up on Doron's comment, Pennsylvania actually has three different reporting systems. The first goes back to the 1980s, and it is the Hospital Performance Report on Hospital Mortality.

It is hard to say that that has a big impact. I mean it is hard to see the impact. I think over time there has been a lot of controversy in the State about whether it has been impactful or not or whether it is just the secular trend in improvement that has resulted in reductions in mortality in various categories. But it does get attention from time to time.

The Patient Safety Authority is an

anonymous reporting system that gets hundreds of thousands of reports. As John pointed out, it is starting to demonstrate improvement in the reduction in wrong site surgery, which happens about once a year at a hospital of about 300 beds across the State.

Then there's the HAIs. What has driven a lot of that has just been the public interest in it.

So lots of different reports created for lots of different purposes, and outcomes that vary with the system and the attention to it.

CO-CHAIR MEYER: We will go to Helen.

DR. BURSTIN: Just perhaps a way to synthesize this a bit is to go back to the actual safety goal that was arrived upon by the National Partnership because it is broad and it was intentionally, and Leah was involved in some of this, it was intentionally broad.

It said, "All healthcare organizations and their staff will strive to ensure a culture of safety while driving to lower the incidence of healthcare-induced harm, disability, or death toward zero. They will focus relentlessly on continually reducing and seeking to eliminate all healthcare-associated infections and serious adverse events."

So there was intentionally a broad net cast, thinking there were logical approaches that you could use to reduce the various entities that could fit that broader categorization.

So I just think that, if we are thinking about what's the point, the point is to achieve this. Then I think you could make the case that, depending on how it is useful, you could stratify the list by whatever purpose is needed.

I don't want to lose Doron's point about the risks thereof because I think it is

a really important piece that, to date, the SREs have not helped us with.

CO-CHAIR MEYER: Here's what I propose: I propose that we actually try to put some of this onto paper that we can project up here while all the rest of you take a break for 10 minutes or 15 minutes, and then we come back and try to really come to some decisions here. Because it is a great discussion, but we've got to think our way through this.

So let's take a break for a few minutes.

Those on the phone, we will be reconvening at approximately 2:25 Eastern Time.

Thank you.

(Whereupon, the foregoing matter went off the record at 2:12 p.m. and resumed at 2:31 p.m.)

CO-CHAIR MEYER: Before I start, if I can just, again, take a quick roll call

of those who are on the phone, if you could identify yourselves?

MEMBER LAU: Helen Lau from California.

CO-CHAIR MEYER: Welcome back.

MEMBER RADFORD: Martha Radford from New York.

CO-CHAIR MEYER: Great.

MS. CANNON: Marge Cannon from CMS in Baltimore.

CO-CHAIR MEYER: Okay.

MEMBER GANDHI: Tejal Gandhi from Partners Healthcare.

CO-CHAIR MEYER: Great.

Anyone else on the phone?

(No response.)

Terrific.

Okay. I am going to spend a couple of minutes just trying to talk through what is before you here. This isn't perfect. This is just a starting point.

But I would really like us to get

in the next half-hour to really try to settle on a few decisions to try to see if we can make this work.

So I will do it from here, if I can.

So, first of all, what we put here is a Venn diagram. The larger circle there is all adverse events. We need a different name there. So let's think about that, okay?

But what we are saying about these events is they are discrete, they are auditable, and they are clearly-defined occurrences or risks thereof. So, in some ways for the safety science folks, they would say occurrence actually already has that in it because occurrence could include a close call.

The point here is that this is very all-encompassing. In fact, if you think about it, even those criminal events that are part of the current SRE list from 2002 and 2006 fit that. And within that, all of them are adverse, preventable, unambiguous.

There is a subset. So, now looking at the Venn diagram, there is a subset of them that meet our definition from this morning. They are preventable. They are serious. They are unambiguous, adverse events that should not occur. Those would be SREs.

There is another subset within those, which are the healthcare-associated infections. Right now, there is not a lot of overlap between the HAI list and the serious reportable events.

The diagram here is meant to say that maybe there ought to be. We are not presupposing anything, but maybe there ought to be.

And I would argue that, if you try to say, what is that border that defines the HAIs that actually would be serious reportable events and those that aren't, from a functional point of view, from a practical point of view, to me, it is pretty clear.

What I would say is I would say,

you know, those that are SREs are nasty numerators. They are just the single thing that happened is so bad that I have to do a root-cause analysis. That is the tool I use to learn and get better.

The rest of those HAIs that are not serious reportable events are those where I rely on the epidemiology tools, too. I look at rates, and it is not the single nasty numerator.

Then, in addition to that, we try to note here that there are some adverse events, again, that meet that they are discrete, auditable, and clearly-defined occurrences or risks thereof. Maybe they are the nausea from chemotherapy that we don't want, and they are non-serious. They are not reportable right now.

There will be some of those, some healthcare-associated infections; maybe some healthcare-associated infections are to the point where we really don't feel like we need

to unleash the tools and the time on them.

Then to recognize that, outside of those three, there is still a host of events. That host of events, which we can't define right now, and, in fact, our Technical Advisory Panels, hopefully, will help us with some of them, but some of them may be important enough that we need to spend more time, energy, and effort on them. That is the black hole or the space between the planets right now that is ill-defined.

So I wanted to throw that up there and see, first of all, all adverse events, lousy title. We've got to come up with a different name for that.

But, beyond that, or if you have an idea of how to improve that, we want to hear that now. But, beyond that, is this model consistent with what we are talking about. What are the flaws in it? What should we change? Because this will help guide us as we start to create lists.

So I am going to turn to P.J., and then we will let folks chime in as they wish.

MEMBER BRENNAN: Gregg, I think there are events that are not rare that are very serious, too. So I think there is another circle to add there.

Maybe it just is a parsing of the list that we currently have.

CO-CHAIR MEYER: And that may, in fact, be the definition of what that white matter is.

MEMBER BRENNAN: I think so. I think so, yes.

CO-CHAIR MEYER: They are not rare --

MEMBER BRENNAN: Yes.

CO-CHAIR MEYER: -- but they are serious enough.

MEMBER BRENNAN: Right.

CO-CHAIR MEYER: But they are not very serious.

MEMBER BRENNAN: Right, right.

Then the other point that I would make is that on HAIs I wouldn't be a lumper. I think that there are some where SREs and the serious or very -- excuse me -- HAIs, some HAIs, and the SRE circles would overlap entirely. I think that bloodstream infections is nearly a complete overlap, and some of the others, where the definitions are ambiguous, there would be a smaller overlap. So I would parse that a bit.

CO-CHAIR MEYER: So, within this all adverse events, there is a circle of serious?

MEMBER BRENNAN: Yes, yes.

CO-CHAIR MEYER: I got that. And SREs are clearly embedded in that circle. The non-serious are, by definition, out of it. Some HAIs are in; some are out. Okay.

MEMBER BRENNAN: And just one other point. Excuse me.

CO-CHAIR MEYER: Group think isn't easy on a computer.

MEMBER BRENNAN: Oh, you can go ahead.

CO-CHAIR MEYER: Okay. Deborah? What I am going to do is I am going to try to go around the table. It would just make it easier to keep track of folks.

MEMBER NADZAM: Yes, I like it, too. It might be that that larger blue circle is non-SREs, serious, and the white matter is the non-serious.

CO-CHAIR MEYER: Right. In fact, yes, that works, actually. That works, and we just would have to have it encompass all of the SREs.

DR. ANGOOD: I am sorry. Say that again now.

MEMBER NADZAM: The large blue, the largest blue bubble is non-SREs, serious, and I guess not reportable, but they are serious. Then all the other white matter is the non-SRE, non-serious, not reportable.

CO-CHAIR MEYER: While I am

wordsmithing with Helen here, I am going to go around the table.

So, P.J., you're okay?

Michael?

MEMBER VICTOROFF: I don't see the need for rare. Otherwise, I like this. I have other comments I am going to pull through later.

But it seems to me that rare is a value judgment that we don't need. Your rare is not my rare. You know, I run a rehab thing for brain-injured vets, and it is not at all rare to see someone fly off the handle and strangle a nurse, but it is still bad.

CO-CHAIR MEYER: Yes, well-taken.

MEMBER VICTOROFF: Well, that is a value judgment again. I am sorry.

(Laughter.)

But it is not that I have never done that.

(Laughter.)

But, if you remove the word

"rare", then I do think I follow the rest of this pretty well. It seems to accomplish everything that we said, except for this one glaring thing that I don't understand you've got to explain.

The healthcare-acquired infections I think fits very well; it is perfectly a little, good, blue bubble there. But we were just arguing for an hour about healthcare-acquired conditions. And if what you meant to do was to erase that list from my mind, I thank you. This does everything that I --

CO-CHAIR MEYER: That was our --

MEMBER VICTOROFF: Am I clarifying? Am I the only one that was stupid about this? But you just erased the list. Let CMS do what they want. What you are saying is that, for NQF purposes, infections are just one of the things that overlap, serious and non-serious, reportable and non-reportable, and wounds could be another thing potentially, and concussions and sprained

ankles, and all kinds of other stuff could be serious, not serious, reportable, not reportable.

But I like this model, if I am understanding what you did there.

CO-CHAIR MEYER: You've got it right.

MEMBER VICTOROFF: Okay, and I will have to hear other comments about rare.

DR. ANGOOD: Part of the problem is most every topic that we choose to speak about is a spectrum, and to some degree, it is a value judgment.

You know, we can get a hugely complicated Venn diagram and our multiple layers of overlap. We are trying to keep it simple.

But we do need to recognize in the practical, real world there is this spectrum of events. So some serious HAIs, some not so serious.

CO-CHAIR MEYER: And just to put a

final point on your comment, Michael, one could well imagine the specter of a report coming from this Committee back to the product of NQF that may not mention the hospital-acquired conditions at all.

Diane?

MEMBER RYDRYCH: I was just going to agree with Michael's comment on rare. I would probably take "rare" out.

CO-CHAIR MEYER: Done.

MEMBER RYDRYCH: But I think this is helpful. We talked about this a little bit during the break, that I think we were getting hung on CMS's list rather than focusing on the concept of HAC or bad things, or whatever shorthand we want to use. So I think it is helpful to think of it this way.

CO-CHAIR MEYER: We are modifying it -- by the way, you are seeing that the "rare" is still up here -- we are modifying it here. We are not connected up. So we will, at the end of this, have a final that we can

throw up and let people see.

Let's do it here. You leave that up here. We will do it here. Then we will put it up at the end. We will transfer it over.

Cynthia, do you have any comments?

MEMBER HOEN: I really like it. I think that we could also use the white matter in the future potentially to draw out additional events as we become more sophisticated in what we learn.

CO-CHAIR MEYER: Because those boundaries shouldn't be permanent, although the boundary of an SRE will be a pretty hard list because you need a hard list to be able to effectuate it.

Eric?

MEMBER TANGALOS: The only thing, in the white matter, why not just leave it adverse events and not include non-serious, non-reportable? Because it gives us better opportunity, and, again, stays away from

definitions that we may not need.

CO-CHAIR MEYER: Okay.

MEMBER RILEY: So now we get to have table mates who are absolute opposites of each other.

So my point I think is that you could have non-SREs that can be serious, but they would still be reportable. So that circle would not necessarily be not reportable, particularly if you are going to have the white matter be non-serious and non-reportable.

CO-CHAIR MEYER: So one would almost imagine that there would be -- I actually need to jump up here for a second. I will talk once I reach a microphone -- that there would be serious non-SREs that are, and there may be some overlap with HAIs, that are reportable. Then there will be a small set that you won't --

MEMBER RILEY: Right.

CO-CHAIR MEYER: And one could

argue, by the way, going back to one of the earlier comments, that that boundary of what would be reportable and not reportable, there are some things that are serious, they are not SREs, and we don't know what to do about them.

MEMBER RILEY: Exactly.

CO-CHAIR MEYER: And therefore, you are reporting just for reporting sake. And by the way, it is not a public accountability reason there. So maybe that doesn't -- but I want to try to make sure that we can define these boundaries because, at the end, that is what is going to be important to people like all of us in the room here who try to make this into something real out on the frontline.

MEMBER BINDER: I have a couple of questions. I want to get back to the earlier point that was made about hospital-acquired conditions disappearing. Was that the term?

What happened to them exactly? I wasn't really clear on what that was.

CO-CHAIR MEYER: On which?

MEMBER BINDER: What happened to hospital-acquired conditions?

CO-CHAIR MEYER: Hospital-acquired conditions are going to be whatever CMS wants. We are not charged -- and again, I turn to Peter and to Helen for this -- but my understanding is that this Committee is not charged with defining the hospital-acquired conditions for CMS. They did not look to the NQF to do that initially, nor do I think that that's what they asked us to do here.

But let me make sure that we are not off-track on that.

DR. ANGOOD: No, that is correct. I will restate that.

We were approached to possibly expand the serious reportable events into other environments and to begin using this term of healthcare-acquired conditions. But at no point has the work of this Committee been charged to look at functions or scope for

CMS and their whole hospital-acquired conditions. That is whatever CMS wants to do.

And the reason we moved towards getting rid of the HAC, which we spent an hour debating on, was, I think, a reflection on the lack of specificity that HHS and CMS has on healthcare-acquired conditions. It is really an open book, as Gregg said at the beginning.

We were getting ourselves confused in that hour of deliberation. So we decided, since it is an open book, let's take that off of the plate and get ourselves back to, what are we really trying to do? We are trying to improve the quality of healthcare.

There's all these things that happen. Some of them are really bad. Some of them are in the categories like HAIs already. So we are trying to simplify by this.

DR. BURSTIN: And part of the charge from CMS specifically, and HHS, was to expand the list beyond those that were very serious and reportable across multiple

environments of care. I think we can do that in this manner without necessarily using their specific term that they are using for payment purposes.

MEMBER BINDER: But, presumably, we could pick some of the HACs from the CMS list and include them in this?

DR. BURSTIN: Absolutely, yes.

MEMBER BINDER: Got it.

I just want to reiterate I also believe "rare", I am glad you took that off.

DR. BURSTIN: Yes.

MEMBER BINDER: You already did. That is good because what is rare in one hospital is not rare in another; it doesn't mean anything, have anything to do with the seriousness of the condition.

Then I want to go back to this reportable issue. What does reportable mean? Reportable to whom? Are we talking about reportable in terms of to regulatory authorities? Reportable to states?

Reportable to the feds?

I am speaking from the purchaser point of view. What we want to see reported is going to be different from what the government wants to see reported. I am not sure that it is the scope of this Committee, or maybe it is, to decide what should be reported and what should not, and what is seriousness enough to be.

You know, the reporting issue, in other words, I am not sure that that should be a differentiator regarding serious versus not serious.

MEMBER TANGALOS: That is another reason why the white matter piece has to have non-reportable removed from it. It really does.

CO-CHAIR MEYER: Yes.

MEMBER BINDER: It's gone.

MEMBER TANGALOS: It was, yes, and let's think about reporting to the patient, too, or the individual.

CO-CHAIR MEYER: The only thing I would say about reportability, I think that point is well-taken. So we will try to remove it here where it is not necessary.

I think the thing that we have to remember is that one of our tasks is for the SRE list, that they are, by definition, the recommendations that states would report on them, and Leapfrog and others may use them for reporting, too.

So we don't want to exclude other things from being reported, but we definitely have to say these things are what we recommend for an accountability purpose to be reported. That is part of our charge.

MEMBER BINDER: So can I clarify that is part of our charge, that what we recommend should be reportable by CMS and states?

CO-CHAIR MEYER: No. Our charge is to develop the NQF list --

MEMBER BINDER: Right.

CO-CHAIR MEYER: -- of serious reportable events. Now that does carry with it and that list was specifically designed for state reporting.

MEMBER BINDER: Okay.

CO-CHAIR MEYER: CMS and others can do, and Leapfrog, you know, they can do what they wish with the list.

MEMBER BINDER: Well, I would say, then, that does not mean that something that we don't put on the list of serious reportable events -- I don't think that we should have the implication that what is not on that list we all believe is not reportable, because we have --

CO-CHAIR MEYER: No.

MEMBER BINDER: Do you know what I mean? Some of us may think that there are other things that are reportable, and this Committee is really looking at what do we all agree is reportable. That doesn't mean we think that other things aren't reportable.

CO-CHAIR MEYER: So the Venn diagram is important here in that there are some things that are SREs that are, we will just say, for accountability purposes, yes, we should absolutely all report on these. There may be other things for other purposes. So you could say, for improvement purposes, we ought to know what is going on with healthcare-acquired infections.

We may want to decide, in fact, to parse it out further, again, to try to decide where the boundaries are between healthcare-acquired infections and where SREs are.

So I don't want to limit -- I want to try to avoid limiting us in a box.

MEMBER BINDER: Yes, I guess I am trying to get at not the white matter, but the large, blue dot, non-SREs, serious, not reportable. There may, in fact, be serious --

CO-CHAIR MEYER: Yes, we ditched that.

MEMBER BINDER: Oh, you did?

CO-CHAIR MEYER: Yes. Yes, we ditched it. We said that there are going to be non-SREs that you still want to report on.

Unfortunately, we are not doing it in real-time.

For those of you who are on the phone, I am sorry because we are trying to work in real-time with the diagram here to make it clear. As soon as we are through with it, we will send it out to you, so you will have something to react to at least tomorrow for certain.

MEMBER LAU: This is Helen on the phone.

As you were talking, I started drawing it myself. I really like the white matter, you know, that you have got there.

I just wanted to challenge the group, you know, because we talk about this, the series of these dots here, can this be looked at as a three-dimensional Venn diagram?

CO-CHAIR MEYER: Yes.

MEMBER LAU: Yes?

CO-CHAIR MEYER: I think we could make it into a six-dimensional Venn diagram.

(Laughter.)

However, I think we want to keep it as simple as we can.

So, just to update people, again, a work-in-progress, but we are saying that the SREs, by definition, these are reportable, that there are healthcare-associated effects that may or may not bleed into the SREs. There are also non-SREs, but certainly important and reportable. So it gets to your point, Leah, that there are some things we still want to learn about.

MEMBER BINDER: It says the same thing as the big circle now, that they are serious and reportable.

CO-CHAIR MEYER: Okay. So let's work on that. Okay?

So your point is well-taken. We don't want to just say that the only thing

that is reportable are SREs. Right? And on the other hand, how do we parse that?

Doron, can you make your comment without the diagram up there?

MEMBER DORON SCHNEIDER: We were going in order. Did you want to go ahead? Are you sure?

MEMBER BINDER: Yes, go ahead.

MEMBER DORON SCHNEIDER: Okay. I think that you need another circle all the way around which would be for anticipated. Okay? Because all adverse events is not clear. That gets to like the nausea if you are chemotherapy, et cetera.

So, to be exquisitely clear, it is really -- and some of these may become more oval as you have to, then, overlap into this new boundary.

But if you had a largest circle, which is all adverse events, and then that circle here becomes unanticipated events, that is really what you are really interested in

reporting. Everything in there becomes reportable. If it is unanticipated, it is reportable. All right?

The anticipated stuff, we may not care as much, although one may argue, for epidemiology purposes, some people would say you do it. But from a safety, quality perspective, if it is unanticipated, that is the one we want, and another circle outside the whole.

Then we can get rid of that big, blue, new circle and have it stay the way it was before. Because then everything else in the white matter is the non-serious -- it is non-serious, it is not necessarily not serious reportable, if you follow me, right? Not SREs, non-serious and reportable.

CO-CHAIR MEYER: You are saying reportable for quality improvement purposes?

MEMBER DORON SCHNEIDER: Exactly.

CO-CHAIR MEYER: Okay.

MEMBER DORON SCHNEIDER: So that

is what the white matter is. It is not serious, not SRE, but reportable.

Then the new concept of a bigger circle would be, you know, everything outside of this sphere is that there are events which are anticipated adverse events because of healthcare.

Do you see what I am saying?

CO-CHAIR MEYER: I understand what you are saying.

Yes, Leah, help.

MEMBER BINDER: I think the reportability issue is confusing all of this. I mean I think we should just take it out. Because, for my constituency, we want everything reported.

I mean I am not saying that this -- you know, there's no need, I don't think, in this diagram and in this conceptualization for us to weigh-in on what we think should be reportable. I mean I think everything, theoretically, could be reported.

Or nothing.

But the point is that the key issue is, are they serious or not and preventable? I just think that it is confusing the whole picture.

And I do think that there should be a larger circle that is also near-misses.

CO-CHAIR MEYER: We are considering near-misses because it is adverse events or risks thereof. So the near-misses are in here. It is just that that part, it has gotten dropped off of the definition above it.

So your argument is that everything is potentially reportable for a variety of purposes? I mean it is potentially reportable.

There is a small group, which we are calling SREs, which we say should ask to have publicly reported?

MEMBER BINDER: Right. I mean I recognize that it is not going to be a

consensus of everyone on what events should be reported. On our end of the spectrum, it is going to be everything. I think others would not agree that that is appropriate.

CO-CHAIR MEYER: Yes.

MEMBER BINDER: But, from a purpose of reaching consensus among the stakeholders, we should be identifying those which all of us agree should be reportable. That doesn't mean the other parts are automatically, we agree, not reportable. Therefore, for a diagram with this, the reportable issue is not key.

CO-CHAIR MEYER: Cynthia, I skipped over you, and I want to make sure that I don't miss you. I want to finish out folks here before I go to others.

Help yourself.

MEMBER McDONAGH: Well, let's see, I thought I had a good sense of it until these circles got added.

CO-CHAIR MEYER: Yes.

MEMBER McDONAGH: But I do think there is a need to differentiate reportable, and maybe we are saying the same thing, but there is that defined body that we all need to agree upon. But it is confusing to me as these boxes now are not reportable. I am having trouble differentiating a couple of those.

MEMBER DORON SCHNEIDER: By definition, a serious event has got to be reportable. That big, blue circle needs to go.

CO-CHAIR MEYER: Yes.

MEMBER McDONAGH: Right.

CO-CHAIR MEYER: So you are saying this circle should go?

MEMBER DORON SCHNEIDER: Yes, that one go for sure.

That was okay. You could have just have made the other one bigger. Just make the other one bigger.

Right, and that is actually okay

because that circle that just got bigger, actually, is quantitatively where the most number of reportable events are coming from.

CO-CHAIR MEYER: You wouldn't have an overlap with SREs, but that would be, otherwise --

(Pause.)

So let's make sure that we've got your -- so what you are saying is that all of the white matter there is potentially reportable, too?

MEMBER BINDER: Well, again, getting back to reporting to who and all those issues --

CO-CHAIR MEYER: Yes.

MEMBER BINDER: -- around what is reportability, from our point of view, sure. I mean I am sure there will be disagreements between what Leapfrog would want or a purchaser would see as appropriate to report and what others might see as appropriate to report within that larger circle.

CO-CHAIR MEYER: And we are ignoring -- I think, Doron, you made the point saying there's another group of things outside of this that includes things that are anticipated, and we are just going to ignore that.

MEMBER DORON SCHNEIDER: Right. So, by definition, everything in that circle now is reportable. Everything in that big circle, including the white matter, is reportable.

It could be. That is fine. Because it is unanticipated, an adverse event.

I just made the motion to have another circle, which is to capture -- because people are still learning the safety signs. We don't want them to report nausea after chemotherapy, if it is anticipated.

CO-CHAIR MEYER: Right. So you are saying there is --

MEMBER DORON SCHNEIDER: There is a lot of healthcare-associated side effects,

but we are not interested in them as much.

CO-CHAIR MEYER: But, to keep it simpler here, I would say, if we focus on the unanticipated, that recognizes --

MEMBER DORON SCHNEIDER: Okay.

MEMBER PHILIP SCHNEIDER: I am not sure I agree with that. I was struck by a conversation, many of which have been humbling, with Dr. Lucian Lee, who said that all adverse events should be considered preventable.

A couple of them that we have focused a lot on that you probably wouldn't necessarily consider reporting. A simple one is vancomycin infusion reactions. You know, it took us a little while to figure out how to prevent those. It turned out it was the rate of infusion.

Chemotherapy, I would argue, if I worked in a cancer clinic, I would want to know what the rate of nausea and vomiting are, to compare different kinds of chemotherapy

that might have equal efficacy, to pick one that was more comfortable for the patient, or to continue to explore innovative ways to prevent nausea.

In our lifetime, we have started to use pretty innovative and out-of-the-box kind of therapies, including haloperidol and GI motility agents and marijuana, and a variety of different things, in an attempt to try to blunt those effects.

So I am not talking about putting those in the NQF serious events list, but I am talking about I am not sure there is -- any organization may want to look at something that is undesirable that happens with a patient that is associated with their healthcare, in the interest of improving quality or finding research areas, like genomics.

CO-CHAIR MEYER: So that may, in fact, define -- Helen, if you want to jump in here in terms of areas of research?

DR. BURSTIN: Just to remember that, really, the purpose of NQF is about public reporting.

CO-CHAIR MEYER: Right.

DR. BURSTIN: So keep that in mind. You may have lots of things you may choose to internally look at for the sake of internal QI, but would they rise to that list of what you --

CO-CHAIR MEYER: And that is the kind of thing to put in the text, to say that, you know, areas for research are we would like to see us push the edge of the envelope and try to find some of these things which we now say we can't do anything about. When we figure out ways to do something about it, when we can, and they move inside this circle.

MEMBER PHILIP SCHNEIDER: Right. Well, it wasn't saying what we should include in SREs because that is clearly there.

CO-CHAIR MEYER: Yes.

MEMBER PHILIP SCHNEIDER: But we

are trying to develop this inclusive diagram that includes --

CO-CHAIR MEYER: So I would say that that would require some text explanation as well --

MEMBER PHILIP SCHNEIDER: Yes.

CO-CHAIR MEYER: -- to say what is around that.

Sally, and then I am going to go to John.

CO-CHAIR TYLER: I was just going to reiterate that because I had had that thought as we were talking along. I mean I think in the report we definitely should underscore that there is a separate and continuing need for data collection around lots of areas, where you are looking at your internal practice and quality, and that those should be ongoing, but they may differentiate from the need for public reporting.

So, yes, I definitely would underscore that.

CO-CHAIR MEYER: John?

MEMBER MORLEY: No.

CO-CHAIR MEYER: Okay. A few more comments, and then I want to try to come to closure on this quick.

MEMBER RYDRYCH: Okay. I've been holding this for a while.

CO-CHAIR MEYER: Fire. Go.

(Laughter.)

MEMBER RYDRYCH: I have been holding this, so I will let a few of them go.

But, given the point that was just made that NQF is really focused on public reporting, I wonder if we are confusing the issue by having reportable there for non-SREs. Because are we then saying we are going to create a whole separate list of non-serious reportable events that are reportable, which seems odd to me.

I would almost argue that we shouldn't even have that one, and it should just be part of the unanticipated adverse

events circle generally.

But my other question is, thinking of the process that this --

CO-CHAIR MEYER: Stop there fore a minute just to make sure.

MEMBER RYDRYCH: Yes.

CO-CHAIR MEYER: So what you are saying is you are saying that NQF is all about reporting and that --

MEMBER RYDRYCH: If NQF is about public reporting, then why are we establishing a separate list of things that don't meet the criteria for being serious reportable events, but that we are still saying are reportable?

CO-CHAIR MEYER: And our job, actually, here is to create that one list, the SRE list --

MEMBER RYDRYCH: Right.

CO-CHAIR MEYER: -- as a product of this Committee.

MEMBER RYDRYCH: Right, unless we want to clarify that we are talking about

internally-reportable or the things that need to be tracked by those facilities.

But my other point is related to that; that given the process of this group, there are going to be the technical advisory groups and there is going to be a call for potential events.

CO-CHAIR MEYER: Yes.

MEMBER RYDRYCH: If we set up something separate like this, are we then saying that the technical advisory groups should not only be considering what might make the list of SREs, but what could also go into this separate box of non-SREs? And do they have to think about what the distinction is between them? And when does something rise to SREs versus when is it in this non-SRE group, but it is still distinguished from the white matter?

CO-CHAIR MEYER: What is expected of you under the contract?

DR. ANGOOD: Well, I think in

terms of what is expected of us at NQF, I think it is still a little bit confusing. That is because of the struggle we are having on the definition and what the needs of HHS are in terms of their perceptions.

I think, as Eddie made comment a little bit earlier, their idea initially was to expand the SREs into other environments, or the concept of SREs into other environments. Rather than just continuing to call them SREs, they sort of reacted to this HAC term.

So, yes, we still all very much need to look at, how do we maintain the NQF serious reportable event list and the value it provides, but how do we take the concept of it and move it into other environments, so that it becomes meaningful for those other environments?

And if it gets taken up in other ways by CMS or others, then that is the market economy.

Now Helen I think has some other

comments as well, but it is sort of the expansion of the concept into other environments that makes it a meaningful listing, if you will.

MEMBER RYDRYCH: But I think in this diagram those would still be SREs, right? They would just be SREs in other settings?

I worry that we are creating a second tier here of events that aren't SREs, but that are somehow differentiated from the white matter.

DR. ANGOOD: Well, we never even got to the language that we had on one of the slides. It is in the slide packet. I don't have one with me, but it is after -- because we are trying to play with multiple computers up here, page 13, that middle slide, where it talks about the broad-based concept whereby untoward conditions or complications are acquired. That is the language that is in the work plan. That seemed to be what resonated with HHS, as we had been talking about it.

But my previous comments are still the same.

DR. BURSTIN: The only thing I would add is just, again, what we heard clearly from CMS, and from others, was that SREs was too limiting. People perceived them as never events. It wasn't broad enough to come up with a list of just never events. They wanted that to be broader and encapsulate, and so going back to our conversation right after lunch, go back to events that perhaps are serious, but maybe could not be called never events.

That is why we began this conversation in saying, are there really two lists of events here? Have we now codified the definition of SREs to the point where, in fact, we have made them serious, but not never events? And maybe that is good enough, just to remember where we started. Then they wanted to get it expanded to other environments of care.

So, you know, if we are making this overly complicated, I just think we don't want to do that. I think we wanted to be able to really encapsulate that broader vision of where we want to go. How you call it and what we wind up with is your decision as the Steering Committee.

CO-CHAIR MEYER: And so let me just put something on the table, just for people to think about.

The point is well-taken about defining a second list here. But, in fact, if you got rid of the non-serious or the not necessarily not serious reportable, if you got rid of that bubble, and then you said the white matter is defined by an untoward -- by the definition on page 13, which is "untoward conditions or complications acquired by patients," and we would have to broaden the word "patient" apropos the discussion earlier about going to other healthcare environments.

Going further, these could be

rare, uncommon, or relatively common. "They may or may not require formalized reportable to various reporting agencies, but should be subject to internal organizational review, at a minimum, should they occur."

So, Michael, you don't think that defines the white matter?

MEMBER VICTOROFF: Well, as bad as that is, yes, it could define the white matter. I don't like almost anything about that definition.

CO-CHAIR MEYER: So what should we do?

MEMBER VICTOROFF: I would get rid of the lower lefthand bubble, for the reason that we just heard. It doesn't add, and it does complicate life.

And I would also remove the language -- I would just leave SREs as SREs because it is an idiosyncratic, local, however, authority list from NQF. And the key to what we are saying about them is that we,

to whom you are not going to report anything, suggest that report-collecting agencies of a certain caliber and interest, we strongly urge them to make these among the things universally which they collect, in addition to whatever else they collect.

But, since we are not a report-collecting agency, we can't say what is really reportable. We are merely exhorting certain kinds of quality organizations to consider these highly above all, for our reasons.

But, when we say, "reportable", and I've got to go back to what Leah was saying, reportable is a local definition everywhere. There are literally -- everything in the white matter, I mean things outside the white matter are reportable somewhere, the Department of Motor Vehicles, and the who knows what, and EPA, and I don't care; NASA wants to hear something.

So, even the word "reportable" is something we are going to stumble over if we

use it in our diagram. So I would say SREs, we have defined that. You know, "See above." We've got what SREs are.

Infections, that is perfect. It is inside there, mostly unanticipated, and some of them are SREs. That clarifies the relationship of reportable events to infections.

Then there is another spectrum of them, and there's other dimensions that we can draw through this, among which are the site of care, the locus of care, the degree of severity, and the type of intervention, the sort of outcome. Then measure the impact and the cost to society.

I just listed three things that helped me understand why a thing would be reportable. They are the three "I's" that I came up with. They had to do with impact, the presence of an intervention, and our ability to identify precisely the item we are discussing. So it is unambiguous.

That is how I read -- I just ambiguated the term unambiguous with those three things, and you don't have to adopt them.

But, so far, I think you have to squeeze those into the -- well, I don't mind if they leak outside of unanticipated. I like to see the point of unanticipated. This diagram is pretty good for me right now.

CO-CHAIR MEYER: Stan?

MEMBER RILEY: So I guess I would argue for replacing that small circle back because I think that is actually the biggest circle, not the overall biggest circle, but the place where most of the events are.

That is, they are non-SREs, they're serious, and they are reportable. So that if we just took out the "not" in that part, that is where about 80 of the things that happen are going to actually live.

MEMBER VICTOROFF: Could I respond? That is already the white matter.

And I think we can annotate the white matter exactly as you said.

CO-CHAIR MEYER: So the point here is saying that, actually, anything inside the white matter is reportable?

MEMBER RILEY: Is non-SRE and --

CO-CHAIR MEYER: And they are not SREs? Does that work?

MEMBER RILEY: Yes. I guess the only other thing that I am concerned about is the unanticipated. Is everything inside that white circle going to be serious? Is that what we are going to say?

CO-CHAIR MEYER: No.

MEMBER RILEY: No?

CO-CHAIR MEYER: No.

MEMBER RILEY: Okay. Then it is not included in the white circle, what I am saying.

MEMBER RYDRYCH: I think the white circle could be serious or not serious, reportable or not reportable, right? It is

the all bad things list that Michael talked about, where it is not dependent on harm; it is not dependent on risk of harm.

CO-CHAIR MEYER: And this Committee is not going to define reportability outside of the SREs.

John?

MEMBER MORLEY: Do we care at all -- at all -- about the non-serious reportable adverse events that we are going to define? I mean what we are talking about here is I think we could come up with a list of somewhere between 100 and 1,000 adverse events, but there is a limit of resources. And we are asking them to focus on a certain category. That category is serious reportable adverse events.

So do we care about any bubble other than that? At this time?

And remember that the 10 or 15 or 20 things, whatever number we end up with, is all going to fit into that one bubble.

CO-CHAIR MEYER: Yes, I am going to let Eric respond. But before he does, let me just say that what I think -- we could say, boy, we spent two hours talking about a Venn diagram; that's great.

But the reality of it is is I think that this Venn diagram, with the definitions that we have done this morning attached to the call to events, will help clarify what people send in to us.

And do we care about -- is our job to define all the things in the white matter? The answer is absolutely no. That would (a) be a Herculean, a Sisyphean task, and (b) -- Sisyphus rolling the ball up the hill.

Eric?

MEMBER TANGALOS: Yes, I think that the non-SRE serious reportable right now is going to distract the next groups that get into play.

I think we shouldn't spend too much more time here because I think we did our

work in redefining the SREs. Although Leah and Leapfrog is wedded to the "never" piece, by taking that word out and changing it a little bit, maybe a little bit more, we have really expanded the scope that we wanted to get to with this particular process.

CO-CHAIR MEYER: Doron?

MEMBER DORON SCHNEIDER: So we are giving special attention to the HAIs. I just wonder, if we are going down this path at all, if we want to think about, just for clarity's sake, the different categories of SREs that we have, at least prior to this current effort, where you have surgical events, product or device events, care management events, et cetera. Theoretically, you could say that each one of those can be, if we want to be clear --

CO-CHAIR MEYER: Absolutely.

MEMBER DORON SCHNEIDER: -- their own circle. Then some may be SREs and some wouldn't be SREs, but everything in the white

big circle is reportable.

CO-CHAIR MEYER: I think the only argument I would make, I would make two arguments for potentially including HAI in the diagram if we sent it out as part of the call. I would use it there, No. 1, because HAIs are special interest kind of nationally. But, beyond that, just for illustrative purposes, to say here's the way one of them overlaps, and, oh, by the way, all of these other things we do the same thing, it just makes it simpler to portray.

Deborah, and I am going to try to bring us to a closing point here.

MEMBER NADZAM: Okay. Just a quick comment. I think we may need to say something about what very serious means as compared to serious. We may need to go back to that definition. I like the impact. I like the impact.

CO-CHAIR MEYER: There, we are taking it out. It is out.

MEMBER NADZAM: We are taking what out?

MEMBER RYDRYCH: I don't think we even need to say very serious. We already know --

MEMBER NADZAM: We are going to take very serious out as well?

MEMBER RYDRYCH: I think we could because we already defined SREs.

CO-CHAIR MEYER: All right, P.J.?

MEMBER BRENNAN: Gregg, I just wondered where actionable fits into this. By way of example, when Pennsylvania started its HAI reporting system, it built initially, but the goal within a very short time was to report all HAIs. There was an enormous effort in that, but at the end of the day there were only four or five that are reported. One of them is multiple HAIs in a single patient. I don't know how to prevent those. There are ways to prevent each one individually, but it is a category that is sort of useless, in my

mind, as is much of the rest.

However, it informs the purchasers very well of all the things that they are interested in, you know, the whole spectrum of costs related to HAIs. So it is sort of a research tool, but in terms of hospital action, it is really confined to a small subset.

So where does actionable fit into this? I think that is an important issue.

CO-CHAIR MEYER: Yes, and again, I turn to Peter and Helen, if they have further thoughts on this.

If you go back to kind of original definitions of SREs, and I am going to flip through here, one of the issues has been, and this gets back not to the specific criteria for this Committee, but the National Quality Forum as a whole, it is there is supposed to be a feasibility and ability to take action as one of the broad criteria for a National Quality Forum consensus standard.

So I would say, certainly, when this goes through the consensus development process and goes through the CSAC and other parts, they are going to look very closely at that actionability piece.

I think it would be hard to put something on a serious reportable event list with a notion that we don't have any idea of what to do about it. I think that that gets filtered; that will get filtered out in the process.

Leah?

MEMBER BINDER: I think, also, actionable, the definition of actionable changes with reporting.

CO-CHAIR MEYER: Right, it does.

MEMBER BINDER: You know, five years ago, I don't think anyone believed that it was possible to get to no central line infections, right? Well, it is possible when we learn it because we start reporting it, and we start seeing it.

So I think that is another element to consider.

CO-CHAIR MEYER: Okay. Yes, Helen has a question.

DR. BURSTIN: I have a question. It is always fun to kind of have that storm and drama of groups, and we have kind of come back to the reference point.

I have a question for John, though. Going back to that list of 40, it would be useful to have that list of 40. Does the expanded definition of SREs we came up with this morning work to fill that list of 40? Are you still going to get left with stuff that people are telling you to put on there that doesn't fit?

MEMBER MORLEY: I think you could come up with, given the definition that we have now, I think we can come up with 40 things.

DR. BURSTIN: Okay. I mean not that we have to come up with 40 things.

MEMBER MORLEY: Right.

DR. BURSTIN: But I just think that it would be helpful just to --

MEMBER MORLEY: I think it is broad enough, and there's lots of room.

DR. BURSTIN: Right.

MEMBER MORLEY: There's lots of places. We have very clearly limited and targeted and started with the low-hanging fruit.

DR. BURSTIN: Okay.

MEMBER MORLEY: There will be slightly-one-more-shelf-higher fruit.

DR. BURSTIN: Okay, great. Because just getting back to that list of the CMS events, and I just pulled those up to remind us, the things that are left on that list that weren't on the initial SRE list include some of the HAIs, which we have now talked about, as well as the only other one, really, that is on here is falls.

I guess the question would be,

just to kind of play this out one more time for us, if that is how people are thinking about it. Would falls or some subset of falls now fit in the new definition of SREs?

MEMBER MORLEY: Yes.

DR. BURSTIN: You have answered my question. Thank you.

MEMBER RYDRYCH: But they already are SREs, falls. Death or serious disability, serious disability or -- no, serious disability from falls is still a part of it.

MEMBER VICTOROFF: What about a busted tibia?

MEMBER RYDRYCH: That is a serious disability.

CO-CHAIR MEYER: That is a serious disability. Yes, it is.

Okay. So I had stopped us there.

Be careful what you wish for was the right thing to start the conversation.

With that said, where I think we are is we have a definition of serious

reportable events from this morning. We have got a kind of conceptual framework, I think, for what we have thought through a lot. I think we will actually have to see a final version, based on this discussion, of the Venn diagram and this notion that everything in that big circle is potentially a part of it.

We are going to define a pretty small circle of what is reportable as SREs. We will kind of finish that off and get that out to folks. And maybe we can try to get that to folks tomorrow in a final form.

Make sure that we are -- I think that we are in the same place. I just want to make sure everyone leaves tomorrow agreeing that, yes, this is what we said. Because that is going to go out in this call for potential events.

Do folks need to take a 10-minute break before we dive into the SRE list? That is the remainder of our afternoon, is to spend time on the SRE list.

Just as a word of warning, I am going to put Diane, Stan, and John on the spot a bit, because I want to start a review of the SRE list with actually going through the state-based reporting agencies' feedback that we all have on our reports.

So do people need a 10-minute break or can we plow forward?

A 10-minute break, raise your hand. Who needs a 10-minute break?

Okay, John, take your break and come back.

(Laughter.)

We're starting without you.

Okay. I would ask everybody, if you could pull up your -- and thank you. That was an awesome discussion, and I think in the end we got to a good place.

If you could please pull up the slide set on NQF state-based reporting? I actually found this to be pretty provocative.

Jennifer, if you can pull that up

as well, I think that will be helpful.

DR. ANGOOD: So where we are at is in the main .pdf document.

CO-CHAIR MEYER: State-based reporting.

DR. ANGOOD: State-based reporting agencies' perspectives.

CO-CHAIR MEYER: I would like us to go to the first slide that says, "SREs most and least useful".

MEMBER RYDRYCH: Although I will say I don't know if either John or I was on that work group, but we might be able to summarize it.

CO-CHAIR MEYER: Well, no, you don't have to summarize it.

MEMBER RYDRYCH: Okay.

CO-CHAIR MEYER: You can react to the feedback that your colleagues gave, I think.

Stan, were you at the meeting?

MEMBER RILEY: Yes.

CO-CHAIR MEYER: Okay.

DR. ANGOOD: What occurred is, during one of the breakout sessions at the state-based reporting meeting, where we had 22 of the involved states present and several individuals, was to review the existing serious reportable events and to sort of kind of evaluate their usefulness, their impact, et cetera.

The handout kind of details through some of the questions that were asked. You know, comment on the criteria and most and least useful, potential new conditions, et cetera.

And where Gregg wants us to focus is on some of the actual outputs on the SREs, SRE by SRE by SRE.

CO-CHAIR MEYER: Right.

DR. ANGOOD: So that is --

CO-CHAIR MEYER: So what I suggest process-wise is that we just review the slide set in just five or ten minutes, just so

people can all get familiar, and we can hear your perspectives on it.

Then we are actually going to go back through the list of SREs as they are in your handout here one by one, and we will do as many as we possibly can.

So, just, again, to start the conversation, this is a list of -- on the left side, you will see the SREs listed there.

I guess what I would ask the three of you -- and, Stan, if you have any further commentary on this -- and then the other two of you to chime in and say, does this comport with your experience or do you take umbrage with this? And this is not what you have experienced here?

This is just for input. We are not making decisions based on this, but this is a good point of input for all of us.

So, Stan?

MEMBER RILEY: I think it is a great place to start. John and I weren't on

this particular Committee. We were on another one at that piece, but we did listen, and I think Diane was there, too, to the presentations.

I think there was actually some pushback about some of these things at that time. So this is not necessarily sort of a consensus document. This was that particular breakout group's feelings about things.

CO-CHAIR MEYER: So they came up with these five that were the least useful, for the reasons they have here on the right side.

MEMBER RILEY: Right.

CO-CHAIR MEYER: And, John or Diane, is that your experience?

MEMBER MORLEY: I would agree that it has not been particularly useful, the large experience that I have, which is not a large number of cases, fortunately. But there's very clear reasons, in my view, as to why.

A little bit the limited number of

times that that event happens, but, more importantly, there's a significant reluctance for open discussion and review and analysis, a real root-cause analysis.

Now maybe there is a root-cause analysis. Part of the problem is that they are reporting to a regulatory body. Part of the discussion we did have three weeks ago was this whole issue of, what happens to the information? Is it going to be used against us? That type of thing.

So we don't get a lot of honest -- we get some, for sure; I am not putting everybody in the same category, but particularly the more likely it is for somebody to end up with a blame issue or being put at risk of defending their license or something, the much more likely they are to provide technical information without useful analysis of the cases.

CO-CHAIR MEYER: Diane?

MEMBER RYDRYCH: I would just say,

yes, I wasn't part of this group, either.

I agree and disagree with it. I would say it is true that the last three events on this page, we have never had reported in six years. But I don't think that the fact that they haven't happened necessarily means they shouldn't be on the list.

I do think the spinal manipulative therapy question, to me, for some of these, there's the question of, is it an individual practitioner or is it a larger system issue? For me, that is kind of the issue with spinal manipulative therapy, is that we are more talking about one practitioner and what they do, rather than a failure in a system of care.

We do have some issues with the post-op death classification. I think in Minnesota we agree that just looking at ASA Class 1 is probably too narrow because it is sort of implies that any other patient, the death was anticipated in them, which I don't

think was the intent of that event.

I think we, generally, would support broadening of that, as the group recommended, to any anticipated interoperative or post-op death, not just Class 1.

But I don't know that I would describe these as least useful. I think they might need further clarification, and there can be discussion about adding or removing.

CO-CHAIR MEYER: Please, John, and then Stan.

MEMBER MORLEY: In things like the manipulative therapy, that is not going to happen in a regulated environment, or virtually not going to happen. We don't get any information from offices or things like that in terms of reporting.

CO-CHAIR MEYER: Right. And just remember that the charge of this Committee is to expand beyond hospitals. So that may be something to consider as we --

MEMBER MORLEY: Yes.

CO-CHAIR MEYER: Which may have been ahead of its time.

MEMBER MORLEY: Yes, and I would appreciate that. I would say, though, that, as we talk about that, one of the struggles that we have with current reporting systems is the amount of reporting that we get.

In New York, we have about 34 reportable events. I have forgotten the exact number now. The ones that are most serious I think, like a wrong-sited surgery, I would suggest -- and I can't say for certain -- that we have between 90 and 95 percent of wrong-sited surgeries reported to us.

Another category is thromboembolic disease. I would say we get about 10 or 20 percent of those cases reported to us. That is in a regulated environment.

So the point that I want to make is, if you go to the nursing home, I suspect that we would see a little less reporting, and home care, a lot less, and a non-regulated

environment --

CO-CHAIR MEYER: Stan?

MEMBER RILEY: So I guess that I would have to agree with Lucien Lee, who says that all reporting is voluntary, whether it is mandated or not. So that is certainly there.

I think, for us, I agree that these are rare events for us to have reported, but just, for instance, the licensed healthcare impersonator, because of the environment that we happen to be in, we have research assistants or researchers who sometimes are from foreign countries. They already have gotten an MD there. All of a sudden, they are participating in the patient's care. So that actually is one of the things that we have particularly seen.

So I agree that just because we see them rarely doesn't mean they need to be taken off the list.

CO-CHAIR MEYER: Okay. And we are not making that judgment here.

P.J., we want to move to the next slide, and then we will move on.

MEMBER BRENNAN: Okay. Gregg, on the first one, I think it meets the standard of being unambiguous, which is the advantage of it. I would certainly agree that there are unanticipated deaths that occur in other classes, but Class 1 is clearly one that is unambiguous, I think.

The second item, these sort of contamination events don't cause death very often in the short-term, but all of those patients injured in Nevada, for example, with hep C are certainly at risk of death or liver transplantation down the road.

The problem is we are, I think, ahead of the curve here with this one --

CO-CHAIR MEYER: Yes.

MEMBER BRENNAN: -- because there is no real reporting mechanism for these practices.

CO-CHAIR MEYER: If we could,

let's move to the next slide, the next slide down.

Again, I would just like the state reporting folks to react to this most and least useful list.

Does that comport with your experience? Or any commentary on these here?

DR. ANGOOD: So, then, the context of this is the subgroup was asked sort of, in addition to those ones that you just reviewed, sort of what were some of the more useful types of SREs, and then kind of what was the least useful overall, separate from that list you just looked at a moment ago.

MEMBER RYDRYCH: And I would just say I don't tend to think of these events in terms of most useful or least useful. So this doesn't really resonate for me personally.

CO-CHAIR MEYER: Okay.

MEMBER RYDRYCH: I think we have found all of them to be useful. As long as you are actually looking at the data and

really using it to identify those system breakdowns and identify what can be put in place, they can all be useful, whether they are more or less rare. I don't find events that report death to be more useful than those that are no-harm events, or any of the others.

MEMBER RILEY: And I guess I agree. You know, I think that the best learning probably is from the ones that aren't deaths. So I would agree with that.

And I think that criminal activities are actually useful to learn from. I mean, you know, with your experience not very long ago, I am certain --

CO-CHAIR MEYER: Three weeks ago.

MEMBER RILEY: -- that you learned a lot from that shooting at your place.

CO-CHAIR MEYER: Folks, just so we are not talking in code, about three weeks ago, we had a mental health provider in one of our psychiatry offices who a patient attempted to stab to death in her office, barricaded

herself in the office, and as he was stabbing her to death, a legally-armed off-duty security officer broke down the door and shot the perpetrator dead, saving the life of our psychiatrist, who is now home after four surgeries. But this is the real world. This is the real world.

Yes, I don't think anybody at Mass General had any problem with that being reported to the Department of Public Health, OSHA, the State police, you know, Interpol, whoever we could get to help us on that one.

DR. ANGOOD: But that actually brings up the point about this term "useful", and it is probably the wrong piece of language. But what drives reporting more are these types of topics versus what drives reporting less, partly because of the frequency.

It was interesting in the discussion, some of the states, Florida, in particular, as I remember it, the criminal

activity was actually a big part of their profile of the State-based reporting. And other states it was, clearly, "No, I haven't seen one in five years" type of stuff.

So I think for us to continue to use this word "useful" is the wrong term, but it is what drives reporting is more the issue here.

CO-CHAIR MEYER: Right.

Leah, do you have any comments on it? Because you also have a lot of experience with this list as well. Any comments from kind of the Leapfrog experience to say, boy, this is what has been very useful, less useful, or --

MEMBER BINDER: No, not entirely. The word "useful", I would just echo what everyone's -- useful to whom, for what? But that would be my only question.

CO-CHAIR MEYER: Okay. John?

MEMBER MORLEY: I confess that, when I first looked at it, I was interpreting

it the way Peter described it in terms of useful, that it does trigger more reporting and more response from the institution. So I thought yes.

Then, as I heard Stan and Diane's comments, I agree that it is not always useful in that sense. But it is a clearer line for delineation for the institution to report, to understand it, what their response needs to be in terms of a root-cause analysis, and so forth.

DR. ANGOOD: So I think it gets back to that sense of urgency that we were trying to get at earlier. What will drive people to report as opposed to kind of let it slide into this voluntary mode?

CO-CHAIR MEYER: Sally?

CO-CHAIR TYLER: Yes, I just wanted to say one thing. Because I wasn't on this working group, obviously, and I don't understand the term "useful" and "least useful" at all. So that doesn't work for me.

So maybe it is a different term that might work. So I am not really sure what people are trying to get at there.

But I know, from our members, in terms of healthcare workforce, frontline workforce, particularly around events to report criminal activities, they certainly feel like violence and assault is vastly underreported. There's a lot of confusion, you know, frequently not demonstrated or explained to them how to report and who to report to. When they do report to one supervisor up, they don't feel like it goes up the ladder. Nothing ever happens to it, and there are no system changes that are put in place because of it.

In particular, I think, in mental health settings, some people feel that the response they get is you have to expect some level of violence. You have to expect to be assaulted at some point. It is very frustrating.

So I don't think they would find the term "least useful" a good term. I don't know, you know, again, what we are trying to get at here. But, certainly, it is vastly underreported, at least according to the healthcare workforce certainly.

CO-CHAIR MEYER: Okay. With that, what I would like to do is I would like people -- Jennifer, if you can pull up the first of the slides of the specific SREs, and it is the surgical event slide?

What I would like us to do is -- and that is on page 15 of your handout -- I would like us to actually march through these.

Let me just make sure that we have the proper context here. What we are going to do now is we are going to provide some input to the existing list of SREs. Remember that we are only a small part of the process. So what will come after this meeting is, in that call for events, it will be asking people to react to the list. So there will be a broad

base.

So we are not going to be making a decision this afternoon. We are going to be providing input, but we are not going to be making a decision on each of these.

But it will be a chance for us to get a sense of the Committee early on about the existing list. Then what will happen, through both the TAP and through the public call, is that we will have an opportunity to get further input on the existing list and some advice about whether or not the list needs to be expanded.

So that part of it, the list expansion part, is not going to be covered, I don't think, during this day and a half. But we did want to at least get your initial reactions to the existing list.

Having no other way to do that, I would like to go through these one by each. Again, if you have a strong reaction to this one way or the other, what I would like to do

is we would like to get your reaction down kind of on paper. So we can make sure it is part of the process here.

So we are going to start with the surgical events because of the order.

So Michael is just aching to jump in.

MEMBER VICTOROFF: My minor simple change is to change that to "procedure". We just published a paper where we identified that, of all of the wrong site procedures, more than half of them were done by non-surgical specialists.

CO-CHAIR MEYER: Right, interventional radiology.

MEMBER VICTOROFF: Well, I'm sorry, ours were internal medicine.

(Laughter.)

But we are willing to compete on any -- point made.

CO-CHAIR MEYER: Yes.

MEMBER VICTOROFF: Surgery is

probably too narrow a word, and I think the word "procedure" covers everything.

CO-CHAIR MEYER: So you would say procedural events as the major heading, and below that, in terms of SRE 1A, procedure performed on the wrong body part?

MEMBER VICTOROFF: Yes.

DR. ANGOOD: Gregg, please may I make a quick comment?

CO-CHAIR MEYER: Yes.

DR. ANGOOD: Before we get too much further into this, I want to just review some of the questions that we had posed in the introductory comments earlier this morning for framing it again.

We have gone through the definition and the criteria. That is now very, very helpful, and it has consolidated that.

So, as we go through this, in the overall process, you know, are there changes to the list, the consolidations? Are there

SREs that will be added or those that need to be omitted? You don't have to do all of that today, but that is the long-range purpose in here.

So I, personally, and this is just a personal comment, but, you know, in this first cluster, that is one that might, as an example, be consolidated a little bit. It doesn't have to be, but that is just one that we might want to think about. And there may be others as we move forward.

So, rather than just getting nitpicky one by one by one, think broadly as well. But there are processes that we have to go through.

CO-CHAIR MEYER: Deborah?

MEMBER NADZAM: Can one of you explain the exclusion that occurs in 1A and 1C, emergent situations? It is in this one as well. I don't know exactly where.

CO-CHAIR MEYER: "Excludes emergent situations that occur in the course

of surgery and/or whose exigency precludes obtained informed consent."

MEMBER NADZAM: I guess I am puzzled by the informed consent and emergent and --

CO-CHAIR MEYER: I will give you a very concrete clinical example. Maybe it might help.

A patient comes in with chest trauma after a motor vehicle accident and is having trouble breathing. We need to put a chest tube into that patient to allow that patient's lungs to reinflate and circulation to proceed unimpeded.

We put the chest tube in in the wrong side. We guess wrong, to start with. We end up putting them in on both sides of that patient. That first one wouldn't be a wrong site surgery.

On the other hand, a patient comes in for an outpatient diagnosis of a collection of fluid in their chest. Clearly, there are

on the x-ray -- this is done as an outpatient -- it is on the left side. They put in the chest tube on the right side. I would say that is wrong site.

So I think the idea was that, I would argue that the problem whenever you put any exclusions is that people want to interpret that broadly, but I would say it is pretty narrow.

But I think in some of these, boy, I put the chest tube in the wrong site. Yes, but it is in the middle of a trauma code, and I just put it in the other side right after that. So be it.

Where I put the chest tube in the wrong side and the patient was coming in for an elective diagnostic procedure, that is wrong site. That is wrong site, and it is tough.

MEMBER RYDRYCH: And I would just clarify that. I mean, for us, that chest tube would still be reportable because we would

look at, what was the intent? If you guessed wrong, you just weren't sure which side, and you put it on the left, that is not reportable. But if you intended the right, and put it on the left -- but I think the reason for that exclusion is that the only way to get at intent is to look at the informed consent sometimes.

We, at least in the early years, ran into problems with people saying, well, sometimes there isn't informed consent. That was sort of the loophole a little bit. If there was no informed consent, therefore, it couldn't be wrong.

So we try to get at intent a little bit more broadly.

CO-CHAIR MEYER: Let me just, again, trying to think broadly about this, the world has changed. When this list first appeared, I can tell you, the anxiety around the 2002 list was off the chart because people had all sorts of ideas about what was going to

be done with this and what the implications would be, and what would it mean when you put this out in the public domain.

That is why it is in place to let's be more precise and let's have more exclusions. Now one could argue and say, boy, 2009 is different than 2002, and maybe we can live with the fact that, boy, that chest tube in the emergency room may end up getting reported. So be it. No one is going to lose their job over it.

DR. ANGOOD: Well, and I think that is an important point to make, Gregg. A number of years, too many institutions were not very good with informed consent, and they oftentimes classified something as emergent when it was just kind of urgent. So I think the more we can tighten it down, because there is a tolerance for tighter processes now compared to five and even ten years ago, so I think there's room to get rid of some of this language.

CO-CHAIR MEYER: John, and then back to you, Mike.

MEMBER MORLEY: To follow up on Mike's comments, New York's experience has been very, very clear. We have two reportable codes, what we call a 911 and a 912. The 911 is a wrong-sited surgery. By definition, it is surgery and it is in the operating room. A 912 is a procedure.

So part of the point I want to make, I agree with changing to procedure. There is an opportunity or a consideration for having a second code for procedure. That is what New York has done maybe.

But I would like to really request and urge at this point -- I wasn't going to mention this until later -- that there is a consideration for expanding it yet one more level. Procedure -- in New York, by the way, the numbers are 20 for wrong-sited surgery, just New York State, 20 wrong-sited surgeries per year, approximately 100 wrong-sited

procedures per year.

And besides radiologists, the other category that is increasing is anesthesiologists doing a block on the wrong side, and the surgeon comes in and says, "No, we're doing the other side," but the block is in. We call that a 912. That is 100 of those versus 20 wrong-sited surgeries.

The other category that I would say I would like to see added, and I am saying it earlier than I had planned, would be radiation, which is not considered by some a procedure.

We had an event in the papers recently, a high-profile case of a pregnant woman in the ER who is asked -- someone calls her first name. So she steps up and gets a CT scan and she is pregnant. The wrong patient got the CT scan.

We have a number of radiology issues. Some of those are radiation therapy on the wrong site.

So it gets a little fuzzy in terms of how some people interpret that term "procedure". "Well, I wasn't using a scalpel." "Well, I wasn't using a needle." Radiology is also an issue for us.

CO-CHAIR MEYER: So I think that is great. It is the kind of feedback to put in. Well said.

We will go to Diane, and then to Doron.

MEMBER VICTOROFF: I don't see any reason here, even after the explanation for this middle sentence here, "Exclude the emergent" and something, something, "informed consent" --

CO-CHAIR MEYER: Yes. We should just ditch -- that was the point we were making. Maybe we are mature enough now to get rid of the exclusion.

MEMBER VICTOROFF: You know, I am sort of in the let-the-chips-fall kind of sentiment, and let us report too much, of

which some of them are excusable and explainable and defensible and some aren't, and that is someone else's problem.

CO-CHAIR MEYER: Diane, then Doron, and then Leah.

MEMBER RYDRYCH: Mine will be short because I am just going to echo what John said. Those are big areas where we see issues as well, wrong-sited blocks and radiation therapy.

CO-CHAIR MEYER: We do, too.

MEMBER RYDRYCH: And a lot of our wrong site, wrong body part, wrong patient are outside of the OR.

I would just say maybe another thing that NQF should think about is more specifically defining what is an invasive procedure. We have a standard list that we use or a list of codes that are considered to be invasive procedures that includes radiation therapy. But, to the extent that the additional specifications can be clearer on

that, rather than just saying, "includes endoscopies and other invasive procedures", I think we will see a lot more consistency across states and a lot less confusion about what should be in there and what shouldn't.

CO-CHAIR MEYER: Stan is nodding in agreement.

MEMBER RILEY: Yes. I agree completely. You know, that is exactly the kinds of things that we are seeing, and the more consistency across states, that would really be helpful.

CO-CHAIR MEYER: Doron, and then Leah.

MEMBER DORON SCHNEIDER: This may not be easily identifiable, but the consent being done incorrectly, in that the body part was done, the surgery was done correctly, et cetera, et cetera. But if you think about the patient partnership, the National Priorities of capturing the patient voice and ensuring that they are a decision maker in their care,

you know, having everything go correctly, but the patient not understand that that was occurring is another variation, that that was going to occur.

CO-CHAIR MEYER: Are you arguing that, in addition to the procedural list, with the exclusions, maybe adding radiation and radiology procedures, and the rest, that even separate from that -- so the patient got the procedure done on the right body part, and the procedure was supposed to be done on the left side, it was done on the left side, but the consent said my right side, you would count that as --

MEMBER DORON SCHNEIDER: Well, either the consent wasn't done at all, you know, the consent wasn't done or it didn't list death or it didn't list the correct list of --

MEMBER RYDRYCH: Or the consent was incorrect.

MEMBER DORON SCHNEIDER: Or the

consent was incorrect. I think that would align us very nicely with the priorities, the National Priorities, just to consider.

CO-CHAIR MEYER: And I would argue that this is, again, where there is, putting on my other hat that I wear, that this is something that the State Practice Committee feels very strongly about, and we have a very specific safe practice on this specific issue.

And whether or not we want to consider that would be a serious reportable event as well is something I think that we should at least take into consideration.

Leah?

MEMBER BINDER: Just to go back on the point about the language "an emergency basis" or patient consent, I agree that that should be removed. I just want to make the point of why.

I think that this should be based on the harm to the patient. It should be a patient-centered experience. So, if a patient

has wrong site surgery, they don't care whether it happened in the emergency room or outpatient, it is a catastrophic event in your life and in your family's life.

So the burden should be on the providers to report it and to prove that it couldn't have been prevented.

CO-CHAIR MEYER: Well said. Okay.

Any other comments on this? This is terrific.

Again, we are providing our input into the process. Others will have the same opportunity.

Mike, before we leave this one?

MEMBER VICTOROFF: This is microscopic on D. The way we state leaving foreign bodies in people is a foreign body --

CO-CHAIR MEYER: Let me go through.

So I am not sure we are done. But we will pull up 1B here.

1B, again, I think some of these

changes carry through to all of the surgical procedures.

Anything else that we want to add to 1B again? Changes to procedure --

MEMBER VICTOROFF: Okay, B is wrong because it shouldn't have anything to do with documented informed consent. It should be the patient's clinical indication.

CO-CHAIR MEYER: Right.

MEMBER RYDRYCH: And that same thing is on the first one, but we didn't talk about it.

MEMBER VICTOROFF: Right Yes, exactly. Those both should be changed because the question -- it is not that that is a question, but that is another question.

CO-CHAIR MEYER: Right. So, if the patient signed off and said, "My informed consent says go ahead and remove my right hand," and actually the right thing to do is the left hand, but you remove the right hand, you still did the wrong thing.

MEMBER VICTOROFF: But it should be the patient's indication.

CO-CHAIR MEYER: Yes.

MEMBER VICTOROFF: And then we have like let's put that on the list of possible things to add to defects in the informed consent, which is another topic for another day.

CO-CHAIR MEYER: And again, I think if we enjoin that conversation, we would want to pull up the safe practices when that comes because I think they cover that pretty well.

Other comments on surgery or procedure performed on the wrong patient?

Again, many of these roll through all of the procedures, the comments that you just made, which is great.

MEMBER VICTOROFF: Does this also comprise identity theft? I don't want to contaminate it, if it is unwanted, but we have a large number of people who use false

credentials or identification to obtain medical services by fraud.

CO-CHAIR MEYER: Yes.

MEMBER VICTOROFF: Or, you know, never mind the fraud; they are pretending to be their cousin because they've got a Medicaid card.

CO-CHAIR MEYER: Yes.

MEMBER VICTOROFF: Whether we include that anecdote in this or not doesn't matter to me, but we should specify whether it is.

CO-CHAIR MEYER: So let me just say, to put some color commentary on that, we had a situation six months ago, or about six or eight months ago. We had a patient come in with appendicitis and ended up bringing that patient to the operating room.

Before the patient underwent the procedure, we discovered that there was a mismatch between our blood specimen then and the prior blood specimen. I mean while they

were ordering the ABO-compatible blood, and that was how we discovered it was her cousin's insurance card. Fortunately, they didn't have the same blood type for them.

I would argue that maybe -- and this is a real issue; this is as real as any of the other criminal events there. And, boy, there are lots of good reasons for it. These are people who are desperate. They don't have insurance.

But, with that said, one could think that maybe that is something, a place where we would want to expand the criminal list. It is a tough thing to raise.

MEMBER VICTOROFF: Can I intensify that, just one more anecdote?

CO-CHAIR MEYER: It's tough.

MEMBER HOEN: This is a big can of worms.

CO-CHAIR MEYER: It is. This is going right up against CMS HIPAA Red Rules.

MEMBER HOEN: Yes, and this is a

bigger issue than I think that we can possibly tackle.

I've got information that shows the number of people who access healthcare, primarily, 85 percent of them, with made-up Social Security numbers. I don't consider that to be identity theft or fraud. They are simply trying to access healthcare. They think that they can't get it unless they give that number because that is the first thing that they ask when they walk in the door.

So I think this is a big can of worms. It has to be addressed. There are specific instances like you have just talked about. I have only had that happen a couple of times, where they actually presented somebody else's insurance card or identification.

More often than not, it is illegals trying to access healthcare with made-up Social Security numbers.

MEMBER MORLEY: Ditto in New York.

CO-CHAIR MEYER: Yes.

MEMBER MORLEY: Ten years ago, I ran the pre-anesthesia screening clinic, and we encountered it. I think it is a very real problem, but I would like to see this clearly more clinical, more adverse event, quality, safety. And while those are very real issues, I would certainly agree that I don't think it is appropriate for this purpose.

CO-CHAIR MEYER: Okay. Let's move on to the next one.

This is the wrong procedure performed on a patient. And again, we have put in the caveats there about getting rid of the exclusions and broadening the definition of procedures.

Any comments?

MEMBER VICTOROFF: Get rid of the informed consent.

CO-CHAIR MEYER: And get rid of the informed consent piece, yes.

MEMBER RYDRYCH: Yes, I think that

has some implications for the implementation guidance, too, in terms of what you are saying about where surgery begins or when surgery begins or when it ends, not just changing it to say surgery or invasive procedure, but there are other ways you would probably want to specify that as well.

CO-CHAIR MEYER: Do you have any ideas about how we can prime the pump to get input on that? Diane?

MEMBER RYDRYCH: I don't know because that is one we are really struggling with in Minnesota right now, is when does a procedure end, and we have been going back and forth on that for a long time.

CO-CHAIR MEYER: We are as well.

MEMBER RYDRYCH: So I don't really have an answer.

MEMBER VICTOROFF: Just to add something, this is a poisonous complication here. I don't know what to do with it.

But, in our taxonomy, we have

several categories of you didn't do the right thing here. Sometimes it is because of a clinical judgment where you chose, you deliberately chose a procedure, but it wasn't under guidelines or standard of care the correct procedure for the indicated condition or it was obsolete, or you shouldn't have made that -- that was the wrong approach to take to the organ. I mean there's a lot of fuzziness under this where you could say, well, that was the wrong procedure, like you should have done a two-level fusion, you know, and what you did was a -- and I am not sure we want to capture the clinical nuances of judgment here.

And I am not sure that this language actually articulates the other thing that we do want to capture, which is you came down for a shoulder reduction, and you got a knee reduction, because we're dumb.

CO-CHAIR MEYER: Yes, I think it raises on general issue. I am going to let Stan respond to this as well.

One general issue is, and some of us talked about this during one of the breaks, we are never going to come up with the perfect list. There are always going to be conversations between people like myself and healthcare organizations, people like Stan, and the Commonwealth of Massachusetts, about, is this right or not?

So we can't get rid of the discussions. I think trying to get rid of as much ambiguity, using the word again, as we possibly can is great, but we are not going to get to zero. So thinking it makes it so.

MEMBER DORON SCHNEIDER: The way the language is, it says, "The event is intended to capture the insertion of the wrong medical implant into the correct surgical site." That's a little different.

CO-CHAIR MEYER: Yes, it is a little different. I can tell you the specifics, the specific issue that came up that led to that language. It has to do with

the wrong intraocular lens, the wrong strength of intraocular lens being inserted. You know, you have a cataract extraction on the left eye. Yes, they did the left eye, but they put the wrong lens in. That is why that added language was there.

MEMBER RYDRYCH: And I would just say, from our perspective, we have certainly had that case, that type of case, a number of them, which we have considered a wrong procedure. We have also had patients who specified a saline breast implant and got silicone. And we have had cases with orthopedic procedures where it was the wrong material. Someone had an allergy to a certain type of material, and then a different kind of implant or different size was put in. To us, it falls into that category and reflects a breakdown in the system.

DR. ANGOOD: And in the data collection systems out there, orthopedics, ophthalmology, device-oriented specialties are

the ones that lead the list in terms of these types of wrong-sited -- wrong surgeries. Sorry.

CO-CHAIR MEYER: Other comments on this one?

(No response.)

Can we move to D? So this is retention of a foreign object in a patient after a procedure. We just shortened that. We just get to after a procedure.

MEMBER VICTOROFF: We use the language "foreign body unintentionally" left in a patient after a procedure.

CO-CHAIR MEYER: Right. So there are many times they leave --

MEMBER VICTOROFF: Yes, we leave, deliberately leave pacemakers in and stuff, but -- yes, we would just move the language from the right column to the left column, to be part of the definition.

CO-CHAIR MEYER: In that center column, are those the additional specs?

DR. ANGOOD: Yes, equivalent.

CO-CHAIR MEYER: Yes. This is a little bit of NQF inside baseball. But, in fact, the actual piece of this that applies to the National Technology Transfer and Advancement Act is both the definition and the additional specifications.

So, if you are seeing it in the first two columns, it is, essentially, that is the stuff you have to do. People will sometimes shorten it just to the definitions, but the real meat is in the combination of the two.

MEMBER RYDRYCH: And I would just say, again, on the guidance or on further defining it, being specific about labor and delivery I think is important here because that is an area where we have seen a lot of retained objects, and a lot of people don't consider vaginal deliveries to be invasive procedures, but we do.

The other area that I think we

want to be clear on is device fragments and things that break off inside the body. Sometimes we find that people don't consider them to be those, like, you know, a catheter sheath or something else to be a retained object. And maybe it just needs to be clarified a little bit in the implementation guidance because I think people tend to think of sponges and clamps and not much else there.

CO-CHAIR MEYER: So I think that that's --

MEMBER RILEY: I was going to say, the other thing is, with all the laparoscopic things, you know, pieces of staplers or things like that, that get left in, even though the whole instrument is pulled out, and they don't see it until two or three days later, whenever they check. So that is huge.

CO-CHAIR MEYER: Okay. Doron?

MEMBER DORON SCHNEIDER: Well, there is language exactly to that. It is right there. It says excludes that, "objects

not present prior to surgery that are intentionally left in, when the risk of removal exceeds the risk of retention, such as microneedles or broken screws." Doesn't that capture that?

CO-CHAIR MEYER: Not exactly.

MEMBER DORON SCHNEIDER: It is an exclusion.

CO-CHAIR MEYER: Yes, I think the classic example would be a patient comes in and has an epidural block done. The catheter sheath shears, and they are left with a piece of catheter in them. I mean it is actually something that you don't want to leave behind.

MEMBER HOEN: We have actually had a couple of cases where it was wound packing that was left in a patient, and the wound closed over it, and later had to go back and extract it.

So I would suggest that that should be an area also --

CO-CHAIR MEYER: That is.

Can we talk about this microneedle issue? So the point here is that, as many of you know, some of the needles that we use are literally you need almost a microscope just to see them. They are incredibly small.

If the needle count is off at the end of the procedure, you have to ask yourself a question: do you go on a safari in somebody's abdomen to try to literally find the needle in a haystack or do you leave it behind?

And if you do leave it behind, is it a serious reportable event or not? And I know what the language says here, but, to my mind, the failure in terms of a lesson learned, it is the process broke down. You left something behind. But that may be a little bit too harsh.

MEMBER DORON SCHNEIDER: But if there's no harm?

CO-CHAIR MEYER: It is hard to know. What the surgeons will say is, they'll

say, "Boy, some of these things are as small as the staples we leave in people, not a big deal."

So I would love to get a sense of the Committee. I am not sure where I am on it. I think I am more leaning on these are serious reportable events still because we've got to learn from them, but maybe I am off the ranch on this.

So I want to hear from Stan and from Diane.

MEMBER RILEY: I guess I sort of agree with a piece of that. Certainly, 70 and 80 needles, if you are doing coronary, for instance, gosh, they are hard to find even in the pericardium when you are looking straight at it.

MEMBER GANDHI: Yes, and our surgeons tell us that a lot of them get sucked up in the drains and things like that, and you just never find them. So you don't even know that you have left it behind.

CO-CHAIR MEYER: So what I am trying to parse out here is, clinically, you can make a very rational decision and say, the benefit of taking it out isn't worth the risk of trying to go and find it. But you decide not to take it out. You close the patient up. Is that a serious reportable event or not?

MEMBER GANDHI: Right, and you could make an argument that that was deliberately left in or left hanging, depending on how you want to phrase it.

CO-CHAIR MEYER: But your needle count was off.

MEMBER GANDHI: Yes, the needle count was off, but, again, they are saying they may or may not be in the patient. They could be anywhere.

MEMBER BRENNAN: You don't know for sure.

CO-CHAIR MEYER: Yes, and these are so small. You are talking about a 70 needle. Finding a 70 needle in somebody's

chest with a radiograph, even with a CT scan, is not easy. You can't do it.

MEMBER GANDHI: It is not possible.

DR. ANGOOD: Do you inform the patient, too?

CO-CHAIR MEYER: If it is me, you are.

DR. ANGOOD: If it is an adverse event, are they going to worry about it?

CO-CHAIR MEYER: No, this is what makes it fun.

So, Diane, what is your experience?

MEMBER RYDRYCH: Well, I think this is exactly the question we have been struggling with, actually. Because we want to not penalize people if their process worked and they identified that the object was likely to have been retained before the surgery was over. That means their process did the right thing, and we don't want to punish that.

We do exclude microneedles and we exclude things from reportability if, for example, in the case of a broken pin during a hip procedure, if you discover that it broke off before you closed, and you made a decision I am not going to take it out because it is not going to cause any harm or it will just be too tough on the patient to take it out. We don't consider that to be reportable. Your process worked. You identified that it was retained beforehand.

CO-CHAIR MEYER: So, getting to Peter's point, my needle count is off. I say I'm missing a 70 needle; we're going to close up.

MEMBER RYDRYCH: That is the exact question we have been struggling with. We have hours of phone calls with hospitals and the hospital association and the health department about this just over the last couple of weeks, trying to decide if there was something -- you think it was possibly

retained. Maybe you have to leave the OR to get a better image, and then you have to come back in. Does that count as being retained or not? To be honest, we don't have the answer. I lean towards saying yes.

CO-CHAIR MEYER: Let me hear from P.J. Do you want to jump in here?

MEMBER BRENNAN: No, go ahead.

CO-CHAIR MEYER: Michael?

MEMBER VICTOROFF: Let's not confound, again, the problem of whether there really is a good remedy or whether it is actually excellent medical judgment to proceed a certain way.

And the other totally separate problem, whether this is information that we or some other patient in the future might wish to capture for epidemiologic purposes or safety purposes.

And I, as the person in the recovery room, have the right, I would to say, to hear that you made a judgment in my behalf,

and it is almost certainly right because you are a genius. And this little piece of needle, first of all, it is probably up in the suction somewhere, and in our study of thousands of people where we reported this and tracked it, these were the outcomes. So this is what I have to tell you about it because we have tons of information about it, and that's why I know I made the right decision.

On the other hand, we could simply say, "Don't worry, honey. Some stuff happened, but I did all the right things because I am a really smart surgeon, and you don't have to worry about us reporting what you don't know about because it probably isn't relevant."

So pick one.

CO-CHAIR MEYER: John, and then our surgical friend to my right. John?

MEMBER MORLEY: I would lean very clearly toward saying it was a reportable event because I would want to know about it

myself as a patient. I would want to be able to track it.

It would concern me a great deal if half the hospitals in my State had it happen once or twice, and there's another hospital, one hospital, that it happened 47 times. So that is one value to tracking it.

There's another value. I think the patient needs to know about it. I think it could potentially be a very interesting finding for the next surgeon that comes into that abdomen who gets stuck with it.

MEMBER RADFORD: Just to clarify my own thinking on this -- this is Martha speaking -- you know, the goal of these reportable events is to report and to form kind of a database around things that are reported.

I mean, to me, some of this is edging toward health services research, which is not a bad thing, and maybe that is one of the goals of these reporting requirements.

So I just want to hear other people's points of view on that.

DR. ANGOOD: This is Peter Angood.

That is a good point, Martha. My comments are, you know, there's, again, a spectrum of need here. Certainly, on a case-by-case basis, you can make an argument for saying, "Well, it is this little, wee, bitty needle, and it is too much fuss to go and find it, and it is not going to bother the patient anyway. So we will just move on past."

But you want to make sure, still, that there are processes in place to serve as a checking mechanism that things are actually being done. If the processes aren't in place, then slippage occurs.

So I think it is important to have this as part of the process check. The outcome patient-by-patient may not make much difference.

I think the point about the greater good and collecting the information is

pivotally important, as well as the patient outcomes, in terms of the knowledge base.

MEMBER RADFORD: Yes, I would just urge people to be somewhat evidence-based here and to be sure that we have some evidence that -- I mean I am just picking on these small needles just because people complain to me about it.

We have some evidence that there is, you know, harm and that something can be done about it. I don't know. I mean the person, the organization that reports one a year versus 47, they could just not even be counting. In fact, I have heard about organizations that stopped counting.

CO-CHAIR MEYER: Yes, I think that that point is an important one.

One thing I would argue is that the policies and procedures that you have that will mitigate the risk of leaving something small behind, one would hope would have some impact on your risk of leaving something more

significant and potentially harmful behind.

So one of the real things that we struggle with in safety science is no harm, no foul, which is kind of a classic way to think, and sometimes you get yourself in trouble if you say, boy, they weren't harmed; we don't really need to pay attention to it. In fact, the next time it happens, it happens differently, and the Swiss cheese is lined up worse, and it hurts somebody badly.

Doron?

MEMBER DORON SCHNEIDER: So, when this was written, this was excluded. You say, "Objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention, such as microneedles or broken screws."

Now I would argue that we should take that exclusion out because it is now ambiguous. We should make it unambiguous, so that if you start a surgery, you have intended things that you leave in. If there's anything

that is unintentionally left in, it gets reported. That is unambiguous.

CO-CHAIR MEYER: And the patient gets informed?

I am sure, by the way -- again, we are just part of this process. So, whatever input we have on this, we will certainly be hearing from the American College of Surgeons and the Society of Thoracic Surgeons, and others, during the public comment period.

Leah?

MEMBER BINDER: There's two issues with this, too. There's whether or not a small needle, whether it was left in or not. Then whether it is appropriate for a surgeon to respond in one way or another, whether it is responsible to search for it, and all of that.

But this document is getting at, was there harm done? Was something serious done? Not what was the clinical remedy and whether that is appropriate. In other words,

the harm to the patient in this case of leaving a small item in is harm to the patient, period, regardless of the fact that it might not have been feasible or clinically appropriate to try to remove the needle.

CO-CHAIR MEYER: And let me remind folks that one of the things we did with that definition this morning, which we did say that there were some close calls that were important enough that they ought to be considered here.

John, and then I think we will move on after this. It is a great discussion.

MEMBER MORLEY: I wanted to agree with what Doron had said, that taking that out would be a good thing.

If I may ask a very quick question for personal -- we have an argument going on in New York. If a thoracic surgeon does thoracic surgery, closes the patient. The patient goes to the ICU, and the following day goes to remove the pulmonary artery catheter

and can't, and learns it has been sewn in, is that a retained foreign body?

MEMBER RILEY: I guess I think the answer to that one is yes, mostly because, as a thoracic surgeon, you know, you can staple across the pulmonary artery and you can see the Swan-Ganz catheter in the artery. So the answer is you probably know that it is there, and you should do something about it. So I would say yes.

MEMBER MORLEY: By the way, Dr. Ganz passed away two days ago.

CO-CHAIR MEYER: It's not easy. There will be discussions, no matter what we say. There will be some interesting discussions.

Leah, and then P.J.

MEMBER BINDER: Just a quick point. I can't read the comments that are being typed. I just want to make certain.

Diane made a point that I think we should definitely include in this, and I don't

know if it is there or not. It is about objects left, vaginal deliveries and the objects left in. That is a very important point that I want to make sure we keep mindful of.

CO-CHAIR MEYER: Okay. P.J.?

MEMBER BRENNAN: Gregg, I just want to come back to my earlier point. The reporting here would occur on discovery, not on miscount.

CO-CHAIR MEYER: Right.

MEMBER BRENNAN: So, at the end of a case, if you have a miscount, that is not the basis for a report.

CO-CHAIR MEYER: It isn't, and I think it really gets to one of the scarier aspects of all of this. That is, if we say, yes, these are reportable, are people going to stop doing counts of microneedles? And the world can respond in perverse ways.

MEMBER BRENNAN: There are a lot of things that aren't counted that can be left

behind.

CO-CHAIR MEYER: Absolutely.

MEMBER BRENNAN: Sheaths.

MEMBER RILEY: So I was just going to say that, in part of the vaginal delivery piece, almost all those sponges in the past have not been radiopaque, so that they couldn't be seen.

One of the changes that we have seen, at least in Massachusetts, is now they have changed to using the ones that are radiopaque. So I think just knowing that has made an important difference.

CO-CHAIR MEYER: Let's move on. So I think we've got some good comments that are going to stir up some reaction from the field.

If we can move on to 2?

As a process check, just so people recognize it, we are required to have a period of public comment. My understanding is there are no public commentators in the room.

Are there any on the phone?

(No response.)

No public commentators on the phone.

DR. ANGOOD: Operator, could you just check and see if there are any open lines, other than the individuals who are part of our Committee?

THE OPERATOR: There are none.

DR. ANGOOD: Thank you very much.

CO-CHAIR MEYER: So what I am proposing that we do is we actually roll through as many of these as we possibly can. I would like to hold close to our adjournment time. I am hoping we can have maybe 15 minutes or so to run over a bit, to get through more of these. We will need to go through the rest of these tomorrow morning. This is important work for us to get through today.

So if we can go to 1E? And this is one, again, that there was some discussion

on. First of all, for those of you, just to make sure everyone is onboard, ASA, American Society of Anesthesiologists, Class 1, these are the lowest-risk patients. These are patients who generally are relatively healthy going into their procedure.

So, Diane?

MEMBER RYDRYCH: And I am not going to comment on that because I think I already made my vote for expanding it beyond ASA Class 1.

But I think what has always been a little confusing for me about this one is, when you look at the implementation guidance, it is not clear whether this is really intended to just capture anesthesia-related events or if it really is unanticipated deaths during or after surgery due to other factors.

Because the discussion is mostly about anesthesia and it is intended to capture events after administration of anesthesia, whether or not the planned surgical procedure

was carried out. So I think there is some confusion there about what the intent was, whether we are really trying to capture reaction to anesthesia or deaths associated with the anesthesia as opposed to the broader category of surgical deaths that may or may not have been associated with the anesthesia.

DR. ANGOOD: My sense is that it has been primarily designed towards the anesthetic-related deaths in otherwise healthy individuals, but it can be complicated.

CO-CHAIR MEYER: Stan?

MEMBER RILEY: So I guess I was going to say that the ones that we have had reported to us, almost all of them have been from C-sections. The mother is an ASA 1, and then the procedure ends up a disaster, and there's a death or some serious disability, a hysterectomy. So those are the ASA 1's we went through.

MEMBER RYDRYCH: Yes, and I will just say we haven't had very many of these

reported, but the ones that we have had reported have not all been anesthesia-related, which is an argument for clarifying I think.

CO-CHAIR MEYER: Doron, and then John.

MEMBER DORON SCHNEIDER: Just a question about, is there overlap here between this one and death associated with medical error, in a sense of PCA errors around C-sections? I just throw that out there as, could that fall into two categories?

CO-CHAIR MEYER: Potentially, yes.

John?

MEMBER MORLEY: I agree with Diane that I would suggest that it be expanded from ASA Class 1, which, by definition, is somebody that takes no medications and is healthy, to include ASA 2's. I would hope that it would go as far as including anyone that has had an elective procedure.

I am just reviewing in my mind, I have been reviewing our codes for unexpected

death in New York State recently. So I am thinking we have had a number of cases of patients that have had a hemorrhage and died of surgical complications, hemorrhage, died within 24 hours.

And finally, the same comments that have been made about procedure before, so that it is clear that this includes endoscopy, should be considered.

CO-CHAIR MEYER: And interventional radiology.

MEMBER MORLEY: Correct. Yes.

CO-CHAIR MEYER: Other comments on this one?

I am sure we will hear a great deal of feedback based on these comments from the field as well.

MEMBER TANGALOS: Well, have the radiologists and the endoscopists been getting a free pass on this? Or are they being reported now anyway?

CO-CHAIR MEYER: You know, my

guess is that varies state to state. I can tell you in the Commonwealth of Massachusetts, if we had a patient who died immediately post-endoscopy, and Stancel Riley didn't hear about it, Gregg Meyer would be hearing from Stancel Riley.

But I don't think that that is -- and again, this would make it a little bit more universal, getting to one of the points you made earlier, that getting some uniformity across states has a value of its own.

MEMBER RYDRYCH: Yes.

MEMBER MORLEY: In New York, the answer to that would be there's variation from institution. Some institutions, clearly indicated surgery, and some are better reporters than others.

CO-CHAIR MEYER: I think the notion of expansion will be provocative, and let's see what we hear.

Diane?

MEMBER RYDRYCH: Well, just one

other comment on anesthesia. You know, when I look at the implementation guidance, I actually don't even remember ever seeing that before, the associated with administration, anesthesia, whether or not the planned surgical procedure was carried out. And I probably just missed it over the years.

But that is something that I would be amazed if that was ever really reported. I mean that is going to be a very, very rare event, but I don't think there's clarity about that; that if anesthesia were administered, the surgery never happened, the patient died. I don't think there would be understanding of that as a reportable type of event.

I don't know. Do you, John?

CO-CHAIR MEYER: So we may want some clarifying.

MEMBER RYDRYCH: It would be?

CO-CHAIR MEYER: Yes.

MEMBER RYDRYCH: Well, maybe that is just us then. We need to clarify that.

CO-CHAIR MEYER: So we get some clarifying language there.

As soon as Jennifer is done typing that one out, we will move to No. 2, product or device events.

Again, I open it up for comments here.

Stan?

MEMBER RILEY: So I guess this brings up something that is being done now for breast reconstruction following surgery for cancer. There is a non-sterile biologic called Alloderm. Alloderm is used to make just a much nicer result, but it is an unsterile product.

One of the things that has happened with the use of this product is the number of breast infections have gone from about 6 percent to about 20-odd percent. So it is one of those things that you go, ooh, wow, that's important to know about.

So I think this is a really

important area for picking up things that you are not sure about until you just sort of see them and they go, oh, wow, this is bad.

CO-CHAIR MEYER: And did those come to you under this SRE?

MEMBER RILEY: No, actually, they didn't come to us under this SRE. They came to us under sepsis. Whenever we saw what the real problem was, we, then, reclassified them as this.

CO-CHAIR MEYER: Other comments on this one?

MEMBER MORLEY: Question? I don't know how this is interpreted in terms of a fairly relatively common issue across the country, which is IMED or IVAC infusion pumps and errors with that. Do you get those reports, do you think, with this?

I think it happens more commonly than we see those reports, just because it is not always thought of. In terms of the reportable events, one of the things that I

have said in defense of hospitals is that there's only a certain number of reports that they can keep track of with the resources that they have as well as we have. So I am not sure that is one of the ones that is enough of a priority that people actually appreciate it.

You know, even if we came up with a list of 100 things, I don't think hospitals could come up, any healthcare facility could come up with the resources to track and find all of those events that happen.

MEMBER PHILIP SCHNEIDER: John, is that related to infections or is that related to dosage errors?

MEMBER MORLEY: Dosage errors.

MEMBER PHILIP SCHNEIDER: Because that would fall under SRE 4A, I would think.

CO-CHAIR MEYER: Yes, if you had death from --

MEMBER MORLEY: Well, I am thinking it is both, actually, but it is a dosage issue. You know, as the pumps have

gotten smarter and people rely on them more, they just sort of -- things happen.

CO-CHAIR MEYER: Yes, Michael?

MEMBER VICTOROFF: Could I ask how attached we are to the term "serious disability"? I am not sure that completely captures stuff like 300 people in Denver that were exposed to hepatitis C because a nurse was diverting Demerol and she used contaminated needles, and several of those people are going to get hepatitis C. I don't know if everyone is going to agree that getting hepatitis C is a disability.

Or a person who was put in a coma and sent to ICU because of a morphine dose who came out fine. They didn't die. They weren't disabled. They came fine. They spent three days in ICU on a vent.

So do you guys call those disabilities?

MEMBER RYDRYCH: That is a can of worms, too, though. I mean that is something

we have worked on a lot, is trying to define what serious disability means, and we do have a whole algorithm for people to work through. You know, was there a fracture? Was there a head injury? Was the person transitioned to a higher level of care for 48 hours or more? Did it affect activities of daily living for seven days or more? So we have a whole bunch of criteria that we look at.

Whether we capture hep C, something like that, I honestly don't know if that would be captured there, but I think that is one of the challenges for the states that do this, is trying to figure out what exactly some of those terms mean. We probably all do it just a little bit differently, I would imagine.

CO-CHAIR MEYER: On this in particular, I would actually ask for John, Diane, Stan, and for you to talk to your colleagues and some of the physicians around the country.

But to the extent that you have operationalized certain definitions to help people work through algorithms to say, yes, this is -- so my answer to both of yours would be, in our institution, yes and yes, that we would consider those to be reportable.

But I think that it would be great to get them into the NQF and get those part of it. It sounds like they may be very valuable, and we want to learn from your experience. To the extent that we can codify it as additional specs here, or even field guidance, it would be terrific.

DR. BURSTIN: And actually, one of the criticisms we have gotten about the SREs over the years is their lack of specificity. So I think if there is a way for us to add the specifications, not just guidance, but the actual specifications, I think, again, why does every state have to reinvent that? Why does Leapfrog have to reinvent that each time? That should be what is value-added of NQF.

MEMBER RYDRYCH: Well, too, I think even the term "serious disability" is sometimes problematic, and we sort of try to move toward serious injury sometimes. Particularly with falls, we have had cases where -- one example, and it seems far-fetched, but it was true, was a case where someone was a paraplegic and was in a wheelchair, fell out of the wheelchair, broke a hip. It didn't actually affect their activities, the broken hip, but it was a serious injury to the patient.

So, depending on how you define disability in terms of limiting someone's activities, if their activities were limited ahead of time, I would argue, absolutely, that is still a serious harm, a serious disability. But there were some who argued against it. So that becomes a difficult area, too, sometimes.

MEMBER VICTOROFF: Well, the reason I raised that, and this may not be a discussion you want to have, but serious

disability doesn't do for me what serious health impact does or serious health consequence.

Let me just give you one, not on this subject, example, but it speaks to disability. I once lost a breast biopsy specimen from a woman. I just did a breast biopsy, and the courier put it on the roof of their car and drove away, and they and a lot of other tubes and stuff -- the woman never found out if she had or didn't have a normal breast biopsy.

The impact on her was significant because we changed her plan of care and we did surveillance and all that kind of stuff. But no one could say whether she actually had cancer there or not. So we really wouldn't know for years whether she had a disability.

So I want to capture weird stuff like that, and the hepatitis C and the broken hip, and the things that I would call profound health impact, life-changing impacts, that

really I don't think even a generous English professor would call them disabilities.

CO-CHAIR MEYER: And I think, you know, if you look at the actual report from the NQF, you will see that there are box definitions of things like disability. But the reality of it is that, when this gets out into the field, there's a lot of -- and so I think to the extent that we can try to not only refine the list of SREs, but really to try to work on the additional specs and make them more user-friendly out in the field, I think we would take a far step forward.

So, again, I would ask the folks who are involved in this on the state side to really help us out and give us whatever materials you have, get them into the process, because I think we will all be better off for it.

DR. BURSTIN: And it sounds like we have to at least define serious disability since that's not defined in the report, and it

is in all the SREs.

CO-CHAIR MEYER: Yes.

Okay, the next one is patient death or serious disability associated with the use or function of a device in patient care in which the device -- can you go back? -- in which the device is used or functions other than as intended.

So, Deborah?

MEMBER NADZAM: Okay, this might be a little bit of a bizarre question on this one, for what is not stated. I don't know if this is where it belongs. And I don't know the full outcome or number of cases that this would happen in, other than I know it happens.

Adult equipment being used on children. Well, I don't know how often it lead to harm. I mean we know that adult equipment on children doesn't work as well as pediatric equipment on children.

MEMBER RYDRYCH: Does that fall under 2B, using a device other than as

intended?

MEMBER NADZAM: That is why I am asking. Yes, that is where we are, on 2B.

MEMBER RYDRYCH: I'm sorry.

MEMBER NADZAM: No, no.

CO-CHAIR MEYER: We are on 2B.

MEMBER VICTOROFF: Well, if they died or got disabled, right, then it would definitely come under this. But they just used it and got away with it, and there was no health situation --

MEMBER NADZAM: Well, yes, then, right. Right.

MEMBER VICTOROFF: -- then they wouldn't come under this. Are you saying --

MEMBER NADZAM: I guess I am wondering about the need to call it out, to pull out the issue of equipment.

MEMBER DORON SCHNEIDER: The question of reportability and the risk thereof, I mean this falls into the risk thereof, even if they didn't have harm

associated with it. And that is the same that goes with contaminated endoscopes, or whatever the examples were before, you know, about the disability. It is the risk thereof. They were exposed to the biologic or the contaminated device. So, even though it is not currently a disability, they certainly were exposed to a risk.

MEMBER NADZAM: Is it appropriate to include it in comments, I guess is what I am asking, because it is so underappreciated, I think, that this could be a place to make a statement about it, that it would include this sort of misuse of equipment.

CO-CHAIR MEYER: Let me, just before we hear from John, turn this on its head a little bit or make it a little bit more complicated.

There is the use of equipment for imaging for adults on children, exposing children to very high doses and inappropriate doses of radiation. It is a real national

safety issue. Does that fall in here or not?

John?

MEMBER MORLEY: To your question, I would say, if it happened at Cedars-Sinai, yes.

(Laughter.)

Otherwise, probably not.

I think, to the question about information that is reportable, if you go back to the goal, the goal is to make things safer. You know, every time you ask the question, it comes up all the time because there are gray cases.

You know, as Gregg was saying earlier, we aren't going to eliminate some level of discussion that is going to take place.

But if the people in the discussion ask the question, well, are we trying to make things safer, will this information cause people to learn and to make changes, in the case that you are describing,

Deb, I would say, yes, I would clearly want it reported. Then I would want to be able to put that into an annual report, which we in New York refer to as the "try annual report". We try to annually put out a report.

(Laughter.)

And we have not been successful in the last two or three years, but we are about to be successful.

But putting that information out, people will learn from that. I think they will also learn the difference of whether it has happened once or 21 or 31 or 101 times. It will make a difference to them.

MEMBER RYDRYCH: And I will just say, now that I have caught up to which event we are on, I would say that would be reportable for us as well, if it met that threshold of death or serious disability.

But I just wanted to clarify something that Doron said about risk thereof. You know, we talked about how we were defining

these events to include death or disability or risk thereof, but we are not saying that we are applying that threshold of risk thereof to each individual event, correct? Because that would mean expanding all of these beyond death or serious disability to include no harm and near-misses. And that is not what we are saying, right?

CO-CHAIR MEYER: No, but I think we have the leeway, right, but we have the leeway in specific instances to do that, though.

MEMBER RYDRYCH: In specific instances, yes. Okay.

CO-CHAIR MEYER: And move to 2C, if we can.

MEMBER RYDRYCH: How do we determine which ones we do that for?

CO-CHAIR MEYER: In this conversation, based on the input from the field. I think that will come.

DR. BURSTIN: I'm sorry. Just to

follow up with that, I am still not clear because I did hear what was said, and it made me think the same thing. So how do they all begin with death or disability if we are talking about a risk therein?

So we need to make -- I think it would be helpful, rather than to do it on an individual event basis, to actually have some sort of principle, some logic of when you would apply "or risk therein" because, otherwise, it feels very haphazard.

CO-CHAIR MEYER: "Risk thereof".

DR. BURSTIN: Sorry. "Risk thereof."

CO-CHAIR MEYER: Cynthia?

MEMBER HOEN: If you go back to our first definition, it is what, preventable -- I'll find it here -- "preventable, serious, and any of the following: adverse", da-da, da-da-da-da.

So why are we changing the definition for the products issues as opposed

to the other issues that are listed? Because now it is just death or serious disability versus serious, which included the at-risk issues.

CO-CHAIR MEYER: To my mind, I think that Doron's comment is a provocative one of saying, should we also do that for this? I think that my interpretation of the way the definition is written is that we have the ability to consider close calls. I think that Helen's is, well, we ought to have some sort of principles about when we would do that.

On the other hand, I also have a sense that, right now, at least in the States of Minnesota, New York, and Massachusetts, we have probably taken away 50 percent of the FTEs working on event reporting right now, and that there is a certain workload that can be accommodated as well.

So, to my mind, we can't make this all inclusive.

MEMBER RYDRYCH: Considering that we only have half an FTE in Minnesota, you have lost twice as much as we have by meeting here.

(Laughter.)

MEMBER PHILIP SCHNEIDER: You have a full half?

(Laughter.)

CO-CHAIR MEYER: You two can have an offline conversation about that. Diane is a better negotiator.

MEMBER VICTOROFF: Yes, job-sharing.

Although I was in total concordance with what Doron was saying about the white matter and the larger white matter in the world, and I am very open to tomorrow hearing about new additions to the list that comprise near-miss events, if we can define a couple that are unambiguous, and all that sort of stuff, you know, yay for that. I am for that.

But I think that is a different matter than imposing and expanding the Venn diagram for these guys to include near-misses, which currently I don't understand them to be at all. I understand the SREs to just be the blue dot in the Venn diagram, meaning, yes, they died, and that is all that is reportable for now.

But if tomorrow you want to bring a near-miss thing that you can really define and you like, I will probably support it.

MEMBER RYDRYCH: I wonder if we just want to -- I hate to go back to the morning, but the place where we added in "risk thereof" was in our definition of "serious". So, I wonder, is it just a matter of making a small change there? Instead of saying serious includes event that result in death, however we worded it, do we change it just slightly, so we say that serious means events that can result in, which captures the deaths, the serious disabilities, the no-harms, but

doesn't say that they all have to be linked to it?

CO-CHAIR MEYER: Yes, that works. We will rework that language --

MEMBER RYDRYCH: Okay.

CO-CHAIR MEYER: -- and get that back to folks. Okay. We will do it offline. Okay, that is helpful.

Other comments? I just want to go to 2C, and 2C is air embolism.

Here it is interesting. I guess this is one where I would appreciate it if the NQF staff could help reach out to the neurosurgical field and see if this exclusion needs to be there still. So this has been there since this initial list.

The exclusion says, "Excludes death or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism."

And I am not familiar enough with the state-of-the-art in neurosurgery to know

if that is still the case in 2009 or not, but I think we should ask their opinion, unless somebody here knows that.

MEMBER MORLEY: The big issue is when they do a sitting craniotomy, which they still do. It is pretty rare, but they still do sitting carniotomies. So, yes. But I am not sure that I would agree it should be an exclusion. I still would be interested to know how often it happens.

CO-CHAIR MEYER: So, if we could --

MEMBER MORLEY: It is a rare event that they do the surgery. It is an even rarer event that you get the air embolism. But it is a high-risk procedure for getting an air embolism.

CO-CHAIR MEYER: So it just makes one wonder whether or not that exclusion should still be there or not. And we should ask for specific feedback from the field.

MEMBER VICTOROFF: Just returning

to the philosophy we had before, childbed fever used to be a really high risk for vaginal delivery. And we were just, oh, well, you know, the informed consent says you could die because I didn't wash my hands, so whatever.

I don't think the fact that a thing is a high risk necessarily means that it shouldn't be counted and accounted for.

CO-CHAIR MEYER: So, trying to be consistent with what we said before, there seems to be a lot of nods about that. Okay, and we will let them push back.

MEMBER RYDRYCH: And it gets back to the Class 1/Class 2 question with the surgical deaths as well.

CO-CHAIR MEYER: It does. Yes, it does.

MEMBER RYDRYCH: Are we saying that the higher risk needs to be excluded?

CO-CHAIR MEYER: Yes. Yes. Fair enough.

MEMBER RYDRYCH: Okay.

CO-CHAIR MEYER: Other comments on this one?

(No response.)

Great. I would still like to forge ahead, if people can stay with us for a little while longer.

The next one is patient protection events. And the first one here is infants discharged to the wrong person.

So, Deborah, let's here.

MEMBER NADZAM: Is this intended to mean a neonate, a newborn?

CO-CHAIR MEYER: Yes.

MEMBER NADZAM: What about other infants and children given to the wrong person?

CO-CHAIR MEYER: You know, my understanding of this, when this first came up, was that people were thinking about a newborn baby. The language "infant" is interesting. Why isn't a "minor" the language

there? And the answer is I can't answer that. I don't know if others have any more history on this one or not.

MEMBER NADZAM: If it is meant to be newborn, it should say, "newborn", I guess. Otherwise, I think it needs clarification.

MEMBER VICTOROFF: How about another dependent person, like a dependent adult?

MEMBER NADZAM: Yes.

MEMBER VICTOROFF: I mean we could easily rephrase this to be more comprehensive.

CO-CHAIR MEYER: So you are proposing to broaden this and to say a dependent?

MEMBER VICTOROFF: Yes, an incompetent or dependent person, e.g., newborn, disabled person, cognitively-impaired person discharged to the custody of a guardian, an inappropriate guardian or inappropriate --

CO-CHAIR MEYER: Flashing back to

the movie "Rain Man".

MEMBER RYDRYCH: I guess I haven't thought about this one that much because we have never had one of these, but how do we define wrong person? I think we sort of intuitively know what that means, but how do we define wrong person in an unambiguous way for the purposes of this list?

CO-CHAIR MEYER: Let's hear.

MEMBER TANGALOS: Well, I would be careful about wrong person, too. Let's say somebody brought a kid in after a beating, and they are the wrong person to get that baby back.

MEMBER VICTOROFF: Maybe we could say unauthorized. We have to maybe narrow it legalistically and say, clearly, the problem with the infant is what is meant by wrong is illegal, unauthorized. And I guess I would be willing to give up all the other wrongs if we could have that.

CO-CHAIR TYLER: But I am not

sure. I think Eric's point was that it could be the legal guardian that brings someone in, but the legal person may be responsible for the injury, so you wouldn't want to discharge them to that person. So legal may not be the --

MEMBER VICTOROFF: We can't capture that. So we just have to get the wrong driver's licenses.

CO-CHAIR MEYER: Cynthia, let's hear.

MEMBER HOEN: Yes, I think the concern here was that people wanted to get little babies so they could put them up for adoption or they could have them. That is what we were trying to protect from.

It gets to be a really sticky legal wicket that I am not sure hospitals are prepared to deal with with respect to what the wrong person is. Who is the legal guardian? Do they have a legal guardian? Did the legal guardian send the person over? I don't have

enough resources to check all that stuff out. At some point, we have to rely upon what people tell us who have been involved in the care all along.

CO-CHAIR MEYER: So you are arguing to keep this and narrow it to newborn?

MEMBER HOEN: That's right.

MEMBER TANGALOS: I think to make this one unambiguous, you tighten it up. You make it the newborn.

MEMBER RYDRYCH: Yes, and I wonder if we maybe seek legal advice on how to word it, so that it is clearer than wrong person.

CO-CHAIR MEYER: Leah?

MEMBER BINDER: I'm shocked. I mean I would definitely want to expand this one. If you trust your child's life to a hospital, I definitely want the hospital 100 percent accountable for who they are discharging my child to. There are custody disputes. There are all kinds of problems that happen that hospitals, yes, it's tough,

but, yes, they've got to be responsible for it. It is catastrophic if they release to the wrong person.

So I would definitely support an expansion, recognizing it is going to be difficult to word it, but that is still an important point, I think.

CO-CHAIR MEYER: Are there any groups that folks can think of that we should specifically ask the Quality Forum to reach out to, to help us clarify this?

We've got a strong case by some to say narrow/tighten. We've got a good case to say, no, let's expand this.

Is there a group that we should specifically solicit --

MEMBER TANGALOS: Point well-taken. Maybe this just needs to be divided. Get the infant piece taken care of, which I think could be relatively easy, and then discuss the other part, which is going to be difficult. So two different --

CO-CHAIR MEYER: Okay. Patient death or serious disability associated with patient elopement, and excludes events involving competent adults.

Comments on this one?

MEMBER TANGALOS: Is the depressed patient that slips out of a facility competent or not?

CO-CHAIR MEYER: If they have capacity, they are medically, legally competent.

MEMBER TANGALOS: And then they go out and commit suicide.

CO-CHAIR MEYER: If they have capacity, they are medically, legally competent. I am not saying that this exclusion is right. I am just saying I think that that's probably the way that it would be interpreted.

MEMBER MORLEY: I think you would find that that information would be appropriately recorded in the chart, or should

be appropriately recorded, in terms of somebody with a little depression because they are sad for some reason versus the patient who was admitted for severe clinical depression.

And I was, actually, thinking about asking the question -- the attorneys I know frequently have changed me from saying, "competent" to "having capacity". I don't know how standardized that is, but --

CO-CHAIR MEYER: I think "having capacity" will probably be the 2009 language.

MEMBER MORLEY: So you want to change that to --

CO-CHAIR MEYER: I think this would probably be 2002 language, yes.

MEMBER RYDRYCH: Well, I think the intent here was, if I am correct, was to differentiate between somebody who is competent to make a decision to leave against medical advice versus somebody who --

CO-CHAIR MEYER: Right, and that is capacity.

MEMBER RYDRYCH: Right. Versus somebody who takes off without going through that process. Right?

MEMBER VICTOROFF: This says elopement. I mean they just sign anything and everybody said, "Okay, whatever, I guess you're competent." This implies that a procedure was circumvented.

MEMBER TANGALOS: No, I think this starts to get into that new universe.

CO-CHAIR MEYER: Eric, I am asking you --

MEMBER TANGALOS: No, no.

CO-CHAIR MEYER: We are not talking just about hospitals --

MEMBER TANGALOS: We are not talking about the hospital anymore.

CO-CHAIR MEYER: We're not.

MEMBER TANGALOS: Now we are talking about people entrusted to assisted living, some kind of step-down. The elopement terminology is very classic in the nursing

home, but I am not even thinking nursing home. I am thinking assisted living.

And I am not convinced that we are getting at what we want to get at. Yes, we can say they are competent or they have the capacity to do this, but, boy, we lose a lot of people that wander off. And how competent or what capacity they maintain in that independent environment is really uncertain because it is a cascade of activities, too. They are looking good at one moment in time. They are in their environment. It's fine. And just like errors, there is a cascade of activities.

We had the Minnesota woman in her fifties with early Alzheimer's disease fairly much unrecognized who drove all the way west and died. We filled her car with gas, did this, that, and the other thing; got directions in the wrong way.

So it is not particularly easy here.

CO-CHAIR MEYER: Leah? Let me just get to Leah, then Diane, and then Deborah.

MEMBER BINDER: I think this is one of those where on a case-by-case basis it isn't necessarily the fault, so to speak, of the providers. You're not tying people down, and they are adults and they have a right. So, in an individual instance, a disappearance or an elopement may be justifiable by the provider.

Nonetheless, this is an instance where counting the incidence of this is very important. When we see variation among facilities or among hospitals, that is very significant. That is where we know there is a very -- if a nursing home has, you know, 50 of these in a year, we should be really focusing on them. And we are only going to know it if they report it.

So I would see this, even though this may not be the fault of the providers in every single case, nonetheless, the reporting

is essential because it is very serious in the aggregate.

CO-CHAIR MEYER: Go ahead.

MEMBER RYDRYCH: And just a comment and a clarification. I agree with what Michael said. I do think that this implies that the process of signing a document to leave against medical advice was circumvented, and maybe that needs to be noted, to differentiate between those situations.

But a clarification, too. I agree with what Eric is saying about how this differs in long-term care settings. I am just questioning, as this group and as the advisory groups start to talk about expanding these serious reportable events into other settings, are we necessarily -- we are not necessarily saying that these exact events are going to translate; in some cases, they may.

CO-CHAIR MEYER: Some will and some won't.

MEMBER RYDRYCH: In some cases, they may morph a little bit. So there may still be an event that is related to elopement, but it necessarily has to be worded a little bit differently, if it is applying to long-term care, than it does to the inpatient setting. We may need to have different caveats for each one.

I mean I think Eric's point is true, but we won't necessarily be transplanting this one to the other setting.

CO-CHAIR MEYER: So let me go to Deborah, Doron, and then to Cynthia.

MEMBER NADZAM: Yes, on the version that you sent to us, there's a phrase at the end that is not up there. After "disappearance", it says, "for more than four hours". Is that still in?

CO-CHAIR MEYER: So, probably you may be looking at 2002.

DR. BURSTIN: No, in 2002, it was in.

MEMBER RYDRYCH: Is it not there anymore?

CO-CHAIR MEYER: So, 2006, it is not?

MEMBER RYDRYCH: I think that was removed.

MEMBER NADZAM: Because that was my question.

CO-CHAIR MEYER: What you see up here is 2006.

MEMBER NADZAM: Okay. Good.

MEMBER RYDRYCH: I think it was removed because it was the harm to the patient that was important, not the amount of time being gone.

MEMBER NADZAM: Right, right, right.

CO-CHAIR MEYER: This is the 2006 version. What you got through the email and what you have is 2002. So, yes, there are a few places, this and with falls, there were important omissions and additions.

Okay. Sorry. So Deborah, Doron, and then Cynthia.

MEMBER DORON SCHNEIDER: I was going to make that point also on the other end, which is that the association -- there is no time element here in the sense of, yes, I mean it is very ambiguous to me to a certain extent because it could be associated, you know, not necessarily in the first 24 hours. It could be down the line. So I think there is a little level of ambiguity there.

And because it is a harm event, and I don't think we are going after what you really were after, which was your rate of elopement, because the harm is not that frequent. That may be one where we do the "risk thereof", if we decide to go down that dialog tomorrow.

MEMBER RILEY: So the only thing that I was going to say about this, too, is this may be an opportunity to sort of put the definition for capacity in, where people can

clearly understand exactly what that whole sentence means, and that it is completely different than competency.

CO-CHAIR MEYER: We would need some legal help with that.

Cynthia?

MEMBER HOEN: I have seen a number of cases where they have used as the standard of care such that you had a person who you believed was legally competent who left, who eloped from the hospital and committed suicide, and they hold this out as a standard.

I think that is really a negligence issue. Did you fail in the hospital to appropriately categorize them? I mean I would be completely comfortable with this if they eloped from a secured area, from a psych unit, from a psych hospital, from the Alzheimer's unit of a care facility. But just for a general open hospital, elopement is awful ambiguous.

CO-CHAIR MEYER: I don't think we

are going to solve this one. So I think what we are going to end up doing is probably hearing a fair amount from the field and revisiting this.

MEMBER TANGALOS: Well, I would like to expand it a little bit before we even leave this. At Mayo, we have a big deal about code pink. All right? A big deal. I don't know where it fits.

It hinges on abduction. I mean we are never sure if a kid is lost or an older adult is lost. But it is a big deal.

And I am sure, I mean, if we are going to expand events, I am thinking about the outpatient setting for the most part, but where do we put that?

CO-CHAIR MEYER: There is a criminal event. We will come to the criminal events, the abduction piece.

MEMBER TANGALOS: Yes, but I am saying that I think every facility ought to have some program in place, not to get to the

criminal event.

CO-CHAIR MEYER: And that is where the nexus would be between this work and the safe practices.

MEMBER TANGALOS: Very good.

CO-CHAIR MEYER: Exactly.

MEMBER TANGALOS: Very good.

CO-CHAIR MEYER: So let's go to 3C, patient suicide or attempted suicide resulting in serious disability while being cared for in a healthcare facility.

Note the word there, "healthcare facility". So it is very broad.

And it goes on to say, "Define those events that result from patient actions after admission in a healthcare facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility."

Any comments on that one? Stan?

MEMBER RILEY: I guess I think we should remove the exclusion. You know, they

may have come into the hospital for I don't know. What if it is a self-mutilator and something happens that way? So I am not sure that that exclusion is useful.

CO-CHAIR MEYER: Yes, I think what was around the exclusion was the notion that somebody comes in after out in the field taking a horrible overdose if tricyclics or acetaminophen, of Tylenol, and you do your best for them. They die. That seems to me that that is not something that -- Diane?

MEMBER RYDRYCH: I only have one tiny comment on this one, and it is related to the exclusion. What about cases where there's somebody in the ED? Because we are saying it excludes after admission.

CO-CHAIR MEYER: Yes, and I think that did come up later in this. That is why it says, that is why I pointed out it says, "healthcare facility". The emergency department is assumed in that.

So, if someone walks up, going up

the entry ramp to Mass General and slits their wrists, or if somebody comes through the emergency room and checks in, and gets checked into the emergency room, slits their wrists there, we are.

MEMBER RYDRYCH: But we are defining that as admission into a healthcare facility, once you're in the ED?

CO-CHAIR MEYER: Right, and that is why the wording here is specific; it says, "healthcare facility", because this came up.

MEMBER HOEN: Admission is a complicated word, though.

CO-CHAIR MEYER: Admission is a complicated word. I mean I note that was specifically why that was worded that way.

MEMBER TANGALOS: In trying to do good with the programs, where do we include investigations of drowning? And the reason I bring it up is that is the modus operandi for old people to finish their lives. That is what they do. They drown themselves.

CO-CHAIR MEYER: Have any of the states here seen a hospital-reported drowning?

MEMBER TANGALOS: It is not hospitals. It is at CCRCs where they wheel themselves into the Jacuzzi.

CO-CHAIR MEYER: More to come in our expansion discussion tomorrow.

(Laughter.)

You have to include Jacuzzis.

Yes, Michael?

MEMBER VICTOROFF: Just to follow on that, I think, as I have been fantasizing about these translating to other environments, I have come up with cases where I think you have to have a separate footnote for what does this mean in this kind of facility.

CO-CHAIR MEYER: Yes.

MEMBER VICTOROFF: You know, on a cruise ship, this would mean, you know --

CO-CHAIR MEYER: Okay.

MEMBER VICTOROFF: And I think that we are going to have to do that.

CO-CHAIR MEYER: And you will see in some of the other NQF products they do -- so Safe Practices says this is what it means in a hospital; this is what it means in a long-term care facility. So that sometimes can be explanatory language around this.

Okay. At this point in time, it is almost five o'clock. We have a fair amount of work still to do. So, just to remind folks, what is left are care management events, environmental events, and criminal events. We are approximately halfway through the list.

At this point, I feel like I have already begged your indulgence long enough by holding you over. On the other hand, I also recognize that Sally, to my right here, is going to be the onsite Chair tomorrow morning who will inherent my failure to take you over the finish line.

MEMBER TANGALOS: I would make a suggestion, though. We shouldn't end on a

vision of an old person wheeling themselves into a Jacuzzi.

(Laughter.)

We should end on a high note somehow.

CO-CHAIR MEYER: I am looking to you.

MEMBER RYDRYCH: Give us a better image, please.

CO-CHAIR MEYER: Just before we close, Peter or Helen, do you have any further business?

DR. ANGOOD: No further comment, really, other than to thank you all for really a heavy load of work today, I think clarifying this, our redefinition, getting us a bit more clarity around this HAC concept, and kind of getting that squared away, basically.

CO-CHAIR MEYER: Anyone left on the phone? Do we have anyone left on the phone?

(No response.)

DR. ANGOOD: Nobody.

CO-CHAIR MEYER: Okay.

DR. ANGOOD: So I think it has been a great afternoon, a great day. Thank you very much.

Dinner is at the Blue Duck Tavern for 7:00, and the reservation is under NQF for National Quality Forum.

CO-CHAIR MEYER: So, to finish on a high note, to quote the sage of sages of epidemiology, who is Mary Poppins, if you didn't know it, "Well begun is half done."

(Laughter.)

Thank you for your work today.

7:00 p.m., it got changed to 7:00.

All right, thank you very much. Hang in there.

(Whereupon, at 4:59 p.m., the above-entitled matter was adjourned for the day, to reconvene the next day, Thursday, November 19, 2009.)

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