NATIONAL QUALITY FORUM

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HIT SAFETY COMMITTEE

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PRIORITIZATION OF HEALTH IT PATIENT SAFETY MEASURES IN-PERSON MEETING

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WEDNESDAY SEPTEMBER 16, 2015

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The HIT Safety Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 9:00 a.m., Elisabeth Belmont and Hardeep Singh, Co-Chairs, presiding.

PRESENT:

ELISABETH BELMONT, JD (Co-Chair)
HARDEEP SINGH, MD, MPH (Co-Chair)
JASON ADELMAN, MD, MS, Montefiore Medical Center
GREGORY ALEXANDER, PhD, RN, FAAN, University of Missouri School of Nursing
GERARD CASTRO, PhD, MPH, The Joint Commission
DAVID CLASSEN, MD, MS, Infectious Disease Society of America
LINDA DIMITROPOULOS, PhD, RTI International
LISA FREEMAN, Connecticut Center for Patient Safety and Patient Advocacy of Connecticut
TEJAL GANDHI, MD, MPH, CPPS, National Patient Safety Foundation*
ANDREA GELZER, MD, MS, FACP, AmeriHealth Caritas Family of Companies
ERIN GRACE, MHA, Agency for Healthcare Research and Quality (ex officio member)

KEVIN HAYNES, PharmD, MSCE, HealthCore, a subsidiary of WellPoint Inc.
LAURA HEERMANN-LANGFORD, PhD, RN, Intermountain Healthcare
GEORGE HRIPCSAK, MD, MS, Columbia University and New York-Presbyterian Hospital
JASON JONES, PhD, Kaiser Permanente
NANA KHUNLERTKIT, PhD, Johns Hopkins Medicine Armstrong Institute for Patient Safety and Quality
WILLIAM MARELLA, MBA, Pennsylvania Patient Safety Authority
DENA MENDELSOHN, JD, MPH, Consumers Union/ Consumer Reports*
JAMES RUSSELL, RPh, Epic
ERIC SCHNEIDER, MD, MSc, RAND Corporation
MARK SEGAL, PhD, GE Healthcare
KAREN PAUL ZIMMER, MD, MPH, FAAP, Independent Consultant, Health IT, Patient Safety and Quality

NQF STAFF:

HELEN BURSTIN, MD, MPH, Chief Scientific Officer
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SHELIA CRAWFORD, Administrative Manager
JASON GOLDWATER, Senior Director
ANDREW LYZENGA, Senior Project Manager
ANN PHILLIPS, Project Analyst, HIT
JESSE PINES, Consultant for NQF

ALSO PRESENT:

DAVID HUNT, Government Task Lead, ONC

*** present by teleconference**

C O N T E N T S

P-R-O-C-E-E-D-I-N-G-S

9:06 a.m.

MR. LYZENGA: So, I just wanted to start out by saying welcome to everybody again. Welcome back to D.C. We're delighted you've taken the time to come back here and be here in person with us.

We've got a busy day for you. So I won't take too long. I'm glad we're not snowed in this time.

Hardeep reminded me that the last time we were in person, we almost got snowed in here. So, it should go a little bit smoother than that.

Again, welcome to everybody. Thank you for coming. And I'll hand it off to our esteemed Co-Chairs for a couple of remarks.

CO-CHAIR SINGH: Good morning everybody. I think we all know everybody. But anybody who wasn't here the last meeting, maybe do you want too just quickly introduce yourself so that -- I think we'll all know everybody.

Is that okay? Should we? Okay.

MEMBER FREEMAN: Okay, I'm Lisa Freeman. I'm the Executive Director at the Connecticut Center for Patient Safety.

And we are an advocacy organization. We represent the patient voice. And we try to be present in many different forums at many different tables.

And we also provide services directly to patients.

CO-CHAIR SINGH: Great. Thank you. So, I was wondering, what would be something useful for me to say just to get the day started?

So I thought, what would the top few things, maybe three things that happened in the last six months since we met? Or maybe seven or maybe eight, whatever that is.

And I thought of, you know, a couple of things. And more came to my mind. So I'm going to just read out a few things.

I might call upon some of you to just give a little explanation of the important things that have happened in the world of Health IT

Safety in the last maybe six to eight months. And if I've missed anything please let me know. And feel free to sort of chime in afterwards.

But I think all of us need to be aware of these things on a national level. All of these things are probably making an impact on a national level. And so that's why I think it's important to mention.

I know many of you are doing things locally. But, it would be good to sort of get everybody on the same page as to what the recent events have been.

And these are not in any order of, you know, importance. So, just -- for the first one, I think it's the Joint Commission Sentinel Alert that came out in March. Maybe a month and a half after we met.

They also came out with an education module. And if anyone has not seen their education module, it's really very good. Very rich material.

In fact the Sentinel Alert talks about

some of the research the Joint Commission did along with ONC. Which is going to be very useful for us to think about measuring these issues and reducing safety concerns.

The second important event, it was the RTI Roadmap. Which I think actually, are you going to talk about it, Linda, right?

So this is the Health IT Safety Center Roadmap. But now I hear that's called Health IT Safety Collaboratory Roadmap. I had to actually look that one up.

But Wikipedia does have a word called collaboratory. So, it does exist. It's a center without walls. I printed it for those of us who are -- were unaware.

The third thing on my list is Jason Adelman, do you want to just quickly talk about a measure? So, this is important because I think it gives us an example of a health IT related safety issue that is very amenable to measurement.

And how sort of Jason worked on

getting a measure through. At least almost through to the -- through the NQF. Go ahead Jason.

MEMBER ADELMAN: I think we talked about the measure I had developed at the last meeting. But it's the Retract and Reorder Measure for Identifying Wrong Patient Errors.

So I -- the Oops Query, thank you. I went back and looked at the minutes and it says Oops all over the place for the last meeting.

So I submitted it to the Patient Safety NQF Committee for endorsement. And it has been -- it passed with like 80 percent approval.

And so right now, they just finished the public comment period. And I answered those questions. We have a follow up meeting in October to discuss those issues.

I don't think that should be a major problem. And I think for it to be an official measure, after this step, then I think it has to be ratified by the Board.

There may be one step in between that

that I'm not -- CSAC and the Board. So, we're -- but I think from what I understand, the hardest hurdle was that initial endorsement.

I, you know, shared that I -- now we've implemented the measure at about ten hospitals with very similar results. We were able to demonstrate it's valid and reliable and meaningful.

And I think if it's endorsed, it will be the first health IT, you know, safety measure. And I should mention that, you know, the general concept is that it looks for orders that are discontinued rapidly.

And then what happens next? Then in this case it's you order the exact same thing on another patient. But I submitted a grant to HRQ to take that concept and expand it to other types of errors, like wrong drug errors. You rapidly just give an order and then order another drug.

And that's going to be reviewed in October. And so hopefully, I, you know, and I sort of portrayed the grant as HIT safety is

important. There's a particular interest that it measures.

I worked on this one measure, I think the concept, it can be expanded. And I set it up so that if we get funded, we will be able to test both the validity and reliability of the measure.

So, it's like set up for NQF endorsement if we get, you know, funded.

CO-CHAIR SINGH: Great. Thanks Jason. I think just something for us to think about and look forward to as to how we develop these concepts further.

How they become measures and how we're going to get them through to actual -- make an actual impact on real world cases.

MEMBER ADELMAN: I just want to say, the grant I submitted, Karen collaborated with me. We were working on it together.

CO-CHAIR SINGH: Great. Excellent. So, the other couple of things on my mind are not events that happened. But are -- well, actually one of them was.

A Pew researcher actually conducted a pretty big meeting on usability related safety issues just a few months ago. I think Nana, you were there. And Jason, you were there.

We haven't sort of heard what the byproduct -- Gerry, I think you were there too, right? So many of us were there.

We just haven't heard sort of what the product from that meeting is going to be. But they brought together a national sort of stakeholder, you know, groups, to talk about usability issues.

One of the reasons I mention it is many of the things that were being discussed in that meeting were very similar to some of the things that we've discussed in the past. And it's important to recognize that we just don't reinvent the wheel and you know, at every place we go.

But, you know, it's good for us to sort of know what they're kind of up to. I think there's going to be a report that's going to come

out. Has anybody else heard anything else?

MR. HUNT: Relatively soon.

CO-CHAIR SINGH: Relatively soon. Okay. Excellent. And then two events that are about to happen are -- that are very substantial, I would say.

One is ECRI Collaborative. And some of you are involved in that collaborative, which is a -- sort of a private partnership which includes vendors. That is looking into many HIT safety issues.

They've actually have a workgroup working on copy paste type issues. The report for that workgroup will be released at the ECRI Collaborative meeting in October. It's a small meeting again, funded by a private foundation.

And the next announcement that they're going to make at that meeting is they're going to -- they're very interested in patient identification types of issues as a next product that they're going to work on.

Again, a need to know because they're

working on simultaneously similar types of issues of measurement of high impact patient safety concerns.

And my favorite upcoming project is that next week the Institute of Medicine is going to release a report on diagnostic error in medicine. What I can tell you, maybe Elizabeth can tell you more, but maybe she can't because she's actually on the -- she's a member of the IOM panel.

But what I hear, it's going to be a pretty comprehensive report on many issues. And it is going to touch upon things like health information technology.

And Elizabeth, go ahead and --

CO-CHAIR BELMONT: So, I'm limited to what I can say. But I will say that there is a chapter on technology issues.

And what I can do is forward a link to the briefing of that on 9/22 to Ann. And ask her to distribute it to the Committee if you all would like. And then you can participate.

And I was chatting with Hardeep Singh and Kathy Kenyon last evening at dinner. And we were talking about how I think we're approaching a tipping point in terms of so many organizations are working on this.

And I think at this point it would be important to see if we cannot recreate the wheel. But sort of build on what other people are doing and trying to advance the ball forward.

So, stay tuned for the IOM report.

CO-CHAIR SINGH: And so I think the point is, there's a lot of movement going on. But if you look at the list, I mean, we're quite high up there.

So we have a huge important task ahead of us in the next day and a half. Because what we do over the next one and a half days would make probably a long-lasting impact.

Have I missed any other event that anybody wants to sort of talk about at a national level? Which is important to HIT safety?

(No response.)

CO-CHAIR SINGH: Okay. All right. Back to you Andrew.

MR. LYZENGA: Thanks.

CO-CHAIR SINGH: Thank you.

MR. LYZENGA: So, just to give a quick -- I should go over the goals here of our day today. We'll just give you a quick -- a few quick updates on our recent project activity.

We'll discuss some opportunities to align our framework with the -- our common formats for patient safety reporting and the roadmap or collaboratory I guess now is what we're calling it.

And then the bulk of our day will be devoted to getting into some group work. And trying to hone down our measure concepts and start our prioritization of those concepts.

You can skip over that. We've already kind of done that. You can skip over the staff and committee as well.

So the goals of this project initially were to develop a conceptual framework for

measurement of HIT safety. We've got our draft framework together.

And that is largely consistent with what you've seen previously. I'll go over a little diagram of it in a moment.

Also, to identify gaps in measurement related to HIT safety. Identify the highest priorities with respect to HIT safety measurement.

We, as you recall, came up with a long list of measure concepts at our last meeting. We've done some refining of that list. And tweaking of it. And reorganizing of it in a variety of ways.

And have come up with a version that we've shared with you recently. And we'll be using that as a sort of basis for our prioritization activities today.

And then to identify best practices and challenges around HIT safety measurement. We would still welcome any input you have around that area.

But we're actually in the process of doing some key informant interviews with a number of folks to get some input on that front.

So, here's just a quick overview of the timeline here. Again, we've gotten through the draft conceptual framework. Our environmental scan.

We had the Common Formats panel the framework. David Classen is going to talk to you a little bit about the results of that review in a moment.

And now we're getting into our actual prioritization activity. Which, you know, again, we'll be doing a lot of work today and tomorrow to do that.

We'll be drafting up a written report with the results of this meeting. And sharing that with you for feedback. And also public comment.

And so again, just to remind you of our framework here. It's a three level framework, which is consistent with the SAFER

Guides as well as a framework that Dr. Singh has been working on and published recently in the British Medical Journal of Quality and Safety, I believe.

The one small difference between that framework and ours, and that we -- it may be a little bit different from the last time you saw it. Is we had moved up the surveillance and monitoring element into the middle level, level two.

Just sort on the thinking that this -- we were sort of -- conceptualized that as surveillance and monitoring of HIT systems themselves as part of the safe use of HIT. And monitoring for issues that might arise as a result of those HIT systems.

And then sort of, we're thinking that the use of HIT to improve safety, using systems to monitor for health risks themselves and safety risks would sort of go into the domain of using HIT to make care safer. But maybe that's worth a little bit of discussion if we have the time at

some point.

So, with that, I will hand it over to Dr. Classen to maybe talk a little bit about our review of the framework with the Common Formats expert panel. Dr. Classen is a member of that panel, as is Gerry Castro, who's also a member of our committee.

They were very helpful in facilitating that conversation. And had a really good discussion with the panel. And got some really good input on our project as a whole and the framework as well.

So, David?

COURT REPORTER: Sir, I'm sorry. Is your microphone on?

MEMBER CLASSEN: Am I on now? I'm here. Okay. Good, I'm glad they can hear me at Fort Meade.

Our panel reviewed this framework. And had some thoughts and feedbacks to the framework. But also saw a great opportunity to work together. Because our panel is about to

begin a major upgrade of our work on Common Formats.

We've gotten a lot of feedback that our Common Formats are overly complicated and burdensome. And that we need to thin them out a lot.

So, we're about to begin that project. So, working together, this is sort of a great opportunity in timing for us.

And if I can get this to move forward one way or another. Maybe not. Right here, I'm aiming. Nope. I'll just say, just move to the next slide, that would be great.

So, we are a part of the Patient Safety and Quality Improvement Act of 2005. And as part of that, we were created to standardize patient safety event data collection. And permit aggregation of collected data for analysis learning and training of events.

And so AHRQ asked a group of us through the NQF to help them develop basically a common set of formats for reporting. And we were

not trying to create a taxonomy.

We were not trying to create a classification system. We were merely trying to create a way to allow common events to be collected the same way.

And we started in the hospital setting. And then we went to the nursing home. And then we went to surveillance. We'll talk a little bit about that.

And then we're now at the ambulatory arena in retail pharmacy. But we will expand much further into the ambulatory arena as well.

So, let me just delve down, a little bit of detail here so you can understand our perspective when we give you your feedback. Next slide.

So, this shows what the Common Formats for the hospital arena look like. And there's a lot going on here as you can probably tell.

And although the Common Formats were to establish some sort of common reporting approach. You see the generic formats there,

which we'll talk about. And the event specific formats.

There is a whole lot more going on here than that. And the reason there's a whole lot more going on here is we believed from the very beginning that the collection of this information on paper was never going to work.

So, we created a system that would be easily programmable into HIT systems for capture of this data. So, everything you see on the right, the technical specifications, underlined our philosophic belief that doing this in an electronic system was the only way to make it effectively used.

And so that underlies a lot of what we're going to talk about. I'm not going to get into that detail.

But, we have basically done this so that all the vendors in this area would program this into an electronic fashion that would be far more usable. And allow flexibility in how these forms were constructed within the HIT systems.

They did not have to be constructed exactly as we created them on paper. So, that's what underlies all of this. Next slide.

So, let's go a little further into the hospital reporting forms. And what we envisioned in terms of workflow was that initially, when any event was detected, we would probably create an identification of that event through the healthcare event reporting form.

And we thought, that's the first thing that would be basically addressed when any event was detected. And then we thought in the workflow that if a patient was actually involved in this event, they'd fill out a patient form.

And then ultimately we believed that they'd probably fill out a summary of the initial form. And if there were an event-specific nature to this problem, then they'd also fill out an event-specific form of which we created an HIT form.

So that's where the HIT form you're going to see came from. And I think what we've

learned along the way, is this is a really complicated process in filling out these forms.

And very often the front line observer cannot fill out most of these forms. So the workflow here is really complicated.

And that's another reason we wanted to put this in electric format. Because it gave a lot more flexibility for workflow in terms of how much the initial detector of this event fills out. And how much everyone else fills out.

So, this was the basic idea behind these things. And these things were to attract not only actual incidents, but also unsafe conditions and near misses.

So, we wanted to go across the waterfront of things that could be captured. And if we go to the next slide, you'll see an example of this very first form.

So, the very first form is the initial form that the initial detector or reporter would fill out. Next slide. And if it affects a patient, they would fill this form out.

And next slide. After they've done their initial review, they would fill out the summary of initial report. Only then would they move, next slide, to filling out a specific form for the type of event it was.

Now, the reason we show you all this is because we do believe that very often, HIT events are not detected as an HIT event. They're detected as something else.

And only later in the analysis do people come to the conclusion that HIT may have played a role. So, when you hear our feedback, it will be heavily influenced by that idea.

And I just wanted to show you that HIT report in detail. And here is the front page of it. And you can see at the very beginning which of the following best discover this event.

And you can see all the different types of events we track. So, we were going well beyond EHR-related events.

And we believe that actually this should probably cross the waterfront of both

medical devices and HIT defined broadly to include not only EMRs, but medical devices and Health Information Exchanges, et cetera. We were thinking very broadly here. Next slide.

Next slide. And so we asked a number of questions about all of this potential. Next slide. Um-hum?

CO-CHAIR SINGH: Are you expecting the end user to fill out that -- the last sheet?

MEMBER CLASSEN: No, we do not. We know in the workflow that very likely the first person reporting might fill out that very first form, the healthcare recorded event form. And someone else would fill out the details here.

So, we think -- we know this is a complicated process.

CO-CHAIR SINGH: And who would that someone else be?

MEMBER CLASSEN: That someone else probably would be someone in quality or risk management who would be filling this out. We do not believe the initial reporter would be filling

out this detail. Next slide.

And you can see here how we break out the different aspects of systems that might contribute to this. Next slide. And in terms of some assessment of what the problem was here.

But, we know from having had this out there for a while that very often, people don't interpret these events to be HIT events. That only comes later when we find out that HIT is a -- basically a contributing factor.

And Gerry's done studies on this and might comment on that.

MEMBER CASTRO: Okay. Is this thing on? All right. Great.

So, yes. That's exactly right. You know, that's exactly -- what we found is, and I presented on this data before, is that the events manifest as medication errors, wrong site surgeries or delays in treatments.

And these types of factors such as ergonomics or hardware location data entry or selection would end up in the root cause

analysis. Or those as findings in the root cause analysis and not necessarily as a -- in the event report.

MEMBER CLASSEN: So, next slide please. So, that forms the basis for our feedback. Next slide.

And here are the members on our committee. And Gerry and I are both here. Next slide.

And basically our role is to receive and review comments made by healthcare stakeholders and make recommendations to AHRQ as they put out new versions of the Common Formats. Next slide.

Next slide. And so as we looked at this, here are the aspects of the framework that we looked at. Next slide.

And here are some of the things that we observed in our feedback. I think all of us believe that the opportunity to work in parallel here as we reinvent the Common Formats and this conceptual framework develops as perfecting

timing, is just perfect as we go down this road.

And so I think one of the first feedbacks we observed was, in our experience very often, these are not identified as HIT events. And so any measures must understand that, that most people will probably not view these as HIT events.

The other thing we noted is that this project was very much focused on the EHR. And as you can tell by our organization scheme, we are thinking far beyond the EHR in terms of the safety.

And we do believe that this should expand into the areas listed below. And we understand the scope of the project is more narrowly focused now. But believe it should expand. Next slide.

I think we have learned over and over again that front line staff will probably not even recognize it as an HIT related event. And that needs to be an important part of any framework and understanding of how you collect

this information. Next slide.

And we felt that patient identification errors are really important. We found them over and over again. And we agreed with this part of the framework that data availability, integrity and security were critical.

And very often, they weren't considered effectively in the design of these systems before the patient ID was presented to the clinician. So we thought this was an important area for measurement. Next slide.

And we also thought the ability of these systems to actually predict or identify problems before they occur and present to the clinicians was really an area that had not received enough emphasis.

So, when critical data is missing, why not point that out to the clinician as they're reviewing the record. And so that when you're looking at data integrity, and a key part of the medical record might be missing, and you show

that information to the clinician to guide care, that might be a really important area for measures. Next slide.

And we also thought that there were a variety of tools that might be able to mitigate against these unsafe conditions. And they should be considered by the committee in its framework.

And a key part of making all those tools work together obviously, is enhancing HIT safety standards. Next slide.

We also felt that patient engagement, as we believe patients will use these systems more and more on their own, is a critical part of these systems. And should be the focus of measurement.

And then finally, considering the cost of these approaches to measurement we thought was very, very important. Next slide.

And there's our feedback. And Gerry, do you want to add anything?

MEMBER CASTRO: No. I think you covered it.

MR. LYZENGA: I should also note that just in general, there are two sort of main levels of an event reported in the HIT form. And one is events that are specifically related to the device or hardware or software.

And then another sort of level for user related errors I think. And keeping in mind all the concerns that you mentioned David.

But, that is in close alignment with our framework. Which I think is worth noting.

MEMBER CLASSEN: And that form you saw is just our first iteration. And so we have always planned to update that form.

And if we can update that with a conceptual framework that you all are developing, and if you're willing to work with us, we'd certainly be very interested in that.

MEMBER SEGAL: David, where are you in the review and the ability to get further input? Your committee's ability to get further input?

MEMBER CLASSEN: So, basically, what we do is we accept input all the time. But

anytime we make any changes to the formats, we put them out for public comment.

And anybody can come back and give those public comments. And Andrew can talk about that. But we do that through basically a website here, the public comment response back to any change in the Common Formats.

And we're about to go through a big change in the Formats as we skin them down. And so you will see those changes published and asked for comment.

I believe it's on the NQF website. Right, Andrew?

MR. LYZENGA: Yes. I think we're in the process of getting it up on the website right now. There's a couple of new modules that are going to be presented for public comment.

And we're also going to be having an in-person meeting of the Common Formats panel in October where we'll be talking over and planning out some more major changes I think to the formats.

Including, I think, something that David alluded to is sort of paring down to a -- some very basic questions. You know, that are more easily answered.

And then have that additional information if possible.

MEMBER CLASSEN: So, what Andrew is saying is we're going to create both a basically a Tier 1 and Tier 2. Tier 2 will look very much like what you see now. Tier 1 would be a minimal data set.

In addition, we've also found that holding focus groups is another way to get feedback. So we will do that as well, as well as the public comment.

We had a round of focus groups last year and got very meaningful feedback where we actually reached out to people and held conference calls to review their concerns. So, expect both.

MEMBER ZIMMER: I just -- one is a comment, and one is just something to think about

for the future.

You're right on about -- that people don't all recognize Health IT. Whether they see it as a contributing factor or the event itself.

So, just keeping in mind that a lot -- from my days at ECRI, we often did see people filling out multiple forms.

Because depending on where they saw the error at the time, and where they went to attribute the cause at the time, which many times is erroneous, you're going to see people fill out multiple forms to capture that same event.

But the other piece that I just want to make sure as you're revising the Health IT, that you sincerely look at information technology with telemedicine. It's no longer a future.

There are a number of health systems that are already training. There are clinicians to rotate call in on telehealth medicine.

And I've already seen issues there because of the systems being put into place that are not fully comprehensive. And, ironically, do

not give -- are already missing key elements of data.

So, I can already see some pitfalls happening.

MEMBER MARELLA: David, if I could ask you to just comment on this aspect of it. In addition to supporting Karen's comments, I wanted to ask about how your committee envisions the Common Formats being used in the future?

So, you know, you and I have discussed about, you know, how the level of detail that's -- the ideal level of detail that's assumed in the Common Formats is pretty excessive compared to the information that people are actually collecting.

And from the perspective of the Patient Safety Authority in Pennsylvania, and ECRI, and other patient safety organizations, most of the data that we get is coming from people's internal, preexisting risk management information systems. Many of which have been -- electronic systems that have been in place for a

very long time.

And people are reluctant to change their own internal taxonomies. The vendors don't necessarily feel any pressure to adopt the Common Formats.

So, as a patient safety organization, you're left with taking the information people do have and learning to live with that.

Now, you know, as you've described, developing a minimum data set, I mean, we've done the same thing. And not all the fields in the Common Formats are equally valuable.

So, like what I've done with the Patient Safety Authority is incorporate some of the HIT questions into our system. But, I basically limited us to the ones that I thought end-users A, would be able to answer.

And/or B, fields that would exist in people's internal reporting systems. Because if it's not getting in there for most of the events, it's not going to get to us.

I just wanted to see if you could

comment on that.

MEMBER CLASSEN: Yes. Bill, we completely agree. And hopefully you'll be very involved and give us lots of feedback as we come up with this minimum data set.

Because that's just the kind of experience that we absolutely need to coordinate the minimum data set. I think the reason for leaving the overall framework up Bill, is that we do believe that ultimately vendors will respond to the whole framework, not just the minimum data set, and begin to change their systems.

We know it's going to be a long process. A much longer than we expected. So, that's the reason to have the broader framework and what we call Tier 2 as well.

But, there's no doubt about it that Tier 1 is going to be our major focus. And we need it to be guided by real-world experiences like yours as we create that.

So, we look forward to your input.

CO-CHAIR SINGH: So, David, do you

know what the state of these affairs is right now in terms of integrating some of these apps that we keep hearing about that facilitate reporting within Common Formats?

Or, integrates sort of systems within the EHRs so that providers with, you know, a couple of clicks can just send the information to somebody else?

And the second point I'm going to make is after you respond about why I think this needs to be done. Go ahead.

MEMBER CLASSEN: Yes. I think building the ability to pull this information out of EHRs and export it into these reporting systems is absolutely critical. You know I'm deeply involved in that with the automation of triggers.

And what we have found is that the impact of meaningful use on clinical documentation has dramatically increased the amount of safety valuable information in the EHR. And what we found is that a lot of information

can be mined out of the EHR and sent to these reporting systems.

However, it gets back to Bill's comment. Which is, that information is basically a subset of what the current Common Formats request.

And it's clear that a lot of the information that is most valuable is where we should probably start our focus on EHR extraction. And so that's why we're going to the minimum data set as a way to guide that to begin with.

But, having done this for a while, I can tell you that very often what we see happening is people have really rich documentation in their EMR. And they're hand entering all this information into their voluntary reporting system.

So, we're not achieving any, if you will, efficiencies here. And so, part of that reflects our focus on building these into electronic systems rather than having them in

paper.

What we've seen is the rise of separate vendors that do voluntary reporting. And none of them communicate terribly well with the EHR or extract data very well from EHR.

What we expect to see over the next ten years is that evolving into a system where these voluntary reporting systems can heavily leverage data from the EHR. Have people validate it and import it.

Do I think we're going to get to a point where these things could be automatically reported from the EHR? I think that's a long ways off looking at the complexity of these events.

But could we use the EHRs as a way to detect these events as they're happening so a human could look at them? Absolutely.

CO-CHAIR SINGH: Yes. So, no matter where the data is coming from, so either it's automated triggers like you are working on, or reported data that people send to reporters, I

think the ultimate goal, and we all agree to this, is will this lead to changes? And will this lead to improvement?

And I often see there is ongoing confusion about, you know, an event. And people say, well, this is bad technology. This is all technology's fault or EHR's fault.

When it's a complex interaction between sort of the human and the computer system. Many of these interactions can only be sort of found out if you investigated like you mentioned, maybe like a root cause.

But where we don't have the expertise at the organization level currently, is teams that have the expertise, you know, in either informatics, human factors, or whatever it takes, to investigate some of these events.

And figure out what's technology related? What's user related? Where did we fail? And you know, put in place improvements to the system.

And so I think people were thinking

HIT Safety Center might end up doing some types of, you know, whatever you want to call them, investigations or have teams that would, you know, do it. But that's not going to happen.

So, what we need to think about, and I don't think this is under -- in our measurement sort of concept right now, are if organizations -- or maybe it is.

But if organizations can build these local teams that could take this data, they could put that to good use. Otherwise this data is going to end up being, you know, useless.

MEMBER CLASSEN: Yes. I think one of the things we have learned with the Common Formats is that greatest learning takes place at the local level.

CO-CHAIR SINGH: Yes.

MEMBER CLASSEN: I think there was a fantasy that if we could just aggregate it all and send it to some galactic database, then we'd get much smarter.

I think we've now learned that's not

where most of the important learnings are going to occur. It's going to occur at the local level.

CO-CHAIR BELMONT: David, I --

MEMBER CLASSEN: But that's not, you know, it's not a -- that's not a direct attack on galactic databases. Because I know there's a lot of money being invested in them.

CO-CHAIR SINGH: Well, I think there is some value for knowing at a maybe like a national level, what are the common things that are happening. So, I think if we get some data that is aggregated, which has been investigated locally, I mean, VA does this.

You know, we get information from several different VAs about there's a problem. And we say put out a call saying here's a problem we need to fix right away.

There is some use to that as well.

MEMBER CLASSEN: But I would argue it only comes after you've had effective learning at the local level, right?

CO-CHAIR SINGH: Absolutely. Totally agree.

CO-CHAIR BELMONT: So David, I have a question about whether any thought has been given to the protection of this data from discovery by plaintiff's lawyers? To the extent this information is reported to a PSO that it will have that protection.

But obviously we want to be able to use it and share it and have it used for the right purposes.

MEMBER CLASSEN: So, much of the work I do goes along with the PSO. And we're pushing the boundaries of the PSO to protect and create a safe learning environment.

I do think that's going to be a big part of the future. So any of the measures that we consider here, we'll probably have to address whether we think these should be reported into a PSO. What role PSO's should play in this.

So, I can't imagine a final report that doesn't address that. The challenge I think

in all of that, and I might come back to David is, you know, the FDA obviously has a role in this.

And so if we find that there's a major product problem, and all this information has been protected in the PSO, how does that get out into the public domain? And I think that remains an essential channel.

And I remember that AHRQ and the FDA had worked out an agreement about how information could be both reported to the PSO and reported to the FDA. And I don't know where that agreement sits David, but I think that's a key part of the public benefit in all of this.

CO-CHAIR BELMONT: You may be aware of the Tibbs Case that came out earlier this year. It was a Kentucky case which in that case, they were able to obtain information that had been submitted to a PSO.

And I think because every State has different peer review laws, I think there is some general guidance you can give to folks who are

submitting this information to ensure that it's protected at the local level. As well as it's shared with PSOs.

And I can provide some information to you on that if you'd like.

MEMBER CLASSEN: Yes. And I'd like -- it's probably helpful for us to know where it sits between AHRQ and the FDA in terms of the reporting of this information about products to both the PSO and the FDA.

There was an agreement. I knew that along the way when we wrote our IOM report. But I don't know what the status of that is.

MR. LYZENGA: Any other comments or questions? Go ahead.

MEMBER HAYNES: So, you've had health information exchange on there. I wonder if you could expand on that a little bit as we move more towards integration where patients are going to be getting care at say Temple and help across the street.

And then you're going to have a health

information exchange and/or the data that resides within the Blue Cross/Blue Shields, the insurance providers of the country. How is this going to start to translate across organizations?

Not just in an EHR? But really, the EHR that really exists for any individual patient on a national level?

MEMBER CLASSEN: Yes. I think Kevin, that's a great point. It's clear that what we're talking about here is not a device in a box.

This is highly ubiquitous. Much like the air traffic control system, it goes everywhere.

And I think when we thought about this at the Institute of Medicine in our report on HIT and patient safety, we said look, you can't conceive of this as a narrow little box. Either EHRs or what have you.

This is a highly ubiquitous system that will get only more ubiquitous over time as we have the rise of health information exchanges. And patient medical records, et cetera, et

cetera, et cetera.

And so we said, the way you think about the system cannot be the traditional view of oversight and regulation. You really need a completely new model when you think about overseeing this from a regulatory perspective.

But I would say you need a completely new model when you think about overseeing this from a safety perspective. Because if you expect to get data reports into the model database about this, you're going to be holding your breath for a long time.

And I think that's a good part of what we're thinking about here. Which is, as you create measures, you probably cannot get away from the fact that how do you think about safety in a highly ubiquitous system that's only going to grow and expand?

And I think you need a -- and we've said this now in one of our -- a completely different oversight model. A different conceptual model.

Indeed, we actually said in the IOM report, the FDA should put together a group and come up with a completely different model for oversight in this area. And so far that obviously hasn't happened.

And I don't see any political realities to it coming soon.

MR. LYZENGA: Other thoughts or questions? David?

MR. HUNT: When you think about actualizing this in an automated fashion, I was just thinking, can you imagine taking say Jason's retraction measure and implementing that? I can almost see it, almost, as an automated function.

And that might be a nice prototype.

MEMBER CLASSEN: Yes. Not only can I see that, but we actively plan to. So, David Bates and I have an AHRQ grant to actually continue the work of a flight simulator for operational HR systems.

And we're going to expand that to include actually Jason's tool. We think that's a

great idea. And expand it to include usability and choosing wisely, and a couple of other things.

So we, David, completely agree with you that the ability to develop sort of simulation tools that evaluate these systems and operation, is a key step. And I think Jason's work just proves that.

MR. LYZENGA: Well, as we roll out the new modules of the Common Formats and begin our work thinking through things like the minimum data set, we would certainly appreciate very much the expertise of this committee. And your input and feedback.

So, we will be distributing that information to this committee and requesting your input at that time when we ask for public comment and other opportunities. So, I look forward to that.

And I think we had expected maybe at having a break after this. But we're a little -- running a little bit early.

So, maybe I'll ask Jesse to get us started with running over our concept list. And kind of introducing us a little bit to what we're going to be doing in the breakout groups. And start to move through our agenda just a little bit more quickly.

DR. PINES: Great. Thanks everyone. So, next I'm going to talk a little bit about the detail for how we're going to work for the rest of today and tomorrow.

Talk about some of our overall goals and where we want to be. So, today there will be -- really the majority of today is going to be group work. Next slide.

So, I just wanted to let you know what work has been done in the last six months, six to seven months since we last met. So, we basically took the list of measure concepts that was identified by the committee and have trimmed that down. And really tried to make that measure concept list more specific along with, as we know, the -- with some additional committee calls

over the last six months.

So, and what we found was really trying to put individual measures into singular domains was actually tough. So, what we found is that we took a lot of the concepts and we found that they actually fell into multiple domains.

So, what you'll see on the current measure list is basically four groups of 27 different measures, each of which is a measure concept that's currently assigned a primary framework domain.

And we've also identified -- and this is really where we need your input --- for each of the concepts, a level of accountability.

Specifically the vendor facility and/or clinician. Or a combination of the three.

So, basically for each -- for the breakout work, there are two main categories. There is -- so four groups. Group A, B, C and D. The two big groups are focused on the design, development and configuration of HIT systems.

And then the second group is the

implementation and use of HIT systems. And again, we, you know, really did our best to put measures in the right bucket, realizing that there are a number of measure concepts that actually fall into multiple different domains.

So, basically what we're asking of each of the groups is each group will have a group leader. You're going to start with 27 different measure concepts, some of which are very specific, and some of which are less specific.

So, really, the first goal of the group is to take that 27 -- those 27 measure concepts and really sort of call down measure concepts that are of lower priority.

So, you know, sort of look through. See if there are any ones that can easily be dropped, or ones that maybe not important and not feasible and just were sort of in the early idea phase. That's sort of step one.

And then the next step is to do a process where we rate the remaining concepts for

two concepts -- importance and feasibility.

And we want ratings for high, moderate and low. So, just to let you know the overall, you know, 27 concepts from each group, all of this will actually remain in the final report in an appendix.

So, this is not information that will ultimately sort of go away completely. All of this will be in the final report.

But really, our goal is to come up with a prioritized list of measure concepts and really discuss in depth what those concepts are, and what the next steps might be, and what some of the issues with measurement might be.

So, basically the group will go from 27 to 5 during the next process. And you know, we chose the number five because what we're going to do on day two is take the 20 that come from the four groups and call down to a top ten list.

So, when you come up with the top five, we don't necessarily want to have the groups -- it doesn't have to be five exactly.

It can be, you know, if there are four great measure concepts and the rest are not so good. Or if there are up to seven, I think that's also okay.

But really, what we want, ones that are either very high importance and/or very high feasibility, or ideally both. Next slide.

MR. LYZENGA: Can I just add something?

DR. PINES: Yes.

MR. LYZENGA: And we realize, as we've been talking through this, there are some areas for example in down time, there's a few specific measures around down time.

You know, I can't remember exactly what they are. But, if you feel like those measures are not, you know, those several measures, you know, we wouldn't want all three of those down time measures to be three of your five priority measures.

Maybe if you feel it's appropriate, maybe call down time sort of a theme or a topic

area that you think is a priority area as one of your five. I think that would be appropriate, and then we'll review it.

DR. PINES: Sure. So, as part of this process, if you do want to combine any measure concepts together, that's totally reasonable.

Hardeep, do you need to comment?

CO-CHAIR SINGH: Yes, I just want to make a quick comment. I still think because of the overlap, we might come with, you know, 24, 25.

But we'll probably have overlaps between the groups. And then that will be another opportunity to sort of, you know, pull this.

DR. PINES: Yes.

CO-CHAIR SINGH: The other thing I was going to mention is, I think it will be important for you all from NQF perspective to sort of just, you know, make it clear about measure concept versus an exact measure.

I mean, should people be thinking

about okay, how am I going to just build exactly what, you know, Jason did? Number of, you know, records or, you know, that were misidentified and all that.

So, it would be good for you to clarify that now so people -- should people be thinking more about concepts only, and don't worry about the exact measure?

Or should we do both? You know, all of that will be good.

MR. LYZENGA: I mean, I would say we'd like to see a little bit of both if possible. If you see a measure concept that we've identified, and you think that's a really good concept, it has some specifics and you think that would be valuable to really push development of a measure in that specific area --- something very close to what we've set out --- that would be great. Identify that as a priority measure concept.

But if you think that the concepts that are there are not quite reflective of what, you know, you would like to see as a priority

measure, maybe just note that during the breakout group.

And bring it up during our discussion in our report-outs that you would like to see a measure in this general topic area, or within this theme, that maybe is not on our list yet.

And then if possible, try to give us a little bit more specifics around what that measure might look like. Helen, I don't know if you have some comments or not on that?

MS. BURSTIN: There's too many of them. Just a quick comment in our other gaps work that we've done over the years, we've clearly heard from developers that specificity matters.

So, you know, seeing you know, general terms -- which you don't generally have in these lists anyway -- isn't as helpful as specifics. That doesn't mean you need to write a numerator and denominator.

But enough specificity that you could imagine handing it off to a developer who could

take your vision and be able to develop it.

CO-CHAIR SINGH: So, just as an example, and please let me know if this is correct. So let's say a group decides we think down time -- measuring down time is an important concept. And we want to push this forward as a measure concept.

But we also suggest that a measure could look like, let's say you have a down time that was unexpected, which lasted more than 12 hours and affected more than 100 patients. That could be a potential measure.

Is that the type of --

MS. BURSTIN: Right. Saying down time isn't sufficient. I think a bit more specificity there. And also, who is accountable for it?

I mean, on some level, is it the proportion, is it a patient level measure? Is it a provider level measure? Is also really important if we're trying to think about who might ultimately be accountable for improvement.

CO-CHAIR SINGH: Fully realizing that

those number that we might be coming up in our groups about suggestions, for instance, the timing or the number could be modified later. So we don't need to come to consensus today.

It has to be 100 people or? Okay. Yes. Thanks for the time.

MR. LYZENGA: We'll actually ask you, once you've sort of honed down to those top five, to try to flesh out if you have some time, a little bit of that information like around who might the accountable entities be? Facility, vendor, clinician.

And then some other possible considerations around implementation of the measure, or how you might do data collection. That kind of thing.

And just as much detail as you can around the measures that we've sort of come to as our top five priority ones.

CO-CHAIR SINGH: Yes. And Andrew, also clarify about what you mean by accountability? And what I think we mean is, who

would be the person responsible for implementing it? Measuring it? Or fixing it?

So I think those types of accountabilities are a bit different too.

MR. LYZENGA: Yes, and -- go ahead Jesse.

DR. PINES: Sure. So, I think accountability is really about sort of who is responsible for, if there is low performance on that measure, to actually improve that measure. That's what we mean by accountability.

MR. LYZENGA: And should we, you know, sort of assign accountability through some sort of, I don't know, program. This is far in the future.

And you know, through some of the programs that are going on with performance measurement right now. Who do you think should sort of be accountable for that measure?

Should it be the vendor? Should it be the facility? Or should it be a mixture? And I think, again, we've talked a lot about shared

responsibility.

So I would expect -- and that's how it's played out so far --- that many of these will have accountability shared across various entities.

MEMBER ZIMMER: My understanding just because to get through the 27 is that details that Helen spoke about -- the accountability sources, considerations per measurement -- is only when we've gotten down to the five.

Initially we're very high level. Look at what works, what doesn't work, where we can combine. And then look at the next level of feasibility, importance, rate those.

And from that rating, hopefully we get down to five to do what you asked.

DR. PINES: Yes.

MEMBER ZIMMER: Okay.

DR. PINES: That's right.

MEMBER ZIMMER: Just clarifying.

DR. PINES: Yes. Mark?

MEMBER SEGAL: Just on the

accountability issue, because I was struck by that as I was reading through. I mean, I think it's one thing to say for a particular issue that happened, there are multiple parties accountable.

I think as we're evaluating the concepts though, I think we're all going to be thinking, because measurement is right, one of the criteria. So what's the unit of measurement?

So some of these -- for example, just wearing my employer's hat -- would imply that you are measuring in effect the vendor was the unit of analysis. I think most of them though as you kind of think about it, it's really with the shared responsibility.

You know, again my sense is NQF measures in general have been sort of provider-focused, whether it's at a clinician or healthcare organization level.

If you were going to be using these let's say to evaluate vendors, then you'd have to think about a whole almost kind of a measurement scheme, right?

So, I think it will be important --- and I don't know if you have any additional guidance -- of how we think about accountability in terms of sort of non-punitive, performance improvement. Versus what's the unit of analysis for measurement?

Because I think the later will become really important as we think about the feasibility and the cost of data collection. So just if you have any further thoughts on that, I would appreciate it.

CO-CHAIR SINGH: So Mark, I'm going to let Elizabeth speak on that. Because she has a document about shared responsibility that she circulated.

Go ahead.

CO-CHAIR BELMONT: Sure. Thanks, Hardeep. So, what I did, included in the measures, you will see some that relate to shared responsibility. They start and go from 21 to 27, and then under Workgroup B, 3, 13 and they are mixed in.

MR. LYZENGA: And they're kind of distributed out throughout a number of the groups actually.

CO-CHAIR BELMONT: Oh, so they actually have this paper?

MR. LYZENGA: But they have -- but they do have that in front of them. You should have a paper copy of the -- of your list among your materials.

CO-CHAIR BELMONT: Oh, okay. So, very briefly, what I did was to do this into two big buckets. One was allocation of responsibility.

And you'll see different measures. And the second was ensuring confidentiality, integrity, and availability of EHR data.

And on the first one, what I did was to -- and actually on the second measure as well -- I tied this to existing regulatory accreditation standards and best practices so you know where it comes from.

So I think as we think about accountability, there is a way to tie it back to

the regulations and industry standards. And in some cases we might find that it's a shared responsibility, and more than one entity or individual has responsibility for that.

Does that answer your question?

MEMBER SEGAL: Part of it; yes.

CO-CHAIR BELMONT: Okay.

MS. BURSTIN: If I could just make one quick comment. It doesn't have to have an assigned accountability.

So it may be at this point it's just really important, and we'll figure out accountability to follow.

I don't want people getting hung up on that. Because I think the point earlier about some of these are going to be great for improvement. And you may not be able to hold an entity accountable.

And that's okay, too.

CO-CHAIR SINGH: Yes, so Mark, just think about if you want to fix too many alerts, how many, you know, people would need to be

involved to do that.

MEMBER SEGAL: So that's a process of picking.

CO-CHAIR SINGH: Yes.

MEMBER SEGAL: Excuse me, that's the part that we'll be addressing even more --

CO-CHAIR SINGH: Yes.

COURT REPORTER: I'm sorry, could you use your microphone please?

MEMBER SEGAL: I was just agreeing. I think there's the measurement part. And then there's the what do you do based on the data and findings you collect, in terms of how you remediate the problem.

MEMBER SCHNEIDER: So, I was scanning through the list, and it's an interesting mix of structure, process, and potentially outcome measures.

And I wanted to find out if there's a preference -- knowing NQF's style -- to avoid structural measures, which are often accreditation -- the fodder for accreditation

standards.

So, are we really -- should -- is there any preference related to concepts that maybe become accreditation standards and those that would be more classical performance measures?

MS. BURSTIN: So, I mean, in general, NQF has a hierarchical preference for outcomes. That being said, this is such an early nascent space that I think we may not be able to get through very many outcome measures yet.

So I think structure and process are going to potentially be the ones we're going to find. Whether they ultimately -- I'm look at Gerry -- become accreditation standards is fine.

And ultimately, whether this becomes a measure or an accreditation standard, I think we should be somewhat agnostic. If it's the right structural definition, it can feed in wherever it needs to feed in.

But I fully recognize that, in this area, we're going to see a whole lot more

structure and process than we will outcome yet.

CO-CHAIR SINGH: And I want to just reflect back. Eric, I mean this is a great point. And I think something for us to think about.

Are we at the words that we might be making recommendations that might influence certification standards or usability standards? I think most of you probably have seen the recent, you know, paper in JAMA about, you know, the evaluations of usability and certification standards by several vendors.

So, I think what you're saying is we could probably over -- you know, go into that area with the intent that we may be able to influence some of those things that are current beyond --

MS. BURSTIN: Yes; absolutely. I mean, just as an example, NQF's earlier work on palliative care practices became the foundation of the Joint Commission's accreditation standards in palliative care. That's okay.

But, I mean, I would defer to David here. I mean, it would be helpful to get a sense from ONC's perspective. Are you willing to have that full breath?

Or should we just assume for this exercise you'd really like them to focus more on what ultimately could be measurable?

MR. HUNT: Well, that actually fits into what I was going to say. I often think about, you know, we are at the National Quality Forum.

And the work that proceeds actually I know looms large in many of your minds. But, remember that for those at the tip of the spear, at the ground level, we often think about multiple layers or utilities for measures.

They are measures that may be useful, incredibility useful just for local quality improvement that never get out of the institution or the practice or the organization that can be -- they don't have to be so pristine.

But they're something that can be used

that an organization can work on things to measure and improve on. Then there are measures that we all think about and often are associated with the NQF.

Measures for public reporting. Measures that will be useful through multiple venues at HHS --- either CMS or ONC.

And then there are that very rarified set of measures that we are really on the forefront of so many people's minds now, associated with the value-based purchasing.

And there's a place for all three of those measures. And I'm hoping that we won't necessarily discount one measure that may be really, really good if a hospital was just going to use it, just internally, to improve on some features or processes of care that will ultimately improve outcome.

So, try to maybe span the spectrum, if you can, in your thinking. Did that help? Was that sort of?

CO-CHAIR SINGH: So, would the

accountable entities then the -- the breadth of accountable entities then suddenly goes up, right?

If we think that we can potentially influence things like usability and certification, I mean, we've got to be thinking beyond what we just said, you know, providers and institutions and vendors. Policy makers included.

MS. BURSTIN: I think David's still reminding you though, this is NQF. So I don't think he wants you to get too much into certification standards or things like that.

There may be structural elements that you'll identify today that may ultimately grow up to be a measure. That may ultimately grow up to be an accreditation standard.

I wouldn't worry about it for today's sake. I would just define what you think you can define, and however it sorts itself out, I think is okay.

MR. LYZENGA: Great. I should note

that toward the end of tomorrow's day, we're hoping to get into a little bit of discussion around how we think about these measures in this sense as well, with the NQF typical measure evaluation criteria.

And whether those would remain suitable for this type of measure -- HIT safety measures --- and how, you know, we might want to sort of modify or tweak those evaluation criteria to account for the different nature of HIT safety measures.

And maybe can get into a little bit more of this discussion then. That's just to sort of start the discussion off. We won't be making any decisions about that at this time.

But I just wanted to note that.

DR. PINES: Great. Thanks, Andrew. So, next, I'm going to talk a little bit about some of the criteria that the groups should consider when moving from the 27 to the five or around five.

So, ideally we want measures that are

important. This is what we mean by important. You can see it up on the screen there.

So, degree of impact on patient safety. Evidence supporting the measurement of this issue. And you know, I know that this is a very new area.

So we may have measures that are highly impactful, but there's really very little evidence.

And then, the third area is actionability. So, will this measure actually drive positive changes at the organizational or individual level, or even vendor level.

So, again, what we want to do is really only choose measures that are important in one or all of these domains to really move forward. Next slide.

In terms of feasibility, so there maybe measures that we do want to move forward that are incredibly important. Where there's potentially good evidence but may not be feasible today.

But, so measures that -- so for feasibility, we want to think about the availability and ease of capturing data. The general measurability of the issue in question, and then also the readiness for organizations to tackle the problem. And again, this is sort of the, you know, three level scale -- high, moderate and low.

And I think different measures will fall into different categories based on these various criteria. Next slide.

So, the next -- once the group has really chosen these top five or so measure concepts, so through either combining concepts, through eliminating concepts, what we want at the end and for the report-out for later today and also just to let you know, one change in the agenda, it will be Group A and Group C will be doing their report-outs today.

And then tomorrow Groups B and D will be doing their report-outs. Basically what we want is for each of these top five measure

concepts, a brief description of the concept.

We talked a little bit about accountable entity or entities. So a brief sort of discussion of what that might look like.

And depending upon the measure, we may have a good idea about who might be responsible or how that might be shared in terms of the accountability across the various levels. Or like Helen said, we may not have a great idea.

And so for some of these important measures, we don't necessarily have to commit to anything there. But if there's some sort of early idea about how that accountability might be shared, I think that would be useful.

Possible data sources or data collection methods. So, again, the more specific the better. But there may be measures that are very important but are just not totally feasible today.

And also, some key considerations for measurement of the concept, such as barriers, challenges and opportunities. And again, just to

reiterate, so we have this huge list of measures concepts.

All of this will be in the final report. And we're going to be presenting a series of prioritized lists back to ONC.

First is going to be this top 20, 25 or so, or what we come up with today. And then tomorrow we're going to be doing another -- a further call of that -- to ten measure concepts that we think really represent some potential next steps for developers or other groups that really want to move forward today on these issues.

MR. LYZENGA: Yes, so maybe we could first do a quick public comment. Open -- I'm sorry. Questions. Yes, let's do questions before we do that.

MEMBER JONES: This could be a question or a comment, I guess. There are two things that I think have been brought up in prior discussions.

One is that as we consider these

issues, a lot of the options that people have in implementing HIT are options and have more to do with implementation then the software itself.

You can choose to have discrete sigs or not. You can choose -- if we take even the second item on the passing of lab results from a lab system to an EMR -- what you choose to pass and how you choose to pass it and these are important decisions that get made. But they're often implementation decisions and not necessarily soft -- you know, sort of vendor software design.

Although they leave that option open. So I think that's important to consider.

And then David, I wanted to follow up on something that you said. The distinction between things that get used at a facility level or a provider level versus what gets used in a more macro level.

For me that kind of bridges the importance and feasibility constructs that we're talking about. But a lot of that has to do with

prioritization.

We find most useful measures that allow us to go between up and down. So we get a macro picture that tells us do we focus on the possible HIT issue which we might not understand, versus antibiotic use and CDET.

All right, I mean, these are practical decisions an organization has to make about where we prioritize. So, then being able to drill down to an individual, where did the problem happen so that we can learn?

If we can find measures that work well across those levels, greatly enhances our ability as organizations to prioritize on where we need to learn, figure out the nature of the problems, and then measure: are we getting better?

And I'll bring up some of the work we've done in surgery here. At many of our individual facilities, if we dropped our surgeon's site infections to zero, it would take an individual facility a full year of cases to even be able to detect change.

So it's really important to be able to link that, the macro measurement, in my opinion, to the micro what went wrong. And I'm just curious on your perspective.

Because you seem to be drawing a distinction we should maybe be doing one or the other.

MR. HUNT: Well I thought -- hold on a second. I mean, I cut my teeth actually at the very macro level. And that was my whole focus for so long.

But, after doing work in the surgical quality improvement and speaking to those on the front line, I found that there was a tremendous utility in need for small groups being able to do work just as -- among themselves.

And we missed that opportunity in developing in previous measurement development work that I had done. And I always said we're never going to really -- I'm not going to -- I'm going to learn from that mistake, in that it's surprising how many folks are out there trying to

do good work. But they're not going to be able to do something on the macro level.

And maybe one unit, one surgical unit may be able to do something. But they don't know where to start; they just need something actionable.

And having a full suite, a full tool chest that they might be able to use and pull out I think is very, very helpful. And I'm taking some of my cues from work from other groups.

I'm not sure how many are familiar with like the ACS NSQIP, very outcomes measure approach. But they are -- much of the work is very actionable at the micro unit level. Perhaps even at the individual OR suites. Or at individual units.

So, not -- always having that -- and I know this sounds silly, particularly coming from HHS. But always having that macro view I think misses a lot of the point.

So, to that end, while we will have a good set of priorities. And the priorities we'll

take to heart at ONC and at HHS very well.

Just having a recordation of those that may not have reached the macro level priority but still might be useful for whatever reason, that transcript will actually have some value later on in the project.

That is to say, I can't imagine completely throwing away all -- as detritus -- all of the other concepts. Because some of those concepts, small, perhaps not a major impact at a national level, may be useful.

And I think this -- the record of this whole project will be useful later on for those who are trying to do work at any level.

CO-CHAIR SINGH: I think I'm going to just quickly reflect on what I think you understand -- what I'm understanding is --

COURT REPORTER: If you could turn on your --

CO-CHAIR SINGH: Oh, yes, okay. So, having the perspective of what's really important. I think we all can sort of understand

that --

COURT REPORTER: I'm sorry, sir; your microphone is still off.

MR. LYZENGA: You need to turn it off and turn it back on again. There it goes.

COURT REPORTER: There should be a red light.

CO-CHAIR SINGH: On now?

COURT REPORTER: There you go.

CO-CHAIR SINGH: Okay. Treatment related issues, diagnostic issues, communication issues, coordination issues. I think as we develop these measures, we should think about are the measures that we are developing, would they actually help serve current patient safety problems that we all know about?

Identification issues. Diagnostics, communications, coordination. All that stuff. So I think that perspective is really important.

The other thing that I was going to tell you -- I was going to sort of mention, you said well, a lot of the things, you know, it

depends on what you implement. And that is right.

But I think as we develop these measures, we should think once you have interface for communication across, you know, to -- across the interface, it's important -- it doesn't really matter what you are communicating.

But are you actually measuring for instance errors related to the interface? You know, maybe that's the measure concept which would be around what -- your first comment about, you know, implementation related issues.

I mean, thinking about what could go wrong types of scenarios in that -- in the interface would probably be a good thing to think about.

MEMBER MARELLA: I just wanted to pick up on that same comment that Jason had made about, you know, where does the responsibility lie for different measures -- with the vendor or the provider organization?

And the way I'm looking at some of

these concepts, you know, many of them have parts of them that apply to one party or the other. And the way that I'm kind of generically splitting them out conceptually is: is there a piece of this measure that the vendor must support in order to, you know, for the measure to succeed?

Or -- and if the vendor supports that, what does the provider organization do in terms of implementing it?

And so just one of the topics that came up last year I think, I was talking to Jim about -- from Epic about whether Epic limits the number of records that can be opened simultaneously.

And I think he said that yes, they do. There's a -- you can configure it so that you can only open one at a time, or up to six at a time.

So the fact that Epic supports that configurable option is one part of the measure. The other part of the measure is: does the provider organization mindfully make that

decision? Or is it just, you know, some random default setting that gets left in at implementation?

So, I think if we can look at the construction of these measures as we go through them and maybe reword them a little bit so that it's clear which part of this is the vendor responsible for, and which part of it is the provider responsible for.

DR. PINES: Okay. And if I could just make one more comment. So, as these groups do go through the discussion, you know, we know this is a rapidly evolving area.

If there are other measure concepts that come up through this process, we're also very interested in hearing about those. And we can certainly include those in our report.

If those -- if any of those new measure concepts get elevated to the top five for each group, you know, we're also open to that. So, we don't want to specifically limit the group discussion in any way.

MR. LYZENGA: I should actually note that patient identification is something that's come up a number of times through comments and through the Common Formats input as well. And I don't think we have anything specifically related currently on our list of patient identification.

So, if you could think about that. Maybe coming up with it. Oh, well, Jason's measure there. But that's actually not on our list currently. But that's one.

That's something to consider as you're going through and adding or removing measures. Any other thoughts or questions? Comments?

DR. PINES: Sure. And just one other thought. And I think there's one more comment over here.

So we will have the opportunity tomorrow to have a discussion at the end. So, you know, this -- through these next two days, we will -- a lot of ideas are going to come out.

And we do have an opportunity at the end to think about what the future looks like for

measure development in this area. And specifically in any issues that may not be specifically measurable today that we may look to in the future as vendors develop systems or they become implemented that we should think about development in the future.

MEMBER CASTRO: Just one more comment. And I find, you know, as I have scanned through the list and drawing on our previous research.

When considering the degree of impact on patient safety, it was helpful for us to consider the contributing factor in relation to the patient. You know proximal or distal to the patient, right?

So, if you think about, you know, a vendor issue such as, you know, that's distal to the patient. You know, whereas closer to the patient, it was more likely a clinical process that failed.

You know, the medication double check. Or the universal protocol program. So, when I look through these measures, it's at different

points during this continuum.

And you think about Jim Reese and Swiss cheese model. It's very -- it's linear that way.

And when coming up with these solutions, you know, what we seek to do is come up with a system fix, right? And so I think of our national patient safety goal on free flow pump protection that is now retired.

And what was the solution? The vendors came up with smart pumps. Right?

And so if we can, you know, just use that same kind of mental model in considering these in relation to, you know, safety, I think that would be helpful. At least it helps me.

So, that's just the way I think about it.

MR. LYZENGA: Any other comments? Or questions about the breakout groups? All right. I think we're going to actually take a quick opportunity for public comment.

Operator, are there any public

comments on the line?

OPERATOR: Okay. At this time if you'd like to make a comment, please press star then the number one.

(No response.)

OPERATOR: There are no comments at this time.

MR. LYZENGA: Great. Anybody in the room?

(No response.)

MR. LYZENGA: It doesn't appear so. All right. Well, maybe we can take a quick break at this point. Fifteen minutes.

So, we'll come back at 10:45 to get into our breakout groups. Ann, do you want to tell everybody where they should be?

MS. PHILLIPS: Everybody, you should have a breakout group assignment list in your pile of paperwork that I left of you.

Group A will meet at the round table on the left. And Andrew will be working with Group A.

Group B will meet at the round table on the right. And Jason will be working with Group B.

Group C will probably meet right here. Because I think that's the best place for you to gather. And Zira will be working with Group C. And Zira is right there.

And Group D should probably meet me at this door. Because we are going in the back to use a temporary conference room on the 9th floor. And we'll need my key fob to get back there.

You may not need your laptop. Certainly bring the pile of documents --- that includes your agenda and your concept list that I left for you all this morning.

MR. LYZENGA: Thanks everyone.

(Whereupon, the above-entitled matter went off the record at 10:28 a.m. and resumed at 3:21 p.m.)

MEMBER DIMITROPOULOS: All right, great. And Ann, you're going to handle the slides for me, correct? Okay. So I just wanted

to give you a really brief update on the roadmap for National Health IT Safety Collaboratory. And I think the first thing I want to -- the first question I want to answer before you even ask is: why is it no longer a Center and now a Collaboratory?

And I think that this was a good choice of words here because, indeed, this isn't to be something that's located in a brick-and-mortar building where people have to come and preform research. It's really intended to be an organization without walls, where researchers across the country can come together, collaborate on issues of importance, without regard to where they're located throughout the country. And so, indeed, it is a great choice of words. So we'll go with it. Next slide, please.

I think everybody in this room really understands the value of having a national collaboratory that's focused on answering important questions around how we can use health IT to deliver safer care and how we can

continuously improve health IT. Next. The concept of the Collaboratory has evolved over time. I think you're also aware of this.

When the IOM report came out and emphasized health IT as a shared responsibility, and we started to think about safe health IT as a public good, the IOM also noted that within this concept of a shared responsibility, that one role of the federal government would be to develop a framework for a public/private partnership. ONC, in the response to the IOM report, set the objective to use health IT to make care safer and to continuously improve health IT, which was followed by, of course, the FDASIA draft report, which really proposed the Center or -- as we're calling it now -- the Collaboratory. Skip, skip, and skip one more. All right.

So, in terms of the Collaboratory Roadmap, ONC founded RTI to develop the Roadmap. And to do so, we really followed a fairly rigorous and really time constrained process, as many of the folks in the room know. Can we go to

the next slide? In terms of this process, the first thing that was really important for us, and we spent a little bit of time on this, was develop the document that really scoped out the all of what we were supposed to do. The scoping document we called the Rules of the Roadmap. It provided guidance for the task force and for the work groups for what needed to be considered, what we were responsible to ONC for developing, and also the final product, which was to produce this Roadmap, that really included a five year plan for bringing up a collaboratory. Next and next.

So, within the scoping document, we focused on these core considerations really. The core activities that we needed to define were -- well, core activities, operations and governance, and assessing funding mechanisms. And within each of these core components, there were considerations that we provided to the task force to think about. And that really framed their work, which I'd like to point out was constrained

between December and April. So this was a lot of work to accomplish in a short time. Next.

Equally important was to define what the Collaboratory would not do. And there were some things within the various authorities of the federal government and the funding agency that we just simply could not include in the Collaboratory. And I know that these caused some concern among certain folks, but this is the framework that we had to work within. And I think the outcome really, really did work within this scope very well and produced a great product. Next.

So we convened a task force and a steering committee -- 22 member task force, included five government representatives. And within that task force, we identified four members who would serve as a steering committee of sorts to help us and our chair work with the work groups and make sure that we kept things in line with ONC's expectations for the end product. There were two work groups. One focused on

functions and activities of the Collaboratory, and the other one focused on the operational considerations. Next slide.

We approached identifying task force members by making sure we were inclusive of all the stakeholders, a wide range of stakeholders -- organizations and so forth that needed to be involved -- but we also were very careful in terms of identifying individuals and making sure that they had the health IT expertise to participate in the groups. Next slide. This is the chart with all of our task force members, steering committee members highlighted in blue. And several of the folks in this room served and I'm sure can chime in as we go forward. Skip. Okay, skip that one. Yes. Okay.

I didn't want to go back to that time line chart because as I said, the time line was very short. We started in December, we wrapped up in April, and had the report released by July, which is pretty rapid cycle for us. If you go to the next slide. The task force first defined a

vision and objectives for the Collaboratory. And the vision was to have safer systems and better care using health IT. And the mission is to serve as a safe place where stakeholders could convene, create a learning health system. And they were committed to two main objectives --- the use of health IT to make care safer and continuously improving health IT. The next slide please.

The task force agreed upon a set of attributes that the Collaboratory needed to have. It needed to be dedicated to sharing learning and sharing responsibility; it needed to be solution focused. In other words, they want it to identify solutions, test them, disseminate them fully. It had to be a public/private partnership. And really important here was that it needed to be a trusted learning, a non-punitive environment. Next slide.

The task force also focused on the success of the Collaboratory really resting with the stakeholders. And it required that major

stakeholders -- major stakeholders have to participate, or this simply won't work out. And so, here's a list of the general overall stakeholders who could be involved and should be involved. Next.

The task force decided upon some of the focus areas and activities. And these really emerged from discussions over time. The set of focus areas include collaborating on solutions, improving identification, sharing of information, reporting evidence, and promoting health IT related safety education. The task force also identified core functions of the Collaboratory. And the core functions are convening stakeholders, conducting research within the constraints of what we have to work in, and dissemination. Okay, you can skip that one and the next one. There we go.

When we got to decisions about how this should be organized structurally, the task force agreed that we needed to have a host organization that could support the

collaboration, could support the activities and functions identified earlier. The host organization also would need to have patient safety and health IT expertise, would have to have a mission consistent with the Collaboratory, and it would have to have the required infrastructure to support all of these activities.

The funding mechanism would be, initially, a cooperative agreement, which provides the seed money coming from the federal government. A cooperative agreement allows a good deal of flexibility for the federal government to participate as a full partner in kind of the direction of how things work. And then the other main piece of this was, once you have this organization in place who can manage and monitor the work, we would have an advisory board comprised of participants, stakeholder participants, who would really make decision about priorities for research and make decisions about what information needed to be disseminated

and how.

So you'd have this leadership role of the stakeholder group. You would also have the work groups who needed to be pulled together again from the Collaboratory members and participants to participate and move the work along. The infrastructure of the host organization would include Executive Director and then Convening Staff, Research Staff, and Dissemination Staff, ideally. Okay, next slide please.

The task force spent a good deal of time identifying the key roles and responsibilities of all the participants. Some of which that belong to the host organization -- including the Executive Director and the Convening Staff -- are paid roles within the program within the host organization. I think it was pretty widely agreed upon that the participants and members of the Collaboratory would be unpaid roles on the advisory board and then on the working groups. Can we skip to --

next one.

The Collaboratory funding model objectives that we were charged with were to estimate the funding needed to support all of the functions of an optimal collaboratory at 100 percent over the course of five years. And then from that, create estimates of 75 percent, 50 percent, and 25 percent. And I can tell you that the discussions with the task force, I think they were able to come to some decisions about what it might look like at 75 percent and what it might look like at 50 percent, but at 25 percent, the feeling really was that it just wasn't enough to have a meaningful impact. And then trying to take something that's not enough to sustain the current work, but then try to build up a sustainability model, it just wasn't feasible. So these were the levels of funding that we worked with.

The task force also agreed that convening and conducting research and dissemination were all extremely important. So

it was very difficult to prioritize out some activities. And so instead, choosing to scale down. So we built up to the 100 percent optimal model and then scaled down the work across the board, across all of those. Next.

The group did look at other organizations that were set up as public/private partnerships and looked to -- and that were also partially funded with federal money and then grew to be sustainable. Some of those organizations that were looked at included Markle, PCORI, NTSB, ECRI, the AHRQ Guideline Clearinghouse, and some others. Just to gather some ideas for how this might be structured. Next.

So, again, as I mentioned, this was proposed as a five year cooperative agreement to a host organization. It would be awarded through an open competition. We think this would provide a rapid launch to the existing organization. The Collaboratory would function as a program within that organization. And I think -- I didn't mention here, but it really does need to be a

501(c)(3) so it can accept external donations. And it's got a phased approach for bringing it up. Next slide.

As we built this model up to develop the funding, we looked at staffing of the organization and built it up as we would thinking about a cooperative agreement and how you would get something like this up and running. We looked at other direct costs that would be associated with the work, and we took into account Collaboratory participants and members and made the assumption that, that work would be volunteer and unpaid. Meaning, they're going to have to get something of value out of this commitment of time. Next. Next. All right.

So this is the estimate that we included. That at 100 percent optimal, it would require close to $20 million over the course of five years. And then we sort of broke it down from there, reducing the scope of work across the board. Next slide.

We do have some final considerations.

And I'd just like to point out that this is a starting point; it's not the end all and the be all, but I think that, at least the task force and we agreed that this would be a tremendous addition to what needs to be done. It would have a great impact. The challenge is to be able to get the funding to be able to get this launched. But we have to start somewhere. And I think even at starting less than 100 percent would still be a terrific win for everyone. All right. Next slide. Next slide.

So the Health IT Safety Center Roadmap -- which was titled and released before the title was changed to Collaboratory -- is out on the Web, and if you haven't gone through it yet, I encourage you to take a look at it. We did have a presentation last week, and we're going to have a follow-up Q&A session coming up on September 25, which is -- I sent you the email with the information, Ann, in case anybody's interested in that. It'll be a Q&A session with ONC, with members of the task force, some of the RTI

project folks, who are more than willing to answer some questions and have a conversation around what the Roadmap means. And that's it for me. Questions?

MR. LYZENGA: This is a question for Linda, and to some degree maybe David as well, how our work as this committee and the recommendations would potentially flow into the work of the Safety Center and influence it or how we can be most helpful with our work in the development of the Safety Center and its activities?

MR. HUNT: This is David. As we looked at how we would do the work that we've done over the last year, originally this piece of it -- this outlining categorization of measures, setting some priorities, and starting to come up with some measure concepts -- would have naturally really been a portion of that overall work, but the opportunity to do this through this task order was really the reason for it being separate.

So that's a long way of saying this is immediately relevant, part and parcel, to our visioning of what the Collaboratory will do. It's one of the most important jobs that you can have in the federal government to have a good set of priorities. Because whenever the discussion comes to resources and what do you want to do --- as we all know -- there's never enough, and there's always a challenge in trying to carve out what you need to do and to be able to always go in front of leadership and say, here's an organized set of priorities that have been publically vetted and has this evidence base, is a huge, a huge leg up and actually the first step in actually getting something done. So the work that we're doing here is immediately relevant and will immediately be useful moving forward.

DR. PINES: Great; thanks. So any other questions about Linda's presentation? Great. So next we're going to do the group report-outs from the break out session. So, just from sitting in on a number of the different

sessions, the methodology used in some of the sessions was not exactly the same, which I think is okay. I mean, I think ultimately it gets us to the same point, which is to have these top five concepts.

So just to remind everyone what we're going to do, we're going to do the report-out. We're going to start with Group C first, then we're going to go to Group A, and then tomorrow morning, we're going to be doing Groups B and D. And as you're hearing these presentations, I think we're going to hear some of the same types of concepts that are the top five within each of these individual groups, and I think that's okay. And actually, that sort of furthers the data to show that this is really sort of a high priority area.

So, again, we're going to be doing quick report-outs, get some feedback to Eric and Gerry today. And then tomorrow, similar report-outs. And then hopefully after that point, we're going to be doing some harmonization across the

measures.

MEMBER SCHNEIDER: Okay. Thanks very much, Jesse. And I want to just start by thanking the members of my group. I had a fantastic group with tremendous discussion. We tried to capture a lot of it in notes, but I'm sure there will be further input on it. Jesse asked me to talk a little bit about our method, how did we get to the list that we produced. And I wrote it out; it's a nine step process. The first was we --

(Laughter.)

MEMBER SCHNEIDER: I think we covered every possible process. The first step was we discussed each of the 27 concepts on our list, mainly for clarification and also to begin the process of eliminating some. We actually only dropped one in that process, but we de-duplicated or clustered or grouped several of them. So the second step was grouping. And for the grouping exercise, we actually used the primary framework that was given, but also a ground-up sort of

emergence of themes across the 27 indicators on our list.

So there were five themes that kind of emerged for us and then this primary framework that was provided in the document. Then we went back and revised some of the concepts based on the rationale that was given in the rationale column and our group discussion. And, again, we had a number of perspectives in the group, which was really helpful for sort of spelling out or specifying some things that might have been vague in some instances. We're also redirecting some of the language. That was the third step.

The fourth step was to -- that yielded seven categories of potential measures. And these concept categories are -- actually there were some of them that were on the list and they were sort of broad categories, they were uber-categories. And then there were sub-categories, we conceptualized that there would be sub-categories within some of those larger categories. So the seven concept categories --

well, I'll get to in a moment.

And then the -- next we, I think we at that point came back from lunch and discussed and refined those seven. And then we went into the rating exercise. And we didn't try to rate on feasibility, because we were still at too conceptual a level to really know what was feasible within particular categories. But we did rate on importance. And four of the categories we created were unanimously rated highly important. And so we started with those four.

We discussed each of those four categories and at that point started to drill in and produce potential measure concepts, either out of the list that we already had or other ideas that the group voted forward. And then we -- having not run out of time yet, we created a fifth category that actually extracted what we thought were some valuable components from the other three categories that hadn't made the cut. And so, now what I'll present to you is the

product of that work.

So we have -- our top five concept categories were technology to facilitate the patient/clinician interaction and support safety in that sense. A category we called simulator use, but it's specifically using the simulator that Dave Classen's group developed to test the EMR, but also to evaluate the competency of clinicians using EHRs and the workflow. The third uber-category was clinical decision support, which actually initially showed up on our list as a set of alert indicators. But alerts being a subset of a broader set of potential measures around clinical decision support, we decided to broaden that category, and I'll say more about that in a moment.

The fourth category was patient-facing technologies that facilitate patient engagement. So different from the first in that we're looking to facilitate patient/clinician interaction, here's the patient-facing technologies that actually are engaging patients directly --- or

their caregivers, I should say, too. And then that fifth category we created was around the availability, integrity, and confidentiality of patient data. And you'll see more -- you'll hopefully see why that makes sense later. Let's go to the next slide.

So Concept 1, Technology to Facilitate the Patient/Clinician Interaction. The problem we're dealing with here is the problem of the clinician looking at a screen while the patient is off to the side and there's not a good interaction. And so we're looking at ways to improve that interaction. And the discussion in the group actually ranged across the technologies, office layout, the positioning, and behaviors in the room. And so, we were trying to figure out ways to capture that in a measurement scheme.

And at this first stage, a survey-based measure seemed to make the most sense. So a survey of patient and provider's experiences with technology, and specifically these problems

that arise in the patient/clinician interaction around the introduction of technologies. And there's even an example of patients texting while they're being examined. So there's actually not just the devices that the hospital has in the room, but the devices that are coming in from the outside that have to be considered in this realm. We think that the accountable entity or entities are the facility, the patient, and the physician. Potentially, you could add caregiver to that group. I'll go to the next slide.

The possible data sources or data collection methods, primarily we think the survey-based measure would be the primary use. But it's conceivable that one could use an audit to inspect rooms with laptop computers or computers in them and there might be an optimally defined layout for the room. And as part of that inspection or accreditation audit or certification audit, you could define whether a facility is meeting a standard. And then mining reports to complaints systems from patients is

another possible source of data. Because not only physicians, but also patients may complain about the lack of an interaction related to technology in the room.

Some key considerations, we think the opportunity there is to improve the patient and physician experience and improve the use of the technologies and the types of technologies that are used in these interactions. And this would extend outside of the office into telephonic and other forms of virtual interaction. And then some of the challenges, I've talked about the physical structure of rooms, the option of changing the way screens are oriented. There's the challenge of the cost of the re-engineering of the technological -- the introduction of the technology and the way it's implemented in workflow.

And I think there would have to be some set of standards in order to really go beyond patient surveys to measuring the appropriate or the ideal or optimal use of

technology to facilitate patient and clinician interaction. So I don't know if you want me to walk through all of these or do we want to discuss? I'm happy to take questions in the middle as we go along.

DR. PINES: So yes, I mean, I think that we can maybe take a couple brief questions or comments.

MEMBER SCHNEIDER: And I also would like if members of the group wanted to chime in with anything I may not have highlighted since it's hard to capture such a rich discussion. Greg?

MEMBER ALEXANDER: Yes, I just wanted to say, just as a point of -- I don't want to be picky, but I think that it's really important that we broaden it beyond just physician experience to, like, in your opportunity there. I think it has to be other clinicians that are working with the electronic health records as well. So we have to sort of be careful of our language so we can be inclusive.

MEMBER SCHNEIDER: Yes. I appreciate that. We tried to actually use the word clinician consciously, but I think it's one of those comments slipped through it. So I would --

MEMBER ALEXANDER: I just thought I'd get it out there.

MEMBER SCHNEIDER: It's great to highlight. Thank you for doing that.

MEMBER ALEXANDER: Sure.

MEMBER SCHNEIDER: Anything else? Okay. Good. So number two.

MEMBER ALEXANDER: I have one quick follow-up. So you're thinking it's going to be a new survey that we will have to develop? Somebody's going to have to develop this type of a survey?

MEMBER SCHNEIDER: So survey items, I guess I would say. And then we'd want to explore what are the vehicles for disseminating those survey items.

MEMBER ALEXANDER: So existing survey items like -- what do you mean?

MEMBER SCHNEIDER: No, no. We'd have to -- there would be new survey items.

MEMBER ALEXANDER: New survey, okay.

MEMBER SCHNEIDER: And the question would be are there existing survey vehicles? Because I think we're all mindful that --

MEMBER ALEXANDER: Got it.

MEMBER SCHNEIDER: -- in fact, surveying clinicians, surveying patients --

MEMBER ALEXANDER: Yes.

MEMBER SCHNEIDER: -- is increasingly a difficult exercise. That's why in all of these categories we tried to think about passive data collection strategies that wouldn't involve going to the patient or going to the provider, clinician. But there's certain areas, like this, well, you're trying to assess engagement, the end result of that engagement is someone feeling engaged probably as maybe the gold standard measure. But we're also very interested in whether there are direct ways to assess whether this interaction is occurring.

There was even a discussion about video, you know, could you mount video and actually do an audit of using the rotor communication scale or something else? It would be very labor intensive unless you could automate it. And then the other opportunity was around the simulator. Whether you could use putting the user in a simulator with a patient and seeing whether that particular setup actually facilitates engagement would be another potential way to measure this without going into the actual clinic, for example. Okay.

So number two, the simulator use. And I may ask David to weigh in here at some point. The brief description of the potential measures -- now I don't know how much background people have on the simulator concept, so it might be worth starting there. David, do you want to say a few words about that?

MEMBER CLASSEN: So, the simulator was developed to help implement a Leapfrog standard, which said that physicians were using order

entry, they were acknowledging overrides, and they were using a system that passed a basic safety test. And so AHRQ and Robert Wood Johnson Healthcare Foundation funded David Bates and I to create such a thing. And we created it in the early '80s -- early 2000s and implemented in 2008.

And basically, what it does is, it takes known scenarios that have caused harm to patients where we can track the harm all the way back to the internet system and it subjects those scenarios to hospitals to implement them to see if their system is operational, prevents the scenarios from happening. Gives an overall test and then a score and then a score in the category. Last year, about a thousand hospitals took the test. So AHRQ funded David and I to expand and enlarge the test and make it more generally available.

CO-CHAIR SINGH: And then while you are at it, why don't you also tell us how many hospitals actually passed the test and what they

did with it when they failed.

MEMBER CLASSEN: Yes. The number of hospitals that have passed the test has gone up over time and improved over time. And the Leapfrog sets the standard of what is passing, we don't. But let me just say that there are several categories in the test that the hospitals do well on. They do very well on picking up critical drug-drug interactions and drug allergies.

But there are certain aspects of the tests that they do terrible on and haven't changed over five, six years. And those are things like adjusting a dose of a drug for renal function, adjusting the dose for a drug level that's recorded in the test case, adjusting the dose of a medication for age, and adjusting a medication use for a diagnosis, so if a patient has a diagnosis of asthma, can the system pick up maybe there's certain drugs you shouldn't give, et cetera.

When we developed them, we did

extensive inter-rater reliability testing and we actually created a version of the test that an individual provider could take. And that's what Eric was most interested in. And so we proved the point. Yes, you could use the test not only to test a facility's safety performance, but you could use it to test an actual provider's performance.

And, interestingly enough, in one health system where we did that and did extensive testing, we found variability in performance of different providers all using the same decision support platform that was supposedly unchangeable. Initially, we thought it was a problem with the test until we found that some of the users at certain sites in this health system had found a way to disable the safety checks at their local facility unbeknownst to any of the operators. Let's just say that caused a lot of chest pain.

MEMBER SCHNEIDER: So you've heard now that this is already used in an audit or

accreditation context. What the group discussed was this idea of applying it to the individual user, to units, to entities below the facility level. And two potential measures were the percent of users that are tested in the simulator each year or the actual user scores on simulation testing. And you could do that overall or by test category. And what's interesting about this is that it could give you insights on the vendor product, the vendor product's implementation, the user at every level. And so I think this could be a potentially powerful tool. We say that a facility and clinician is the accountable entity or entities, but actually I think vendors should be in that list as well. Next slide.

The simulator program provides the data, so that's an advantage. Of course, people have to participate in the simulation, which I think is a four hour simulation. The key considerations -- the opportunity is that this actually could be part of facilitating the learning healthcare system. You've got the IT

vendor -- I'm sorry, the CIO or someone from IT, you've got the quality person and you've got the medical director all sort of observing as someone is going through this user testing. So there are lessons generalized beyond the individual. The other opportunity is to extend this into ambulatory settings potentially. Which is, I think, not a current application, although it's totally feasible.

Some of the challenges are the compliance, the cost, the availability of simulator. So there are some issues to be worked through there about how one would deploy this simulator construct. Okay, next -- unless there are questions I'll keep going. Or comments from our group.

CO-CHAIR SINGH: Yes, sure. So this is -- I think this is a great sort of a concept and I'm wondering when you guys were discussing this, were you thinking this would be only for something like targeting medication error type issues or other instances as well?

MEMBER CLASSEN: So, right now, it goes beyond medication safety to things such as overloading, so that's a category of the test, cost, but what AHRQ has done is funded this for five years to expand it into Choosing Wisely, expand it into cost control, expand it into usability, and expand it into error detection using a version of Jason's measure.

MEMBER JONES: So the other thing that I sort of like about this is it also solves a problem that I think a lot of our health IT development shops have now, which is that horrible knowledge that you can't actually know if the thing that you're doing is going to break something else until it goes to production. And that vastly slows down a lot of activity and I think we then build workarounds that increase the likelihood that we can't discover something's wrong until it goes to production. So one of the things that I like about this if it can become ubiquitous is not only can it pick up on possible safety issues, but I think it could over time

actually increase our ability to generate better systems for a known problem that we have in our organizations.

MEMBER SCHNEIDER: So thank you for adding that. I mean, it's a nice -- I mean, in the way that another domain's quality measurement gets incorporated into a quality improvement cycle, this is an instance where that synergy was apparent I think to our group. Okay. So the clinical decision support concept category, as I've mentioned, generated out of the alerts as the sort of focus area that was in our set, but also recognition that actually there are several aspects of decision alert -- of clinical decision support that are potentially related to patient safety.

And I had partially recalled a framework that David had developed which notes that alerts are just one of a class of reminders, prompts, triggers, protocols, order sets, and other forms of decision support, all of which actually have potential safety implications. So

we wanted to just reflect that there's a broader set of things here that a measure development team might try to work with. And we also didn't want to foreclose by sort of prematurely closing in on this the idea that there might even be better measures than the ones that were proposed.

But what we did in our second round of this was to propose several alert-type measures that we thought would be useful to push forward. The one last on the list there, number 18, is actually from the document. And the document was very helpful in terms of stimulating thinking. But two aspects of this that the group felt were important that aren't well reflected in the current alert measures are the notion of providing context, not just an alert that says you're about to do something dumb, but how did -- why do we think you were about to do something dumb? Is there some piece of data in the system that needs to be altered or has triggered the alert that could be erroneous or would give you knowledge that might lead you to a different,

better practice?

And so the idea of incorporating some form of context into alerts that is not done routinely now. And also the notion of the alert occurring at the time of the decision so that it better supports the safety objective. I mean, to get an alert later in the evening in your inbox or two weeks later when you finally get to that one that you've just done something really stupid is probably not useful to the patient for sure. So, the indicators that -- and we actually had a pretty active discussion of all the set of potential alert indicators. And these were the ones that for our group thought were the most promising.

The first two there would need further development, obviously, they're concepts, percent of alerts that are useful at the time of decision making, percent of alerts that provide context. Those are the concepts I was describing that are novel. The number of patient allergic reactions divided by the number of patient overrides, is an

indicator of the effectiveness of alerts. The percent of alerts on things that should never be alerted, which apparently is an indicator in the simulator and actually does occur with quite a bit of frequency. And then number 18, which was the alert rate, sort of the raw alert rate, either as a percent of total orders or the number of total patients.

The accountable entities would be the healthcare system or the facility. Can we go to the next slide? This possible data source is EMR metadata. Surveys of clinicians are possible, although surveying people on things they really hate is never a good idea because you get all sorts of comments in the margins that you don't want to analyze. But EMR metadata we think would be the primary opportunity here.

There are a lot of opportunities here. One is to optimize the number of alerts more, reduce it probably, make them more effective. The opportunity to generate more team-based care through tiered alerting or triage of alerts more

effectively within a team. And then, some of the challenges are broadening this measure concept to these non-alert type clinical decision support and better measuring context and timing, which is a relatively new development or thought. Let's go to the next slide unless there are any questions. I'll keep cruising along here.

So number four was the area of patient-facing technologies that facilitate patient -- and it should say patient and caregiver engagement because I think we thought that in many instances the proxy is the one that is interacting with these technologies about a patient who may not be able to do it on their own.

The brief description of some of the potential measure constructs were the acknowledgment of lab test results as a feature of the patient-facing technology, typically a portal, but there may be others under development. So the ability of a patient or caregiver to acknowledge receiving lab test

results. The capacity of patients to contribute to or correct information in the medical record. The ability to access the record. The ability to annotate the record, meaning to potentially suggest corrections or suggest or add information that's not there.

And then a measure of portals that would look at the percent of patient portals that include viewable patient progress notes. And there's an open notes initiative that's been underway for some time that's showing an acceptability to the notion of patients, not just annotating notes, but in the new iteration of that work, which is sponsored by the Commonwealth Fund, actually the co-production of the notes by patients and their clinicians. So that's a little more in the future.

There was also a discussion about the extent to which now portals are proliferating so that if patients have multiple portals that have different password requirements and other user names, but we didn't get to the point of

recommending an overuse measure of portal activity, but optimizing portal inter-operability seems like another important footnote to this. The accountable entity would be the facility and the vendor who are designing these technologies. And if we can go to the next slide?

Again, the EMR metadata or the portal metadata would provide this. A survey of patients and caregivers is most likely to get at whether these technologies are effective from the perspective of the patient or caregiver. And then the clear opportunity here is better patient engagement, which we hope is associated with safer care. And then there's several challenges about how to reconcile the patient provided information that comes into the EMR with other recorded information there, the legal and medical liability issues. I mentioned already the excess of patient portals. I'll stop there and ask if there are questions. I have one more to describe. Okay, good. Next.

Last, but not least, some of the

things that we didn't -- didn't hit the high rating were disaster preparedness and downtime. And downtime in particular, I think, triggered a desire to move some material back which had been off our list. But what we created was this concept of availability, integrity, and confidentiality of patient data. And some of the measures here selected out of the document. And they are primarily audit-type measures or accreditation- or certification-type measures -- or actually its accreditation or audit.

Availability of disaster preparedness plans that support patient care processes and billing. And then the concept that these should not be static documents on a server, but there have to be drills. There has to be actual practice. And so the frequency of drills on disaster recovery. And by this, we don't mean once a year everyone gets together and does a disaster recovery drill, but that there's some ongoing process with some regularity that addresses the inability now of many people to

deal with paper or carry out business activities without the computer support. Frequency of security risk assessments, so getting at the issue of breaches of data, which we're all aware of.

And then system downtime and, in particular, the rate of -- one subset indicator, the rate of unilateral vendor lockout of clinicians who, for whatever reason, are not -- are in a contractual dispute. The system downtime in particular seemed like a useful measure. Accountable entity or entities would be the vendor and the healthcare provider. And if we can go to the last slide? The possible data sources are the audit function and security breach logs would be another source of data for this.

The opportunity is to ensure that patient information is not just protected, but also available and accurate. And then the challenges, there's several challenges around this, but one is the evolving nature of security

threats to data. So I'll stop there. If there are any points I may have not highlighted, if the group wants to weigh in, I'd be grateful. Otherwise, I open it to this -- or hand it back to the Chair.

MEMBER SEGAL: Okay. Just a question on the one, on the downtime. Can you scroll back to that? On the -- obviously the downtime is critical. I mean, the unilateral vendor lockout strikes me as a pretty rare occurrence and I'm not sure who you would be measuring. I mean, it certainly wouldn't make sense to measure the provider organization. And, yes, that's sort of a negative on a vendor, but again it just strikes me that that is likely to be such an infrequent occurrence that it's probably not -- strikes me as not being very well suited for a measure. So I would just kind of think about that.

CO-CHAIR BELMONT: That was actually just included as an example. And that language is actually common in a lot of EHR license and maintenance agreements that the vendor, if there

is a dispute between the parties, has the right to lock the hospital out of the system until it's resolved. And, of course, the challenge you have with that if the vendor chooses to exercise that right, is patient data becomes unavailable and can cause problems. And just because of the frequency that that language is in contracts, we just used it as an example. That's certainly not the only example. Obviously, system downtime can occur because of maintenance issues or other types of emergencies, natural or manmade.

MEMBER SEGAL: So I mean, if that's the case, then I think it would just be important to be clear, you're talking about a possibility due to a contractual provision as opposed to an actual occurrence.

CO-CHAIR BELMONT: I totally agree with that. I'll be honest and tell you we were a little bit rushed at the end, so this section didn't get quite as fleshed out.

MEMBER SCHNEIDER: And actually if I could just offer a comment in general as having

spent 20 years as a measure developer. What we have put forth here are areas where measure development teams would need to do more work. I don't think any of these, certainly not the uber-categories -- but, well, I think the uber-categories would be the framework within which measure developers could take some of these concepts, test them, and in some of these areas, there could be hundreds of proposed measures that would then need to be -- data would need to be brought to bear. To your point, what's the frequency of the occurrence of this event. I don't know the answer to that at this point, but someone might and that would inform the process.

MEMBER CLASSEN: Yes. Just one other comment to add to this. In the old days, most of these applications were hosted at the health system or hospital level. And so they were in charge of disaster recovery. And I think it would have been kind of hard for the vendor to lock them out when they were hosting everything on their own site.

But we've really, I think, transitioned a lot and most health systems are moving to host these applications on the vendor's site. And so then the disaster recovery and downtime and even the lockout become issues related to the vendor's performance here and I think that really does put us in that shared responsibility of how we deal with those together. But I think we really have changed the landscape. And if I had to guess, we're probably going to go almost completely to vendor hosting of these applications soon.

CO-CHAIR BELMONT: The one additional note I'd make on this, and again we got a little rushed towards the end, but I think a lot of the EHRs are being hosted in the cloud now. And cloud vendors are very reluctant to give one as much assurance as you might like in an emergency situation. So that's another issue that we can potentially address in terms of what emergency provisions cloud vendors will provide.

CO-CHAIR SINGH: So, Eric, I noted you

have quite a few things that I realized at the end you were actually -- of the three, I mean, because you deal with I think different concepts, like availability, integrity, confidentiality, do you think it would be the availability that you would want to focus on? Especially because it's something measurable. Unexpected downtimes, for instance, is much more measurable and it's probably not affected -- is not being already addressed by some other rule. So there's security rules, there's lots of laws about confidentiality, but we've got some areas that are not touched by other rules, so therefore we should focus on one of those and would that be one of the ones you would recommend?

MEMBER SCHNEIDER: Yes. And it's hard. It was a relatively quick discussion and I don't know that all of the members of the group had a chance to weigh in. But my sense is the reason we went forward with that was the downtime measure, at least from my perspective, it was the downtime as an issue.

CO-CHAIR BELMONT: I would agree with that. But I think, Hardeep, I would argue that availability and integrity are important and I know that they're different concepts, but the security rules address all three in one provision. And the SAFER guides address that, the joint commission alerts address that. So maybe we can do some further thinking and refine it to make it more cogent. Again, we kind of got rushed at the end.

CO-CHAIR SINGH: And I would also sort of think about sort of functional downtime, right? I mean, the response time is so slow that you can't even work with the computer. So I think beyond just like the computer's totally out, but as you maybe do more discussions or as we all do discussions, think about functional downtime and response time.

DR. PINES: Great, any -- so really great ideas and I thought your group did a fantastic job. So next, we've got Gerry. He's going to talk -- let us know about Group A.

MEMBER CASTRO: So, well first of all, I want to thank my group members. Aaron, Jason, who has just stepped out, Nana, Jim, and Marcy, who is not in the back of the room any more. But of course, also Andrew, who struggled to capture everything that we actually discussed. I would characterize our discussion as extremely robust. And the development process as organic. Not nearly as stepwise as Eric's group, but I think we ultimately got to a point where we landed on what was important to -- what we thought was important and feasible.

So with that being said, I'd like to remind everybody we focused primarily on the design and the development of the Health IT -- the technology itself. So many of the concepts that we reviewed of the 27 concepts that we reviewed dealt primarily with structural measures. We talked about structure process and outcome, a lot of them were structural. So that led us to a lot of, I'd say, collapsing of the concepts and wordsmithing. We had to refine some

areas because -- so for example, one of the concepts, and I'm just paging through here, concept number 13, the ability to chart necessary information. That is very broad, right? So we struggled with a lot of concepts like that and how to deal with that.

And so, we sought to combine and consolidate these concepts and make them more specific. Other concepts fell into general themes. Which were system-to-system interaction, usability design, and feedback and shared experience. Okay. Now, with these particular concepts, what they tended to be were measures associated with a yes or no answer, right? So you can either say, yes, this is absent or present. Or this is either absent or present. So we kind of grouped those all together and you'll see what we did there. And I'll not give away the surprise.

(Laughter.)

MEMBER CASTRO: It is quite a surprise. And then finally, there was one concept which we

will characterize as aspirational, which we'll -- and you'll see what we're talking about when we get to it. So, all right. Let's go ahead and jump into this one. So, the first concept we rated highly, which ultimately made it to our top five list. And I should say, we started with the list of 27, we narrowed it down to a list of, I think, approximately ten, and then we finally, by process of elimination, were left with five. So these are the five concepts we were left with. So the first one is number of times key test results not available for diagnosis, specifically as a result of system-to-system interface issues. Okay.

MEMBER RUSSELL: I meant to remove the diagnosis. We meant to make it a little bit more general.

MEMBER CASTRO: Oh, that's right. That's right. We did remove that.

MEMBER RUSSELL: So it'll be i.e., diagnosis.

MEMBER CASTRO: I.e., diagnosis, that's

right. And so, actually it just so happens that Jason -- and I'm going to pick on my group members here to speak up, because your experience is actually relevant to what we chose here because this is some work that you're actually embarking on, if I'm not mistaken.

MEMBER ADELMAN: Yes. I had mentioned that Hardeep and I actually are collaborating on a grant with an investigator back at Montefiore on this exact issue. It's an AHRQ grant about pediatric diagnostic errors and next week we're presenting on this issue of labs not being available. And so when I had -- in preparation for the meeting next week, I had interviewed a lot of editor sites about issues with labs not being available because of interface issues and other issues. And so I shared that with the group and I think it's definitely an important and very relevant issue.

MEMBER CASTRO: Absolutely. And as far as feasibility is concerned, we were talking about error reports made available by the vendors

or the vendor software about what are the actual results that made it through or were communicated. So those are possible. There is -- we would need some sort of IT intervention or some IT personnel to run the report or the vendors. So that's why we said the accountable entities would be the vendors or the facilities. So, let me stop there. Are there any questions or comments?

MEMBER HAYNES: So real quick. I mean, system-to-system, do you mean within a health system? Or what about the lab value that I had drawn last week at Montefiore? Is it available at the hospital at the University of Pennsylvania today? Is that where you're going?

MEMBER CASTRO: I think we were speaking at the organizational level at this point. Because we talk about the -- what was that category again? That was the system-to-system interaction, internally and externally, in another concept. So I think that's where that is captured.

MEMBER ADELMAN: It's poorly written, but we meant more like an out-patient office maybe getting labs from Quest, labs from the local hospital, labs from a specialty. And what I learned from my interviews that sometimes the labs from Quest come over perfectly and readily available and from the hospital they come over, but they're not displayed right. And from a third-party, they didn't come over at all. And that's what we meant, but it's not clear by that term, system-to-system.

MEMBER JONES: So, sorry, just to clarify. So you don't mean the lab system to the EMR necessarily? It's Quest to the EMR or the hospital to clinic or something like -- what's a system? Is a lab system a system or is a healthcare delivery or testing organization a system?

MEMBER CASTRO: Yes, go ahead.

MEMBER ADELMAN: Yeah, we didn't take the time -- sorry. We didn't take the time to define that exact term. So I can only talk about

it in the way we spoke of it. And we meant it to be, I guess, the different entities by which send labs to the person of interest. And we talked using examples like Quest, the local hospital, and really any entity. That's what we meant.

CO-CHAIR SINGH: So I might sort of add, and this we can discuss tomorrow as well, but I think maybe this is a little too specific and I think what you really mean is test results availability and display within the electronic health record and no matter where that comes from. So it could come from the lab, it could come from any other place. But if it is displayed wrong or it's not available when it should be because it never crossed the interface from the LIS to the EMR, then that's a problem. Right? So is that the right framing then?

MEMBER ADELMAN: Yes, that's well said.

MEMBER CASTRO: Okay. Any other questions or comments about number one? No? Okay. Hearing none, let's move on. So the second concept that we thought was -- you know,

made it to the top five was unexpected downtime affecting clinical care and lasting more than one hour. So this is actually a modification of the original concept that was proposed. We made it somewhat -- we just made it specific to clinical care and I think the original concept was --

MEMBER ADELMAN: Affecting more than 100 patients, I think.

MEMBER CASTRO: -- affecting more than 100 patients and lasting greater than eight hours, right. So we thought the idea of just clinical care in general, the impact of clinical care in general and why limit it to greater than 100 patients? What about a smaller organization with maybe 50 beds, right? So why greater than 100? And then, with the timing, greater than eight hours, we thought, well, any time that clinical care is disrupted, I think that's important. So we modified the language a bit and we went with clinical care and greater than one hour.

That being said, there were the issues

of -- we also discussed what the other groups would be considering as well, the contingency planning issues, whether or not organizations do that as well. But we thought that this would be -- as a result of a -- one of the issues and I think that Jim brought this up actually was that there are a lot of -- this could be a multi-factorial problem that could cause downtime. It could be the network itself or where the information is housed, those kinds of things. So it was somewhat difficult to say with certainty, well, it's the vendor's issue or is it just the facility issue, so we assigned it to both vendor and facility. So --

DR. PINES: Just a question about, how did you -- I agree that eight hours is too long, but even downtime for two minutes is probably too short, but one hour seems a little bit long. Especially at a place like the emergency department where one hour is sort of a really long time, especially if things aren't working.

MEMBER CASTRO: That is true.

MEMBER GRACE: It was arbitrary. I think I'm the one who threw it out there. Eight hours is a whole shift, you know, why isn't it one hour? And so then it sort of became on the paper. So I don't --

MEMBER CASTRO: Right.

MEMBER GRACE: -- I mean, that needs to be worked out, I would say.

MEMBER CASTRO: Yes. We were saying that for the benefit of saying that it was an hour. If it was 24 hours, then if we went to an hour, it would seem okay. Meaning like --

(Laughter.)

MEMBER CASTRO: All right. Any other comments or questions about number two? Okay. Next slide, please. Okay. So number three was the percentage of potential duplicate patients in the EHR. So here's our patient identification issue kind of emerging. And there are actual metrics for this and I will ask my colleague here, Nana, to speak to the work that Hopkins is actually doing on this. And we use that as our

example.

MEMBER KHUNLERTKIT: So it does -- for this one, we started off with the recommendation in the list as the percentage of duplicate patients in EHR. And we were talking about what if it get merged? How are we going to measure the duplicate patients in the EHR? Hopkins is measuring potential duplicate patients by looking into the numbers of records that get created that has the exact match of the first name and last name and the date of birth and probably the suffix match, right, over the total of numbers of EHR that's created at the same period of time. And we rated that as very important because it's very important to patient care and it is feasible to capture because we are already doing that.

MEMBER CASTRO: Can you speak a little bit about the overlay of patient info also?

MEMBER KHUNLERTKIT: Oh, yes. And we also talk about the -- in addition to potential duplicate rates, we may want to also capture the patient overlay, which means that another person

gets documented on another person. Which is also a patient ID issue that we are trying to prevent it from happening. Yes?

PARTICIPANT: So, would the -- I think I understand, potential duplicate means possibly across a number of avenues.

MEMBER KHUNLERTKIT: Correct. And there are weighted criteria on which each institute would have to come up with their own. So we are relying on the exact match of the first name, last name or alias, and also the exact match of date of birth. It has to be both.

CO-CHAIR SINGH: So were you thinking of -- because I know Jason was in the same group, are you thinking that this would be the measure concept and then you'll have a separate -- this is a measure or a measure concept? And then you'll have another measure using Jason's tool?

MEMBER KHUNLERTKIT: I think that's --

CO-CHAIR SINGH: All yours entered on duplicate patients?

MEMBER KHUNLERTKIT: Oh, this one is

actually a measure first. Right now at Hopkins. So I think it's more like a measure within the concept of patient ID if you want to take it that way.

MEMBER ADELMAN: We for the most part reviewed the measures that were assigned to us and didn't -- so I didn't ask and I thought perhaps that the retracting of order measure was in another group as more of a front line issue than a developer issue. Because we were talking mostly from the perspective of before it actually reaches the hospital, but now as I'm saying it that doesn't really make sense with this kind of thing. Because you really would only have this once you're in the hospital. But we didn't discuss my particular measure in my group.

MR. LYZENGA: I think we went -- from my understanding, we were considering those sort of separate concepts. That this would be identifying issues within the system that are creating duplicate patients or allowing for duplicate patients. And then Jason's measure is

kind of an indicator of the same thing, but an indicator of when things are going wrong. When you've actually got events or near misses as a result of that.

MEMBER HRIPCSAK: You had mentioned overlay and the metric we used for that to figure it out at our medical center, that is doing it on the wrong patient, was looking for gender mismatches and notes and then looking at those. But that was our thing. If one gender and then you write a note, it looked like they had put a note into the wrong record. And so that was something we used as a tool, which is kind of related to that.

MEMBER CASTRO: Any other questions or comments? Okay. So, number four was time spent on testing versus time spent on development. This is a ratio. And this was our aspirational measure or concept. Because what we were really trying to get at is the amount of testing that a vendor does. And we've all seen Raj Ratwani's paper where he reports on the available metrics

that we have now. And so what we were trying to get at here is -- and we don't have a great method for doing this right now and I think, Jim, you can actually speak to this because there's so much variability amongst the vendors. They use different processes, as we saw in the paper. They use different number of individuals to do the usability test.

And so there's no standardized way of testing. And so we're not even sure if this ratio will tell us what we really want to know, is how much time and effort was spent on testing. And so right now we thought that this concept was important, but there's no great way of measuring it. And I'll ask my group members to jump in here for further detail.

MEMBER SEGAL: Question. So when you talk about testing, were you primarily talking about usability testing? Or testing generally?

MEMBER RUSSELL: I guess I'll answer. I think what we did right now, just because of trying to differentiate between if it's usability

testing because usability can be at the forefront, can be at the backend, be formative, summative, that we kind of reined back in to saying, it's just generically how much testing is done at this point. Just because of the measurement.

I just know for us that it would be, at this moment in time, really difficult to pull out the exact hours. For instance, how much of that time is strictly usability versus it's just workflow testing versus other types of testing? So trying to just get more of an overview right now and then maybe towards the future, look towards, can we break it out by how much usability testing is actually done, things like that?

MEMBER SEGAL: I mean, I guess my concern would be, I mean, maybe if you think about testing as in effect part of development, but particularly now with agile methodologies, testing and iterative testing of various types is so integral. And again, Raj Ratwani, he actually

testified this morning before a Senate committee, he was focused on usability, but I guess I'd be concerned that if you're being very heterogeneous in terms of how you're defining testing, then -- and I totally agree with you that it would be problematic to pull it out, then I'm not sure what you'd be measuring.

MEMBER RUSSELL: So I think we got here, Mark, was this was just kind of a gross test to see if we can -- if the data's even there to be able to kind of come out. Do we even know what that ratio means?

MEMBER SEGAL: Okay. Thanks.

MEMBER RUSSELL: Not at all.

MEMBER CASTRO: And hence, the rating of importance is moderate and the feasibility is moderate. It was -- obviously, the other ones were high and high. And to Jim's point, if you rate everything high, nothing is high, right? So -- yes?

MR. HUNT: One question. So it sounds as though what you really want, and I know this

sounds like a very bland sort of, you want a measure of usability. Because does it really matter how much time they spent if they got it right? It's the old adage about you hire two different lawyers. One is an old sage and another one is a young upstart. The young guy, he has to go and do hours and hours of research and the old guy, he knows the answer.

(Laughter.)

MR. HUNT: Notice I used lawyer rather than doctor so I wouldn't --

(Laughter.)

MR. HUNT: But is it that the concept that you want to get to, and I know it's hard and it'll be incredibly difficult to define, the devil's in so many details, but is the concept you want to have a measure of usability of the system?

MEMBER ADELMAN: I think it's both. It's testing and usability with distinct meanings. So testing is programmers could just have written 100,000 codes of line and somebody

just has to test it to make sure it works, there's no bugs. And different vendors can spend different amount of effort and take that in different ways with different levels of seriousness. And then there's usability, which is just how useful and judging the interface. We spend a lot of time trying to understand how we might be able to quantify those two separate concepts and turn them into measures so that we can see who's doing what and how much and we struggled with both of them.

And we wound up with this sort of like compromise. It was introduced as aspirational. And generally we understand that when programmers do their work, they log their time and they do in some sense log what they are doing at that time. So in a big company like Epic, there is some database somewhere that says, I spent this much time doing regular testing, possibly usability testing. If they don't have it today, they theoretically could. And then we use a benchmark of total hours of development to put it into

scale so there's something to put it in context. But it's really more of a concept than a well-defined idea.

MS. ZIMMER: I'd like to expand on this a little bit. I heard -- a lot of times we're talking about testing and development, testing at staging -- you know, initially. But when things go to production, even if someone talked about you check and maybe this worked and that worked, everything can be fine, but when it gets into real life, it's now having to interact with other systems that vendors can't test for. So I'd like to take that concept of testing and not just apply it at the vendor's shop, but I'm talking about I would like to see more testing at the site where it's implemented with the whole environmental interaction of other systems. But then there's another testing that's missed.

And so I have an issue also with the word development, which is, even something when you have software upgrades, you need to still go back and test how everything else around that one

system hasn't been changed. So I'm not sure what the right word is, but it just seems like there needs to be a general concept of more testing. It's really making the implementation much more effective. And we're not talking about new implementation, we're talking about any change in a current system, whether it's an upgrade, a replacement -- you get the point.

MR. LYZENGA: And maybe this was -- maybe I was a little bit too strong in stressing that our group was focused on sort of design and development issues. We tried to --

(Laughter.)

MR. LYZENGA: We kind of tried to stay back a little bit from the sort of implementation and use side and thought that -- because we do have a number of measure concepts that were being considered by other groups around testing of work flow within conjunction of testing of the systems. So we were trying to kind of focus on what was happening sort of, as you said, in the shop, and making sure that was happening at the

right time. And we had a number of -- we were talking about a lot of things and the right type of testing and what kind of testing and those sorts of things. And, again, this was kind of a compromise of sorts that we thought may be doable given the data we have. And I don't know, I'll turn it over to my group members.

MS. ZIMMER: I'm sorry, Andrew, I appreciate that. But I think that's one of the holes we tend to fall into. We think of design being at the shop and I think design needs to be thought of also at the institution where it's implemented.

CO-CHAIR BELMONT: -- and the customizations that can go on during that phase?

MS. ZIMMER: It's not just the customization, it's the environment in which it has to operate. It's sort of like efficacy and effectiveness. I mean, you don't really know how it's going to operate until it's in the real environment because you can't replicate that in a shop.

MEMBER GELZER: No, I just agree wholeheartedly with what Karen's saying. And I will tell you, even as a payer, we have population health management platforms. So our care managers -- it's essentially our record.

And when we implement upgrades, it isn't just that we have to do more testing, we have found we continue to have to do more testings with each release and each fix because of redundancies and implications to other pieces of the system. But it isn't just that, it's also that the IS team has to do testing and the business functional end users have to do testing. So our IS team thinks that they do this -- they have done a magnificent amount of testing, but if they don't coordinate with the business and the functional end user, it's not optimal.

MEMBER RUSSELL: So, just to be clear, we really did talk about all that and we really came down to this very generic term of testing. Just because this could have gone on forever. And I don't want to blow your minds waiting for

the next slide, but --

(Laughter.)

MEMBER RUSSELL: I kind of leaned into that, but we talked about a lot of this.

CO-CHAIR SINGH: But I'm wondering if we may have to -- and we're going to be discussing this tomorrow, what's left here -- under usability, we may have to think about these two concepts staying sort of separate. This usability as one concept and I think we're talking about interviews to be done with external stakeholders, we've got to chat with NIST and see what their recommendations are in terms of measurement. But also, remember, the Ratwani paper, they said that the vendors were not even doing the existing usability stuff, right? So they weren't doing the 15 docs and the processes were different.

So there already are some existing usability things that we could measure anybody up to in terms of sort of standards, which people were not meeting accurately. So in testing -- by

the way SAFER guides recommend several types of testing as well, which is not to do with usability, but it's testing after an upgrade or when there's a new interface and things like that. So we may have to sort of separate out these two concepts and dive down maybe tomorrow when we discuss more.

MEMBER KHUNLERTKIT: I actually share the same concern with you, Karen. I can't separate my mind between usability or testing with implementation. This is all still one big circle, right? At the end of the whole, long discussion about this, I think we came down to why don't we just look at this work group as what do we need to do before we launch the product to the market? Is that right, Jim? Before we release the EHR to the market. And that's the mindset that we had for this listing.

CO-CHAIR SINGH: Yes. I think it's okay. Because we know -- I think we all agree that all of this should be done across the life cycle of HIT, right? Which is design,

development, implementation, use, and evaluation.

MEMBER CASTRO: Any other questions on this one?

PARTICIPANT: We were wondering what's next.

(Laughter.)

MEMBER CASTRO: Oh, you just wait. It will blow your mind. Please --

(Laughter.)

MEMBER CASTRO: So as I stated earlier, a lot of these concepts could be answered in a yes or no question. And so what we did is we lumped them all together because -- and the concept was coming up with some sort of weighted composite or some sort of checklist, much like the SAFER guidelines or maybe these are additions to the SAFER guidelines. But in general, we found that they hit the concepts of system-to-system interaction, so that's the first group. The second group is usability and design. And the third grouping is feedback and shared experience.

So I'm not going to read these all to you, but in -- so the system-to-system theme here was we talked a lot about interoperability, the transmission of information, internally, externally. We talked about mobile health applications, the transmission of information to those devices. And then ultimately, end user involvement in the design and development process. So the second bucket, is what I'll call it there -- oh, that's right. The end user involvement and design and development process actually should be in the second grouping of usability and design.

So if you read through those concepts there, we talk about testing, we talk about simulation, the concept of simulation. And when we talked about simulation here, we were talking about the vendors doing the flight simulator. And of course there are some limitations to that because I believe the Leapfrog simulator is not available to vendors, just organizations. But coming up with some sort of simulation system so

that vendors have the ability to test their systems before it goes out the door.

Finally, the third theme was around the feedback and shared experience. So this is just kind of a, I'd say, a mix-and-match of the ability to share information about problems across -- you know, from vendor to users to the ability to share fixes, to share lessons learned, and the ability to share lessons learned from user to user. So, the whole idea is that we are able to develop that learning system essentially. And so those are the concepts that are there. And so, the idea was that we would format this in as a yes or no question. So does your system support interoperability internally? Yes or no? Does your system support interoperability externally? Yes or no? So, I mean, obviously we can parse that out into more detail, but I will leave that for your perusal in all of its glory.

(Laughter.)

MEMBER JONES: So aren't some of these, maybe?

MEMBER HAYNES: Right. Like external data can be added to the patient record, sometimes. Like, I can do it when I'm getting an Anthem patient, but I can't do it when I'm getting a United Health patient. I mean, there's a million permutations to yes and no to the binary world. Believe me, I want to live in the binary world, I'm a data guy.

MEMBER ADELMAN: We took the ideas that we posted on yellow stickies last time we met and were asked to turn into concepts. So we didn't go -- like, we didn't mean to make an actual tool or measure or checklist, but just to take the ideas and I think that the general theme being that there may be some structure measures that are yes/no, they may be more nuanced than yes/no, maybe we can drill down on them.

But we didn't take the time to start doing that, but just delineated out the ones that would be hard to have a numerator and denominator, it's more like do you do usability testing on alerts? Like is that something that

you value and do? To turn that into a numerator and denominator measure seemed too difficult so we put them into this bucket and that's as far as we got.

CO-CHAIR SINGH: So I think there's one piece which is really important here and I'm not sure other groups are going to be covering it, so I want to mention and then maybe we can re-discuss it tomorrow. I think the stuff that you have on vendors is really good because some of it is -- everybody we talk to it's like, we need to have a 360 degree review of safety and we don't get that unless we have vendors on the table with us.

And if vendors can share lessons across themselves, across institutions, through vendor groups or whatever, I mean, I know there's lots of recent buzz around gag clauses as well, but I think that is the most useful that I can immediately sort of say that I think we're going to have to come back to this if none of the other groups have touched upon it. Because it gives a

sense of sort shared responsibility of some of the things that we've been talking about here. So I really think there is value here, especially if nobody else addresses it.

MEMBER ADELMAN: Hardeep, when we were meeting as a group, I was trying to recall what you just called the gag clause and I couldn't get my finger on it. Can you just say what that is, because we -- it's something about the contracts, right? I knew there was an issue, but I couldn't quite put my finger on it when we were discussing.

CO-CHAIR SINGH: Lawyer, you want to go?

(Laughter.)

CO-CHAIR SINGH: We have a lawyer here.

CO-CHAIR BELMONT: Essentially a gag clause is language in a contract that prevents you from discussing certain actions that occur or events that occur in conjunction with the contact.

CO-CHAIR SINGH: So essentially it's a

protection of the intellectual property. And I'd love for vendors to sort of step in and clarify what you all think they are, right?

CO-CHAIR BELMONT: Well, some -- depending on how they are written, what vendors are typically doing in this context are relying on their intellectual property clauses to say that by sharing this information there's a potential to share their protected intellectual property. And that's why they would prefer not to. But if you look at the way some of that language is drafted, it's usually drafted very broadly. And the way I approach it at MaineHealth is to draft carve-outs to that.

Similarly, there's usually a confidentiality provision in contracts. And that confidentiality provision can be drafted very broadly to prevent the discussion of some of these events. And part of that reason is the vendor doesn't want to be the subject of negative press.

MR. LYZENGA: I should note that we did

have some more discussion around some of these issues before they were sort of folded up into this monster composite and talked about these issues quite a bit and about the issue of, just kind of the hot-point issue of screenshots in particular. And there was some agreement that there was reasonable ways to share screenshots, but there were also reasonable limits. And it was reasonable to put some controls around that or for certain purposes or uses. And I don't want to put Jim on the spot necessarily, but we had some discussion around that and it may be worth some broader discussion with the group, I think, as you suggest, Hardeep, if this isn't addressed in some of the other groups.

CO-CHAIR SINGH: I mean, given the amount of buzz that is out there recently in the policy circles, I think we really should have a robust discussion tomorrow to see what types of things we want to sort of address in that list. And include the things like gag clauses and things that we just talked about.

CO-CHAIR BELMONT: And I would add, again, going back to our theme of shared responsibility, we're not looking to make this an unbalanced situation. I think there are ways that we can approach this that protect the vendor interest as well as protect the provider interest. And that what we're seeking here is really a balance to that.

MEMBER SEGAL: And just, and I guess we'll be discussing it tomorrow, but just while we're talking about it now, it strikes me that some of these issues, like to what I think David was talking about earlier even in the continuum of how you would use measures, right, internally to an organization versus all the way up for value-based payment, that some of these are clearly important policy issues, the gag clause issue and all of that.

But I guess I just have real concerns thinking in the context of measurement about even taking the screenshot issue, and I can understand why a researcher wanting to publish a paper might

want to use screenshots, that strikes me as it's important systemically, potentially, in terms of safety. It's very different than the ability of let's say the customers of a vendor to be able to share information with each other in terms of a safety event. And I just worry that many of these things that are going to be ultimately subjective, you know, what is the appropriate use of an IP protection?

And also between, what's actually in a contract, and I think Elisabeth has talked about this, and what's actually used in practice? So I just think as we look at some of these concepts, that we really have to think about them in the context of the measurability piece and the feasibility as a measure and really hold that distinct and not feel that wherever we come down on that is a judgment on the importance as a policy issue. Because I think those are somewhat separable issues. And I think particularly the things below the last line, some of them fall into that.

MR. LYZENGA: Okay. Any other questions or comments on this one? Very good. All right then. I think we can call it a day for now. We'll come back and talk about the other two groups. I actually want to call for public comment very quickly before we adjourn. Operator, do you have any comments on the line?

OPERATOR: Okay. At this time, to make a comment, please press star then the number 1. There are no comments at this time.

MR. LYZENGA: Any comments in the room? It doesn't appear so. We are having dinner scheduled at Mio, which is just right around the corner from our office here. The reservation's at 6:00. Based on our contractual requirements, we do have to have separate checks, but we will reimburse you for up to $36 plus one alcoholic beverage. So we would welcome everybody to come join us at Mio for dinner. So thanks for all your work today, we'll see you tomorrow.

(Whereupon, the above-entitled matter went off the record at 4:58 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: HIT Safety Committee

Before: NQF

Date: 09-16-15

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R Gross

Court Reporter