

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
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Quality
WILLIAM MARELLA, MBA, Pennsylvania Patient
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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
MARCIA WILSON, Senior Vice President, Quality
Measurement
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

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

2 9:06 a.m.

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

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

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

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

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

22 Is that okay? Should we? Okay.

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

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

8 And we also provide services directly
9 to patients.

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

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

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

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

1 Safety in the last maybe six to eight months.

2 And if I've missed anything please let me know.

3 And feel free to sort of chime in afterwards.

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

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

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

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

22 In fact the Sentinel Alert talks about

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

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

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

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

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

22 And how sort of Jason worked on

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

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

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

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

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

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

22 There may be one step in between that

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 out. Has anybody else heard anything else?

2 MR. HUNT: Relatively soon.

3 CO-CHAIR SINGH: Relatively soon.

4 Okay. Excellent. And then two events that are
5 about to happen are -- that are very substantial,
6 I would say.

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

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

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

22 Again, a need to know because they're

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

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

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

15 And Elizabeth, go ahead and --

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

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

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

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

10 So, stay tuned for the IOM report.

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

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

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

22 (No response.)

1 CO-CHAIR SINGH: Okay. All right.

2 Back to you Andrew.

3 MR. LYZENGA: Thanks.

4 CO-CHAIR SINGH: Thank you.

5 MR. LYZENGA: So, just to give a quick

6 -- I should go over the goals here of our day

7 today. We'll just give you a quick -- a few

8 quick updates on our recent project activity.

9 We'll discuss some opportunities to

10 align our framework with the -- our common

11 formats for patient safety reporting and the

12 roadmap or collaboratory I guess now is what

13 we're calling it.

14 And then the bulk of our day will be

15 devoted to getting into some group work. And

16 trying to hone down our measure concepts and

17 start our prioritization of those concepts.

18 You can skip over that. We've already

19 kind of done that. You can skip over the staff

20 and committee as well.

21 So the goals of this project initially

22 were to develop a conceptual framework for

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 some point.

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

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

13 So, David?

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

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

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

1 begin a major upgrade of our work on Common
2 Formats.

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

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

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

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

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

1 not trying to create a taxonomy.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 out this detail. Next slide.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 this information. Next slide.

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

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

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

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

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

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

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

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

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

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

21 MEMBER CASTRO: No. I think you
22 covered it.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 And then have that additional
6 information if possible.

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

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

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

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

1 for the future.

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

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

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

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

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

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

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

3 So, I can already see some pitfalls
4 happening.

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

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

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

1 very long time.

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

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

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

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

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

22 I just wanted to see if you could

1 comment on that.

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

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

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

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

21 So, we look forward to your input.

22 CO-CHAIR SINGH: So, David, do you

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

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

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

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

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

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

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

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

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

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

1 paper.

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

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

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

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

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

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

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

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

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

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

22 And so I think people were thinking

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

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

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

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

17 CO-CHAIR SINGH: Yes.

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

22 I think we've now learned that's not

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

4 CO-CHAIR BELMONT: David, I --

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

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

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

19 There is some use to that as well.

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

1 CO-CHAIR SINGH: Absolutely. Totally
2 agree.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 And then you're going to have a health

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

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

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

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

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

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

1 cetera, et cetera.

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

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

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

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

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

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

8 MR. LYZENGA: Other thoughts or
9 questions? David?

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

15 And that might be a nice prototype.

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

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

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

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

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

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

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

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

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

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

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

1 over the last six months.

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

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

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

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

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

22 And then the second group is the

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

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

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

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

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

1 two concepts -- importance and feasibility.

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

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

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

15 So, basically the group will go from
16 27 to 5 during the next process. And you know,
17 we chose the number five because what we're going
18 to do on day two is take the 20 that come from
19 the four groups and call down to a top ten list.

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

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

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

8 MR. LYZENGA: Can I just add
9 something?

10 DR. PINES: Yes.

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

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

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

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

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

7 Hardeep, do you need to comment?

8 CO-CHAIR SINGH: Yes, I just want to
9 make a quick comment. I still think because of
10 the overlap, we might come with, you know, 24,
11 25.

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

16 DR. PINES: Yes.

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

22 I mean, should people be thinking

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

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

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

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

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

1 measure, maybe just note that during the breakout
2 group.

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

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

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

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

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

1 take your vision and be able to develop it.

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

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

13 Is that the type of --

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

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

22 CO-CHAIR SINGH: Fully realizing that

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

5 It has to be 100 people or? Okay.

6 Yes. Thanks for the time.

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

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

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

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

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

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

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

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

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

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

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

1 responsibility.

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

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

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

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

17 DR. PINES: Yes.

18 MEMBER ZIMMER: Okay.

19 DR. PINES: That's right.

20 MEMBER ZIMMER: Just clarifying.

21 DR. PINES: Yes. Mark?

22 MEMBER SEGAL: Just on the

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

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

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

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

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

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

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

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

16 Go ahead.

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

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

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

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

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

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

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

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

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

5 Does that answer your question?

6 MEMBER SEGAL: Part of it; yes.

7 CO-CHAIR BELMONT: Okay.

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

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

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

19 And that's okay, too.

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

1 involved to do that.

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

4 CO-CHAIR SINGH: Yes.

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

7 CO-CHAIR SINGH: Yes.

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

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

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

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

1 standards.

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

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

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

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

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

1 structure and process than we will outcome yet.

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

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

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

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

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

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

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

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

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

22 But they're something that can be used

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

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

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

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

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

22 CO-CHAIR SINGH: So, would the

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

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

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

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

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

22 MR. LYZENGA: Great. I should note

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

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

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

16 But I just wanted to note that.

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

22 So, ideally we want measures that are

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

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

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

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

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

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

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

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

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

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

1 concepts, a brief description of the concept.

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

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

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

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

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

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

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

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

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

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

22 One is that as we consider these

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

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

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

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

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

1 prioritization.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 take to heart at ONC and at HHS very well.

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

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

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

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

18 COURT REPORTER: If you could turn on
19 your --

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

1 that --

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

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

6 COURT REPORTER: There should be a red
7 light.

8 CO-CHAIR SINGH: On now?

9 COURT REPORTER: There you go.

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

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

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

1 depends on what you implement. And that is
2 right.

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

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

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

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

22 And the way I'm looking at some of

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 points during this continuum.

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

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

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

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

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

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

22 Operator, are there any public

1 comments on the line?

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

5 (No response.)

6 OPERATOR: There are no comments at
7 this time.

8 MR. LYZENGA: Great. Anybody in the
9 room?

10 (No response.)

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

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

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

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

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

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

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

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

16 MR. LYZENGA: Thanks everyone.

17 (Whereupon, the above-entitled matter
18 went off the record at 10:28 a.m. and resumed at
19 3:21 p.m.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 and how.

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

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

1 next one.

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

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

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

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

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

1 501(c)(3) so it can accept external donations.

2 And it's got a phased approach for bringing it
3 up. Next slide.

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

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

22 We do have some final considerations.

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

12 So the Health IT Safety Center Roadmap
13 -- which was titled and released before the title
14 was changed to Collaboratory -- is out on the
15 Web, and if you haven't gone through it yet, I
16 encourage you to take a look at it. We did have
17 a presentation last week, and we're going to have
18 a follow-up Q&A session coming up on September
19 25, which is -- I sent you the email with the
20 information, Ann, in case anybody's interested in
21 that. It'll be a Q&A session with ONC, with
22 members of the task force, some of the RTI

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

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

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

1 So that's a long way of saying this is
2 immediately relevant, part and parcel, to our
3 visioning of what the Collaboratory will do.

4 It's one of the most important jobs that you can
5 have in the federal government to have a good set
6 of priorities. Because whenever the discussion
7 comes to resources and what do you want to do ---
8 as we all know -- there's never enough, and
9 there's always a challenge in trying to carve out
10 what you need to do and to be able to always go
11 in front of leadership and say, here's an
12 organized set of priorities that have been
13 publically vetted and has this evidence base, is
14 a huge, a huge leg up and actually the first step
15 in actually getting something done. So the work
16 that we're doing here is immediately relevant and
17 will immediately be useful moving forward.

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

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

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

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

1 measures.

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

12 (Laughter.)

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

1 emergence of themes across the 27 indicators on
2 our list.

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

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

1 well, I'll get to in a moment.

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

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

1 product of that work.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 MEMBER ALEXANDER: Sure.

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

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

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

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

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

3 MEMBER ALEXANDER: New survey, okay.

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

7 MEMBER ALEXANDER: Got it.

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

10 MEMBER ALEXANDER: Yes.

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

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

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

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

1 entry, they were acknowledging overrides, and
2 they were using a system that passed a basic
3 safety test. And so AHRQ and Robert Wood Johnson
4 Healthcare Foundation funded David Bates and I to
5 create such a thing. And we created it in the
6 early '80s -- early 2000s and implemented in
7 2008.

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

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

1 did with it when they failed.

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

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

22 When we developed them, we did

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 better practice?

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

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

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

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

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

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

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

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

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

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

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

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

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

22 Last, but not least, some of the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 (Laughter.)

21 MEMBER CASTRO: It is quite a surprise.

22 And then finally, there was one concept which we

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

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

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

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

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

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

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

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

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

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

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

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

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

19 MEMBER CASTRO: Yes, go ahead.

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

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

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

18 MEMBER ADELMAN: Yes, that's well said.

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

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

7 MEMBER ADELMAN: Affecting more than
8 100 patients, I think.

9 MEMBER CASTRO: -- affecting more than
10 100 patients and lasting greater than eight
11 hours, right. So we thought the idea of just
12 clinical care in general, the impact of clinical
13 care in general and why limit it to greater than
14 100 patients? What about a smaller organization
15 with maybe 50 beds, right? So why greater than
16 100? And then, with the timing, greater than
17 eight hours, we thought, well, any time that
18 clinical care is disrupted, I think that's
19 important. So we modified the language a bit and
20 we went with clinical care and greater than one
21 hour.

22 That being said, there were the issues

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

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

22 MEMBER CASTRO: That is true.

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

6 MEMBER CASTRO: Right.

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

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

13 (Laughter.)

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

1 example.

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

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

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

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

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

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

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

19 MEMBER KHUNLERTKIT: I think that's --

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

22 MEMBER KHUNLERTKIT: Oh, this one is

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 MEMBER SEGAL: Okay. Thanks.

14 MEMBER RUSSELL: Not at all.

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

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

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

9 (Laughter.)

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

12 (Laughter.)

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

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

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

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

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

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

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

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

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

13 (Laughter.)

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

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

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

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

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

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

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

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

1 the next slide, but --

2 (Laughter.)

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

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

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

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

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

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

1 development, implementation, use, and evaluation.

2 MEMBER CASTRO: Any other questions on
3 this one?

4 PARTICIPANT: We were wondering what's
5 next.

6 (Laughter.)

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

9 (Laughter.)

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

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

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

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

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

20 (Laughter.)

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

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

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

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

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

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

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

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

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

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

15 (Laughter.)

16 CO-CHAIR SINGH: We have a lawyer here.

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

22 CO-CHAIR SINGH: So essentially it's a

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

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

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

22 MR. LYZENGA: I should note that we did

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

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

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

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

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

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

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

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

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

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

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

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In the matter of: HIT Safety Committee

Before: NQF

Date: 09-16-15

Place: Washington, DC

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