

NATIONAL QUALITY FORUM

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HIT SAFETY COMMITTEE

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**PRIORITIZATION AND IDENTIFICATION OF
HEALTH IT PATIENT SAFETY MEASURES**

IN-PERSON MEETING

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**THURSDAY
FEBRUARY 19, 2015**

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The Meeting met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 9:30 a.m., Elisabeth Belmont and Hardeep Singh, Co-Chairs, presiding.

PRESENT:

ELISABETH BELMONT, JD,, MaineHealth, Co-Chair
HARDEEP SINGH, MD, MPH, Veterans Affairs Health
Services Research Center of Innovation and
Baylor College of Medicine, Co-Chair
JASON ADELMAN, MD, MS, Montefiore Medical Center
GREGORY ALEXANDER, PhD, RN, FAAN, University of
Missouri School of Nursing
GERRY 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

ERIN GRACE, MHA (ex officio member), Patient
Safety Program, Agency for Healthcare
Research and Quality

KEVIN HAYNES, PharmD, MSCE, HealthCore, a
subsidiary of WellPoint Inc.

LAURA HEERMANN-LANGFORD, PhD, RN, Intermountain
Healthcare

JASON JONES, PhD, Kaiser Permanente

NANA KHUNLERTKIT, PhD, Johns Hopkins Medicine
Armstrong Institute for Patient Safety and
Quality

WILLIAM MARELLA, MBA, Pennsylvania Patient
Safety Authority

DENA MENDELSON, JD, MPH, Consumers
Union/Consumer Reports

JAMES RUSSELL, RPh, Epic

ERIC SCHNEIDER, MD, MSc, RAND Corporation

MARK SEGAL, PhD, GE Healthcare

KAREN PAUL ZIMMER, MD, MPH, FAAP, Independent
Consultant, Health IT, Patient Safety and
Quality

ALSO PRESENT:

HELEN BURSTIN, MD, Chief Scientific Officer, NQF

JASON GOLDWATER, Senior Director, NQF

DAVID HUNT, MD, Office of the National
Coordinator for Health Information
Technology

KATHY KENYON, Senior Policy Analyst, Office of
the National Coordinator for Health
Information Technology

ADEELA KHAN, Project Manager, NQF

ANDREW LYZENGA, Senior Project Manager, NQF

ANN PHILLIPS, Project Analyst, NQF

JESSE PINES, MD, Consultant, NQF

MARCIA WILSON, Senior Vice President, Quality
Measurement, NQF

* present by teleconference

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

9:32 a.m.

MS. KHAN: Good morning, everyone.

Welcome back. I just quickly wanted to welcome you all and go over our agenda really quickly and recap what we did yesterday.

Yesterday, we went and reviewed the preliminary results of the environmental scan. We were able to break up into three groups where each group was assigned a SAFER phase and we heard from two of our groups about how to measure safe health IT and using HIT safely.

We're going to be hearing from our last group today, Group C, which is using health IT to improve safety. And then we'll be continuing our discussion. We're going to be hearing from David Classen today about opportunities for alignment with the Common Formats Project. And we're also going to be hearing from David Hunt about all of the HIT and safety projects across ONC where we'll be able to find more opportunities for alignment. We'll

1 have some more discussion and then we'll be
2 adjourning today at 3 p.m.

3 So I will turn it over to Andrew who
4 will go over Group 3's progress.

5 MR. LYZENG: Thanks, Adeela. So as
6 you may remember, we reported out the results
7 from Groups A and B, yesterday, had a bit of
8 discussion around that. And so I'll just try to
9 quickly run over some of the thoughts we gathered
10 in the third group and then we can sort of open
11 it up for discussion about that and some broader
12 issues raised in the other groups as well.

13 So we were assigned to Phase 3 which
14 is using HIT to make care safer. So we tried to
15 sort of view issues through that lens to the
16 extent possible. As you might expect, again,
17 there's a bit of overlap with some of the other
18 groups, I imagine, and some overlap among the
19 different categories, as well. But I'll just
20 sort of run over some of the insights we raised
21 during that sessions.

22 So in terms of the hardware and

1 software issues, the participants noted that
2 hardware is a bit more difficult to address than
3 some other issues. There are a lot of a
4 variability in hardware. There's some difficulty
5 in trying to interrogate hardware itself in terms
6 of monitoring for safety issues and trying to
7 ensure that the hardware that you're using is
8 safe. Organizations, to some extent, have had to
9 come up with different ways of addressing these
10 issues. There are no real off-the-shelf
11 solutions so they've had to come up with so-
12 called middleware solutions to measure whether
13 safety is being achieved in this area.

14 An issue that was raised that's hard
15 to implement, bar coding, in many aspects of
16 patient care. Some participants noted that RFID
17 should be more prevalent in healthcare, but we
18 may not have quite reached the right price point
19 for that to be spread as widely as it should.

20 There's certainly patient privacy and
21 data security issues that need to be addressed.
22 Patients need to be confident that when they

1 enter information or use information in a portal
2 of some sort, that it will be secure and not
3 compromised.

4 There's also an issue that came up
5 around what some people called bring your own
6 device issues. People, clinicians, and others
7 want to use their own devices, use different
8 kinds of devices and this sort of opens things up
9 to a wealth of potential problems in security and
10 issues that might emerge. Some organizations ask
11 clinicians to use their own devices and patients
12 as well, but when you ask patients to do that,
13 their capacity and their access to technologies
14 may be issues.

15 Overload of devices, again, with this
16 bring your own device sort of issue, overloaded
17 devices can be a problem; people carrying around
18 four separate phones and doing different tasks on
19 them and using them for a variety of different
20 things. And then there are issues with
21 clinicians who staff multiple hospitals, even
22 when you have established sort of security

1 principles and policies within an organization.

2 If a clinician is moving across different
3 hospitals, there's still a need to -- or it can
4 cause problems when they're using their own
5 devices and there's variations between the
6 policies and procedures across those different
7 hospitals.

8 Gerry brought up that the Joint
9 Commission has tried a product demo around
10 standardization of devices using devices of
11 access point to physiological information, I
12 believe, for patients and if they leave the
13 system network or clinicians leave the system
14 network, the device shuts down and does not allow
15 continued access to data. That's one sort of
16 potential solution to the security problem. We
17 didn't come up with any particular measures in
18 this area.

19 With respect to clinical content,
20 configuration of software is obviously an issue.
21 That's sort of another issue where it's a little
22 unclear if that falls within the hardware and

1 software domain or the clinical content domain,
2 but there's some questions around who's
3 responsible and accountable for correct and
4 appropriate configuration of software. There are
5 many different options available and there's some
6 issues around upgrades when upgrades are pushed
7 out or implemented, it could potentially reset
8 previous configurations that had been implemented
9 and established within the organization and had
10 proven to be useful.

11 Let's see. Movement, sometimes from
12 one HIT or EHR system to another can cause
13 problems. Some systems offer greater flexibility
14 than others. There was some discussion around
15 when organizations create custom code or sort of
16 custom configuration of systems and whether there
17 would be some potential for those to be shared
18 publicly. Some folks in our group thought that
19 in this area we could maybe use some open-source
20 principles in terms of making public clinical
21 decision support rules or configuration settings
22 or other sort of coding approaches and spread

1 those around to make them public so that others
2 could use them.

3 It was noted that sort of consistency
4 itself is an important goal. Configuration or
5 these, sort of, software issues don't need to be
6 good or bad necessarily, but consistency in
7 features and functions across platforms and
8 systems is an important objective.

9 Some of us wondered whether it would
10 be possible to measure the accuracy of clinical
11 elements in clinical documentation. Completeness
12 is a little bit easier to measure the accuracy of
13 the clinical information, but within
14 documentation or a system is a little bit less
15 easy to measure. One suggestion was something
16 like routine surveillance with peer review to
17 look at areas known to be problematic and have an
18 independent reviewer check to see if the
19 information is complete and accurate within the
20 system.

21 And in general, the participants noted
22 that there is a need to create an environment

1 where hospitals can be creative in customizing
2 health IT for their needs and to be able to share
3 helpful solutions, useful decision support
4 protocols and other things together and to learn
5 from others' successes and failures.

6 With respect to human-computer
7 interface, we talked a little bit about the
8 patient perspective and that patients should be
9 able to understand the technology. First barrier
10 with regard to that is access to the technology
11 for the patients, but usability is also a concern
12 for them knowing where it is, sort of click
13 through or whatever. They may not have access to
14 all the pertinent information, for example,
15 information that went into their diagnosis. They
16 have sort of high level -- access to some high-
17 level information, but not to the detail that
18 might be useful or relevant for them. So we
19 thought that if patients are being asked to
20 partner in these efforts, they need to know what
21 they're being asked to do. The technology should
22 be accessible and usable.

1 Another important principle within
2 this domain is being able to access the info when
3 you need it to avoid work-arounds. Both
4 clinicians and patients need to have the
5 information they need, again, when they need it.
6 It was noted that other industries, including the
7 aviation industry, have moved further in ensuring
8 cognitive support and usability of technology and
9 tools.

10 Some of the potential measures in this
11 area have been discussed already; alarm override
12 rates or Dr. Adelman's order-retract-reorder
13 measure or the "oops query."

14 Within the domain of people, we noted
15 that some are beginning to see something like
16 learned helplessness. It was raised that Hopkins
17 had a home-grown system and then moved to another
18 system and it led to a sort of a sense of
19 demoralization and helplessness among clinicians.
20 Newer clinicians are becoming more and more
21 dependent on technology and that could
22 potentially be impacting the development or

1 maintenance or clinical skills.

2 The thought is that we need to look at
3 the actual physical interaction between
4 clinicians and patients versus their dependence
5 on technology or recommended actions and the
6 like. Errors that result from these sorts of
7 issues may not be easily apparent so are a little
8 bit difficult to assess and measure. But
9 training is one potential solution.

10 We noted that people need to feel like
11 they can provide feedback and input on the
12 systems that they're using and ask questions,
13 otherwise it does lead to work-arounds and one
14 potential measure we raised was the number of
15 work-arounds. Again, that's a little bit
16 difficult to measure that maybe you could
17 approach it through assessing the degree to which
18 people are not following established pathways,
19 maybe mapping out the work as imagined, versus
20 the work as performed.

21 In terms of work flow and
22 communication, we noted copy and paste issues.

1 There's always an element of clinical judgment
2 involved and information can be fractured across
3 and within the systems, never sort of synthesized
4 or taken account from an over-arching
5 perspective. The group thought that we need to
6 understand practice patterns more, understand
7 what problems occur and when and why, and this
8 could inform our measurement efforts. There's a
9 need to be able to find information quickly and
10 easily. An inability to be able to do this can
11 have consequences for quality and safety and
12 efficiency of patient care. The sort of pointed
13 question that was raised is how long does it take
14 someone to solve the particular clinical problem?
15 I don't know if there's a way to sort of quantify
16 or measure that, but that's sort of a key
17 question.

18 There's an expectation among
19 clinicians and among patients as well, that the
20 system will lay out the more important elements
21 that are needed for an informed decision, that
22 expectation or assumption may not always be well

1 founded. We noted that there's an absence of
2 cognitive support, again, with these tools and
3 wondered if there's a way that we could quantify
4 cognitive burden on clinicians.

5 In terms of -- again, there's some
6 overlap here in terms of internal organizational
7 policies and procedures. We again discussed
8 these sort of learned helplessness issues. We
9 noted that you always need to acknowledge
10 cultural issues. Some thought that solutions to
11 organizational silos, cultural issues, and the
12 like are a manifestation of leadership.

13 Leadership really needs to impart that
14 the activities taken to facilitate communication
15 within the software systems about the software
16 systems, about the problems that occur, and the
17 errors and hazards that might exist needs to be
18 supported. The communication about those things
19 needs to be supported and promoted by leadership.
20 And organizations need to understand what is
21 important for safety in their organization, and
22 then take steps to make that happen.

1 We discussed for a moment the AHRQ
2 safety culture survey. There may be a couple of
3 questions that are somewhat related to HIT, but
4 this could be an area where HIT issues could be
5 further incorporated into the AHRQ culture
6 survey, maybe a separate module even.

7 And then in terms of external rules,
8 regulations, and pressures, there is a lot of
9 pressure for extraction of data for eMeasures and
10 a need for easier extraction of data for
11 eMeasures to sort of reduce the burden of data
12 collection on clinicians and providers. There's
13 a lot of potential for HIT to be helpful in this
14 effort, but it is a place where harmonization is
15 needed. There's many different groups asking for
16 data. There are many different formats across
17 those groups for collecting and submitting data,
18 so again, harmonization is a major concern here.

19 David Hunt, and he acknowledged that
20 he may regret bringing this up, but he actually
21 suggested some potential measures for government
22 agencies, the extent to which they have

1 harmonized measures that they're using or you
2 know, for how many measures were there, how many
3 measures were there opportunities for
4 harmonization, and how many of these cases did
5 harmonization, in fact, occur.

6 Let's see. In terms of system
7 measurement and monitoring, we just noted that
8 there's going -- we will need to develop reliable
9 methods and avenues for reporting safety
10 information, reporting events, and testing of
11 functionality and reliability systems would be
12 very important. We're going to need to learn
13 from voluntary reporting and then develop tests
14 based on reporting results. We can develop both
15 measures and interventions this way, sort of
16 similar to the IHI trigger tool.

17 In terms of measures, we wondered if
18 there's a way to develop some systems or methods
19 to evaluate the reliability or accuracy or
20 appropriateness of alarm systems or other systems
21 within HIT.

22 And then I guess I would just open it

1 up to some of the other members of my group if
2 I've missed anything or mischaracterized anything
3 or if you have any thoughts or comments to add, I
4 certainly welcome those.

5 Jason?

6 DR. ADELMAN: Yesterday, in our
7 conversation, I had two, let's say, a-ha moments.
8 One was that, you know, many times in our
9 conversations we were asked to think about
10 potential measures. First, I just clarify for
11 myself the difference between using EHRs to
12 extract patient safety measures like NHSN is now
13 asking us extract data about CAUTIs and CLABSIs.
14 And that's separate from HIT safety measures.
15 And people often talk about the retract and
16 reorder tool as an example of an HIT safety
17 measure. But I think the fact is that that was
18 mostly luck like it's based on a trigger and
19 triggers are like all David Classen's work with
20 the IHI trigger tool. If you're lucky enough
21 that there's an antidote for a drug, then you can
22 have a trigger for that error. If there's no

1 antidote, or something else then, so you have a
2 few triggers on the trigger tool and then -- and
3 so I don't think that it's likely that we're
4 going to be able to create dozens of HIT safety
5 measures. I just don't think we'll have the
6 creativity or that luck.

7 I think what's more likely to lead to
8 safer HIT systems is adverse event reporting
9 through the common formats and then the other
10 work that David Classen is doing with David Bates
11 which is testing systems. So for example,
12 somebody reports that a high dose of potassium
13 got through in a system and killed somebody. And
14 so then we take that scenario and test all the
15 different vendors, all the different versions,
16 all the different configurations and it turns out
17 that most systems block lethal doses of
18 potassium, but a few don't. So then we put in
19 those protections and we move on.

20 Even though adverse event reporting
21 may only capture one percent -- again quoting
22 David's research, one percent of adverse events

1 with common formats model and the PSO model, one
2 percent of all adverse events will be quite a
3 lot, enough to like identify some major problems
4 that we can use to keep building the Leapfrog
5 test.

6 My feeling is that it's most likely
7 that that system of identifying and then building
8 it into a test and then either the vendor testing
9 the systems or the hospitals through the Leapfrog
10 test testing the systems, that will be much more
11 likely improve the safety of our systems than
12 next like were tracked and reorder tool. So that
13 was one thought that I had.

14 And just the other thought, I kept
15 thinking of the rapid expansion of smart phones
16 and how we're fortunate that Apple and Android
17 have these open source systems where as soon as
18 the phones came out, thousands and thousands of
19 programmers got to make all these apps, be very
20 creative and our phones are that much more
21 powerful because of it.

22 And so if the vendor society allowed

1 for some of the creative work like Brigham did
2 when they had a home-grown system and they owned
3 all the code, could make creative safety decision
4 support and then -- so if our vendors would have
5 systems that allowed that kind of creativity and
6 freedom and control of the code, and if we had a
7 system to then spread these solutions rapidly,
8 the way Apple and Android allow for creative, you
9 know, and rapid spread. So whatever the next
10 creative decision support, if we can build it in
11 Cerner, have that control in Cerner, spread it
12 throughout Cerner, and even spread it through
13 Epic, I don't know that it's likely that will
14 have some sort of open source model in the EHR
15 vendor world like we do in the -- but something
16 that promoted a rapid development, I think, would
17 help. Anyway, those are my two thoughts that
18 came out of that conversation.

19 MR. LYZENG: Thanks, Jason.

20 CO-CHAIR SINGH: I'll just sort of
21 reflect back a little bit. That was a great sort
22 of a recap, Andrew.

1 So I was thinking as you were sort of
2 walking through on some of the Level 3 work that
3 we've done which is sort of using technology to
4 prevent harm or reduce errors, and I thought
5 okay, as you were walking through, I said how
6 would this work for test result follow-up issues
7 that I study. So this is when there's an
8 abnormal test result and then there's no follow
9 up in X number of days. Sometimes it's months,
10 but we want to prevent that. So let's assume
11 that the trigger says here's an abnormal test
12 result. This is an abnormal x-ray which is
13 suggestive of cancer. And then 30 days later,
14 there's like no follow up. And we want to try to
15 use our electronic health record to tell us which
16 patients amongst the thousands and thousands and
17 maybe millions of patients that we see in our
18 system, can we extract patients who have not
19 received follow-up actions on their abnormal
20 chest x-ray because some of these guys are going
21 to end up getting cancer. That's bad for them,
22 bad for the system.

1 So then I thought okay, as you were
2 walking through, I thought okay, what would we
3 need to do that? So in software and hardware, we
4 have got to have a data warehouse infrastructure
5 to do this. So VA has this beautiful data
6 warehouse infrastructure hosted in a corporate
7 data warehouse called VINCI, V-I-N-C-I, where all
8 the real time clinical data, except for just a
9 few fields, gets aggregated on a nightly basis
10 and then researchers have been provided access to
11 it.

12 So I'm going to ask all of you around,
13 do our systems including sort of the developers
14 here, do we have robust data warehouses which
15 would allow us to query these things if we build
16 the algorithms, which sort of brings me to the
17 next dimension which is sort of clinical content.

18 Let's assume we have data warehouses.
19 So we do have data warehouses? How many of you
20 have robust data warehouses you can access or
21 query? Intermountain, Maine, and WellPoint.
22 Okay, great.

1 So some of us have. VA has it.

2 Kaiser has it. Did you raise your hand?

3 DR. JONES: Sorry, I don't want to
4 slow you down -- Jason Jones. That seems like a
5 really straight forward question. It's not a
6 straight forward question.

7 CO-CHAIR SINGH: But I can tell you,
8 Michael Kanter's group in Los Angeles does have
9 the data warehouse because I have talked to them.
10 They do queries.

11 DR. JONES: I can tell you because I
12 run it.

13 CO-CHAIR SINGH: They've got a paper
14 on this, so we need to talk after this, a paper I
15 wrote an editorial on.

16 (Off mic comment.)

17 Exactly, on diagnostic error.

18 DR. JONES: And I was at
19 Intermountain.

20 CO-CHAIR SINGH: We can talk about it.

21 DR. JONES: When we say that, it's not
22 a straight forward --

1 CO-CHAIR SINGH: Sure.

2 DR. JONES: And the cancer with non-
3 follow up radiographic --

4 CO-CHAIR SINGH: They don't do that.

5 DR. JONES: -- is a grave example of
6 somehow the data are there. What do the data
7 really mean.

8 CO-CHAIR SINGH: Exactly, so I'm going
9 to that. So that's a content issue, right?

10 So the next one is sort of content.

11 DR. JONES: Details, yes.

12 CO-CHAIR SINGH: How do we build these
13 algorithms? So we started when we found this
14 out. It's in the VA. We record our abnormal x-
15 rays as abnormal. So they're suspicious for
16 malignancy. They've got a structure code.
17 That's a suspicious malignancy. And then we look
18 ahead and see was it a CAT scan? Was it upon
19 reappointment? Was there any action done which
20 could have satisfied that abnormal x-ray. When
21 we don't see that, that's sort of a positive
22 trigger for us, if you will.

1 And Jason, I would say I think you're
2 right, there's not a lot of triggers in the area
3 of the general patient safety harm and the
4 specific HIT patient safety related harm, but I
5 think we need to sort of build them. And I think
6 as the research rigor increases, we probably
7 ought to be having the conversations about how we
8 build more triggers, but I think we can build
9 them. Just because you had the a-ha moment with
10 your trigger, I'm sure as the science progresses,
11 we'll have a-ha moments with sort of other
12 triggers as well, potential triggers.

13 So most systems do not code their
14 abnormal chest x-rays and correct me if I'm
15 wrong. Most EHRs are not coding sort of the x-
16 ray as sort of abnormal. If we do, we could run
17 these queries, so that sort of brings me to the
18 content issue. We don't have sort of
19 standardized algorithms to do this.

20 We also have missing sort of
21 longitudinal data, so I was having a conversation
22 with Kevin, a lot of these systems would have

1 data warehouses, but there's like no idea about
2 when these patients go in and out of the system
3 as to what happened to them. So they may have
4 had a CAT scan for that abnormal chest x-ray 60
5 days later at another hospital, but if you're
6 working in this hospital, you're not going to be
7 able to know, unless maybe you get Kevin to tell
8 you because of their -- yes.

9 Okay, so the third thing is human-
10 computer interaction. So one is we don't have --
11 we could potentially think of sort of having
12 dashboards and all of that, but I was thinking I
13 am going a little off my trigger topic, but you
14 talked about the patient portal example. I think
15 that's a great one. Right now, the patient
16 portal interface really is not very robust.
17 Patients often get confused. They can't find
18 their previous information. They don't have
19 links as to what these test results mean on
20 there. I think one of our papers came out and
21 there's a beautiful website called Lab Test
22 Results Online which gives you a very good idea

1 about what that test result means. A lot of
2 portals aren't using them. But we wrote an
3 article and the VA found out and they actually
4 now add that to the release attached to those.

5 We need to have a robust human-
6 computer interface if you're going to have
7 patients be more proactive in their test result
8 follow ups so we can sort of help them understand
9 the results.

10 The fourth one was people. We really
11 have a tough time trying to get programmers to
12 extract this data. Very few people -- I don't
13 know about the analytic capabilities at your
14 institutions, but we can't get data out because
15 what they tell us is they're too busy with other
16 things. Other institutions we work with, non-VA,
17 they say we're too busy with meaningful use, too
18 busy with ICD-10, don't have time for doing
19 patient safety research. That's the usual
20 response we get from a lot of these people.

21 In the VA, we are very lucky, so we
22 have our own sort of research programmer that we

1 can access. So people-wise, we really need -- if
2 you're going to use technology, we're going to
3 need to build people capability to sort of
4 extract this data from the EHR.

5 The fifth one is, sort of, work flow
6 and communication issues. The problem is who to
7 give this data to. Clinicians, we've tried to
8 give this to clinicians. We send them reports
9 saying your patients have probably lost follow
10 up, too busy, so we often found that there was
11 still no follow up action, even after we tell
12 them that the patient has an abnormal test that
13 needs follow up and they would still not follow
14 it up because they're too busy getting their
15 alerts and so we email them, we call them, we
16 can't get hold of them. It does not fit into
17 their work flow. When they have missed test
18 results and we are telling them here are the
19 dropped balls and we keep sending it to them, it
20 doesn't fit into their work flow.

21 So we decided, which brings me to the
22 next thing, were organizational issues. We

1 talked to leadership and said we need somebody at
2 the institutional level to follow up these
3 issues. If you're going to find patient-safety
4 events, we're going to need some institutional
5 action on this. So I thought you brought up
6 leadership and I think the key here to try to get
7 things sort of done.

8 The seventh, rules and regulations
9 were the seventh issue. Joint commissions was
10 sort of mentioned. I think that's a good one, a
11 good example. Joint commission has some sort of
12 stake in the game about trying to get people to
13 use their data warehouses to extract such
14 patients and to maybe encourage people to code
15 data in the EHR so that we can use the EHR for
16 improving patient care. Right now, Gerry,
17 correct me if I'm wrong, there is no sort of
18 direction of pushing people to use data
19 meaningfully from the EHR to sort of improve care
20 and that's correct, correct? We don't have it
21 yet. We don't have a direction.

22 We need support, I think like you were

1 trying to say, Andrew. We need support from
2 external agencies and maybe NQF, too. We need to
3 think about measures that then can be
4 operationalized and that push needs to come from
5 somebody else. Just like MU and ICD-10, various
6 people. These things need to worry people at the
7 organization level, otherwise they won't do
8 anything about it.

9 And the last one was sort of
10 measurement and monitoring. These algorithms can
11 change. I think we talked about sort of these
12 things that suddenly stopped working in
13 institutions, the decision support and the
14 algorithms not working, so we need from time to
15 time we need to check the validity of the
16 algorithm. So we actually have in the extracted
17 data, when we told the computer to tell us
18 abnormal film followed by no action in a patient
19 who is sort of nonterminal and so and so age, we
20 want to make sure all that data is accurate.
21 Otherwise, the information is useless and
22 clinicians will have every right to ignore that

1 information as they find it useless.

2 Sorry I was a little long, but I
3 wanted to sort of put that in context of what I
4 think is using health IT to improve patient
5 safety. I know lots of people have raised their
6 hand -- I lost count.

7 Jason, do you want to go first?

8 DR. JONES: Jason Jones. So this
9 could be a lengthy discussion. I think you sort
10 of illustrated some of the issues. We've
11 addressed this several times over several years,
12 how do we use the information better. And I
13 think the issues you raise, somehow if someone is
14 too busy calling them and emailing them and
15 showing up at their door after they didn't
16 respond to an alert probably is still not fitting
17 in their work flow somehow.

18 CO-CHAIR SINGH: Do you have that
19 problem, too, at Kaiser?

20 DR. JONES: No, we don't have that
21 problem, ever.

22 CO-CHAIR SINGH: Thought so.

1 DR. JONES: We just do like control-A
2 delete the inbox. It fixes everything.

3 (Off mic comments.)

4 DR. JONES: Yes, we do. If we go down
5 the path of -- and this is where I was hoping we
6 were going to get to because a lot of what I've
7 heard in the report-outs, I wonder, Hardeep, if
8 you feel like we're conflating the three levels,
9 because I'm not seeing a clear distinction in the
10 report-outs between one, two, and three.

11 I think the reason I thought everyone
12 would want to be in three was because everyone
13 would want to talk about exactly what you raise
14 which is really not only how do we prevent harm,
15 but how do we improve care. And I think that's
16 still even a little fuzzy in the definition. So
17 we might want to think about that and making it
18 clear, no, no, no, we're really just talking
19 about preventing harm. And maybe we extend the
20 prevention of harm to not following up on an
21 abdominal ultrasound that was abnormal or a chest
22 x-ray or something else. But we're going to have

1 to clarify that and then figure out how we don't
2 conflate the three levels if we find those three
3 levels are useful.

4 We can have a fairly long discussion
5 about the contents of data warehouses and if
6 those are the appropriate places for ensuring
7 safety. I think in the ambulatory world or when
8 follow up is not that critical, meaning split
9 second to minutes or even an hour, that's
10 feasible. We run into trouble when we need to
11 prevent a med error now, like before it gets
12 administered between the order and the
13 administration. Now the warehouse is not
14 feasible for us anymore. It's too slow.

15 So there are issues like that we could
16 begin to work through, I think. But that -- I'm
17 not sure that's going to get us to the safety
18 measures. I'd be happy to talk about it. Be
19 happy to talk about it. Be happy to talk about
20 how we can spread these alerts because we
21 haven't, although it's not open source like
22 Android or even how we might think about the App

1 Store with Apple. We absolutely can share these
2 things across organizations, but it boils back
3 down to the content, if you want to do something
4 off an abnormal chest x-ray, Intermountain is the
5 only other large organization that I think has
6 gotten close to that and I think it's only at
7 Primary Children's where you've had success in
8 getting radiology to discretize and make more
9 computable the radiographic results. I might be
10 outdated on that. We've tried and struggled and
11 we run into this over and over again.

12 From a content perspective, one of the
13 most vexing issues that we face is a patient
14 disoriented. We have eight ways of coding acute
15 mental status for patients within Kaiser
16 Permanente. And how do we then figure out
17 whether we have -- for a programmer -- and you
18 ask a simple question, tell me if a patient is
19 confused. It's a reasonable question. The
20 programmer goes in and has eight different places
21 where that can be coded. And that's what keeps
22 tripping us up.

1 If we think we want to get all the way
2 to really leveraging that -- really getting to
3 that third tier and that third tier in that
4 picture even leaks over to the right-hand side
5 where we talk about outcomes and value, we're
6 going to have to tackle that content piece. And
7 that's a hard one.

8 That's really where you run -- I mean,
9 it's one thing, people get irritated when you
10 send them an alert, but at least they can ignore
11 an alert. If you change how they document
12 whether a patient is confused or you try to get a
13 radiologist to discretely identify that somebody
14 else might be missing a tumor, that's a whole
15 different level of organizational change.

16 I hope -- I'd loved for us to get
17 there, but if we're going to get there, I think
18 we have to be really up front about it and say
19 we're going all the way to value and outcomes and
20 how does HIT get us there. We're not just
21 stopping with is there -- has the server gone
22 down? Up time type stuff.

1 CO-CHAIR SINGH: You know, those are
2 some great comments, actually. I think you're
3 right about sort of there's a little bit of an
4 overlap between the three levels. And that's why
5 it's like a hierarchy. Really, to get to that
6 third level of using technology to improve
7 safety, we're going to have to address all the
8 issues we discussed with bad technology and
9 software bugs and unable to use. If I can't even
10 put data into my EHR, where are you going to get
11 in a data warehouse, for instance? All you're
12 going to get is junk. We talked yesterday,
13 garbage in, garbage out.

14 There's a little bit of overlap. It's
15 just sort of a way of thinking and if it's not
16 useful, we can think about it more. Yesterday,
17 we talked about the fact that maybe we need to
18 enrich each of the levels with some more
19 principles. So just like in the first level
20 there were three principles. We could come up
21 with more. Some could be sort of patient-
22 centered set of principles. And each of those

1 levels, if that's what helps people to think
2 about what kinds of measures.

3 I just think that the Level 3 is a bit
4 different because we're talking about preventing
5 harm, all kinds of harms, not just from
6 technology, but the usual patient safety stuff
7 that we've been talking about for the last two
8 decades and haven't gotten a whole lot further.
9 Maybe we'll come back to this discussion. Who
10 else?

11 DR. HAYNES: I was just going to say
12 that I really did want to be in Group 3 for
13 exactly that reason for preventing harm. But I
14 also think that being in Group 1 sort of opened
15 up my eyes as well to making sure that you get
16 those types of things right with regards to the
17 trust that you have in the data.

18 Being sort of a payer representative
19 in the room, I would love to know what docs
20 aren't getting a hold of patients because of the
21 payer. I would probably want to make sure that
22 those patients are getting the care that they

1 need. So where does a -- like CMS, being the
2 biggest payer in the room, step into the role of
3 more active management of care with regards to
4 providing the data that's needed to do medication
5 reconciliation which is still done by pharmacists
6 calling pharmacies from the hospital for
7 medication reconciliation which is a big
8 component of joint commission, yet that data is
9 already sitting there electronic. So I really do
10 think that a lot of this is about
11 interoperability.

12 Penn has a data warehouse. VINCI has
13 a data warehouse. And there's VA across the
14 street from Penn. Are they in the same common
15 data format model so that they're easily
16 queryable? Absolutely not.

17 So I think the question of having
18 warehouses and creating more warehouses creates
19 more silos. We ought to start talking about how
20 those warehouses then become integrated so that
21 both researchers in a payer perspective and
22 patient safety people within a payer perspective

1 are equally engaged as folks who are at hospitals
2 and health systems because health systems are
3 trying to keep people from being readmitted for
4 30 days. So are payers. So patients are getting
5 bombarded with they're going to have their portal
6 from their insurance company. They're going to
7 have their portal from when they go to one
8 hospital A. They're going to have a separate
9 portal when they go to hospital B. It's only a
10 matter of time before they demand a common
11 portal.

12 CO-CHAIR SINGH: And you know, again,
13 we can come back. I know Jesse has a question.
14 But we can come back also to the EHR developers.
15 Are there possibilities -- I mean you say, I mean
16 right now, at 30 or 40 percent of patients are on
17 Epic. Does Epic have a data warehouse for all
18 those 40 percent of patients that they have? You
19 can answer that. And if not, then what will it
20 take to get us there so that to answer, well,
21 maybe at some level at least if the patient goes
22 to all Epic places we have the data across all

1 the systems, but anyway.

2 DR. PINES: Sure, thanks. So sort of
3 stepping back a bit, I think our ultimate goal
4 here is safer health IT and health IT that's more
5 usable for the end users, for clinicians, and
6 understandable to patients. A lot of the
7 discussion has been about sort of think about
8 those elements that sort of go into making safer
9 health IT whether it's having some sort of a
10 trigger program or sort of effectively using your
11 data to actually do quality improvement. And I
12 wonder sort of from a measurement perspective
13 whether we should sort of shift more to outcome
14 measures.

15 And to give you a sense, in the
16 Patient Safety and Complications Committee that
17 Jason is also on, there actually was a measure in
18 the last cycle that was very similar to the one
19 we mentioned about the follow up for biopsy
20 results to making sure the patients actually were
21 notified of their biopsy result. And actually in
22 the last cycle it went down on evidence criteria

1 because there was really sort of not sufficient
2 evidence that this measure was linked to
3 outcomes. And those measures in sort of the
4 current measurement environment are sort of a
5 challenge to get through, at least the NQF
6 process, and which is not to say that doing these
7 triggers and doing these -- making sure the
8 people are getting appropriate follow up is not
9 something that organizations should be doing.
10 The question from a measurement perspective is
11 how proscriptive should we be with organizations
12 about how to make health IT safer. And if we
13 sort of box organizations into what we think
14 today, makes health IT safer, like alerts and
15 triggers and sort of whatever is feasible with
16 the technology, and this is such a rapidly-
17 evolving area that in five years from now someone
18 is going to come up with a new technology and
19 maybe alerts are going to be totally gone because
20 they're going to be replaced by something else.

21 So you know, I think as we step back
22 from this, we do want to really focus making

1 sure, sort of focusing on where we want to go and
2 sort of setting up the goal posts, potentially
3 with outcomes rather than -- and as we write this
4 report, having guidance around what we think
5 today may be some guidance to organizations about
6 how they can get from here to there with the
7 alerts and with triggers and with some of the
8 novel stuff that's happening in Kaiser and
9 Intermountain. But essentially, these are sort
10 of local innovations and sort of taking those
11 location innovations and saying this is what
12 everyone should be doing. I think -- I'm not
13 sure we can necessarily make that jump and if we
14 do make that jump, then we could be potentially
15 stifling innovation which we don't want to do.

16 CO-CHAIR SINGH: So Jesse, let me
17 respond. I think the point here is not sort of
18 having one type of a local innovation such as
19 Jason's or the ones we have in the VA, or Kaiser
20 for that matter.

21 The point is do institutions have the
22 data analytic capabilities to mine useful data

1 out of their EHR.

2 DR. PINES: I think part of this does
3 appear in the SAFER guides which is a -- I'd like
4 to get your thoughts on sort of how that element
5 of -- the recommendation of having an
6 infrastructure to actually do quality improvement
7 around health IT and making sure the data gets
8 fed back, sort of how do we measure that? Or is
9 that measurable or is that something that the
10 Joint Commission would come in and take a look
11 at?

12 CO-CHAIR SINGH: Yes, I think that's
13 all up for discussion as to how do we measure
14 that and what kind of roles do the IT staff and
15 the EHR developers and the rest of the community
16 play. I think the issues that have been brought
17 up are all sort of real, but we just cannot
18 ignore the fact that we now put in all this
19 health information technology and we're not
20 putting that data to good use. So we're going to
21 have to figure out how do we actually measure
22 some kind of capability of effectiveness of

1 putting the EHR data to some good use. Most of
2 the people are saying yes, we've got these EHRs,
3 where is the benefit of trying to use that data
4 at a population level or either for quality
5 improvement or patient safety.

6 I know there are several others.
7 David, and then Karen and Tejal.

8 DR. HUNT: David Hunt. One thing that
9 I sometimes fear that we fall into a little bit
10 of an allure, the IT allure, that is to say with
11 information technology, we've gotten so used to
12 being able to leverage it to do many things with
13 one click of a button. You can reply to all or
14 you can change all of my misspellings for one
15 word, with one click. We have cascading style
16 sheets that -- it may be that we won't be able to
17 code all radiographic interpretations, but maybe
18 we can look at doing some incremental things and
19 prioritizing some things.

20 So I would make a strong case that
21 chest x-rays and lung cancer, that's a huge
22 thing. So maybe we can have measures that look

1 toward that. Because one thing people need to
2 get used to on a regular basis is, as you said,
3 that this technology will be able to have them do
4 something. So if they can't identify all
5 radiographs that are abnormal, maybe we can
6 prioritize and maybe hit the lung cancers or hit
7 the COPD, or whatever we decide that we can do it
8 incrementally. That actually would feed into
9 well, we won't be able to have huge data
10 warehouses with everything, but maybe we can talk
11 about connecting with more and more registries.

12 Yes, in many ways registries are
13 siloed, pieces of information that still don't
14 get us all the way. But I worry that we too
15 often will try to have that one click have a
16 cascading effect throughout everything. And
17 maybe we can pick one or two. I personally don't
18 have a problem with prioritizing one or two
19 things if we could.

20 CO-CHAIR SINGH: Yes. David, that's
21 a good point. And I think it fits very well with
22 what Jesse was trying to say. Let's go and look

1 and see where the evidence is and then maybe
2 focus on just those areas. I'm not only an
3 advocate for lung cancer, but about 20 to 30
4 percent of patients who ultimately get lung
5 cancer have missed opportunities on their chest
6 x-ray. So to me, that's good evidence, just as
7 an example.

8 Karen?

9 DR. ZIMMER: There's a lot of thoughts
10 going on here so I'm going to probably bring up
11 also lots of random things to address some of
12 the things I've heard.

13 One thing I feel like is really
14 missing is that and I've said this before, I
15 think we need to really build on what already
16 exists. So one of the things I've suggested, and
17 I apologize for repeating myself, but to do a
18 cross walk of all the different government
19 measures and see which ones fit into our HIT
20 model. Because if people are really reporting
21 these things, then you already have a minimum
22 data set, so to speak. But what people aren't --

1 at this point, they're hiring FTEs to deal with
2 all these mandated reported measures, so why
3 don't we figure out which of those -- synthesize
4 it, so we can see what is applicable here and
5 then build on that based on all of our
6 discussions. So it's a little bit of a gap
7 analysis. So that was one suggestion.

8 I then feel like we -- I really
9 appreciate Jason's comments. I think the trigger
10 tools is a great way to go and the reason I
11 suggest that is when I was at ECRI, one of the
12 analyses, Exhibit HIT, as we found, a lot of HIT
13 is in all areas. So it's not like it's siloed
14 into HIT. You have issues with falls and
15 pressure ulcers and infections. So it makes it
16 difficult to silo it and the fact that a few
17 years ago it was already in all areas medicine.
18 Today, it's even more omnipresent. So when you
19 talk HIT, we are talking about everything. We
20 are talking about delivery of care. So you can't
21 really silo it off the way we traditionally have
22 and so we needed some kind of an integrated

1 model. And I feel like the trigger tools do that
2 because you're looking at the whole document and
3 then pulling out elements that likely would fit
4 into the model that we've been discussing.

5 I love the idea, too, to share
6 findings at a higher level. We mentioned that
7 yesterday. I reiterate that would be a fabulous
8 way to go. And the open source is a fabulous way
9 to go because when you look at open source
10 applications, they have over hundreds of
11 developers looking at that. Well, that's huge.
12 No offense, but we talked about testing. Nobody
13 has the resource to put 100 developers on
14 testing. But as soon as it's open source, you do
15 have that in place. I would just put that into
16 the consideration when we talk about resource
17 limitations.

18 You put out, Jason, the coding is very
19 difficult. Anything multi-factorial is just
20 difficult. I have to be honest. I was a
21 complete cynic when we were asked to do
22 readmissions because all I could think of was

1 well, there's no one cause for readmission. I
2 can't believe they're doing readmissions. You
3 know, that model actually -- as I said, I was a
4 little bit of a naysayer and I was actually very
5 impressed with how they did end up doing
6 readmissions because I thought how are they going
7 to do that? It's a multi-factorial issue.

8 Well, HIT is a multi-factorial issue.
9 So I think someone here had mentioned that we
10 could use -- and maybe it was you, Jason -- start
11 that as an approach, but that isn't a model that
12 has worked in the past so maybe we should think
13 about that.

14 And someone mentioned the groundwork
15 at each of the home grown places have come up
16 with the innovations. We need a better way to be
17 sharing that. Because if you want to know what
18 your problems are, just ask your front line
19 staff. They all know. And some of these
20 hospitals have more resources to create local
21 innovations, but they don't know how to get it
22 out to the market. They don't know how to share

1 it with other people and maybe is that our role?
2 I don't know, but I put that out there because
3 the solutions are out there. They're just not
4 disseminated well.

5 And the very last thing, sorry, I'm a
6 little bit long-winded here is when we collect
7 data, we need to make sure it's really clear what
8 the purpose is. We get really good at collecting
9 data and describing data and I feel like that
10 mode is already passe and we need to let the
11 people who are taking the time to put data in,
12 what are we doing with that data? They want
13 action, they want solutions. They don't want to
14 just be told what to do. They actually need help
15 with implementation. And I don't want us to get
16 lulled in the traditional way of thinking where
17 we collect data and we describe it. Again,
18 people know what's going on. So they are looking
19 for us to assist them and facilitate.

20 CO-CHAIR SINGH: Thanks, Karen. Tejal
21 and then Mark.

22 DR. GANDHI: I just wanted to build on

1 two points. One is around the chest x-ray
2 example and at Brigham we did a lot of work on
3 this as well with codifying abnormal results and
4 so on and then having the closed loop and so on.
5 But you might want to think about it also in
6 terms of is it really the chest x-rays or do you
7 want to think about incidental pulmonary nodules
8 in general, for example, because it's much
9 broader than chest x-rays where you find these
10 things. So I just wanted to make that point.

11 We can talk offline about some of the
12 other stuff that Brigham's been doing on this
13 work. But to that point, I think getting back to
14 -- I think we do need to have innovation for
15 sure. And Karen made this point as well. There
16 are pockets where people have created really good
17 stuff around how we optimize HIT to improve
18 safety. And I totally agree that that sits in
19 pockets without being spread. So these measures,
20 I think, have the opportunity to really say we
21 know that there's a way to do this. Now let's
22 kind of bring everybody else on board to actually

1 start doing it.

2 And so your point about having this
3 capacity for analytics, it's important, but I
4 think that capacity could start with here's some
5 core stuff that we know you need to do and then
6 yes, please innovate beyond that and let's figure
7 out how to spread it. But I don't think we want
8 to give a blank slate when we know that there's
9 some core that's already been developed.

10 CO-CHAIR SINGH: Yes, the capacity
11 sort of includes being able to sort of implement,
12 take things, not just IT capacity, but to put
13 things in place. We're going to need people in
14 leadership to put these things in place and do it
15 often. Great points.

16 Mark, and then David.

17 DR. SEGAL: Yes. Mark Segal. So one
18 of the things I think we've seen in the past few
19 years and I think it was touched on in the
20 literature review is the pretty rapid, very rapid
21 rise in adoption of health IT particularly EHRs.
22 At hospital levels, we're looking at well in

1 excess of 80 percent. And depending on how you
2 measure it on the physician's side, certainly
3 approaching that 70, 80 percent level.

4 And I think a lot of what we've been
5 talking about is making good use of the data
6 that's in the EHRs and also making sure that the
7 data is high-quality data.

8 One of the things just sort of from an
9 advocacy standpoint that I think certainly the
10 vendor community and I think providers and a lot
11 of folks as we look ahead to the next stage of
12 meaningful use, one of the themes, I think, has
13 been be more focused so that, among other things,
14 in addition to interoperability which is getting
15 a real level of emphasis, that people really have
16 the time and space to generate the value from the
17 investments they've made in health IT.

18 Just by one example, the requirement
19 to use SNOMED to code problems. That is a major
20 change. And it's one that it's going to take
21 people time to kind of fully get into using
22 SNOMED well and extracting the value. Obviously,

1 we've got to move to ICD-10.

2 So it seems to me that one of the
3 things that the community can work on and again,
4 we have different EHRs and different database
5 structures and all of that, but there's also
6 increasing commonality about what data is
7 structured. There are expectations about the
8 kind of analytics that can be done. Often, what
9 you'll find is ERHs, again, it's going to vary in
10 patient, outpatient. They'll have some core
11 analytics and then people using Crystal Reports
12 or other things, integrating with the database,
13 increasingly through things like SMART. We had
14 apps as a way to access the data. And to really
15 focus on guidance of how organizations that have
16 invested in health IT are investing in having
17 structured data can get value and in a sense to
18 minimize the distractions and disruptions that
19 get in the way of people actually getting the
20 value out of what they've done. And perhaps
21 guidance about if you're interested in doing
22 population analytics, you know, what are you

1 doing about test results that haven't been
2 followed up on? Well, again, recognizing people
3 are going to be using different tools and
4 different databases, but what are some common
5 approaches that can be used. And I think that's
6 an opportunity and a nondisruptive and pretty
7 inexpensive way to get a lot of value.

8 CO-CHAIR SINGH: Good point. David.

9 DR. CLASSEN: Yes, I just wanted to
10 build on Tejal's comments and Jason's comments.
11 There are things we can do right now, right?
12 Last year, almost a thousand hospitals took the
13 flight simulator's Leapfrog test we've been
14 talking about and learned something from it and
15 used it and actually AHRQ has just funded another
16 five-year extension on that work to expand that
17 into a whole lot of different categories. And
18 that works. And it's been used since 2008. It
19 needs to be updated, but --

20 CO-CHAIR SINGH: David, could you just
21 give a 30-second overview for everybody --

22 DR. CLASSEN: So if you don't know

1 about this, David Bates and I have been working
2 on this for about ten years. And what we did is
3 we did, Jesse, what you suggested. We went into
4 IT systems and looked for actual adverse events
5 that were documented in the IT systems that we
6 could link all the way back to the ordering
7 stage. So there are a couple of databases in the
8 United States where you could do that. It's
9 really clever.

10 So we found actual scenarios of
11 patients who have been harmed where you could
12 trace it all the way back to the lack of
13 decisions supporting the order. VA has one such
14 database. There's a couple others that we used.
15 Then we just built scenarios around those actual
16 cases. And then we created a flight simulator
17 that is web enabled that any hospital can take
18 through Leapfrog and actually run those test
19 scenarios through their system to see if they can
20 pick them up. And it actually calculates an
21 overall score and it calculates a score in all
22 relevant safety categories. So AHRQ just funded

1 us to markedly expand that and make it more
2 broadly available. So that's available now.

3 I agree with Tejal. What she said was
4 exactly right, there are pockets of this going on
5 and not many people know about it. I mean if I
6 asked everybody in the room how many people know
7 about the Leapfrog test, probably not a lot of
8 hands would go up. Yours, but not many others,
9 right? And Helen funded it, so back to Tejal's
10 comments, we're not spreading what we already
11 have.

12 The other good news is that we've been
13 running this national collaborative with AHRQ and
14 AHA to demonstrate that you actually can automate
15 triggers in current releases of the EMRs. And
16 then in all the leading EMRs, we demonstrated you
17 could do it. We have a trigger library of
18 probably 130 triggers now that have been
19 automated. You can do it in current -- so it
20 goes back to what Tejal said, right now, you can
21 do this.

22 CO-CHAIR SINGH: So David, so just to

1 sort of bring the point back, Mark sort of made a
2 point about sort of value. So 130, we also don't
3 want to say okay, run all those 130. Let's just
4 start with the best, where the best evidence is
5 and then maybe that's five which have high
6 predictive values.

7 DR. CLASSEN: Exactly.

8 CO-CHAIR SINGH: So give us your five
9 best high-impact, high PPB triggers and then run
10 them.

11 So Tejal, and Mark, are you still up,
12 right? And then Jason.

13 DR. GANDHI: I totally agree that the
14 flight simulator is a great example. I would
15 just say let's think about how we can expand that
16 model to think about similar simulators for other
17 things. So you and I at breakfast were talking
18 about bar code medication administration which is
19 if it's done well has demonstrated value. But
20 there's lots of work-arounds and other things
21 that can happen that can diminish that value. So
22 I think we need to really expand outside of CPOE.

1 And then also, just because you took
2 the test and found out that you had a problem
3 doesn't mean you actually fixed anything. So I
4 think really closing the loop on that as well.
5 Check, I took the test and I gave my score to
6 Leap -- not that I have personal experience with
7 this, but maybe I do, you check it off, yes, I
8 did the test. Doesn't mean that anything has
9 gotten better. So I just think we need to be
10 really careful about that as well.

11 DR. ADELMAN: I'm sorry. I'm
12 reiterating what I said before and following up
13 on what they said. I just want to use an analogy
14 from my personal life. In my family, I'm the
15 only the person who's in healthcare. Everybody
16 else works for my father who has a company that
17 makes software for trading systems, which is why
18 I think I got interested in IT and healthcare.

19 Every time I talk to my father about
20 this stuff, he sort of laughs and thinks this is
21 kind of funny in that I believe that, first of
22 all, healthcare's use of IT, as I think we all

1 know, is way behind everybody else's use of IT
2 and they don't operate in this way, meaning like
3 they don't make measures to look for when their
4 software fails. They have these systems of
5 building software and testing it rigorously and
6 if they find a problem, they fix it. For
7 example, we can make a measure that looks for how
8 often lethal doses of medications just go through
9 and then track that measure. Or we could just
10 like test it, zero it out, be done with and move
11 on to the next problem. And I think that may be
12 we can draw some lessons from other industries of
13 just typical software development techniques.
14 The difference between healthcare and everybody
15 else is that when there's an error, somebody gets
16 hurt.

17 Although in my father's industry, lots
18 of dollars are lost, and they take that very
19 seriously as well. But I just wanted to
20 reiterate that I think that they really rely on
21 lots of testing, errors being reported. A trader
22 accidentally traded a million dollars and that

1 bypassed their risk management system. And then
2 they plug in that hole, test other systems, make
3 sure it doesn't happen again and move on to the
4 next problem. They don't make like a measure for
5 each one of them.

6 CO-CHAIR SINGH: And David, you
7 probably could reflect on this. There's a lot of
8 variability between the systems.

9 DR. CLASSEN: Correct.

10 CO-CHAIR SINGH: I mean there's some
11 clearly --

12 DR. CLASSEN: There's clearly a lot of
13 variability in the systems, but the reason we did
14 the demonstration project, we're showing all the
15 leading commercial EHRs. Even because of
16 variability, you can still technically do it. So
17 that's the good news, right? We can leverage
18 what we have right now.

19 Well, for the flight simulator, it
20 actually goes beyond CPOE and the AHRQ funding is
21 going to take it way beyond CPOE. So it does
22 address cost of care. It does address over-

1 alerting the flight simulator. So it goes beyond
2 the traditional layers have thought up. But with
3 the AHRQ funding, it will get end usability. It
4 will get into Jason's error detection. It will
5 get into successfully preventing certain serious
6 complications. It will go far beyond where it is
7 now.

8 CO-CHAIR SINGH: Eric?

9 DR. SCHNEIDER: So I think I predicted
10 yesterday that I was going to struggle with
11 understanding how we would make forward movement
12 here. And I'm now -- it's confirmed. The
13 breakout groups have been terrific in terms of
14 surfacing all of the issues around HIT and safety
15 and actually and actually other topics like
16 quality, more generally. But the committee
17 charge around identifying and selecting measures
18 seems a little out of reach right now, given kind
19 of the variety of different things we're talking
20 about. And there may be measures associated with
21 several of these activities, so the simulator
22 testing could become a set of measures. It would

1 probably look something like the ABIM maintenance
2 of certification program. And there probably are
3 several measures we could think about that would
4 help people design better vendor systems or IT
5 systems and that may be completely within the
6 charge of the committee.

7 But I think we are running the risk
8 that we -- I think we're at a decision point
9 around -- and others have, I think, said this as
10 well, the degree to which we focus on systems
11 engineering, designing -- helping people redesign
12 their IT systems, helping organizations to
13 redesign their socio-technical interfaces, and
14 helping to figure out how patients can make
15 better use of IT or be better informed by IT.
16 And that's a vast territory to try to identify
17 and select measures in.

18 I think one of the other things I'm
19 hearing in the conversation today is we're sort
20 of breaking beyond the boundaries of what I would
21 think of as safety. And the follow up of
22 abnormal test results has been somewhat reframed

1 as a safety issue, but actually in the 1990s we
2 tried to develop follow up of abnormal test
3 result measures at NCQA. And using health plan
4 data which actually at the time were probably the
5 best available data may actually still be the
6 best because many of the HR systems you couldn't
7 reliably across organizations measure those
8 constructs very readily because the data aren't
9 well standardized.

10 So I was trying to figure out if
11 there's a way to again constrain the problem
12 we're trying to solve and I think to the extent
13 we try to focus on a relatively narrow definition
14 of safety as risk reduction and maybe in just the
15 areas that safety researchers have identified as
16 sort of the big leverage areas for reducing risk,
17 and then think about where we want to be on this
18 spectrum in terms of the use of the measure
19 results. Is it really to inform designers, to
20 inform CEOs and CIOs or to inform patients who
21 are choosing doctors or hospitals or asking the
22 question which vendor system does my ACO have and

1 is it a vendor system that's the best in terms of
2 all these things.

3 I think we might try to either figure
4 out like there's one or two of those areas we
5 really want to focus our efforts on where there
6 will be a novel contribution outside of a lot of
7 other work that's going on and NQF staff probably
8 would have a better view of kind of the landscape
9 of this.

10 But I do worry that we're so broad
11 right now that on day two I'm thinking oh, boy,
12 how are we going to get to a list of measures and
13 then even think about what are the priorities for
14 measurement. I don't know if others share my
15 anxiety.

16 CO-CHAIR SINGH: Eric, first about the
17 abnormal tests just as an example like I
18 mentioned yesterday, banana, apples, oranges,
19 they're all fruits, so you just pick the fruit
20 you want to eat as long as you're having fruit.
21 So you know, we can pick any other example and I
22 think David Classen's work on medication errors

1 is another way of running triggers on a sort of
2 enterprise level to improve safety. So we can
3 just pick any area that we want to including
4 medication errors.

5 And the second point about measures,
6 I've been sort of going back and forth with
7 Jesse, this is what I had sort of asked the
8 groups yesterday, sort of challenging them okay,
9 tell me the five or ten things that you would
10 want to focus on going forward and I think maybe
11 we've got to have that conversation again, Jesse,
12 after maybe -- go ahead.

13 MR. MARELLA: So I guess I wanted to
14 build on some of Eric's comments and some of
15 David's. Sometimes we have the Achilles' heel of
16 letting the perfect be the enemy of the good and
17 I think there are some pragmatic and incremental
18 things that we could do that are achievable in
19 the short term. And I'm trying to think of these
20 things, both from the perspective of things that
21 the providers are responsible for and things that
22 the vendors are responsible for.

1 So for the providers, a lot of the
2 measures that we've talked about and that we
3 struggle with are -- we're trying to parse
4 differences between are they doing something that
5 we think is beneficial to do and then the higher
6 bar is are they doing that thing well. So for
7 example, asking somebody if they're monitoring
8 their alert firing and override rate is probably
9 a structural measure. And the harder thing to do
10 is to determine what is the optimal alert firing
11 rate and alert override rate or what are the
12 acceptable rates. And trying to figure out what
13 the evidence, what kind of evidence we would
14 accept to make those cutoffs is problematic.

15 The first thing seems easy to do. The
16 second thing is much harder, so maybe we focus on
17 the first. From the vendors, I think we could
18 focus on things like do they support features and
19 functionality that we think is associated with
20 better usability and better safety. So, for
21 example, we know that tiered alerting systems
22 are more acceptable to clinicians and less likely

1 to desensitize them to the alerts that matter.
2 So is it fair to ask of the vendors do you
3 support this functionality? And I know some of
4 the criticism of the SAFER guides has been about
5 whether they require things that a lot of vendors
6 don't support today. But I guess I would say in
7 response to that, a measure that everyone does
8 well on has very little utility. So just because
9 it's not there today doesn't mean it's not a goal
10 to strive for.

11 In terms of -- another example from
12 the provider side is and this gets back to the
13 role of evidence and what sort of evidence do we
14 need, do we really need good, high quality, RCT
15 evidence that following up on patients with
16 abnormal test results is a good thing to do? I
17 don't know that anybody is going to question that
18 if we go on poor quality or circumstantial
19 evidence on that.

20 So anyway, those are the points that
21 I wanted to make.

22 CO-CHAIR SINGH: Thanks, Bill. So I

1 think -- great points. We had this discussion a
2 little bit yesterday as to sort of what level are
3 we going to be thinking about with these
4 measures, sort of more of the enterprise level,
5 more the providers, more the vendors, more
6 shared, sort of having one measure that actually
7 has three or four responsible people. That's
8 another thing up for discussion in addition to
9 sort of getting down to a little bit more doable
10 lists like Eric suggests.

11 DR. BURSTIN: Just one response to
12 Eric and also Bill. Those are great comments,
13 but I think I've just been around for a while.
14 This is so classic a conversation around emerging
15 areas of measurement. We could replace measures
16 reflecting a patient's sense of affordability,
17 identical conversation for a day and a half. How
18 you get to measurement for patients with multiple
19 chronic conditions? Identical conversation.

20 So I think part of this is it's just
21 a new area of measurement. We see this all the
22 time. It's okay to just start somewhere and

1 perhaps part of this exercise could be that we
2 define perhaps things that are measurable right
3 now that may not be perfect, but can at least
4 start us down the path and at least begin
5 sharing. I think clearly what we heard from
6 Tejal and others is there's stuff out there
7 already happening that we could pull in, at least
8 begin sharing and perhaps really look upon this
9 as almost an evolutionary exercise of getting to
10 the really good measures.

11 That's not going to happen tomorrow,
12 David. But you know, at least we're on the path
13 you've identified what the right targets are.
14 And again, I think this is just great. I think
15 it would be wonderful to actually try to get a
16 sense from people around the table when you're
17 giving your wish list. So you know, what are
18 things you think could actually be built on
19 what's happening now and what's really
20 aspiration? And what would it take to get to
21 those aspirational measures because it's not
22 going to be simple.

1 (Off mic comment.)

2 DR. BURSTIN: For those who couldn't
3 hear David, he said "all measure work follows the
4 five stages of grief." I couldn't agree more.

5 DR. SCHNEIDER: And if I could just
6 follow up. I hope my comments weren't taken as
7 any criticism of the process today because I have
8 learned a tremendous amount from the discussion
9 and I think it has set us up beautifully for the
10 next phase. I'm eager to get to the meat. Well,
11 maybe that was the meat. Maybe it's the dessert
12 now.

13 CO-CHAIR SINGH: It does look like you
14 had reviewed a lot of my papers.

15 DR. SCHNEIDER: And actually in that
16 spirit, I think one of the things that's a
17 potentially unique space here is on the patient
18 engagement piece where patient engagement
19 measures, in general, have been difficult to come
20 up with, but it's an important area for work.
21 And the IT interfaces with patients and care
22 givers seem to me to be a really important issue.

1 So if there's a wish list that somebody is
2 starting I'll cast the first wish.

3 MS. MENDELSON: This is Dena
4 Mendelsohn. I would also definitely agree with
5 that. HIT is an excellent opportunity to measure
6 patient engagement. It's one of the first times
7 the patient can easily access their records and
8 be able to work with their providers by going
9 through it and making sure all the information is
10 correct in there. So this is one place where you
11 can measure if patients are actually active in
12 the portal. Obviously, it's the very beginning
13 of what we would want them to do. But then maybe
14 you want also to be able to measure whether
15 corrections are being made. And if they're
16 recommending corrections, whether the doctors' or
17 providers' offices are actually following through
18 and correcting it not only on their portal, but
19 also on whatever records are being kept in their
20 office and shared around.

21 I also wanted to --- because you know
22 on the previous thought that was suggested that

1 we should look at measures that are already being
2 used, there are a lot of them out there that
3 obviously that are already being used, especially
4 the patient readmission, consumer representative
5 patient readmission measures. So this a great
6 opportunity to look at it. I hope IT is
7 something that could avoid patients coming back
8 into the hospital, whether it's just giving the
9 patients their statements when -- what are they
10 called, checkout summaries, and patients get that
11 information when they leave the hospital and they
12 have it available and when their care giver,
13 family care givers, or hired care givers are able
14 to access that discharge record and everything,
15 it does reduce the number of times they're going
16 to be readmitted. So there's a way that we can
17 connect all that together.

18 CO-CHAIR SINGH: So we are still a few
19 minutes away from the break. And I'm actually
20 wondering if we should take a little of a middle
21 ground between what we have been discussing. And
22 we had a thought yesterday of each of these areas

1 and again there could be overlap. Come up with
2 some principles which could inform our measure.
3 So I totally agree. I think sort of the patient
4 engagement or patient centeredness ought to be
5 some sort of high-level principle. And again,
6 not exactly that same term, but you could change
7 the term for each of those levels and that could
8 inform sort of additional measures at each stage.

9 Do you all think that would be a good
10 idea to maybe expand our list of principles which
11 right now in Level 1 is only confidentiality,
12 data availability, and integrity. So just have
13 more of these for every level. I think shared
14 responsibility -- I'm not sure if that's a
15 principle, but that's kind of the sense of in
16 terms of what I'm thinking that we could then at
17 a high level say -- because we have to do the
18 same exercise in SAFER guides as well, so that's
19 where we came up with these high-level
20 principles. Then we said okay, let's develop
21 practices that nobody could argue with which are
22 very generic, not examples, but very generic,

1 high-level practices that inform these
2 principles. Would that sort of help people to
3 think through some type of measures and sort of
4 to get Eric's sort of point out what next and
5 let's move us forward? Thoughts from the room?
6 Karen?

7 DR. ZIMMER: Can I just question --
8 you keep saying shared responsibility. Can we
9 try moving to shared risk?

10 CO-CHAIR SINGH: Yes.

11 CO-CHAIR BELMONT: Yes, I had promoted
12 the idea of shared risk and I think risk -- I
13 think it is about sharing risk and I think the
14 responsibilities might be different depending on
15 if it's a provider or a patient or a payer. So I
16 would applaud going and using risk.

17 MS. FREEMAN: This is Lisa Freeman.
18 I think though that there are actually two
19 separate issues that they both have a place.
20 Because from our discussions yesterday, there is
21 the need for the shared risk which then leads to
22 the responsibility, but there seem to be a lot of

1 confusion expressed about who had
2 responsibilities for things, so that seems to
3 need clarification and focus.

4 CO-CHAIR BELMONT: We certainly can
5 make sure that we clearly articulate both
6 principles.

7 CO-CHAIR SINGH: So I want to hear
8 from some of the NQF folks. I mean is this sort
9 of exercise of maybe having some sort of a high-
10 level principle informing certain types of
11 measures? Is that something that you all have
12 done or could pursue?

13 DR. BURSTIN: I would ask David as
14 well. I mean I think it's useful, but I think
15 we'd also have to make sure as part of the
16 exercise we get some measure concepts on the
17 table, either ones that we could kind of prospect
18 that may be out there for sharing or ones that
19 may need a lead in ONC/CMS potentially to start
20 funding some development of some new measures.
21 So I think it's both. I don't think principles
22 alone would get us, I think, where you want to

1 go, David. Okay.

2 CO-CHAIR SINGH: So what next in terms
3 of measure concepts? I think Kevin --

4 DR. HAYNES: So real quick. I mean I
5 don't know if it deserves to be a principle, but
6 the word interoperability which we keep talking
7 about has direct applicability to data
8 availability, to data confidentiality, are you
9 able to touch it and then what we talked about in
10 our first group, data quality and integrity, do I
11 trust it. And so I wonder where you want to feed
12 in the principle of interoperability and then to
13 get to Eric's point, are there ways to measure
14 interoperability and to then say you are
15 interoperable or you get a star or whatever it
16 is. Is that an approach that we're approaching?

17 CO-CHAIR SINGH: And Kevin, and I'm
18 also thinking there's also additional levels,
19 right? So using health IT safely and so some of
20 these concepts, again, could go into can
21 interoperability fit better in Level 2 with a
22 little refined definition. I don't know. I'm

1 just sort of throwing it out on the table.

2 So each of these then would have --
3 what sort of measure concepts would we be
4 thinking about? Like do you want to give us some
5 examples of -- oh, sorry. Gregory and then Eric.

6 DR. ALEXANDER: Greg Alexander. So I
7 have a project that's funded by the National or
8 by Agency for Healthcare Research and Quality and
9 it's a national study about the use of
10 information technology in nursing homes. And one
11 of the concepts I use in that is called IT
12 sophistication. And it's a measure of
13 functionality which basically I have the
14 functionality available, yes or no. I have then
15 once they identify the facilities they're
16 measuring, IT sophistication. Once they identify
17 whether they have the functionality, then I ask
18 them to identify the extent of use of that
19 functionality on a scale. And then once they
20 identify that they are using it, then what's the
21 extent of integration?

22 So there are three levels of

1 measurement across functionality, extent of use
2 and integration, and it's measured within
3 resident care clinical support and administrative
4 activities. So it gives you a nice score. This
5 survey that I use gives you a nice score to be
6 able to sort of stratify where facilities are in
7 relationship to their IT sophistication. And
8 what my study is doing is looking over three
9 years, trying to get adoption over three years in
10 a national sample of nursing homes and looking at
11 quality measures and impact of quality measures
12 on IT sophistication. And that seems like, for
13 me, as I begin to think about how I would
14 understand the use of EHRs and their development
15 and implementation, it seemed like I had to know
16 what the functionalities were that were present,
17 how they were used, and how they were integrated
18 before I could begin to understand how to
19 measure, you know, each facility in a specific
20 way because everybody is at a different level of
21 adoption, level of integration, level of
22 functionality. And that measure was sort of the

1 first step for me. And I don't know if that's
2 applicable here, but it's certainly something
3 that I see used in health systems and hospitals
4 as well because my instrument, I actually
5 developed from a measure that was used in Canada.
6 It was actually an international survey that was
7 done in hospitals several years ago. And so I
8 just sort of throw that out there as a concept
9 that could be used as a measure.

10 DR. SCHNEIDER: Eric Schneider. Just
11 in terms of coming to criteria, actually, having
12 done measured prioritization, concept
13 prioritization and development exercises over a
14 couple of decades, one of the things I'm already
15 thinking ahead to is that we're going to need a
16 sheet that for each concept or measure describes
17 the attributes of that measure. And one of the
18 attributes could be which of the levels, the
19 three level framework does it touch or include.
20 One could be is it structure, process, outcome,
21 access, patient experience, cost or efficiency or
22 all of the above? Not usually.

1 One could be -- I think, Greg, you
2 might have even been suggesting one about is it
3 assessing integration. So anyway, there were
4 several questions we might ask about these
5 measures and coming up with that set of what will
6 become columns in some sort of scoring sheet
7 might be a useful exercise now because it will
8 guide -- what comes out of the group then is and
9 this is harkening back to my RAND life, what
10 comes out of this collective process is a set of
11 -- a sense of what are the things that we care
12 about that are important. We don't have to
13 settle on any one of them. We just need to
14 represent them in a way that everyone understands
15 what they are and then we can use them to select
16 and prioritize measures or measure concepts since
17 we are in prospecting mode which I think is a
18 great way to think about this.

19 CO-CHAIR SINGH: Eric, I'm going to
20 sort of see if you can tell us from your
21 experience and from what you've heard, can you
22 sort of give a little example so that everybody

1 can start thinking about starting from the
2 measure concepts and just go through? And you
3 don't have to do it right away, maybe at some
4 point in time I think it would be good for you to
5 just lay that down.

6 DR. SCHNEIDER: Yes, I'll share one
7 insight. For me, as I was musing about our
8 discussion yesterday that the eight component
9 framework you showed of the --

10 CO-CHAIR SINGH: Eight dimensions,
11 yes.

12 DR. SCHNEIDER: Eight dimensions, that
13 entire framework is really a structural look at
14 IT systems and so any measures that we would
15 develop about interface, for example, would
16 probably call in a structural category. And so I
17 found it useful in what's outside of that box.

18 And I think people raised the question
19 is the patient in the box or out of the box? And
20 then so the degree to which patient engagement is
21 directly assessed might be another attribute of
22 each of the measures. And it's not to say that

1 every measure would have to have all of these
2 attributes, but it would give us a sense of
3 whether we're covering several important areas.

4 So access is another one that has come
5 up. And since measurement is usually a
6 comparable exercise, we're interested in saying
7 is entity A -- how does entity A compare to
8 entity B? And that could be vendor A versus
9 vendor B. It could be hospital A versus hospital
10 B, physician A versus physician B.

11 What started to occur to me was we
12 haven't talked about access so there are probably
13 areas of the country that have the benefits of
14 functioning IT systems preventing harm and there
15 are other areas that don't. If they don't, we
16 would want to know that. So that's a useful --
17 that's an important area where you would want to
18 use measurement to sort of allow people to see
19 where they stand in relation to other
20 organizations in that regard.

21 These kinds of meetings tend to be
22 where all the high-functioning organizations

1 gather together and compare notes, but actually,
2 much of the country doesn't look like where we're
3 coming from.

4 Anyway, I'm happy to try to expand on
5 this as we go along, but that's just another
6 thought about how we might prepare for the next
7 round.

8 CO-CHAIR SINGH: Thanks.

9 DR. KHUNLERTKIT: This is Nana. So I
10 think what is missing from the measurement phase
11 is the implementation process. I think the first
12 one we are addressing, the design of the HIT and
13 the second one we are already jumping to the use
14 of the HIT, how to use it simply, but I think the
15 most very important things between the first
16 phase and the second phase is the implementation
17 process. I think it's going to be very difficult
18 to put measurement on the implementation process,
19 but you can at least just to ensure that you have
20 the right people at the table to voice their
21 concerns, meaning end users, about the
22 implementation of HIT, do they know how the

1 process is going to change, what the
2 responsibilities are going to be before the
3 implementation.

4 And we can probably do a shared risk
5 or shared responsibility here and ask the HIT
6 vendor to kind of address the most critical
7 concerns identified by the end users before the
8 implementation of technology. I think that's
9 very important.

10 CO-CHAIR SINGH: So Nana, it's almost
11 break time, do you have specific example of what
12 a potential measurement area or measurement would
13 look like? I mean a little bit more specific?

14 DR. KHUNLERKIT: I don't have a
15 specific measure because when I look at the
16 measures, I think it's the outcome, but this is
17 more like a process based, process focus. So I
18 guess at least an example would be I did the
19 workflow analysis for some of the units when we
20 implement HIT. And we did an FMEA, kind of the
21 same simulation process. We identified a lot of
22 potential communication breakdowns in the process

1 in which some of them are very critical and some
2 of them aren't. So we addressed the most
3 critical ones.

4 So if you say that after the analysis,
5 you have six very critical concerns that you have
6 to address, can the six critical concerns get
7 addressed before the implementation? That could
8 be the measure.

9 DR. SCHNEIDER: I'll also throw in the
10 example -- would be in the patient center medical
11 homework. People have talked about the
12 productivity loss associated with transformation.
13 And actually, I think an IT implementation, too,
14 or at least you see these numbers. We have 20
15 percent loss of productivity related to the six
16 months or a year of implementation. So that's a
17 measure.

18 And actually, that measure, I think,
19 is relevant in not so much -- it's relevant in
20 economic terms, but the relevance to quality and
21 safety is that that loss productivity is
22 probably, if you built out the logic model,

1 putting people at risk during that implementation
2 phase. So minimizing the productivity loss may
3 be an important measure of the safety of the care
4 that's being delivered by the organization during
5 that time.

6 DR. ALEXANDER: Greg Alexander again.
7 So I wanted to use your analogy of the apples,
8 oranges, and bananas. I think that's a good
9 analogy, sort of in this measurement discussion
10 because from the concepts that I was talking
11 about, you -- they may be all fruit, but you
12 can't really compare apples, oranges, and
13 bananas, if they have different functionalities
14 and different levels of integration and different
15 levels of extent of use.

16 And in regards to shared risk, that --
17 the vendors may provide the functionality, but
18 the organization makes the decision of whether to
19 implement it and how to use it and how to
20 integrate it. So some of those measures almost
21 need to have in order to understand how to
22 compare consistently apples to apples, oranges to

1 oranges, bananas to bananas, you know. I think
2 there's a level of granularity within that --
3 those fruits that we have to think about
4 measurement in this space.

5 CO-CHAIR SINGH: Yes, so good points.
6 And maybe for some we could get done to that
7 granularity and for some we may not be able to.
8 We've struggled within thinking about how to
9 measure some areas, yesterday and today, so maybe
10 those would be a little more higher level and
11 then some areas that we know better could be more
12 lower levels, maybe.

13 DR. ZIMMER: In Group 1 yesterday, we
14 did talk about FTEs for training, but we could
15 easily -- about FTEs for implementation as well
16 and sort of what's the commitment there because a
17 lot of times you are taking healthcare providers,
18 ancillary staff away from what they're doing to
19 do implementation or training, so somehow we
20 could tie that into some measure there.

21 DR. KHUNLERKIT: I think in addition
22 to the FTE for the implementation, I think you

1 have to have the right people who know exactly
2 how to do workflow analysis. Workflow analysis
3 is very time consuming. It's more like an FMEA
4 process and we should have to look into each step
5 very carefully. And you can't just go ahead and
6 ask one of your clinicians to do workflow
7 analysis because the results that you are going
8 to get is going to be very different.

9 I look at them more like expert
10 opinions, so you pull them onto your table
11 talking to them about your current work flow and
12 how the new work flow is going to be. But you
13 almost have to have that facilitator who can
14 facilitate the process and draw out the work
15 flow.

16 CO-CHAIR SINGH: Thanks so much. I
17 think we're at break time. So when do we return?
18 11:15?

19 DR. PINES: 11:20.

20 CO-CHAIR SINGH: 11:20. Thanks.

21 (Whereupon, the above-entitled matter
22 went off the record at 11:03 a.m. and resumed at

1 11:27 a.m.)

2 DR. CLASSEN: I'm just going to very
3 briefly go over another activity going on at the
4 National Quality Forum that would be nice to
5 integrate with this activity. The National
6 Quality Forum has a committee that has been in
7 existence for at least five years called the
8 Common Formats Expert Panel. And it's a group of
9 people that have been advising AHRQ on aspects of
10 the Patient Safety Act and those aspects relate
11 to reporting of safety problems using standard
12 formats. And Andrew is very involved in this and
13 so are a number of other people. And that group
14 has been helping AHRQ develop something called
15 the common formats.

16 And I wanted to give people a little
17 bit of background about patient safety
18 organizations because I don't know that a lot of
19 people know much about them. They've existed
20 since 2005 when the act was passed which created
21 patient safety organizations and established the
22 authority for reporting safety problems in common

1 formats and gave oversight of the program to
2 AHRQ. And the goal of this act was to improve
3 safety by reducing fears of malpractice
4 litigation, inadequate protection of safety
5 information by state laws, and inability to
6 aggregate this data on a large scale.

7 So this act created, if you might, the
8 peer review organization of the future based at
9 the federal level with protections at the federal
10 level. There have been lots of court challenges
11 to this law and it has survived every court
12 challenge so far, unlike court challenges to
13 state based peer review organizations which have
14 been slowly unraveled, so this may be the future,
15 if you will.

16 And AHRQ oversees this program. It's
17 been listing PSOs since 2008 and they're all over
18 the place. They vary. Their numbers are usually
19 somewhere in the 70s. They can get up into the
20 80s and down into the 60s. And these
21 organizations receive no federal support
22 whatsoever. So they have to find a way to keep

1 themselves in existence. And that's one of the
2 challenges with this particular program.

3 In all these states, and I'll just
4 skip through all of this, and almost anybody
5 could become a PSO except the ineligible
6 organizations that are listed at the bottom
7 there. So some big players cannot become PSOs in
8 the current format.

9 I'm actually -- here are some of the
10 first PSOs. ECRI was one of the first. So was
11 UHC and ISMP as well. But we're now somewhere in
12 the 70s.

13 And so PSO activities, they collect,
14 analyze patient safety data. They assist
15 providers to improve quality and safety. They
16 disseminate that information and they maintain
17 confidentiality and security of the data. The
18 data contained within PSOs, if it's correctly
19 designated, can be barred from discovery. So
20 there's the PSOs.

21 What the PSO legislature did not
22 address, as we've discussed, is what do we do

1 about vendors? And I think that's an oversight
2 that ultimately will need to be corrected in the
3 PSO approaches.

4 So let me skip through and go right to
5 the common format. So the idea is that PSOs and
6 providers would collect and analyze patient
7 safety data and PSOs would collect it in a format
8 that could allow the comparison, if you will, of
9 apples to apples. These formats are called
10 common formats and that's what the NQF committee
11 has been working with AHRQ on to develop. The
12 idea is that these common formats would allow all
13 PSOs to report data that could be aggregated up
14 at the national level and analyzed together.

15 And the way this would work is
16 providers or hospitals report data to PSOs. PSOs
17 would take that data, send it to something called
18 the Privacy Protection Center, which would de-
19 identify the data and then it would send that
20 data on to the network of patient safety
21 databases for national analysis. And that the
22 only way this would work is if there was some

1 sort of common definitional approach to this
2 information. And that definitional approach is
3 called the common format. So that's why they're
4 there.

5 And what AHRQ has been doing is
6 creating these common formats with the help of
7 the NQF Committee that would standardize common
8 language and definitions and standardize rules
9 for data collection and the whole idea was to
10 create content here that could be automated. So
11 from the very beginning, we were creating
12 content, we hope, would go into voluntary
13 reporting, incident reporting, vendors and DMRs,
14 what have you. This would be electronified. So
15 we were not trying to create a lot of paper
16 forms, although you're going to see them. We
17 were trying to create things that would go right
18 into IT systems.

19 So we wanted them to be driven by the
20 front-line user and we wanted them to be
21 scientifically valid and we wanted them to
22 conform where possible to any existing

1 definitions such as the CDC's hospital acquired
2 infections. So there was a lot of work to
3 harmonize that.

4 We decided to focus on harm at the
5 beginning here. We started to focus on hospitals
6 at the beginning here, but we've now expanded
7 from hospitals to long term care to now we're
8 moving into the ambulatory pharmacy world. And
9 we constructed modules. And we tried to address
10 all safety issues whether they be actual events
11 or near misses or unsafe conditions. So this was
12 intended to be something that would address all
13 these areas, not just incidents.

14 And we created a modular format for
15 these things. And the part of this that is going
16 to be very relevant to us is the event-specific
17 forms. But it was felt that there needed to be
18 some overall forms and there needed to be some
19 event-specific forms. So in terms of the overall
20 forms, we call them the HERF, the PIF, and the
21 SIR, and they're basically crazy names for things
22 such as summary of initial report, patient

1 information form, and healthcare event report
2 form. They're general forms that would apply to
3 any condition. And then the idea was that in
4 addition to them, we'd have more event-specific
5 information and that event-specific information
6 is listed here on the lower left.

7 And you can see one of those event-
8 specific things relates to HIT, our charge here.
9 And that's what I'll show you.

10 On the right, you see the technical
11 specifications and that was the idea that all the
12 content we created would be easily programmed in
13 IT systems. So a lot of effort went into taking
14 what we developed in terms of content and turning
15 it into technical specs. And a lot of instant
16 patient reporting vendors have done that.

17 So here's the form that relates to
18 what we do and I would call this version one.
19 And we seek any input to improvement and one of
20 the things I hope that comes out of this is that
21 this committee can give us some guidance and work
22 with us over time to improve and refine this

1 common format. And the decision was made to
2 include HIT with medical device, but I call this
3 1.0 because we're certainly willing to take any
4 feedback if this group feels that maybe they
5 should be split and we had a lot of debate about
6 that. That's fine. Or enhanced in any way.

7 There is an enormous amount of
8 pressure for us to make a minimal data set from
9 our common formats because a lot of the vendors
10 and the front-line users have said it's just too
11 much detail in here for us. I'm sure Bill can
12 hear that loud and clear. So one of the things
13 we are in the process of doing now is to create a
14 tiered approach with the minimum tier and that
15 would be a small subset of what I've shown you.

16 So I don't know that we need to go
17 through this form, but we're glad to send you a
18 copy of it, but it clearly is version 1.0 in my
19 view, although we call 1.2, it can be approved.
20 So I'll stop there and see if you have any
21 questions.

22 DR. SEGAL: Two quick questions. One,

1 I have a recollection that folks have talked
2 about the common formats being more focused on an
3 in-patient basis and let's say less applicable to
4 a five doctor physician practice. And the follow
5 up is there's also been work that Jim Walker, I'm
6 sure you're well aware of, has done on hazard
7 manager. And I think that's actually -- both of
8 these are being used at ECRI. And I'd just be
9 interested in what you see as the relationship
10 between the hazard manager kind of instrument and
11 the common format as it stands now, so both the
12 ambulatory piece and the hazard manager.

13 DR. CLASSEN: Thanks, Mark. The
14 ambulatory piece is our next generation. So we
15 started in the hospitals and we went to the
16 skilled nursing facilities. And I think our next
17 stop is going to be the ambulatory. It's
18 starting in the pharmacy ambulatory arena, but I
19 hope that we're going to expand much further in
20 ambulatory. We've got a lot of feedback that
21 ambulatory is a critical area that we need to
22 focus on, so it is my understanding that's where

1 we're headed.

2 And then the other issue of the
3 hazards measure and integration with this, I
4 really think it would be helpful to integrate the
5 two and that might be one of the recommendations
6 that comes out of this group that we would react
7 to. This is to me version 1, although we call it
8 1.2. I think we need to move on to version 2, 3,
9 and 4. So if you're willing to make that
10 recommendation, I think we'd love to entertain
11 it.

12 DR. ZIMMER: So I was the ECRI lead
13 for hazard manager with Jim Walker when we built
14 it. And I would at least encourage you to look
15 at that taxonomy because when we talk about the
16 HIT and we've talked about upgrade issues and
17 things like that, the hazard manager uses the
18 language that a lot of the vendors use and this
19 was so much that I know for Toby they actually
20 incorporated it in some of their own
21 classification. So it's at least worth -- I mean
22 the taxonomy is up on the web. It's public

1 domain.

2 CO-CHAIR SINGH: Jason.

3 DR. ADELMAN: If I may, I'm just going
4 to use this opportunity to give feedback from one
5 -- the patient safety officer from one
6 institution that -- I'm a big believer in the
7 common formats and the mission here, so I require
8 that we strictly follow it at Montefiore. We're
9 a 2000 plus bed health system. Most of our
10 adverse events are reported from nurses. We're
11 trying to get more from house staff and from
12 attending physicians.

13 We have about 50,000 reports a year.
14 And what I'm told is that many, many of the
15 nurses don't understand the questions here. And
16 there's a lot of pressure to change the language
17 that's in the common formats including like
18 what's a HIT device? They don't convert it to
19 HIT. They just don't understand what it is. I'm
20 just looking at the screen now like ergonomics
21 and I'm wondering if any of this has been user
22 tested and if there's been any similar feedback

1 like this about just the general language that's
2 used in the common format, especially on the
3 issue of HIT.

4 DR. CLASSEN: I think we should ask
5 Bill to comment. He has had a lot of experience
6 with it. So --

7 MR. MARELLA: Yes, as has Karen. So
8 I mean I think we probably have the same
9 experience. So I guess with the AHRQ common
10 formats, there are two problems. One is the one
11 that Jason is describing where clinicians are not
12 going to necessarily appreciate the nuances
13 between what's third-party content in my EMR?
14 What's the EMR? What's CPOE? And how is that
15 different from the EMR? So that's one problem.

16 The second problem is that some of the
17 questions being asked, there's probably no way
18 that a front-line clinician who is using the
19 internal risk management information system could
20 answer these questions, like what software
21 version am I on? They have no idea. So that's
22 one issue.

1 The other is that a lot of the data
2 being collected by patient safety organizations,
3 including ECRI, is coming in mapped from internal
4 risk management information systems. And those
5 mappings range from okay to absolutely horrible.
6 And if people don't have fields in those RMISs,
7 they can't map from those fields. So even though
8 we have a place to put the data, they're not
9 necessarily collecting it.

10 So what we're looking to do is
11 hopefully to use some natural language processing
12 tools to mine the narrative and the stuff that we
13 do get pretty reliably so that maybe we can start
14 to answer some of these questions and the
15 background. And in some ways I kind of think
16 that's where the future lies for the EHR in the
17 clinical environment is you're not going to teach
18 the doctor or nurse on the floor SNOMED, or at
19 least we shouldn't be trying to do that. Let
20 people figure that out in the background and let
21 them document the way they want to document and
22 we need to code the data for them.

1 CO-CHAIR SINGH: Jason Jones.

2 DR. JONES: So I just learned a
3 technique. If you hit the red button and then do
4 that immediately, you remember. That's a process
5 improvement. Thank you.

6 I was explaining earlier how I have
7 five urinary catheters because I keep forgetting
8 to remove them.

9 Do we have early data? Is there
10 anything you can share about is it working like
11 to your point, people don't understand the
12 questions and we're seeing it in the data?
13 Because geez, I hadn't known about this and I'm
14 just looking at some of the questions that we've
15 talked about. Maybe they would be useful and a
16 lot of them are in here, plus a bunch of others.
17 What are the data showing at this point?

18 DR. CLASSEN: The data are showing
19 that it's really hard to collect all this
20 information up front. The idea was originally
21 that these common formats would be the minimal
22 data set in any instant reporting system and that

1 hospitals or PSOs might ask more questions in
2 addition to it. And that the only thing that
3 would be reported up would be this. Those other
4 questions of PSOs would never go to the national
5 databases. The problem is, it turned out, that
6 this was so much more information than was
7 already being collected that it was not a minimal
8 data set. It was a maximal data set and so
9 feedback came, this is just too much in addition
10 to we don't understand, etcetera. So now we're
11 going back to a process to really slim this down.

12 But I think in addition, we heard that
13 users don't really completely understand these
14 questions and I think the intent originally was
15 that you would never see a form like this. This
16 would all be programmed in an instant reporting
17 system and it would have levels of questions for
18 the front-line reporter and then the
19 investigator. And so the front-line reporter
20 would not see a lot of these questions. They'd
21 see very simple versions of these and then it
22 would go up the food chain and be more thoroughly

1 investigated and evaluated.

2 And so I think the hope was that the
3 incident reporting vendors would start
4 programming this into their system, so that when
5 Bill gets it, he gets it in this format because
6 the vendors have adopted it and I think that
7 challenge has been a real big one to date because
8 a lot of the incident vendors have not moved
9 quickly. So I think there are several challenges
10 here. That's why I call this 1.0. Although we
11 call it 1.2.

12 DR. JONES: Is it out?

13 DR. CLASSEN: It's out.

14 DR. JONES: So are there fields where
15 you feel like you are, we are getting some
16 populated --

17 DR. CLASSEN: Yes, we are getting
18 information from it, but the problem is we have
19 pretty strict requirements in terms of how that
20 information will be accepted by the Privacy
21 Protection Center. And there have been some
22 efforts to submit data there and it had so many

1 problems with it, it couldn't get cleared to move
2 on to the network of patient safety databases.

3 DR. ZIMMER: It was an ONC-sponsored
4 project with West that ECRI actually looked at
5 HIT forms and all the information that goes into
6 the common format.

7 MS. KENYON: I would recommend that if
8 you're interested in -- we did a study of -- we
9 financed a study of two PSO databases, one, the
10 ECRI database, and the other the UHC database.
11 And the results of those analyses are in a report
12 that I can -- we can add to the share drive if
13 you'd like.

14 Among other things what they found is
15 that people aren't answering the question about
16 the involvement of health IT at all, especially
17 in the ECRI database. It was actually not enough
18 people answered in a database that had several
19 hundred thousand people in it to do much of an
20 analysis.

21 Am I correct, Karen?

22 DR. ZIMMER: Yes, but one thing that

1 was interesting that came out where people did
2 answer information is when they talked about a
3 device, they felt very comfortable following all
4 the way through. But for HIT it did not fall out
5 that way which made me question are people just
6 not able to identify it and we did write also an
7 ONC-sponsored guide on identification of health
8 IT.

9 MS. KENYON: It also does not have
10 great predictive value. In other words, when you
11 compare the answer to the structure data on
12 health IT to them looking at the narrative
13 fields, you find that often things that are
14 identified is health IT related or not and things
15 that are not identified as health IT related are.

16 So clearly AHRQ is aware of the
17 results of that analysis and I think they are
18 struggling with the fact that in fact, the common
19 formats are not being used as designed. As David
20 said at the beginning, they really were designed
21 to be used where there's direct entry into them
22 and not the kind of mapping that Bill just

1 described. And so we also did a study on risk
2 management that Eric led when he was at RAND, and
3 Karen worked on. And it is the case that people
4 find reporting right now using the common formats
5 to be burdensome.

6 And so I think that where we are right
7 now, we've got a pretty good framework, although
8 you can't identify diagnostic errors as Dr. Singh
9 will note. But that you've got a good, basic
10 kind of framework, but that it's not really -- it
11 needs to be improved to be used as intended. And
12 a lot more education needs to occur.

13 DR. ZIMMER: And one other thing I was
14 going to add which I can also send to you which
15 is also public domain, the hazard manager final
16 report. The hazard manager final report would be
17 useful, but what was interesting, David, I would
18 just add, is what we saw with hazard manager,
19 depending on who entered the information, the
20 type of information, the completeness varied. So
21 if it was a front line versus someone from the IT
22 department, you had very different information

1 coming in to your hazard manager which gets to
2 your point. It's not set up that the front line
3 sees some questions and it goes up the chain.
4 It's never been set up that way, although that
5 would be a logical way to do it.

6 DR. CLASSEN: We thought that the
7 vendors of these systems would do that and
8 obviously, it hasn't occurred.

9 DR. GANDHI: So just to echo a couple
10 of points. I mean I was involved for about a
11 decade with a safety reporting system and trying
12 to get 10,000 employees of an organization to
13 fill this thing out in a consistent way is
14 impossible. And so then to map what they're
15 filling out to these, bad data leads to bad data.
16 So I don't want to sound heretical, but I think
17 that the safety-reporting concept has had some
18 value, but it's really hard to get really solid
19 data, especially since those safety reports are
20 being reported within a couple hours of the event
21 happening. The person reporting has no idea
22 whether it was an HIT-related issue or not.

1 There's usually not good processes to go back and
2 update it once people have actually done the
3 investigation and figured out what it is or isn't
4 because those resources aren't in place to go
5 update things.

6 So I think this is really challenging.
7 And so I want to come back to a comment that Bill
8 made which is I really think we're going to have
9 to think about other novel ways like natural
10 language processing to look at narratives and
11 triggers and those kinds of things, because I
12 just think that to expect front-line people to be
13 able to provide this data and the way it's
14 currently set up at least is going to be very
15 challenging.

16 MR. MARELLA: Two other quick points,
17 to build on what Karen was saying. There are
18 silos in the healthcare organizations so a lot of
19 the -- in addition to sort of not recognizing or
20 clinical people not recognizing the IT component
21 of a safety event, there's also the situation
22 where IT related information is getting into the

1 safety systems and we do have thousands of health
2 IT related events in our reporting systems, but
3 there's also the situation where there is safety
4 information in the help desk logs in the IT group
5 that is not necessarily recognized as safety
6 issues and may never be brought to the attention
7 of the risk managers of patient safety officers.

8 So those silos need to be broken down.
9 Some people do pretty well with that and there
10 are IT people who participate in root cause
11 analysis when IT is involved in an error. But I
12 think that's the exception rather than the norm.

13 The other -- I guess the other
14 confounding factor with the common format
15 specifically is that they call out health IT
16 errors as a separate category when as several
17 people made the point yesterday, IT is usually a
18 contributor to other problems or problems that a
19 clinician would frame in another way, like a lab
20 test not followed up on or a medication error
21 that got to the patient. There are forms for
22 those and that's where a lot of the health IT

1 events are winding up.

2 CO-CHAIR SINGH: So I'm going to sum
3 up and I think I've heard lots of good things
4 here. First and foremost, I think HIT ought to
5 be separated from devices. That was a quick,
6 easy answer I think.

7 I agree with Tajel. I think if you're
8 going to get -- especially if ONC is going to --
9 and AHRQ, is going to heavily invest and make
10 reporting such a priority, we've got to make it
11 easier on people to report this to us. So I want
12 to know from everybody else if I, as a clinician,
13 just can put in very basic data, is that data
14 could then be analyzed at that institutional
15 level or at the PSO level? So I want to know are
16 the PSOs getting involved with health IT
17 expertise so that they can go figure out whether
18 there's something going on that is HIT related.

19 I really think you need to do a
20 crosswalk, not just between the hazard manager
21 and what the current categories are, but also
22 within the five dimensional categories that we

1 have in our paper in JAMIA which is the five
2 categories I showed you yesterday which sort of
3 breaks it down.

4 I don't think clinicians can do that.
5 I don't think nurses can do that. It has to be
6 done by somebody else, whether it's having an IT
7 person on an RCA type of a team on an
8 institutional level or having the PSOs involved.
9 I actually want to know what the PSOs are doing.
10 Do we have any transparency? I know that's
11 protected data and what are they doing? Can we
12 see what they're analyzing not just at the PSO
13 level. We want NPSD, National Patient Safety
14 Databases -- so I know we haven't come to that
15 level. That is now our only source of nationally
16 aggregated patient safety data related to
17 potentially HIT, correct? Am I missing
18 something?

19 (Off mic comment.)

20 Which nobody sort of reports on. So
21 if I want to know if lab results are being
22 terribly displaced, sorry if vendors are here,

1 are terrible displays in EHRs and clinicians are
2 missing critical test results because the flags
3 and the displays of lab results are bad across
4 most EHRs and again, I'm taking an extreme
5 example, how do I get to know that at a national
6 level?

7 MR. MARELLA: So there are a couple of
8 barriers there. One is that AHRQ and the
9 National Patient Safety Database, I'm not sure if
10 this is part of the statute or part of the
11 interpretation of the statute, but AHRQ is not
12 going to be getting the free text of these
13 events.

14 And it's a very severe limitation in
15 terms of their ability to do anything with this
16 data because not only does it prevent them from
17 mining that data which frankly that's the single
18 most important field to us and that's the basis
19 of most of the analyses that we do. But it also
20 prevents them from using it to QC the structure
21 data they get and as a couple of people
22 mentioned, you can't train a clinician who is

1 only going to use the patient safety reporting
2 system a couple times a year to be an expert in
3 the taxonomy. That's just not realistic. So I
4 think that's one limitation.

5 Another is the extent to which even if
6 AHRQ did have that, would they be able to turn
7 that loose and make that available to researchers
8 to mine that more broadly. We know that
9 reporting is a tool. It's not an end in itself
10 and it's good for some things, not good for
11 others. It's generally not good for developing
12 incident statistics other than maybe getting to
13 like a floor of how many things might be
14 happening. You can say the problem is at least
15 this bad. And I think at the PSO level, ECRI,
16 ISMP, a lot of other PSOs, UHC, have been doing
17 really good work aggregating data, synthesizing
18 it and putting out recommendations. The extent
19 to which those recommendations are followed, you
20 know, chalk it up to clinical guidelines, how
21 often are they used. A lot of times we don't
22 really know. We don't get that kind of feedback

1 in a systematic way.

2 So I think if we want to move the
3 field forward, PSOs already have a lot of
4 information on health IT. We're publishing it.
5 We don't know the extent of the uptake of
6 whatever recommendations we're putting out and
7 when those recommendations are even helpful or
8 maybe themselves have --

9 CO-CHAIR SINGH: Exactly, Bill. I
10 mean you have lots of -- ECRI has a PSO, so
11 ECRI's had a great report two years ago, right,
12 or two and a half years ago. What changes have
13 occurred at the institutional level from those
14 reports? Has the feedback gone to the
15 institutional report -- your system-to-system
16 interfaces are a real problem and things like
17 that?

18 MR. MARELLA: So that's -- I'll ask
19 Karen to come in on this, too, because she was
20 responsible for that report. But I think we
21 don't get that level of feedback in a way that we
22 can synthesize easily. I mean we get anecdotal

1 feedback from people about the reports. But the
2 extent to which changes are made as a result of
3 those recommendations, we don't get that any more
4 than guideline developers typically get that kind
5 of systematic feedback.

6 What we have seen and actually Mark
7 referred to this study earlier at the Patient
8 Safety Authority in Pennsylvania, we're getting a
9 lot of data and we're getting about two million
10 reports a year at this point, more than that,
11 actually, sorry 250,000 reports a year. From
12 basically every hospital and ambulatory surgery
13 center and nursing home in the state. And we did
14 a study looking at whether implementation of an
15 advanced EHR improved or was a detriment to
16 safety. The only way we can look at that is
17 through the imperfect lens of adverse event
18 reports and medication errors and things like
19 that. So we know that not everything gets
20 reported that happens, but we ask ourselves what
21 happens after implementation of the EHR. And
22 what we found was that 25 percent declined when

1 we compared facilities to themselves one year
2 earlier. We found like a 25 percent decline in
3 all adverse events and medication errors
4 specifically.

5 So we didn't -- I was talking to David
6 about this this morning, we didn't know what the
7 null hypothesis should be in that study. Was
8 health IT going to make things better, worse, or
9 have no effect. So we were actually kind of
10 gratified to see that there did seem to be a
11 positive effect at least in terms of spontaneous
12 clinician reporting. So that's at least one
13 measure we can point to, but an imperfect one.

14 CO-CHAIR SINGH: So I think it's Mark,
15 Greg, and then back to Karen.

16 DR. SEGAL: A point and then a point
17 question. So the point, I think, Hardeep, you
18 mentioned distinguishing HIT from device or not
19 including devices and I guess there I would just
20 do a caution that if we're going to think about
21 the FDA's definition of a device some health IT,
22 PACS systems, others, they would consider a

1 device. It seems to me that rather than keeping
2 them separate, you just don't conflate the
3 concepts. In other words, we want to focus on
4 health IT, however defined, whether or not it's
5 defined as a device from a regulatory standpoint
6 because if you think about the kinds of issues
7 we've talked about, they are every bit as
8 applicable to a PACS, FDA-regulated as a device,
9 than to an EHR.

10 What I think the problem in looking at
11 the common format is that it combines the terms
12 in ways that are confusing. The point or
13 question is in terms of the data that's collected
14 by PSOs through the common formats or otherwise,
15 one of the questions that I've had persistently
16 and this came up when there was a PSO who is no
17 longer around that was working with -- they were
18 going to really focus on EHRs, was the extent to
19 which they were in a position to do root cause
20 analysis. And I know from our company
21 standpoint, as I talked to our experts who work
22 on this, root cause analysis is really critical,

1 particularly was it HIT or not and in what way.

2 So I'm interested in to what extent is
3 the reporting, using the common formats,
4 generally, sometimes typically, reflecting a root
5 cause analysis or is it sort of information
6 that's really before the institution has done a
7 formal root cause analysis. And I think that
8 becomes really important as we look at national
9 aggregation. So if someone can address that,
10 Karen or Bill?

11 DR. ZIMMER: A couple of things. One
12 thing I think we can really take away from the
13 Pennsylvania process is there's -- that's the
14 only mandatory reporting, near-miss reporting in
15 the country. And remember, PSOs are voluntary,
16 so you've got to keep those apples and oranges
17 separated.

18 But one of the processes that we saw
19 as a real benefit with the Pennsylvania data is
20 they actually have something set up where someone
21 might trigger an initial event, but then the
22 patient safety officer then goes in and adds

1 information. And I happen to sit on a committee
2 of a hospital in Pennsylvania where I see the
3 discussions of their patient safety committee.
4 And so I know that they're then working on
5 submitting to PACeRs on adding with all that
6 additional information. That doesn't happen with
7 the common formats. One person enters and then
8 it's done. So there's a disconnect there, but
9 something clearly can be learned from
10 Pennsylvania because in many ways they get more
11 details and a little more accuracy in the details
12 as opposed to someone just complaining about Dr.
13 X or Nurse Y because that's where they are
14 emotionally.

15 The other thing on the West data, I
16 just wanted to realize the project had a couple
17 different steps. So we strictly looked at not
18 only how the structure fields were formed in the
19 common formats, but then knowing that we already
20 knew we were dealing with map data and it
21 wouldn't yield what we were hoping, we did look
22 at the free text. And we took that free text and

1 reapplied the free text to both our common
2 formats and Magrabi. And there wasn't enough
3 information in there to talk to -- address it to
4 Magrabi's classification.

5 I don't know if you're familiar with
6 the Magrabi. It's what's used for the FDA. It
7 was a little bit more drilled down, more
8 granular, whereas we could at least answer the
9 high-level questions of the AHRQ common format.
10 Again, we're repeating ourselves to get to that
11 more detailed level. You need other eyes on it,
12 like a hazard manager.

13 DR. CLASSEN: The original intent was
14 that there would be different forms filled out
15 by, Karen, by different people. So we've been
16 just talking about the event forms. But if you
17 look, the idea is there would be an initial
18 report and different people in the organization
19 would fill that out. My understanding is that
20 the vendors have really not followed that idea
21 and have left it up to some one person to fill
22 everything out which we never expected would

1 happen.

2 CO-CHAIR SINGH: So Greg and then Jim
3 and then we should move on to the next.

4 DR. ALEXANDER: Greg Alexander. Mark
5 actually said what I basically was thinking is
6 that I have my clinician hat on and I'm thinking
7 about incidents that have occurred in the past
8 where a patient was given ten times the normal
9 dose of potassium because the nurse thought that
10 there was saline in the vial that she drew the
11 potassium up. And when we got to looking the
12 vials of potassium and saline were both green
13 colored that looked almost exactly the same.

14 So I was thinking about how I would
15 use this common format as a way of reporting that
16 and at the time that that happened on the shift
17 that we were working, the nurse was devastated.
18 I don't know that she could possibly comprehend
19 all the things that were going on at that time
20 because she just nearly killed somebody. So
21 reporting at that point in time was probably
22 going to be a difficult thing for her to do.

1 And at the same time, we all
2 immediately recognized the problem, so everybody
3 was afraid of these vials all of a sudden, so
4 practice was affected around that time. And once
5 we did the root cause analysis which was probably
6 within a week of getting that done, we realized
7 that there was sort of this chain reaction of
8 events that needed to be dealt with from the
9 nursing staff to the supplier of the vials to the
10 purchasing department that made it all the way up
11 to the vendor. And that probably took months to
12 really generate the solutions to make that
13 activity possibly not happen again.

14 And I was wondering how you would
15 utilize this common format in a way to capture
16 all of that because all those points of entry
17 into that problem, all the way up the supply
18 chain are really critical to making that -- and
19 that has a national potential impact because the
20 vials were being purchased by multiple
21 facilities. So you know, I could see where this
22 could be helpful, but you've got to get that sort

1 of root cause analysis and process all the way
2 through captured.

3 DR. CLASSEN: So just to answer that
4 question, it was AHRQ's view that they would
5 create common formats beyond these that would
6 address the root cause analysis process.

7 MR. RUSSELL: This is more of a
8 question for Bill and Karen. At least my
9 understanding what is the timeliness of the
10 information that you get from the organization
11 through the PSO and how that can work for you?
12 Because my understanding is the timeliness is
13 very variable.

14 MR. MARELLA: It's very variable,
15 probably among PSOs, and even within a PSO, it's
16 variable among institutions submitting the data.
17 So one of the things that we're doing is we're
18 going to be implementing a lot of automated
19 systems that are going to push information
20 directly from the RMIS into our systems and I'm
21 sure other PSOs do the same, are looking to do
22 the same things. So it will start to get much

1 closer to real time for more people, but then
2 there's also the distinction between PSOs, like
3 UHC, for example, they're getting probably better
4 and more information than a lot of PSOs because
5 they are an internal RMIS as well as a PSO. So
6 there's no lag there for them in the way that
7 there is for ECRI or for the PSA.

8 CO-CHAIR SINGH: Thanks. Karen, we've
9 got to move on unless you want a quick five
10 seconds.

11 DR. ZIMMER: Because Bob, RCA's,
12 that's the other reason we might have a delay.
13 What often will happen is they'll put an initial
14 event in. They'll revise it and we at ECRI, I
15 had integrated a section on RCA because of that
16 importance and developed a lot with our whole RCA
17 service.

18 CO-CHAIR SINGH: Thanks, David. So
19 David, thanks so much. I think you got more
20 feedback than you probably wanted.

21 Okay, great. And also I think so
22 Jason made this point as well sort of maybe doing

1 a little bit more user, end user testing and trip
2 to the field and talking with some of these guys
3 who are actually using.

4 David, all yours.

5 DR. HUNT: Thank you. In case I
6 really haven't formally said this before, I want
7 to make sure that I thank all of you on behalf of
8 Dr. DeSalvo and Andy Gettinger and the entire ONC
9 safety team for all of the work that you have.

10 Now I'm going on a strict, self-
11 imposed time limit for this primarily because I
12 promised to be a phantasm at this meeting, you
13 know, barely seen and infrequently heard. As my
14 kids can confirm time and time again, I've been a
15 spectacular failure in that regard.

16 So the main idea is that I want to
17 make sure we can really maximize your freely
18 offered and well considered input. You see, time
19 is always at a premium and we would do well to
20 get everything we can out of the precious two
21 days that we have with you here.

22 So I want to discuss our safety

1 program writ large. But before I say anything
2 else, I have to make it very, very clear that at
3 ONC we hold this truth to be self-evident that
4 the first, second, and third job that we have
5 over these next few years is to liberate data
6 that is locked in EHR silos, interoperability.
7 And securing those blessings of liberty for
8 ourselves and our posterity, will remain an issue
9 of patient safety.

10 So with that, I'll offer this overview
11 of the very work that we're either leading or
12 coordinating in safety at ONC. And I really want
13 to emphasize the fact that we at ONC do our best
14 when we're behind the scenes often as
15 matchmakers, sort of linking resources with
16 opportunities. And that said, I should make it
17 very, very clear that the ONC health IT safety
18 program begins and ends with an incredible debt
19 to our teammates at the Agency for Healthcare
20 Research and Quality, AHRQ. They are the
21 department lead on patient safety and everything
22 that we at ONC that we've done that's been

1 positive in this domain has been with the full
2 knowledge and support of AHRQ.

3 So it's really fitting, actually, that
4 I begin this discussion with some of the early
5 work that AHRQ commissioned, looking at patient
6 safety data standards. Now this work was
7 actually led by Paul Tang who, as many of you
8 know, is the co-chair of our Health IT Policy
9 Council. And well back in 2003, Paul and some
10 others wrote a report that was issued through the
11 IOM on patient safety data standards.

12 Now I fear that myself, Paul, maybe
13 David Classen and Jim Battles were the only ones
14 who read this report. It was -- oh wow. Okay.

15 See, that's the fear. It was an
16 excellent report and one of the reasons that I
17 really love it is that it provided the clearest
18 exposition that I've heard on the relationship
19 between the work that we do in quality and the
20 work that we do in patient safety. And I love
21 the way that they phrased it.

22 See, Paul and his team really wrote

1 that patient safety is indistinguishable from the
2 delivery of quality care. And I find that
3 statement profound in its subtlety as well as its
4 gravity. And that fact is really echoed again
5 and again in the next IOM report on the
6 intersection of health IT and patient safety.

7 And as you know, we commissioned this
8 report in 2011. Paul was also on the IOM team
9 that issued this and as you've heard, they made
10 ten major recommendations which in analysis
11 really translates into 31 specific actions that
12 ONC might do. And the key findings are always
13 appropriate to highlight again and again, namely
14 that we know some of the great low-hanging fruit
15 in health IT patient safety, medication
16 management, for example. But beyond that, there
17 are some significant gaps that we have in our
18 knowledge in this domain. They really took note
19 of the complex social technical system and the
20 environment the health IT is in. And we
21 discussed that yesterday. And because of that
22 complexity, they really made it clear that

1 success can only be possible if all stakeholders
2 really have a voice in our direction and the
3 speed that we have moving forward.

4 So with that in mind, we at ONC, we
5 advanced our health IT patient safety plan with
6 the two foundational goals. And I'm again very
7 happy that these concepts have really found a
8 prominent place at the table in our discussion,
9 first, that health IT can make care safer, and
10 second, that we must provide to improve the
11 safety and safe use of health IT.

12 With that, all of the work that I'll
13 describe further on has a connection to the plan
14 and to these goals. And to those ends, we think
15 that the plan was a really good first response to
16 the IOM recommendations. In particular, it
17 emphasizes building on existing authorities
18 within the Department and I hope you'll see that
19 our work to date really strengthens some patient
20 safety efforts inside the Federal Government as
21 well as in the private sector. Now this has been
22 a real brief overview of the plan and the work

1 that led up to it, but let's look at some of the
2 few things that we've done since the plan's
3 publication.

4 Now another important initiative that
5 has been recently started actually with this
6 fiscal year has been the health IT safety roadmap
7 project which, as you know, is being led through
8 RTI and Linda's group. Now the project has three
9 main aspects: to assemble a task force that
10 develops a road map, education and engagement,
11 and analysis and research.

12 Now they'll produce a road map for a
13 national health IT safety center using a planning
14 process that really solicits private sector
15 stakeholder and input. They'll conduct programs
16 and analyses for the immediate advancement of
17 health IT with an aim to really raise the
18 awareness of health IT safety-related initiatives
19 and the research around them and some of the best
20 practices. Now they currently are collecting
21 information on stakeholder acceptance and uptake
22 for possible health IT safety center activities.

1 Now the potential considerations that
2 the task force will ponder, in addition to some
3 of the educational programs and data analysis
4 that we've already mentioned, they'll look at
5 support for the work of this group as they
6 develop a system of measures for specified goals.
7 So they're going to incorporate a lot of our work
8 product and thinking as we go on. And most
9 importantly, the plan is, the idea is that
10 they'll provide a safe forum for open and frank
11 discussion.

12 Now obviously, governance and funding
13 are particularly acute areas of interest that
14 they're going to have to really weigh in on and
15 so clearly I think that we are all very, very
16 interested in the work products that Linda and
17 her team will create.

18 Now one product that's already a hit,
19 no pun intended, is the health IT safety webinar
20 series. I highly recommend that everyone here
21 stop in for one of them and encourage your
22 colleagues to do so also. Now again, I can't

1 emphasize enough how much our work at ONC is
2 really enriched and predicated on our partnership
3 with AHRQ. AHRQ is, as I mentioned before, the
4 patient safety lead for the Department and they
5 house the bulwark of the Department's resource
6 and expertise in this domain.

7 So we at ONC, we meet with the AHRQ
8 team formally about every month with weekly,
9 sometimes daily conversations in between. We've
10 been very fortunate enough to have been able to
11 share John White from AHRQ, as our deputy
12 national coordinator for the last few months.
13 And I'm not sure if any of you know, but AHRQ has
14 recently announced another round of grants with
15 special interest and emphasis on health IT
16 safety.

17 Now I've taken an excerpt from that
18 recently-published notice that you have right
19 here. And you can see the funding will help us
20 better understand design, usability, and
21 implementation issues. Now you should know that
22 this is actually the second consecutive year for

1 this funding. Last year, you may have heard
2 already that we have grants from Montefiore,
3 looking at the risk of wrong patient errors when
4 a number of different records are opened at once.
5 We have two grants -- they have two grants to
6 Brigham and Williams, one for the CPOE flight
7 simulator, as you've already heard, and another
8 reengineered CPOE to incorporate drug indirect
9 indications in the orders.

10 Finally, there's one at the University
11 of Nebraska for improving EHR work flow with some
12 pretty specific and well-tailored scenarios that
13 we have.

14 So AHRQ's strength is clearly in
15 research. And ours at ONC centers more around
16 policy and development, particularly for the
17 certification program, but also for meaningful
18 use also. And two key resources that we have are
19 our health IT policy and our standards advisory
20 committees. Now each of those, you know that
21 they are legislatively mandated, each of those
22 committees has a number of work groups and here

1 you can see six of the work groups of the Policy
2 Committee.

3 Now the health IT implementation
4 usability and safety work group which is an
5 offshoot of the Policy Committee, they'll provide
6 input and make recommendations on some policy
7 issues and opportunities for improving how health
8 IT is designed, certified, implemented and used
9 to minimize safety risks and leverage some of the
10 data to support improvements. And obviously,
11 there should be a strong cross pollination or at
12 least awareness of the activity of that work
13 group on our work.

14 And here you can see that we really
15 are very fortunate to have an extraordinary list
16 of individuals and this work group will consider
17 some of the existing work, including the IOM
18 report, the FDASIA reports, the National Quality
19 Strategy which is an important thing that we
20 haven't really said yet here, as well as the ONC
21 safety plan. And an important charge of the
22 group is to be reflective of the summary of

1 experience in the field thus far and creating
2 another forum for public discourse. You'll hear
3 that theme again and again as an important aspect
4 of all of the work that we're doing.

5 So some of the examples to be
6 considered include, but they're not limited to
7 some of the lessons from implementing,
8 implementation experiences, some transparency on
9 usability and safety, improvements on the
10 certification program, some more discussion on
11 safety reporting, as well as analysis of some of
12 the aggregate data for some of the lessons
13 learned. And here you can see some of the near
14 horizon plans up through almost the first half of
15 this year for that work group.

16 Now as I mentioned, one key focus of
17 this work group is around usability and you
18 should all know that they're not starting from
19 absolute scratch in that regard. Already,
20 they've been informed by a tremendous amount of
21 work out of both NIST and out of the MedStar
22 group led by Terry Fairbanks. Earlier MedStar

1 had a contract with us at ONC to look at how the
2 sector's initial implementation of our user
3 center design policy was going. In that work,
4 they actually performed site visits to about a
5 dozen vendors to see and understand what the
6 vendors saw as the important aspects of user-
7 centered design. And that group has really been
8 strong advocates of using these two big buckets
9 for usability, thinking about them in terms of
10 user interface and design and that's displays and
11 controls, screen design, clicks and drags, and
12 cognitive task support. We mentioned this
13 yesterday in Group 3 where you have work flow
14 design, data visualization and functionality.

15 Now they found vendors in three broad
16 categories for UCD. They've categorized them in
17 three big groups. One is a category with no true
18 user center design activity of any merit at all.
19 The second is they have a very basic and
20 fundamental rudimentary understanding of user-
21 centered design. And the third is that they
22 found vendors with very well developed user-

1 centered design programs.

2 Now just to head you off at the pass,
3 the categories of vendors had no consistent
4 relationship to either market share, market
5 capitalization or the product cost. And we're
6 not releasing that information. That was
7 provided in confidence.

8 Now as you can tell, we are slipping
9 away from just the work, strictly speaking, of
10 the Federal Advisory Committee, but we still have
11 some areas in the domain of certification program
12 that I'll talk about for just a minute. The
13 first of two important policy pieces in the
14 certification program really are the ACB -- I'm
15 sorry, the accredited certifying body
16 surveillance also known as ACB program. And
17 that's where we ask the ACBs to let us know how
18 they think post-market surveillance of EHR safety
19 should be performed.

20 Now I have to let you know that the
21 mills of government grind incredibly fine, but
22 very, very slowly. I say that just to say that

1 we'll just be getting the very first actual
2 results of some of their surveillance. They've
3 already provided us with their plans, but we'll
4 just be getting some of the actual results of
5 their surveillance a little later on this
6 quarter. So I can't really speak to any real
7 knowledge of how that actually turns out.

8 But now another aspect of our
9 certification rule that's been percolating is our
10 support of the FDA rule around the universal
11 device identifier. Now my very good friend and
12 colleague, Karson Mahler, really drove this
13 policy at ONC and he was working very closely
14 with Terrie Reed who at the time was at the FDA.
15 She actually spent a detail over with us at ONC.

16 Now I'm convinced that when it's all
17 said and done, our support of UDI, or universal
18 device identifier, in the EHR will always have
19 been seen as one of the most substantial patient
20 safety aspects of EHRs. Right off the bat, there
21 are some pretty solid cases that we have for
22 incorporation and the use of UDI, supporting

1 patient safety directly, enhancing clinical
2 decisions support and care coordination,
3 informing hospital systems, both the supply chain
4 and the billing aspect, as well as enabling
5 analyses of device safety and quality.

6 Now to support patient safety, we know
7 that patient records and clinical software
8 currently lack a standardized field to list
9 devices that are implanted in patients. So this
10 first use case may actually be its very best.

11 Now as a surgeon who would regularly implant
12 ports, reservoirs, grafts, pumps, I can attest
13 that having a reliable and fast way to identify
14 my patients who may have a recalled device or
15 other issues with a prosthetic that I implanted,
16 will be a wonderful time savings.

17 Many of you know that our orthopedic
18 colleagues would love to catch up with their
19 Scandinavian counterparts where device registries
20 have been around and used in improving the
21 quality and safety of care for their patients for
22 years. Knowing which patients have which devices

1 and are being able to track those and correlate
2 those to the safe operation has really put them
3 at the forefront, that is the Scandinavian
4 countries, in orthoprosthetic safety.

5 For example, just think of the value
6 of knowing MRI device compatibility at the time
7 the MRI is being ordered rather than when the
8 patient arrives at the radiology center for the
9 study. To those ends, you can immediately see
10 the value of this work. And that's sort of a
11 great segue into enhanced decision support that
12 enhanced decision support aspects of UDI. You
13 see at the point of care, clinicians often lack
14 information on which devices are implanted in
15 their patients. Linking UDI to an external
16 database can provide very, very detailed
17 information much more than would be available
18 with just the UDI alone.

19 So the possibility of providing the
20 entire care team, I may know as the implanting
21 surgeon, but does the primary care physician
22 know? Does the cardiology consultant know?

1 Letting the entire care team have a complete
2 listing of all devices with the details such as
3 the implant date would be considered remarkable
4 in the extreme just a few years ago and today is
5 easily within our grasp, just with the use of the
6 UDI in an EHR.

7 And again, I think you all understand
8 my excitement really stems from some of the
9 realizable benefit to my own practice. You know,
10 surgeons are all narcissists at heart. So some
11 of the real wonderfulness of this opportunity
12 with UDI and electronic health record is that
13 device information is available well beyond the
14 clinicians that are directly responsible for the
15 insertion. As I mentioned, all care team members
16 get to know, including, including the patient's
17 family and their other care team.

18 So what's more, this information has
19 rich implication for any number of clinical
20 decisions and this information is not perishable.
21 It's durable and persistently actionable. Now
22 that's huge. And that really brings me around to

1 one other benefit of UDI. The analysis of device
2 safety and quality using this. Now this is the
3 public health case or use case for UDI. And as I
4 mentioned earlier, how our Scandinavian
5 orthopedists have a much more informed and
6 sophisticated understanding of the devices and
7 device combinations that they use and that's
8 wholly because they can really analyze and
9 leverage a knowledge base of device registries.

10 In the United States, post-market
11 surveillance often lacks any real detailed
12 information on the devices used in care. And
13 with that information, recalls and adverse event
14 reporting really takes on a completely different
15 tone and tenor when individually and
16 collectively, all patients and relevant
17 stakeholders can really answer the question, does
18 this pertain to me? Or how many of my patients
19 does this actually affect?

20 And then you can have systems actually
21 moving away from the Herculean, but wholly menial
22 tasks that I have our clerical staff do of

1 identifying who actually has a specific device if
2 there is a recall notice issue. And they can
3 move on to the real question of what should we do
4 now? And then they can really have that most
5 satisfying of endeavors, they can begin to say
6 well how can we prevent a recurrence of this?
7 How can we make this better? Now that type of
8 strategic intelligence is really invaluable and
9 you can really see why it really helps and why
10 we're so excited about UDI use.

11 And finally, I'll just say one more
12 thing about UDI, it will inform other hospital
13 systems or other institutional systems. You see
14 with this information, we're afforded a capacity
15 to make informed decisions on safety, on quality,
16 as well as for logistics, billing, supply chain,
17 and even some predictive modeling. By informing
18 the business systems of hospitals, some of the
19 long-term implications on cost savings for our
20 enterprise writ large is actually very, very
21 huge. So I hope you can see why I'm pretty
22 jazzed about our work with UDI and I think that

1 that will be one of the real cornerstones to all
2 of our safety work moving forward.

3 Now finally, let me talk a little bit
4 about our support for CMS value-based purchasing
5 initiatives. Now I mentioned before Paul Tang's
6 formulation of the articulation between quality
7 and safety and that really comes to full flower
8 here. And just so you know, I'm neither cynical,
9 naive about how this work will advance safety.

10 You see, for all of the altruistic and high-
11 minded intentions of our colleagues, we all know
12 that there's been one key driver to success and
13 that key driver has been clear ever since the
14 Phoenicians have been around. And that's why
15 this real announcement, this announcement by
16 Secretary Burwell, can only accelerate all of our
17 efforts and our work.

18 In case you hadn't heard, she
19 announced plans to tie 85 percent of all
20 traditional Medicare payments to quality or value
21 by 2016 and 90 percent by 2018. Things just got
22 very, very real. And again, not to be overly

1 cynical or jaded in this view, the practical
2 realities of our work have long been with us.

3 Now this gentleman right here is one
4 of my heroes and he's a giant in surgery, John B.
5 Deaver. Any of you who have spent any time in
6 the operating room you must have heard someone
7 ask for a Deaver retractor. Now Deaver reminded
8 us that to do our work well, we really have to
9 diagnose well. He was high minded, but he was
10 also very practical. You see, one of the reasons
11 I love John Deaver is he had the well-known and
12 very professed goal of wanting to operate on
13 every single person in the city of Philadelphia.
14 The thing is he darn near did, too. But this
15 concept of diagnosing well has come up before in
16 the context of health IT. We hear about it again
17 and again.

18 And another personal hero of mine, my
19 chief of surgery, Dr. Leffall, taught me why by
20 looking at the question of accuracy and diagnosis
21 in another way. Now he asked this of all his
22 trainees, but I'll tell you the first time I

1 heard it it really scared the bejeebies out of me
2 because on morning rounds he picked me out of the
3 crowd, inquired, he said, "Dr. Hunt," and you
4 know when you're early in your residency
5 training, doctor is a pejorative, "Dr. Hunt, what
6 two diagnoses will you never make?" And after a
7 very, very long and uncomfortable silence that
8 reinforced to me that there are no rhetorical
9 questions on attending surgical rounds, I started
10 to venture some kind of lame excuse or lame
11 answer like a parathyroid adenoma. And then he
12 told me this truth that remains an ever-present
13 reminder of our collective expectation for health
14 IT, namely, that the two diagnoses that you will
15 never make are the one you don't know about and
16 the one that you don't think about.

17 Now I'll finish up where I started off
18 by making the point that the work we're doing
19 here, here at NQF and by extension, the ONC
20 safety program is very painstaking. It is long.
21 And Eric, I hear how are we going to get there.
22 But it's very, very much worth it. This flower

1 is very slow growing which is all the more reason
2 that we have to hurry with our work now and get
3 to it.

4 So with that, I'll thank you.

5 CO-CHAIR SINGH: Thank you, David.

6 This is a great presentation. Thanks for sort of
7 putting this in the big picture and I think
8 you've almost sort of elevated our importance of
9 what we're about to do even further, you know,
10 with the HHS announcement on January 26th where
11 most reimbursement is going to be tied to quality
12 and value. And we're still trying to understand
13 how to measure just the routine quality and
14 value. Let alone, by the way, there's no measure
15 for diagnostic quality and safety that has been
16 used, just FYI. So we're trying to write a paper
17 on that, but haven't been successfully published
18 yet. So with that said, I think health IT
19 related safety and using health IT to sort of
20 measure some of these things going forward is
21 going to be even more important.

22 And we talked about this morning and

1 I think Helen also nicely put it, we're doing
2 this -- this is a new science. We don't know a
3 lot. We need to learn a lot more. And there's a
4 bit of a concern with AHRQ's funding. I know
5 there's been a recent announcement with special
6 emphasis notices and all of that, but we're going
7 to need a lot more going forward in terms of
8 converting that measurement into improvement in
9 dissemination and implementation.

10 So what do you think about in trying
11 to foster research implementation and
12 dissemination activities in this area, who are we
13 going to look towards? I know ONC is not in the
14 research-funding business. AHRQ is very limited.
15 I love AHRQ, by the way. I have several grants
16 from them. I just don't think they have enough
17 research funding to support the kind of work that
18 needs to be done. I mean PCORI -- I don't know
19 if anybody has had luck with PCORI. Certainly
20 our group has never had any -- CMS innovation
21 maybe. And then health systems that could
22 potentially support some of the innovation, I

1 think Kaiser does some of this, are running out
2 of money because reimbursements are being cut.

3 So to support this measurement from
4 the part of measurement going into improvement,
5 how do you see us transitioning over the next
6 five to ten years in terms of getting evaluation
7 done of these measurements and concepts? We're
8 going to come up with these beautiful, hopefully,
9 a beautiful report, right, at the end of the
10 year. What next? And how do we translate that?

11 DR. HUNT: I think there are a number
12 of things. One, I think the one big pot of gold
13 from one agency or resource, I don't think that's
14 going to happen, but I think cobbling together
15 grants and resources from multiple funding
16 sources is probably going to be one way that a
17 lot of people are going to move forward. But
18 also, I think that making sure that you're
19 understanding that we're tying all of this work
20 together into a question of overall quality and
21 value. So now it really becomes a compelling
22 proposition for institutions and providers alike

1 to ask how are we going to be able to do this
2 because again a tremendous amount of your
3 reimbursements are now going to be tied directly
4 to quality. I hate to sound Darwinistic about
5 this, but the reason I said that with Secretary
6 Burwell's announcement, this gets very, very real
7 is that somehow or another, we're going to have
8 to figure out how to understand what's going on
9 so we can improve quality because this is the new
10 game in town.

11 Now I'll tell you, when I did my work
12 over at CMS on the surgical care improvement
13 projects, I used to count how long it would take
14 when I'd get questions from the audience for them
15 to use the unfunded mandate term. It was just --
16 sometimes it was first, usually it was a little
17 bit later, almost always starting off with "with
18 all due respect." And if any of you have
19 answered questions you all know that when they
20 start off with all due respect, it's going to go
21 very low quickly.

22 But one thing that I found and that I

1 realized is that there is an absolute
2 conservation of resources in this domain. And
3 we've been telling people we talk about an
4 unfunded mandate, but it really hasn't been an
5 unfunded mandate. The cost for areas of quality
6 that can be improved and are in need, those costs
7 are being paid every single day and the idea that
8 we're going to now tie payment to quality isn't
9 necessarily a complete change. It's just a
10 shifting of costs. And what that means is that
11 the people who are getting UTIs that are
12 preventable get tired of paying for it.

13 The people who are having drug-drug
14 interactions that could have been prevented,
15 they're tired of paying that cost. Surgical site
16 infections, the families are tired, okay, of
17 paying it. And so now we see that providers are
18 a little bit more at risk. And as a practicing
19 physician, I am scared also. I don't know what
20 this is going to actually do to my practice, but
21 I think the bottom line is we're going to have to
22 look and see some of the resources that we're

1 using for other things. Now the idea that you've
2 got to measure in order to improve, as I said,
3 this has become a prima facie part of what we
4 need to do to maintain an active business
5 concern. And I think we're going to have to find
6 the resources. I think AHRQ still has a
7 tremendous amount, I think, of creative funding.

8 You mentioned CMMI, those folks are
9 really great. And I think that and I'm not
10 speaking out of turn, out of school, I don't
11 really, really know, but I think we're going to
12 see a lot more out of PCORI also.

13 CO-CHAIR SINGH: I just want to say
14 that I think we'd love for other, not just AHRQ,
15 who's been being sort of pioneering this, but
16 other people stepping up as well to convert what
17 we recommend in terms of measurement into
18 improvement.

19 DR. HUNT: And another thing, gosh,
20 this was -- that was such a set up and I
21 completely forgot. The TCPI, the transformation
22 of care -- I'm mangling the acronym, the

1 Transformation of Care Initiative that Secretary
2 Burwell actually announced a few weeks even
3 before this latest announcement, is a huge source
4 of funding where they're actually looking at how
5 we're going to be able to -- I think it was on
6 the order of, again, I should have been more well
7 versed, \$800 million or so. It was a tremendous
8 amount of resources that are going to be
9 provided, particularly looking at how you can
10 leverage quality improvement to actually achieve
11 improvements and goals. In a way, I've heard of
12 it talked about as sort of an extension or
13 further going on of the partnership for patients
14 initiative.

15 CO-CHAIR SINGH: Thanks, David. Now
16 I have Bill and then Jason Jones.

17 MR. MARELLA: So I wanted to pick up
18 on one part of your presentation, David. You
19 talked about the health IT surveillance plan and
20 I wanted to connect that to an issue that Mark
21 raised yesterday. If part of the surveillance
22 plan's success rests on sort of the transparency

1 and sharing of information which you brought up
2 at the end of the day yesterday, one of the other
3 barriers that's in place preventing that and
4 we're seeing this in the health IT partnership
5 that ECRI's been facilitating is it's been
6 difficult to get vendors to feel comfortable
7 sharing safety information and sharing the
8 results of things that are analogous to like root
9 cause analysis investigations in the hospital.

10 Jim mentioned yesterday that you feel
11 comfortable being -- or you'd feel more
12 comfortable sharing that kind of information if
13 vendors were protected in something similar to
14 the way that providers are under the Patient
15 Safety Act.

16 And I think that we haven't gotten a
17 clear blessing, I guess, from AHRQ and so Erin as
18 the sole AHRQ representative, I'll lobby you for
19 a minute. We haven't gotten good feedback from
20 AHRQ about whether it's kosher to sharing that
21 kind of information by making the vendors part of
22 the PSOs. And I'm sure there are other PSOs

1 besides ECRI that are looking at that.

2 But to the extent that we can make the
3 vendors part of our PSO workforce for the purpose
4 of investigating specific events, that would be
5 beneficial and I think would achieve the goal
6 that you were looking for yesterday, David, about
7 having the vendors share that information so that
8 whatever learning is generalizable from those
9 investigations can be shared and broadcast.

10 DR. JONES: I had a question and I
11 think you might be the perfect person to answer
12 it, so you're -- I was going to ask whether that
13 was followed with Dr. Hunt. Your Slide 27 which
14 is the one about the goals being tied to quality
15 or value, one of the things that I asked
16 yesterday and I'm still puzzling about for this
17 group is you can't have quality without safety,
18 but you can have value without benefit.

19 In your surgical work, it bothers me
20 that all of our measures of surgical quality are
21 harm avoided. We were talking yesterday no one
22 has their hip replaced to avoid an SSI, but we

1 measure the SSI because we can.

2 Do you have advice as we go forward
3 with this about whether we should focus on safety
4 because it's measurable and there's so much to
5 improve and it's something we can make progress
6 on, and Eric has pointed this out earlier today.
7 Do we need to go to something around what are the
8 benefits of HIT or do we have to go all the way
9 to value to try to get the traction, especially
10 with an organization that there's not going to be
11 money raining down from other places. What
12 should we be setting our sights on as we come up
13 with these measures from the spectrum of safety
14 through value generation within HIT?

15 DR. HUNT: This is going to be a
16 little bit of a long-winded answer. But it's
17 been a little bit of a personal journey with me
18 because I started with some of the very first
19 surgical quality measures over at CMS that they
20 developed. And the process of developing those
21 was a little bit I want to say perverted, but it
22 wasn't completely understood. And I still go as

1 often as I can almost every Monday to my training
2 facility, Howard University, Grand Rounds,
3 Surgical Grand Rounds. And you know, if you've
4 never been to a Surgical Grand Round, there's no
5 more fun than seeing the residents skewered.
6 This is a true blood sport.

7 But we ask them questions and we probe
8 them to see about their judgment and their skill.
9 I find it remarkable that I would always get
10 pushback that David, those measures that you talk
11 about with SCIP, the use of antibiotics or
12 heating or whatever it was, we never bring that
13 up in our discussions at Grand Rounds and so
14 that's a defect in the measures.

15 I have long wanted to tell people that
16 the measurement process, particularly for SCIP
17 was never about having the complete set of
18 measures to measure quality because the fact of
19 the matter is if I grabbed any one of my
20 residents on the ward this afternoon and asked
21 them what can you do to prevent a surgical site
22 infection, they would hopefully rattle off ten

1 things rather quickly, and hopefully none of them
2 would be any of the measures that are involved in
3 SCIP. And that's because the things that we
4 really know how to do as clinicians to prevent
5 say surgical site infections are things that are
6 incredibly hard to measure. How to measure
7 tension on the wounds, not using too much suture
8 material, making sure you get rid of dead space,
9 eliminate any serous material. All of these
10 things, they're what you do, but the fact of the
11 matter is I can't stand over somebody's shoulder
12 and measure, those sutures, that 2-0 chromic that
13 you're putting in, that's a little bit too tight.
14 That's going to cause a problem.

15 So the fact of the matter is is that
16 the measurement process was really a proxy to
17 give you something to do to change your culture.
18 That was really it. That was the bottom line and
19 we never got to really explain that in a fulsome
20 way with surgical quality measures. We never
21 believe that this was the end all and be all for
22 measurement and I would venture to say that the

1 same story is happening here. Whatever we come
2 up with and I know we're going to come up with
3 good ones, this is not the end all and be all of
4 health IT safety. It really is just a vehicle or
5 a way to get you to do something so you can
6 attack the real problem which is really a
7 culture, a cultural issue.

8 The questions that we have on Surgical
9 Grand Rounds every Monday morning really are deep
10 and probing, not did you use this antibiotic
11 within 60 minutes? Should you have taken that
12 85-year-old woman into the operating room at all?
13 And those are the questions that we want to --
14 but we're never going to be able to ask those.
15 But the fact that we're scrutinizing the way we
16 do things and what comes out of what we do, is a
17 way to begin to start to talk about the cultural
18 aspects of what we do. And maybe I'm going off a
19 little bit too far, but that's really the whole
20 point to all of this.

21 We're going to come up with some great
22 measures. I absolutely know we're going to come

1 up with some great measures. Are they going to
2 be the entire universe? They're not even going
3 to come close to the entire universe and they
4 never could. The burden will be too great. The
5 length of time and our data, value data sets,
6 they're never going to meet it. But we just have
7 to have something good enough to have a start of
8 a discussion. And I think now that having tying
9 more of it to quality and value will make those
10 discussions, will bring them up a little bit
11 more. And we'll be able to have -- be able to
12 have more fulsome discussions around that way.
13 That's a real long answer to say it's not about
14 the measure. It really is about your culture and
15 your mind set.

16 That's why I asked actually the
17 vendors. I told Bill this morning, that's why I
18 asked the question about whether Mark and Jim,
19 whether or not you had offered up any insight to
20 the larger community because it's not whether you
21 did and whether you had ten or whatever, I really
22 want to know what is your mindset? Do you want

1 to do this? Do you want to work with us and help
2 you if you're a closed space, if you're thinking
3 proprietary, me, my, mine, mine, my precious,
4 we're going to lose. We're really going to lose.
5 But if you have a mind set what can I do to make,
6 yes, we're going to make a profit and things are
7 going to go well, but what can I do to make the
8 whole system better because we're all going to
9 really win when we do. That's what I want to
10 hear. Sorry. That's it. That's the answer.

11 CO-CHAIR SINGH: Karen, really quick
12 here, we are late for public comment.

13 DR. ZIMMER: I just want to note what
14 I hear then is really we should be focusing on
15 outcome measures, but come up with suggested
16 processes for organizations to figure out how to
17 get there.

18 DR. HUNT: I think that's a good way,
19 but I'm going to defer to Helen. You know, I
20 mean --

21 CO-CHAIR SINGH: She's going to tell
22 you after lunch.

1 DR. HUNT: They're the master of all
2 of this and how we actually get to it is probably
3 a mixture of outcomes. Outcome is the first
4 derivative of process, so we have to have some
5 process, some structure. I don't know the exact
6 recipe that has to be made, yes, we're going to
7 have to have some outcomes because people love to
8 see that. But what the exact recipe is, I'm not
9 sure, but whatever it is, it has to be something
10 that will hopefully open up the discussion and
11 get everybody engaged. I think that's the big
12 point.

13 CO-CHAIR SINGH: Thanks, David.
14 Andrew?

15 MR. LYZENGA: So operator, could you
16 let us know if there's anybody on the line who
17 would like to make a public comment?

18 OPERATOR: Yes, sir. If some of you
19 would like to make a comment, please press *1.
20 There are no comments at this time.

21 MR. LYZENGA: Thank you. There's some
22 folks in the room, I know in the audience. Would

1 anybody in the room like to make a public
2 comment?

3 MS. FREEMAN: This is Lisa Freeman,
4 could I just jump in for a moment?

5 MR. LYZENGA: Oh, sure. Go ahead,
6 Lisa.

7 MS. FREEMAN: On a very grand scale,
8 as you're talking about all these different
9 components and everything, there are a few things
10 that have kind of struck me. One is that I kind
11 of think of the airline industry and I'm thinking
12 when a plane goes from one controller's control
13 to another as we go from one hospital system to
14 another, we're a very mobile society, one doctor
15 within a system to another, what we find is that
16 the handoff is so important. And in healthcare
17 the handoff is important, too. But the problem
18 is that we're not all talking to each other. The
19 systems are totally independent and I know that
20 that's a component of the way we're set up in our
21 capitalist society.

22 But I think this idea of getting

1 people together and really talking, number one,
2 is super important, and I think in some way
3 communication has to be able to be measured. I
4 think that's one of the things we need to
5 measure, be it the ability for a patient to
6 access their portal and get some meaningful use
7 out of it. It's one thing to just go on line,
8 but if there's nothing there that's really
9 available, some portals share almost nothing with
10 the patient. Others share the minutiae of every
11 test result.

12 We need to measure, I think, outcomes
13 of actions as has been said before. I don't
14 think I'm saying anything new. And we need to
15 focus on communication and I agree that we have
16 to get people together. We keep having people
17 working in so many different silos and
18 duplicating the efforts of each other very often
19 where if we're talking about limited funding and
20 everything else, we need to bring groups of
21 people together to share their ideas and work for
22 the better common good I think.

1 CO-CHAIR SINGH: Thanks, Lisa. We're
2 actually going to have an exercise during lunch.
3 If you don't mind sort of staying on while we're
4 all going to be having lunch. Actually, the
5 committee may not know this, but it's going to be
6 a working lunch. Not only my idea, so don't
7 shoot the messenger.

8 We're going to go over some measure
9 concepts and we'll talk about some of the exact
10 things you just mentioned.

11 I'm going to hand it over to Kathy and
12 then we'll go take lunch.

13 MS. KENYON: Hardeep, are you sure --
14 Hardeep actually asked me to make some comments.
15 And part of the reason is because I've managed a
16 lot of the health IT safety projects, so
17 substantively I've been looking at the merits of
18 where we're actually seeing health IT related
19 events. And I've done that with a lot of people
20 who are actually in this room.

21 David's presentation was a tremendous
22 overview of ONC efforts right now. What I want

1 you all to note is that ONC policy has been use
2 health IT to make care safer -- I'd add and
3 better -- which the IOM did. And the second is
4 the continuously improve the safety and safe use
5 of health IT. Those are built into the three
6 levels that Hardeep laid out, the one of use
7 health IT to make care safer and better is where
8 we're headed. And the continuously improve the
9 safety and safe use of health IT is really levels
10 1 and 2.

11 That is a CQI process as well and that
12 is relevant because it's integral to general
13 approaches to safety and risk management that are
14 out there and operationalized, both in the
15 provider community and in the vendor community.
16 Although those of us who work in the provider
17 community know less about what's going on in the
18 vendor community. What's going on in the vendor
19 community is based upon international standards
20 about quality management and risk management that
21 are very similar to what we've got on the
22 provider side if we're paying attention to high

1 reliability organizations and culture of safety,
2 the kinds of things that the Joint Commission and
3 AHRQ and CMS, actually in its conditions of
4 participation, have in some ways forced us to
5 develop in the provider community to have an
6 actual base for doing safety in the private
7 sector in healthcare organizations.

8 I think that where we are right now we
9 actually have information on where we know there
10 are some health IT related safety issues from the
11 RAND study, from the two PSO analyses, from the
12 Joint Commission stuff, from the VA material, and
13 they are pretty consistent.

14 So where we are right now is I think
15 we're ready to take on three things. First, a
16 health IT specific operational platform on
17 safety, so we've got safety risk management
18 programs out there. What we haven't done is to
19 drive health IT into those. The Joint Commission
20 is going to issue a sentinel event alert. CMS is
21 going to start paying attention to this in their
22 surveys. There's an educational, Joint

1 Commission has an educational program out there.
2 We're going to start seeing some effort to
3 actually push health IT into the safety
4 infrastructure of healthcare providers.

5 Now the question is how that's going
6 to show up on the developer side. And I also
7 think that there are real things in play on that
8 side that should coordinate with what's going on
9 in the provider community.

10 Now this is all very relevant to you
11 because the next two things that I think we're
12 ready for, one is that shared risk, shared
13 responsibility. We're at the point where it has
14 to stop being a platitude and part of the reason
15 I like the shared risk idea is it does take it a
16 little bit off of the platitude. Everybody has
17 embraced shared responsibility. It is in the EHR
18 developer code of conduct. It came out of the
19 IOM report. It's basic to the ONC health IT
20 safety plan.

21 Everybody loves shared responsibility.
22 No one knows what that means as the next step.

1 That's been the problem. We need to actually say
2 specifically what we think that means and we need
3 to build it in to the operational platforms of
4 both healthcare organizations and vendor
5 organizations. And we have to find a mechanism
6 right there, especially at the transition between
7 design development and implementation and use in
8 maintenance over time that we're dealing with
9 shared responsibility, shared risk for patient
10 safety.

11 The third thing that I think we're
12 ready for is measurement and it's related to
13 those other things and I think that if you view
14 measurement, what you're doing within the context
15 of we need to build operational platforms for
16 health IT safety, somebody needs to care about
17 these measures.

18 The people who need to care in order
19 for them to actually get used are governing
20 boards, risk managers, who by the way have a lot
21 more money than the quality people in most
22 healthcare organizations, am I right about that?

1 I was general counsel of a large health system.
2 At least in my health system, the people who did
3 risk management, who tried to avoid liability
4 cases had more money than the quality folks.
5 It's because you just need one million dollar
6 diagnostic error to really rivet the board's
7 attention. What we need to do is we need to
8 start figuring out how to take that million
9 dollar diagnostic error and spend some of that on
10 avoiding the diagnostic error through the use of
11 health IT.

12 And so how is it that we build
13 measures about patient safety that are useful to
14 people who care about safety and organizations at
15 the governing board level, at the risk management
16 level, at wherever we think safety happens in
17 healthcare organizations. I happen to think one
18 of the places it happens is in the security rule
19 implementation so the security officer, a huge
20 amount of what you all talked about yesterday
21 with availability is built into the security
22 rule, as Elisabeth and I, as old HIPAA lawyers,

1 can tell you.

2 So I think that I hope that -- I'm
3 sitting next to Eric who keeps trying to make
4 everybody here be practical. I'm hoping that
5 this helps with people being more practical. I
6 think you need to figure out who the audience is
7 that can actually use the measures and I think
8 that you then need to figure out what they're
9 going to think is important, what are the high
10 priority areas for them. It's going to be
11 related to what the Joint Commission thinks is
12 important because boards think what the Joint
13 Commission thinks is important is important to
14 them. What CMS thinks is important. It's going
15 to be related to liability because there's money
16 on liability. And it's going to be, I think,
17 related to the evidence on health IT safety.

18 And so I've actually sent a list of
19 kind of in the three levels of safety IT, safe
20 use, optimizing it. What I think the evidence
21 suggests should be high priority and Hardeep and
22 Elisabeth have that and I'm quite happy to share

1 it, but it's not far off of what's in the SAFER
2 guides. And if you look at the SAFER guides
3 which are based upon the best available, the best
4 evidence that was available in 2013, it's not a
5 bad place to begin at looking at the real areas
6 where we are doing -- where there is harm that
7 can be avoided from the use of health IT and that
8 people might care about. And therefore, if you
9 can find measures in those areas, it might
10 actually drive change. So thank you.

11 CO-CHAIR SINGH: Thanks so much,
12 Kathy. We really appreciate it. I think we're
13 ready for lunch and I wanted to just let you all
14 know that a gang of six, you can figure out who
15 the six are, came up with a plan that during
16 lunch what we would do is actually, Kathy, this
17 is a nice segue to what we were going to do, is
18 to just lay out some of the key high priority
19 measurement concepts or measure concepts, put
20 them on sort of white boards or something and let
21 people reflect upon them and prioritize them, if
22 you will.

1 The gang of six, please add on to some
2 of our thinking as to what we can do. A few
3 things, don't worry about the levels when you do
4 this exercise. Don't worry -- but think about
5 the levels. Don't worry about categorizing which
6 level. Also don't be concerned about the five
7 HIT safety concerns that we showed you from the
8 JAMIA paper with David as well. Don't worry
9 about which levels, but as long as you're
10 addressing those five levels of HIT safety
11 concerns, think about the socio-technical model,
12 but don't try to categorize.

13 Keep the levels in mind. Keep the HIT
14 safety concerns in mind. Keep the socio-
15 technical dimensions in mind, but don't
16 categorize anything. If you want to say system
17 process outcome, sure. But just put some
18 measurement concepts out there on some white
19 boards and again, I'll let Andrew take on the
20 rest and we can do that during lunch, while we
21 eat.

22 DR. BURSTIN: If people want to get

1 their food and come back, we'll have the
2 instructions all ready for you to go when you sit
3 back down.

4 CO-CHAIR SINGH: So now you know who
5 the second team of six was.

6 (Whereupon, the above-entitled matter
7 went off the record at 1:05 p.m. and resumed at
8 1:22 p.m.)

9 DR. BURSTIN: All right. Let's go
10 ahead and get started. Hi, everybody. You can
11 keep eating, drinking, whatever you like.

12 So as you're finishing your food, you
13 can finish your food first, we've got a short
14 exercise for you. Again, you can finish eating
15 first. We thought we'd explain it to you so
16 you're ready.

17 So one thought was everybody's been
18 sort of throwing out some measure ideas, measure
19 concepts, some actual measures as well through
20 the course of the two days. We just want to make
21 sure we have a good opportunity -- I think it was
22 Hardeep who called it a good opportunity for us

1 to have a brain dump of everything you've been
2 talking about or thinking about.

3 And so the idea behind you on the --
4 behind David and Greg behind you is the list of
5 the five areas that Hardeep presented yesterday
6 in their work of the five categories of HIT and
7 safety. And then we've added two additional
8 ones, one on patient engagement, because we've
9 heard a lot about how patients -- the role of
10 patients in terms of being part of this. And
11 then secondly this idea of shared risk has also
12 come up a lot during the last couple of days. So
13 these are the categories.

14 And we'd like you to do, after you've
15 had a chance to finish eating, is just go up --
16 you've all got pens and stickies in front of you.

17 Do you want them to put the stickies
18 up or just write? Put the stickies? Okay.

19 So actually take an opportunity even
20 while you're eating then and just write down the
21 measure concepts that come to mind and then try
22 to go back there and put them on that wall. So

1 just a little bit about what the heck's the
2 concept, since we live in this space a lot. Some
3 of you may not.

4 So we would love to think about what
5 would be defined enough such that it's such a
6 really important area that if David Hunt had
7 money or Erin or their wealthier friends at CMS
8 had dollars to turn around and say to developers
9 here are the top five measure concepts that
10 emerged out of this meeting on health IT and
11 safety, they kind of have enough to run with it.

12 So for example, you probably wouldn't
13 want to put up there care transitions, right?
14 Not enough. Important area. Probably very
15 sensitive to HIT and safety issues, but you might
16 put up a concept that says something like timely
17 transmission of critical patient information at
18 transitions. That's the kind of thing we're
19 thinking about. And then at the end of it even
20 try to prioritize that. We'll do a lot of post
21 hoc work to kind of -- particularly Hardeep, to
22 put them in the levels and think about different

1 categorizations of them.

2 (Laughter)

3 DR. BURSTIN: It's all Hardeep. But
4 as a starting point we just wanted to -- as
5 you're thinking and you've got the little
6 stickies next to you, just start writing what you
7 think would be either measure concepts. Or to
8 the point that's been raised a couple of times
9 over the course of the two days as well is there
10 may already be measures out there that may be
11 used only at a local level, a particular health
12 system, a vendor. Put those down as well and
13 attribute a source. And we'll also just try to
14 prospect for some of those as well and see if we
15 can bring them in.

16 Sound like a reasonable exercise while
17 you're chewing and drinking and chatting?
18 Questions? Yes, go ahead.

19 DR. SEGAL: Helen, is this a voting
20 exercise where the more something appears the
21 more weight it's going to have, or are we going
22 just get the ideas up and then we'll prioritize

1 them next?

2 DR. BURSTIN: I think it will depend
3 how many little stickies you guys put up there,
4 to be honest. If we start seeing that there's a
5 whole lot of stickies, we'll probably do the
6 analysis after the fact and try to group some
7 together and see if there are some common themes
8 and shoot them back at you. since this isn't the
9 only time we'll be with you over the course of
10 this work. So, if it looks like there's not that
11 many up there, we could even ask you to go up and
12 put stars next to your top five or something like
13 that. But let's at least while you're eating
14 start writing down some concepts or some ideas
15 for measures you think might be useful in this
16 space.

17 CO-CHAIR SINGH: Eric, did you want to
18 add anything to the spirit of the exercise?

19 DR. SCHNEIDER: No, really at this
20 point it's really idea generation, and I suspect
21 that -- Eric Schneider. The notion is idea
22 generation. And as they go up there, people may

1 want to circulate and read them because it can
2 trigger additional thoughts and people might
3 write additional Post-Its and put them up there.
4 Don't anyone feel embarrassed. There's no such
5 thing as a dumb measure concept. Only ones that
6 can't be implemented. But those are welcome,
7 too, because sometimes it's easy to solve the
8 problems that are associated with implementation.
9 Sometimes it's not, but it's doable over time.

10 (Whereupon, the above-entitled matter
11 went off the record at 1:27 p.m. and resumed at
12 1:58 p.m.)

13 DR. PINES: What we're going to do now
14 is I'm going to go ahead and just briefly read
15 through some of these Post-it notes, actually all
16 of them. And then we're going to take a brief
17 pause and see if there are other measure concepts
18 that sort of come out in these categories.

19 So the first category here is HIT
20 fails during use or is not working as designed.
21 We have the use of the Adelman order-retract tool
22 to measure wrong patient orders. Categorized HIT

1 help desk calls. Documenting after shift.
2 Delayed documentation. Downtime. User
3 satisfaction. I think we saw that in other
4 sections. Missed alerts during patient care due
5 to delayed documentation. Help desk reports.
6 Analytics based on risk.

7 Who put that up? Is that -- can you
8 clarify a little bit that -- what you were --

9 DR. ALEXANDER: Help desk reports
10 based on maybe level of harm or potential for
11 harm, or some risk stratifications that could be
12 thought about.

13 DR. PINES: Okay. Percent of records
14 not completed or percent complete during patient
15 visit. A scheduled clinical shift. Downtime and
16 length of downtime and testing or measure on
17 post-downtime to ensure all systems are up and
18 running. Evidence of backup plans for inevitable
19 failures. Simulation completed before
20 implementation. Wrong patient orders. Retract
21 order events. We had that over here. The
22 percent of clinicians participating in a downtime

1 drill in the last 12 months. Downtimes tend to
2 usually be whenever I'm working the Saturday
3 night overnight shift, so I qualify there. EHR
4 does not provide accurate drug/drug or
5 drug/allergy interactions. Patient portal has
6 overly simplified summaries or is difficult or
7 confusing to navigate. Unexpected downtimes that
8 affect greater than 100 patients and last greater
9 than 8 hours, so a threshold measure. Analysis
10 or RCAs where health IT software was identified
11 as the main issue.

12 So why don't we take a pause and see
13 if there are other thoughts that come up in this
14 particular area? So where HIT fails during use
15 or is not working as designed.

16 (Pause)

17 DR. PINES: Move on? So the next
18 group is where health IT does not meet user's
19 needs or expectations. The first one is a
20 usability scale, some sort of a system usability
21 scale. The number of workarounds employed.
22 Alert fatigue. Appropriateness of alerts. Which

1 there's a little mark that says this is for the
2 vendor. And user involvement in the development
3 process. The number of hours per provider FTE
4 spent charting after a shift. We heard that
5 before. Ability for all care team members to see
6 and contribute to patient care goals and
7 preferences. User interface does not display as
8 intended with some browsers. And there's
9 something else I can't read here.

10 Poor ways to display data. Speed of
11 system. Lack of data availability. End users
12 are involved during the design/pre-implementation
13 process. Software bugs/time to fix. Time
14 required to locate relevant clinical information.
15 Unable to retrieve necessary information and
16 unable to chart necessary information. System
17 limitations determined and communicated with end
18 users. Poor drop-downs. Documentation does not
19 reach intended recipient. Use of different
20 clinical content modules. Response rates within
21 clinical work flow. What are mental models and
22 do they match the cases used for training?

1 Whether error messages are human readable.

2 That's kind of funny.

3 Number of help desk calls. Length of
4 help desk calls. Robust availability. Robust
5 usability evaluation for system redesign. Users
6 know what to expect after implementation or work
7 flow changes. We have another one for help desk
8 availability and response time percentage.

9 Physician adoption of CPOE. Availability of key
10 decision support. Look at IT call logs. Lack of
11 adequate data security and is not continuously
12 improved to address new threats.

13 So let's take a pause there. Any
14 additional ideas?

15 (Pause)

16 DR. PINES: Is that it? So these are
17 great. This is definitely sort of more than we
18 expected. So this is really great, the number of
19 measure concepts we have here.

20 So for the next one, this is for
21 health IT is not configured, implemented or used
22 in a way anticipated or planed. We have the

1 number of times cut and paste is used. The
2 percent of orders entered by the prescriber or
3 the percent of verbal orders. The cognitive
4 load/burden, time on task, self-reported levels
5 of stress, presumably by providers. The number
6 of work-arounds as an indicator of poor
7 configuration. User satisfaction. So, we've
8 seen that before.

9 Clinical documentation. Cut and paste
10 length. That's the second time we saw that.
11 Survey end users on work-arounds. And then
12 analyze from a human/computer work flow process
13 and hardware/software perspective. Measure time
14 or clicks performed for common tasks compared
15 across users into three categories. So new,
16 experienced and power users. The percent of CPOE
17 use, which we saw. The number and types of work-
18 arounds. The use of scribes. Survey assessing
19 perceived usefulness and usability after
20 implementation.

21 Average and max alerts per day per
22 provider in-box. Number of test or dummy

1 patients in production. The number of active
2 orders on them. Health IT in relation to
3 workload. Free text charting when there is a
4 coded item available. Number of use and user
5 errors. Proficiency testing of users. Match
6 work flow with expected use cases. Clinician
7 docs not enter data with safety-related
8 dependedness.

9 Can we clarify that one? I'm not sure
10 I'm reading that right.

11 The percent of delinquent charts on
12 audit related to a Joint Commission requirement.
13 The number of randomly selected charts with
14 active problems, allergies and free text not in a
15 problem list/allergy fields.

16 I think I missed these down here.
17 Repetitive proficiency testing of users annual to
18 accommodate updates and changes. Alerts with
19 greater than 98 percent overrides or percent of
20 clinicians with greater than 100 in-basket
21 alerts.

22 Yes?

1 DR. SEGAL: So was the repetitive --
2 was that intended to be -- was repetitive
3 intended to be pejorative so that more of those
4 are bad, or more of those are good?

5 DR. PINES: Who put up that concept?
6 Let me go back to that one. That was -- so
7 repetitive proficiency testing of users annual,
8 question mark, to accommodate updates and
9 changes. So I guess --

10 CO-CHAIR SINGH: I think this came up
11 yesterday when somebody said that as we use EHRs
12 we should be getting better and better. So I
13 think it's --

14 DR. SEGAL: Oh, no, that's fine. Just
15 because "repetitive" I also think of as a
16 negative.

17 CO-CHAIR SINGH: Yes, right.

18 DR. SEGAL: So I just wanted to
19 understand what direction we're looking at as up.

20 DR. SCHNEIDER: Regular I think was
21 the intention.

22 DR. PINES: Where was I here? So the

1 percent of abnormal test results not followed up.
2 Information overload. User docs not trust/rely
3 on CDS -- can't read what this says here. Is
4 this outpatients or outlets? Outlets? Okay.

5 DR. SEGAL: They won't rely on the CDS
6 outputs.

7 DR. PINES: Okay.

8 DR. SEGAL: So that's -- yes.

9 DR. PINES: Okay. That's a good idea.
10 Percent med scanned prior to administration. And
11 one is a general comment. Assess display
12 screens.

13 Before we move on, any comments on
14 this area?

15 CO-CHAIR SINGH: So I just had a quick
16 question and maybe a comment. I think some EHRs
17 -- and I think copy and paste in documentation
18 came up quite strongly over the last few.
19 There's a way to sort of highlight some sections
20 that are copy pasted. I'm not sure all of them
21 have some sort of a standardized --

22 DR. CLASSEN: Anything that's pasted

1 forward can be highlighted separate from the rest
2 of the --

3 CO-CHAIR SINGH: Automatically
4 highlighted.

5 DR. CLASSEN: Automatically
6 highlighted.

7 CO-CHAIR SINGH: That might be an
8 additional one, I mean, we can maybe think about
9 as sort of strategies to come back -- unintended
10 consequences from copy paste, such as this one.

11 DR. PINES: Okay. And there was one
12 additional one. The percent IT eval in clinical
13 settings. So can you clarify that, IT eval?

14 DR. ALEXANDER: Yes, so yesterday we
15 talked a little bit about actually testing the
16 technology in the clinical setting before --
17 rather than just in a lab.

18 DR. PINES: Okay.

19 DR. ALEXANDER: So, that's what I was
20 referring to.

21 CO-CHAIR SINGH: Yes, so it's almost
22 like that socio-technical usability testing in

1 the real world rather than just the sort of --

2 (Simultaneous speaking)

3 DR. PINES: So simulation in the real
4 world then?

5 CO-CHAIR BELMONT: Yes.

6 DR. PINES: Right.

7 DR. CLASSEN: And actually that's
8 really important because what we found with the
9 Leapfrog test is a lot of people try to take it
10 in their test system rather than their real
11 system. And that's a problem because the test
12 system is now what takes care of patients, and
13 the test system can be different than the live
14 system.

15 DR. PINES: Okay. Any additional
16 comments for this group?

17 MR. MARELLA: Yes, I'll add one more.
18 Just the presence of hybrid work flows.

19 DR. PINES: Okay.

20 MR. MARELLA: So having clinicians
21 have to look at both paper and electronic to get
22 a complete view of the patient's situation.

1 DR. PINES: Okay. I'll put it up.

2 DR. GANDHI: I have one more as well.

3 I don't know where this actually fits, but the
4 issue of kind of lack of availability of
5 hardware. So, if there's one computer for 10
6 docs on a floor leading to delays and that sort
7 of stuff. So kind of availability of hardware,
8 but also the issue of how it's configured. So I
9 think about a primary care office where the
10 computer is such that when you're typing on it
11 your back is to the patient.

12 DR. PINES: Okay.

13 DR. GANDHI: So, I wasn't sure which
14 bucket that goes in, but --

15 DR. PINES: Okay. Put it up.

16 CO-CHAIR SINGH: And if you could just
17 put it in two or three right now. We won't worry
18 about the levels right now.

19 DR. PINES: Okay.

20 DR. ZIMMER: Sorry, just another way
21 to say it. Just in general we talked a lot about
22 simulation testing yesterday in our group.

1 DR. PINES: Okay.

2 MR. LYZENG: I think Lisa's got one
3 on the phone, too. If you want to just jump in.

4 (No audible response)

5 MR. LYZENG: Lisa, are you there?

6 (No audible response)

7 MR. LYZENG: Or are you on mute?

8 (No audible response)

9 MS. PHILLIPS: Okay. Lisa has a few,
10 Lisa Freeman. To measure patient engagement can
11 a measure frequency of patients accessing their
12 portal be added? So, that's patient engagement.
13 And let's see, measure filling of medication
14 prescriptions by patients following discharge
15 from hospital or other facility. I think we
16 talked about that yesterday. And a measure would
17 be post-hospital -- post-hospitalization test
18 diagnostic studies being completed by patient
19 and/or results of in hospitalization test studies
20 being communicated to primary care physician and
21 followed up on.

22 DR. PINES: We can transcribe those

1 and hang them up.

2 MS. PHILLIPS: Yes, it sounds like
3 care coordination.

4 DR. PINES: So those would probably
5 all be in the patient engagement bucket.

6 So, any additional ideas for this
7 section here?

8 (No audible response)

9 DR. PINES: So, the next one is HIT
10 interacts with external systems. The first
11 comment says IT sophistication integration in
12 resident care, clinical support and
13 administrative activities. The number of times
14 key test results are not available for diagnosis.
15 Is your system interoperable with other health
16 care systems regionally, nationally within the
17 same vendor system? Health information exchange
18 or claims. Measurability of health IT system to
19 pick up problem prescriptions across different
20 systems.

21 The number of times data is available
22 from/through HIE and that someone

1 accessed/reviewed and how often it's actually
2 used. The percentage of surgical patients with
3 UDI recorded in patients' EHR and
4 national/international registries. Incomplete
5 data received/imported from a device or other
6 HIT. External data via HIE is not added to
7 patient record. Med reconciliation
8 discrepancies. Accuracy of data. Handling of
9 external documents. PDF versus manually entered.
10 Usability of information from external systems.

11 Content and timeliness of discharge
12 documentation. How often is medication
13 reconciliation performed through interoperable
14 information exchange? Shared data warehouse
15 within regions. Missing data/labs/consults.
16 Percent of lab results that do not cross
17 interface between EHR and LIS, lab information
18 system. Quality of external prescription data.
19 Interface consistently terminology, icons, risk
20 stratification.

21 Can we clarify this one here?

22 DR. ALEXANDER: Sorry, I have a lot of

1 clarification apparently.

2 (Laughter)

3 DR. ALEXANDER: So I was thinking with
4 the interface consistency -- so, if you have
5 people exchanging information does the interface
6 look the same on both sides? Are the data
7 elements and the content the same on both sides
8 so that they can consistently communicate about
9 the same issue in the same way? Do the icons
10 look the same? Do the colors look the same?
11 Does red, green, yellow mean the same thing in
12 two different interfaces between a long-term and
13 hospital administrations? That's what I was
14 thinking.

15 DR. PINES: Okay. Any additional
16 concepts around interactions with external
17 systems or interoperability?

18 MR. RUSSELL: I just wrote one down
19 for -- because I think we got hung up on external
20 systems --

21 DR. PINES: Okay.

22 MR. RUSSELL: -- and not looking at

1 what -- the lab one just triggered it in me --

2 DR. PINES: Oh, good.

3 MR. RUSSELL: -- of just interface
4 monitoring cues, because all the different -- you
5 have lab interfaces, rad interfaces. You name
6 it, there's interfaces.

7 DR. PINES: Okay. Great. Thank you.

8 CO-CHAIR SINGH: Yes, so you mean
9 monitoring including some sort of testing and --

10 MR. RUSSELL: More the internal --
11 yes, so internal interfaces, not the ones that
12 you're going to --

13 CO-CHAIR SINGH: Yes. Yes.

14 MR. RUSSELL: -- external to your
15 organization, but all your internal interfaces.
16 There's lots of problems.

17 CO-CHAIR SINGH: Right, but you
18 include sort of testing to make sure --

19 MR. RUSSELL: Testing and continuous
20 monitoring.

21 CO-CHAIR SINGH: Monitoring? Okay.
22 Great. Excellent.

1 DR. PINES: Okay. All right. Yes,
2 Kevin?

3 DR. HAYNES: Real quick, and I'll
4 write it down. So, I guess the question would be
5 how does it interact with external systems? So,
6 is it fully integrated versus Alt+Tab?

7 DR. PINES: Okay.

8 DR. HAYNES: I'll leave that up there,
9 because that's not necessarily integrated, right?
10 Alt+Tab to -- a browser to actually get the
11 information that you need.

12 DR. PINES: Okay. Any additional
13 concepts for external systems?

14 (No audible response)

15 DR. PINES: Okay. I'll move on. So,
16 features or functions not implemented or
17 available. The first one is IT sophistication
18 functionality in resident care clinical-supported
19 administrative activities. I think we saw this
20 one over here, too. Survey of users. Do you use
21 XYZ function or do you know if this exists? The
22 number of times CDS or alerts module turned off.

1 Patient record transmitted electronically to
2 specialist by referring physician X number of
3 days before appointment.

4 Use of AHRQ EMR flight simulator to
5 measure risk. Use of trigger tools: IHI, EDC.
6 CDS to set default. Sorry, CDS set to default.
7 That makes sense. Use of bar code scanning in
8 medication preparation. Whether the
9 EHR/implementation supports tiered alerting. End
10 users requirements determined prior to
11 implementation. Latest patch/update not
12 implemented. Advanced decision support.
13 Geriatric dosing and renal dosing, etcetera.
14 Medication adherence data.

15 Time from request to completion of
16 function by vendor. Number or percent of request
17 to vendor completed. Whether order assessed
18 exists for most common admit diagnoses. Percent
19 use of bar coding. Full close-loop test result
20 management systems. Measure times wrong record
21 is opened. Tiered alerting. We saw that before.
22 Multidisciplinary and fast clinical

1 documentation.

2 Can we clarify this one? So
3 multidisciplinary and fast clinical
4 documentation, what that means?

5 DR. GANDHI: I think that was me.

6 DR. PINES: Go ahead.

7 DR. GANDHI: So of this concept of not
8 having the physician's notes in one place and the
9 nurse's notes in another place --

10 DR. PINES: Okay.

11 DR. GANDHI: -- and so on. So it's
12 actually two concepts. The second is kind of
13 getting at what someone else talked about in
14 terms of how much time it takes to actually
15 document.

16 DR. PINES: Okay. And then abnormal
17 test results with no follow up.

18 Before we move on, any additional
19 comments or --

20 CO-CHAIR SINGH: So, Jesse, a couple
21 of related sort of comments. Oftentimes we hear
22 from folks that we saw patient safety issues and

1 we told the vendor. They recognize it, but they
2 said we're going to address it in the next
3 version. And the next version might be like, I
4 don't know, like a year or two away or -- I mean,
5 I'm sort of exaggerating. But is there any sort
6 of way we could sort of put some type of a
7 measurement as to what your responsiveness is?

8 And number two, people are now coming
9 up with all sorts of tracking tools and new
10 innovations that layer on top of the EHR. So the
11 capability to integrate such new innovative novel
12 applications into the EHR and sort of sharing
13 amongst them for tracking capabilities and so on
14 and so forth.

15 So just two things. And if you want
16 to reflect, guys, just go ahead. But those were
17 the two things I wanted to bring out.

18 DR. PINES: Okay.

19 MR. RUSSELL: I think it goes back to
20 something that Mark said yesterday, too.
21 Sometimes customers throw a patient safety flag
22 in there because they think it's going to move

1 things up and stuff. And so, that has to be
2 vetted internally first to come up with (1) is
3 there a fix; (2) how long does the fix take to --
4 how long does it really take to make a fix if
5 there really is a fix that needs to be made; and
6 (3) how fast can we push it out to customers?

7 So I think there are so many variables
8 in that that it's really hard to measure what's
9 truly a rapid response, if you would, to actually
10 putting out some new development.

11 CO-CHAIR SINGH: So maybe for a
12 critical safety issue? And we can sort of come
13 up with a definition. I'm sure Joint Commission
14 folks can tell us what critical safety issues
15 are.

16 (Laughter)

17 CO-CHAIR SINGH: But for critical
18 safety issues, then maybe we could say that we
19 could be -- I don't know, some sort of --

20 DR. PINES: Time to --

21 CO-CHAIR SINGH: Yes, time to address
22 it.

1 DR. PINES: -- change?

2 CO-CHAIR SINGH: Yes, for like a
3 version --

4 MR. RUSSELL: I'll finish and then
5 I'll let you go, Mark. I think there's also the
6 -- the time to address is -- then that becomes a
7 subjective thing, too, as how you address it is
8 going to be different in many circumstances.

9 DR. SEGAL: Yes, I mean, I would just
10 add to that that something can be critical and
11 easy to fix, quick to fix. It could be critical
12 and take longer just by its nature, including
13 just finding the root cause of these things. You
14 can alert a customer that a function is causing a
15 problem and maybe they should do a work-around,
16 but it may take longer to actually figure out
17 definitively what it is so then you know how to
18 engineer the fix. So I think it's one of those
19 where having a single number even around critical
20 is problematic because the types of things that
21 can be critical can be quite variable.

22 MR. RUSSELL: Right. And maybe the

1 better way to look at it is is there a mitigation
2 strategy? And the mitigation strategy can be
3 different.

4 CO-CHAIR SINGH: Yes, and actually the
5 measure could be putting in place mitigation
6 strategies for those types of things.

7 MR. RUSSELL: Right.

8 CO-CHAIR SINGH: Right. That could
9 also move to shared risk, but I thought I would
10 mention that here.

11 DR. PINES: Okay. Jason, you had a
12 comment?

13 DR. JONES: Yes, I didn't know how to
14 put this up so I left it off. But one thing is
15 the vendor fixes. The other is a lot more of
16 what we run into is implementation issues and how
17 long it takes to get a change put in place. Like
18 an order set, right? I mean, we configure our
19 own order sets. How long before someone says can
20 you make this modification to an order set until
21 it's there? I don't know how we would do that,
22 but that for me is more common and more

1 meaningful I think to both the safety and utility
2 of HIT than a lot of the vendor pieces.

3 DR. PINES: Okay.

4 DR. JONES: I don't know how other
5 people feel about that though. No one configures
6 your systems? You just put them in?

7 (Laughter)

8 DR. PINES: Why don't we make it a
9 sticky and put it up there.

10 DR. HEERMANN-LANGFORD: Yes, put a
11 sticky up there. I mean, we do a lot of internal
12 configuration and even development on things as
13 well, I mean, additional development. So, it's
14 not just on the vendor side of the response time
15 to those changes.

16 DR. PINES: Okay. So, let's go ahead
17 and move on. So we've got a lot for patient
18 engagement here. So, we've got patient portal
19 data incomplete. Patient preferences for access.
20 OpenNotes. Proficiency of patients to use
21 portals. Are there education modules? Can they
22 use the systems? Test results released via

1 portal to the wrong patients. Use of OpenNotes
2 input, I guess, outpatient and inpatient.
3 Measure patient validation of abnormal test
4 results. Number percent of patients that access
5 their patient portal. So, a lot of the same
6 concepts here.

7 Patient's discharge summary offered in
8 print and digitally available via patient portal
9 or email. Patient's choice. Response to secured
10 message sent by patient received within 24 hours.
11 Timely transmission of patient lab test results
12 to patient portal. Include timeliness of
13 clinical phone call/before release of lab test
14 results. Human/computer interaction diagnostics
15 or testing with patients. Member use of portal.
16 Physician knowledge of my condition. Member
17 involvement in development process. Patient
18 satisfaction on portal and clinical interaction
19 with patient.

20 Patient involvement with HIT-related
21 committees. Percent of the complete record
22 including progress notes available to patient in

1 the PHR. Ability, slash -- I don't know if I can
2 read this one here. Ability/training proficiency
3 of patient to contribute to the record or be able
4 to see their contributions in the electronic
5 health record. Measure routine patient
6 verification of medication list. Risks/benefits
7 of tele-health and apps.

8 Percent use of patient portals or
9 completeness. Percent duplicate patients in EHR.
10 Measure post-hospital studies and diagnostic
11 tests and in-hospital studies diagnostic tests
12 communicated to primary care provider. Frequency
13 of patients filling prescriptions after discharge
14 from hospitalization. Frequency of patients
15 accessing the portal.

16 We've got a few in pencil here. Post-
17 discharge test studies being completed and
18 communicated to the PCP. Filling of prescription
19 following discharge. Frequency of patient
20 accessing patient portal. And the final one is
21 here recording of patient preferences and how it
22 is transmitted to whom.

1 So a lot of the same concepts within
2 the patient engagement. Are there any additional
3 ones?

4 (No audible response)

5 DR. PINES: Incorporate patient portal
6 with clinician view. Okay. Any additional ideas
7 for patient engagement?

8 MS. FREEMAN: This is Lisa again. I'm
9 just wondering, is there a way to measure how
10 many different patient portals a single patient
11 has?

12 DR. PINES: Number of patient portals?
13 Okay.

14 DR. SCHNEIDER: Portal burden we call
15 that.

16 (Laughter)

17 DR. PINES: What?

18 MS. FREEMAN: There you go.

19 CO-CHAIR BELMONT: Do you mean if
20 you're managing one for yourself and then for
21 other members of your family?

22 MS. FREEMAN: No, I mean that when I'm

1 -- in my primary care practice I have one patient
2 portal. I have another patient portal for
3 diagnostic studies with the X-ray company. And
4 they don't talk to each other. Not all the
5 providers are linked together yet.

6 CO-CHAIR BELMONT: Multiple portals
7 based on multiple providers.

8 MS. FREEMAN: Yes, and one patient.

9 DR. PINES: Okay.

10 MS. FREEMAN: And I think that carries
11 over in some way over into not just the patient
12 engagement side, but for providers. My physician
13 has to go to different portals to get my test
14 results versus my medical records.

15 DR. PINES: Okay. David, did you have
16 one? This is for shared risk.

17 (No audible response)

18 DR. PINES: Okay. Any additional
19 comments on patient engagement? Additional
20 measures?

21 (No audible response)

22 DR. PINES: Okay. That was Lisa's?

1 Okay. So, the last one is shared risk. We have
2 self-assessment with SAFER guides. Effective
3 vendor user groups. Frequency of electronic
4 health information exchange. Involvement of IT
5 in RCAs. So, that's root cause analyses. Health
6 IT safety reports to board. Best practices for
7 implementation and CDS and knowledge shared
8 across organizations and vendors.

9 Communication/training systems update
10 and system build. Work flow with cognitive
11 mapping completed before implementation where
12 identified errors are fixed. Incorporate
13 external advisory boards of stakeholders. Vendor
14 involvement post-implementation. Types of
15 functionality. Vendor versus functionality used
16 at the end user level. Increased costs of system
17 work-arounds. Overtime scribes.

18 Decrease patient throughput shared by
19 vendor. Health information exchange between
20 multiple vendors. Information easy to access and
21 is accurate. Possible system redesigns get
22 addressed in a timely manner. Critical system

1 redesigns done before the implementation.

2 Vendors share lessons across each other.

3 Provider arranges for needed training.

4 Percentage of time dedicated to training and
5 implementation. Vendors share lessons across
6 institutions.

7 Shareholder involvement in root cause
8 analyses. Vendor notification to all users
9 following identification of
10 software/hardware/other issues that materially
11 affect patient safety. Vendor provision of
12 solutions to identified issues to all users ASAP
13 following event. Software-related patient safety
14 tickets response times. So on the vendor side
15 the vendor response times.

16 DR. HUNT: Actually, it fits right in
17 with those other ones. The number of patients
18 exposed to a defect after it's reported. So once
19 it's known and it's in the vendor's hands, or
20 whoever is to handle it, how many patients then
21 get exposed to that? Because almost by
22 definition they're at the very least a near miss.

1 DR. PINES: All right.

2 MS. GRACE: Erin Grace. A lot of
3 these sound to me -- I'm missing the shared risk
4 part and I'm hearing the hospital or organization
5 risk part. So and the one about reports, annual
6 reports to the Board on health IT safety is
7 perhaps health IT safety reports back to the
8 vendor?

9 DR. PINES: Okay. Put it up. So this
10 is really, really great and this is exactly what
11 we needed for today. So any additional comments
12 for shared risk? Yes?

13 DR. HUNT: With the one I just
14 mentioned, as far as patient exposure, I thought
15 of that as a shared risk because in quantifying
16 that, both the hospital is acknowledging that now
17 we know that patients may be harmed. And then
18 the vendor also has some skin in the game,
19 because they can then tally the number of
20 patients that were exposed to this until we had
21 it fixed.

22 DR. PINES: All right. Thank you,

1 everyone.

2 CO-CHAIR SINGH: This is great. I
3 want to sort of see if, Helen, either you or
4 Eric, sort of the senior people who've done some
5 quality measure development, want to reflect on
6 this and see what sort of potential next steps
7 and --

8 DR. SCHNEIDER: Well, I'll just say
9 this is terrific. I mean, this is terrific
10 output from what I heard during the two days of
11 discussion. In one project where we developed
12 quality measures for cancer care I think we had
13 somewhere on the order of this many. I don't
14 know how many are up there, but 60 to 100 measure
15 concepts. We actually developed 180 measure
16 statements which then went through a series of
17 different reviews and got boiled down to 109
18 measures that went into testing in a five-city
19 study. I think 30 percent of those died in terms
20 of implementation and feasibility of
21 implementation.

22 And I won't go through all the cascade, but

1 ultimately there were three measures that were
2 adopted into a national program for quality
3 measurement.

4 So that's kind of a preview of coming
5 attractions is there will be a lot of attempts to
6 try to implement, design ways of implementing
7 some of these measures if they pass muster from
8 this group. Probably some new measure concepts
9 will come into the mix as we digest what was
10 given today. And what comes out the other end
11 actually are some really well carefully selected
12 measures where hopefully we will know what the
13 performance characteristics of those measures are
14 and we have a good sense that they'll be
15 influential. So just my reflection.

16 CO-CHAIR SINGH: Okay. Helen?

17 DR. BURSTIN: I knew you had it in
18 you.

19 (Laughter)

20 DR. BURSTIN: So, it's great to
21 actually see all these concepts. It's
22 interesting how many relate to each other. I

1 think the exercise next will be to do a little
2 bit of an exercise of grouping them together into
3 some sort of grouping. And I think they
4 logically group. It's fascinating to see how
5 many actually are in the patient engagement
6 group, which was something -- as David Classen
7 pointed out, was not something other than a small
8 chapter in the original IR report. And I think
9 given the context now it's very different.

10 So, I think this is great. And again,
11 not everything has to rise to the level of being
12 a fully reportable accountability measure for CMS
13 programs or otherwise. Some of these just may be
14 very good shared information for learning that
15 ONC could promulgate, some of which could then
16 become sort of an important substrate for
17 measures. And some of it could also be topics
18 you put out there and then we hear from the field
19 where somebody may have a measure like this that
20 we can at least begin that shared learning we
21 heard a lot about the last couple of days, too.
22 So, remarkable.

1 DR. ZIMMER: I would just ask the NQF
2 members that summarized yesterday's findings if
3 there's anything that you can recall, since you
4 actually have the notes, that's missing that
5 wasn't mentioned today?

6 MR. GOLDWATER: Nothing from me. I
7 mean, that was one of the things I was listening
8 to, so I didn't hear --

9 MR. LYZENGA: Yes, nothing off the top
10 of my head, but I'll go back to our notes as well
11 and we'll add in things up here.

12 DR. PINES: Yes, I don't think so in
13 my group, but again we'll go back through and
14 make sure.

15 CO-CHAIR BELMONT: Okay. So, Jesse,
16 do you want to talk about some sort of
17 harmonization-type issues while we close up, or
18 any final sort of -- we've got about 15-20
19 minutes.

20 DR. JONES: So, someone; I think,
21 Jason, it might have been you, asked about
22 wouldn't it be great if MR vendors had app

1 stores? Was it you?

2 DR. ADELMAN: It might have been.

3 DR. JONES: Yes.

4 (Laughter)

5 DR. JONES: So, you've just changed
6 the world, because one of the vendors has just --
7 one of the large vendors has just announced an
8 app store.

9 DR. ADELMAN: Really?

10 DR. JONES: Yes, and maybe that can be
11 one of the measures up there, is how many apps on
12 the app store like Android or something. Anyway.
13 So, that just happened.

14 DR. ADELMAN: You're welcome.

15 (Laughter)

16 DR. PINES: Just maybe one question
17 for David Hunt. I know that there's a lot of
18 stuff going on through ONC right now in this
19 area, so a lot of sort of overlapping projects.
20 And just wanted to make sure that at least in
21 your mind sort of what we're doing with this
22 measurement prioritization is sort of clear,

1 clearly distinct from other projects. And we'll
2 certainly be following up with you, but wanted to
3 see if you had any comments for the Committee in
4 terms of differentiating this project from other
5 ones from what you've heard today.

6 MR. LYZENGA: Or opportunities where
7 they could be harmonization or sort of sharing of
8 information or deliverables or anything like
9 that.

10 DR. HUNT: Yes, I think that I would
11 say it's probably 80 percent unique. There is
12 some overlap. I would be surprised if there
13 weren't a little bit. It would be a little bit
14 scary if we were completely. But what I would
15 say is let's let the process continue. So let's
16 see what kind of development we get and then
17 we'll have sort of a reconciling where we'll see
18 some of the other areas that are overlapping and
19 make -- it's almost -- we can almost have an
20 embarrassment of riches. We can decide, well,
21 which way should we go with this? Because
22 obviously with the RTI project there's going to

1 be some natural overlap between those two areas.
2 But I think we're fine as we are right now.

3 CO-CHAIR SINGH: The only additional
4 sort of question building on that is do you
5 envision some type of these measurement concepts
6 going within the umbrella of the ONC Safety
7 Center, or is this just going to be totally two
8 separate things and sort of be running in
9 parallel? Do you see any overlap?

10 DR. HUNT: No, no, that's an easy one.
11 No, we always thought that this work would be
12 folded into and become a part and parcel of the
13 work of the ONC Safety Center.

14 I guess I'm not speaking out of
15 school. When we were developing the contract
16 vehicles for both, the opportunity to have
17 resources to do this project through the NQF Task
18 Order came up, but originally we said we knew
19 that this would have to be done and that this
20 should be housed eventually in the Safety Center.
21 And it was just a quirk or a feature of our
22 resource allocation at HHS that allowed us to do

1 this work through the NQF Task Order. So
2 definitely every expectation is that this would
3 fold into at very least the Safety Center.

4 But as you've seen time and time
5 again, measures after a while have a little bit
6 of a life of their own in some respects. And if
7 they have applicability to other aspects and
8 other programs, I'm sure they will be cross-
9 pollinated.

10 DR. BURSTIN: We're delighted to be a
11 quirk.

12 (Laughter)

13 MS. GRACE: And with all due respect,
14 whenever you start by saying I'm not telling
15 tales out of school, I get nervous.

16 (Laughter)

17 MR. LYZENGA: Maybe one more thing, if
18 I could. Oh, yes, there's the definition issue.
19 And then also I just wanted to see if anybody had
20 any sort of general thoughts about the framework
21 at this point, whether we've got sort of this
22 kind of a framework of sorts up here on the wall.

1 We've discussed a little bit the three-phase and
2 eight-dimension socio-technical framework. If
3 anybody has any thoughts on what might be most
4 useful moving forward and how we're going to sort
5 of draft up a conceptual framework in our report.
6 If you have any thoughts on that, we'd certainly
7 welcome it. But we can also talk about the
8 definition quickly, if you want to do that.

9 CO-CHAIR SINGH: So, why don't you
10 pull up the definition? I think Mark has a
11 comment.

12 DR. SEGAL: You're actually talking
13 about the definition of health IT?

14 CO-CHAIR SINGH: Yes, the one we
15 discussed yesterday.

16 DR. SEGAL: Yes, that was part of what
17 I was going to address. And maybe I'll just make
18 another comment just to kind of get it on the
19 table. I think this is terrific in terms of
20 everything that we gathered. Thinking about
21 measures, some of what was identified were
22 preferences, right, in terms of how portals work

1 or just various things. Again, all really
2 important, all the kind of things that James and
3 I and our colleagues take to heart as we hear
4 from our customers.

5 I guess I'd probably suggest that not
6 all of those are appropriate for measures and
7 that thinking about measures we really want to
8 identify those things that are not only
9 preferences, but preferences that are sort of
10 backed by underlying science. If they're not
11 backed by science, it doesn't make them
12 important. It's just not clear they belong kind
13 of in the measure thread ultimately.

14 CO-CHAIR SINGH: Yes, Mark, great
15 points. And just to sort of show an example,
16 just because somebody accesses a portal is
17 probably not as much connected to sort of patient
18 safety as getting somebody else's result. For
19 instance, an abnormal mammogram that actually was
20 another patient's, that we interviewed a patient
21 who received that. So I think you're right that
22 we probably need to sort of go one step further

1 to say what is the patient safety implication of
2 this?

3 DR. SEGAL: Or just another example,
4 OpenNotes. Again, really important. Strikes me
5 as probably premature to organize a measure
6 around whether people are using OpenNotes.
7 There's probably other vehicles to try to push
8 that out.

9 DR. ZIMMER: To build on what Mark
10 said, there's almost two areas. There's the
11 measures. And I do think we'll have to write in
12 some suggestions. And this comes back to
13 disseminating tools that are out there. So that
14 may not be a measure, but there's a lot of
15 knowledge in this room about local successes, and
16 that needs to be disseminated. So I don't know
17 if there will be a separate section in the paper
18 of suggested tools and methods to help you with
19 implementation in all these different areas we're
20 talking about. So I just want to make sure that
21 we don't lose all this other great information
22 just because it doesn't fit into a measure.

1 CO-CHAIR BELMONT: So, Helen and I
2 took the IOM definition from yesterday and we
3 incorporated feedback we got from the Committee.
4 And on the screen I think that we're showing --
5 yes, we're showing the first paragraph which
6 stayed the same.

7 Adeela, if you could please scroll
8 down to the second paragraph?

9 And this is the paragraph that Helen
10 and I modified and tried to include everyone's
11 comments. I also received an email this morning
12 from Erin who shared with me that AHRQ had come
13 up with a definition of health IT. And so since
14 we're being complete, we will show that to you,
15 too. And I guess if people want to take a quick
16 look at this, if you have comments today, great.
17 And we'll talk about it for just a couple
18 minutes. And then people can always email us
19 comments, too.

20 So, Erin?

21 MS. GRACE: I just wanted to clarify
22 that the definition of health IT comes from our

1 funding opportunity announcements for grants.
2 And it was developed specific for that purpose,
3 not to be the be-all-end-all definition of health
4 information technology. So I just wanted to be
5 clear about that. But I thought some of the
6 language in there might be helpful.

7 CO-CHAIR BELMONT: Thank you. Mark?

8 DR. SEGAL: Yes, just one point.

9 Where we say "technologies including the
10 components of electronic health records, patient
11 imaging and other related technologies," I think
12 it's probably worth specifically calling out;
13 again, we can kind of work on the English,
14 specialty health IT solutions.

15 CO-CHAIR BELMONT: Yes, that's good.

16 DR. SEGAL: Because EHR is kind of a
17 -- I mean, you can take that broad term that it's
18 all part of the EHR, but I think we have to think
19 about how it's used almost kind of commercially.
20 And so, to make sure -- I think we want a
21 definition of health IT that's really inclusive
22 of what the industry generally thinks of as

1 health IT. And that would be one specific add
2 that itself kind of is an umbrella, specialty
3 health IT solutions.

4 CO-CHAIR BELMONT: Yes. No, we can do
5 that. Greg?

6 DR. ALEXANDER: Yes, I just wanted to
7 say about the fifth line up where you start with
8 "clinicians," you're sort of outlining the people
9 that are sort of involved in this from the way it
10 looks.

11 CO-CHAIR BELMONT: Yes.

12 DR. ALEXANDER: And then I think
13 families need to be involved in that, because in
14 different settings families are going to be
15 making decisions about patients that aren't able
16 to make their own decisions. And so, they'll be
17 using the technology as well.

18 CO-CHAIR BELMONT: Yes, we can do
19 patients and their families. Thank you. And
20 because of the comment yesterday about payers,
21 that's why we included reference to payers in
22 this.

1 DR. HAYNES: Yes, I was just going to
2 make a quick comment to that, because we're sort
3 of in the second sentence, but really that
4 exchange of health information --

5 CO-CHAIR BELMONT: Yes.

6 DR. HAYNES: -- you know, CMS probably
7 has the most health information anywhere, right?
8 So I mean, they're definitely a technology that
9 would warrant in this space.

10 CO-CHAIR BELMONT: Okay. So we can
11 make that change as well, too. James?

12 MR. RUSSELL: Just on the listing of
13 clinicians, payers, patients, we're leaving out
14 people who are non-clinicians who are using
15 health IT in all sorts of different ways.

16 CO-CHAIR BELMONT: Do you want to say
17 administrative personnel?

18 MR. RUSSELL: I don't know what word
19 I want to use, but --

20 (Laughter)

21 MR. RUSSELL: -- I know those people
22 exist.

1 DR. BURSTIN: Or maybe just highlight
2 "users including" to be more broad.

3 CO-CHAIR BELMONT: Yes.

4 MR. RUSSELL: Yes, something that's
5 broader, because --

6 CO-CHAIR BELMONT: Sure. We can do
7 that.

8 DR. ZIMMER: Or "health care
9 providers" instead of "clinicians."

10 CO-CHAIR BELMONT: Other comments?

11 (No audible response)

12 CO-CHAIR BELMONT: Okay. Then why
13 don't we -- Adeela, if you'd be willing, if we
14 could just show folks the AHRQ definition?

15 Is there anything that jumps out from
16 that definition that we should make sure is
17 included in the working definition that we have?

18 Yes, David?

19 DR. HUNT: Kathy, do we have -- I know
20 this sounds silly, but does ONC have a strict
21 definition of health IT?

22 MS. KENYON: (Off microphone)

1 DR. HUNT: Okay.

2 PARTICIPANT: She said no.

3 CO-CHAIR BELMONT: My experience has
4 been that it's sort of an evolving definition.
5 As the technology grows the definition seems to
6 grow.

7 DR. SEGAL: Yes, just I think that
8 this is great. I think the prior definition
9 probably has a level of specificity in terms of
10 the actual technologies. That's important for
11 the work of the measures. And I guess what I
12 would just suggest is off-line look at whether
13 there are concepts in here that kind of add to
14 the more general statements. But I think the
15 level of detail that's in the prior one that you
16 all worked on is probably important in terms of
17 supporting the measure development process.

18 CO-CHAIR BELMONT: Okay. We will do
19 that. And, Erin, thanks again for sharing that.

20 And the last observation I'd make on
21 this, Helen and I tried to write this from a
22 patient safety perspective and I think that's one

1 way how our definition may differ from others
2 that currently exist. So, thank you.

3 MR. LYZENGA: Well, I think we could
4 maybe ask for public comment at this point if
5 there are no other questions or comments in the
6 room.

7 Operator, are there any public
8 comments on the phone?

9 OPERATOR: Okay. At this time to make
10 a comment, please press star then the number one.

11 (Pause)

12 OPERATOR: There are no comments at
13 this time.

14 MR. LYZENGA: Thank you. Adeela, do
15 you want to quick run through next steps and just
16 we'll take a look at the timeline moving forward?

17 MS. KHAN: Thank you, everyone, for a
18 really productive second day. We're actually
19 going to be meeting again via conference call on
20 April 21st. During that meeting we're actually
21 going to be finalizing our environmental scan.
22 And I'm thinking probably during that meeting

1 we'll be able to disseminate all of these Post-it
2 notes and organize it a little bit for everyone
3 to take a look at. And we'll start thinking
4 about the framework as well.

5 We have another conference call on
6 July 21st where we're going to be reviewing the
7 draft framework. And then our second in-person
8 meeting is September 16th and 17th. And you
9 should have all of those dates on your calendar
10 as well. We'll then be reviewing the report
11 again on January 26th. And then our final report
12 will be due in February, mid-February.

13 So that's all we have for dates.

14 CO-CHAIR SINGH: There's a public
15 comment period?

16 MS. KHAN: Yes, there is a public
17 comment period to the January meeting. I don't
18 have the exact dates with me, but we will share
19 that with you as it gets closer.

20 MR. LYZENGA: Yes, I think it will be
21 just prior to that, or shortly before the January
22 conference call. So we'll sort of compile those

1 comments for you, categorize them, etcetera, and
2 just ask you for some responses or thoughts. We
3 may propose some responses based on the committee
4 discussions prior to that, but that's where we'll
5 kind of adjudicate the public comments.

6 MS. KHAN: That's the end of the
7 meeting.

8 MR. LYZENGA: Anything else? Well,
9 thank you all so much. Really this has been a
10 fantastic meeting. Really productive. I think
11 we've gotten everything just about that we wanted
12 to get out of it. We thank you all for coming
13 through the bad weather, making it here and
14 preserving. We look forward to continuing to
15 work with you over the next year.

16 I don't know, do you guys have any --

17 CO-CHAIR SINGH: And as Co-Chairs I
18 guess we can just really appreciate everybody's
19 input and putting through all of the hard work
20 that we did. I want to thank NQF as well, Helen,
21 and everybody, and, Eric, for keeping us sort of
22 on task what to do some of these things. And

1 especially it's been great actually right from
2 EHR vendors and stakeholders to hear everything
3 from all kinds of angles. So, thank you.

4 DR. BURSTIN: And thanks to our
5 Chairs, obviously. And also thanks to David for
6 not being silent, because it was very useful
7 having you at the table.

8 (Laughter)

9 MR. LYZENG: Safe travels.

10 (Whereupon, the above-entitled matter
11 went off the record at 2:51 p.m.)
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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: HIT Safety Committee

Before: NQF

Date: 02-19-15

Place: Washington, DC

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