

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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WEDNESDAY
FEBRUARY 18, 2015

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The Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:30 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*

ANDREA GELZER, MD, MS, FACP, AmeriHealth Caritas
Family of Companies

ERIN GRACE (ex officio member), MHA, Director,
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

GEORGE HRIPCSAK, MD, MS, Columbia University and
New York-Presbyterian Hospital

JASON JONES, PhD, Kaiser Permanente

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

WILLIAM MARELLA, MBA, Pennsylvania Patient
Safety Authority

DENA 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

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

2 (8:34 a.m.)

3 MR. LYZENGA: All right. Well,
4 welcome, everybody, to the meeting of the Health
5 IT Safety Committee at NQF. We are going to
6 start out just by doing a few introductions of
7 our staff and our co-chairs. I will actually
8 just turn it right over to our co-chairs to
9 introduce themselves first.

10 CO-CHAIR SINGH: Thank you. Welcome,
11 everybody. Thanks for being here in this great
12 weather. I am not sure where you guys are coming
13 from but I flew in from Tucson with 70 degrees,
14 sunny weather. So, it is kind of a change for
15 me.

16 My name is Hardeep Singh. I am one of
17 the co-chairs for the committee. I am a general
18 internist and a patient safety researcher at
19 Baylor College of Medicine at the Houston VA.
20 And I have studied health information technology
21 and patient safety, mostly as an academician for
22 the last few years and also was heavily involved

1 in making the SAFER Guides.

2 CO-CHAIR BELMONT: So, I am Elisabeth
3 Belmont and I am Corporate Counsel for
4 MaineHealth in Portland, Maine. And I flew in
5 from about four feet of snow and was looking
6 forward to coming to a nice, warm, sunny, D.C.

7 Well, I have a long background in
8 health information in technology issues. I
9 founded the Health Information Technology
10 Practice Group for the American Health Lawyers
11 Association a number of years ago and I am a past
12 president of that organization.

13 I am also currently a member of the
14 Institute of Medicine's Health Care Services
15 Board and their Study Committee on Diagnostic
16 Error in Medicine which is also looking at some
17 of the HIT-related issues. So, I think this is
18 an important issue and I am very delighted to
19 have the opportunity to collaborate with all of
20 you on this project.

21 MR. LYZENGA: And I am Andrew Lyzenga.
22 I am a senior project manager here at NQF. I

1 have been here for about five years or so and
2 worked primarily on safety-related projects,
3 although a number of other related projects
4 across our sort of scope of work.

5 DR. PINES: Hi. I am Jesse Pines. I
6 am a consultant here at NQF and I have been
7 working with NQF for the last four years on
8 various projects in patient safety and
9 complications, Health IT and emergency medicine.

10 I am also a professor of emergency
11 medicine and health policy at George Washington
12 University.

13 MS. KAHN: Good morning. My name is
14 Adeela Khan. I am the project manager for this
15 project. I have been at NQF for three years.

16 MR. GOLDWATER: Good morning. I'm
17 Jason Goldwater. I have been at NQF for a month,
18 as of today. So, I have been involved in Health
19 IT for a long time and I have been involved in
20 the patient safety world for some time as well.

21 MR. LYZENGA: And actually, before we
22 get into the committee introductions -- actually,

1 maybe I will just say a few words about the sort
2 of committee charge first, just to sort of give a
3 little context. And then we are going to have
4 actually Helen Burstin, our Chief Scientific
5 Officer have our committee introductions but also
6 do a quick disclosure of interest at that point.

7 Just again to say a few words about
8 the committee charges for context. We are asking
9 this committee to help us provide guidance on
10 identification of best practices, challenges, and
11 barriers to measuring and preventing HIT-related
12 safety events. And then to also provide us input
13 on what you think the highest impact measures and
14 measurement areas are, how we can sort of
15 prioritize that and make recommendations on gap-
16 filling and future development. We would like
17 you to provide input on all phases of the
18 project, including the environmental scan, which
19 you will hear a bit about the preliminary results
20 but will be ongoing in the next several months.
21 Some guidance on our development or modification
22 or use or adaptation of a conceptual framework

1 for thinking through these issues. And then
2 generally, to act as a proxy for the NQF multi-
3 stakeholder membership and the general public.
4 You will notice that there is some sort of
5 variety in stakeholder representation here, which
6 we try to do on all of our NQF committees and we
7 ask that you do act as an individual subject
8 matter expert but are also, to some degree here
9 to represent a particular perspective in
10 stakeholder group.

11 And then we will, as with all NQF
12 projects, be accepting public input from our
13 membership, from the general public. We try to
14 keep our processes transparent as possible and
15 provide ample opportunities for public comment
16 and input and we will ask you to help us review
17 and adjudicate that input as it comes in.

18 In terms of this meeting, our
19 objectives are really to, again, review these
20 preliminary scan results and to get some feedback
21 from you, some input on carrying forward with the
22 rest of the environmental scan, to help us

1 identify it, measurement and other considerations
2 to guide development of the conceptual framework,
3 areas we should prioritize or focus on for the
4 remaining environmental scan, to identify some
5 key opportunities to be consistent with other
6 programs into this area, including our common
7 formats, a number of other safety and quality
8 measure programs that you will be hearing about
9 later.

10 And then again, to give us some
11 direction on development of the conceptual
12 framework, your thoughts about that, some ways we
13 could improve it or adapt it and so on.

14 And with that, let's skip over this
15 and just go ahead and hand it over to Helen for a
16 quick introduction and then disclosures of
17 interest.

18 DR. BURSTIN: Great. Good morning,
19 everybody. I am Helen Burstin, the Chief
20 Scientific Officer here at NQF. I am delighted
21 you could join us. This is, I think, a really
22 important area of work that we were delighted to

1 work on for ONC and CMS. Some of you may know
2 this was a pretty significant session at the ONC
3 annual meeting last week. It was also heavily
4 talked about at Academy Health last week as a
5 part of a session I led on Health IT. So, I
6 think this is front and center and we are hoping
7 we can really help do what was in our task order,
8 which is to deliver the definitive report on this
9 topic and try to think about what measures might
10 be possible.

11 So, I also want to introduce Marcia
12 Wilson, who is our Senior Vice President for
13 Quality Measurement who will be in and out with
14 us through the course of the day.

15 But for the disclosures part, as we go
16 around the room and ask you to do introductions,
17 we have all seen your CVs. We know you because
18 we picked you to be on this committee. We don't
19 need a recitation of your CV. We would ask you
20 to share any disclosures, anything you are
21 working on that might be directly relevant to the
22 work of this committee. And sometimes it is not

1 really all about financial disclosures. It may
2 not be stock, for example, in a given company,
3 but it may also just be perspective or a bias
4 that it would be helpful for others around this
5 table to be aware of.

6 So with that, I will turn to Elisabeth
7 and then we will go around the room.

8 CO-CHAIR BELMONT: In terms of
9 disclosures, currently I am a member, as I
10 mentioned, of the IOM Diagnostic Error Committee.

11 Additionally, I am working on several
12 health information and technology-related
13 articles but none of them are specifically
14 related to measurement. So, thank you.

15 CO-CHAIR SINGH: I have received
16 funding from the Department of Veterans Affairs,
17 NIH, AHRQ, as well as ONC for the development of
18 what is known as ONC SAFER Guides. So, I guess
19 that is a potential disclosure I would like to
20 make.

21 MS. MENDELSON: Hi. This is Dena
22 Mendelsohn. I am here from Consumers

1 Union/Consumer Reports. And my only disclosure
2 is that I am grant-funded group from the
3 California Foundation for Healthcare -- sorry --
4 California Healthcare Foundation doing health
5 advocacy focusing on Health Information
6 Technology.

7 DR. DIMITROPOULOS: I'm Linda
8 Dimitropoulos from the Research Triangle
9 Institute and I need to disclose that I am the
10 co-lead for the ONC-funded project to develop the
11 roadmap for the Health IT Safety Center. We
12 primarily do a lot of work with the federal
13 government, with ONC, AHRQ, and CMS.

14 MR. RUSSELL: I'm Jim Russell. I am
15 a pharmacist and I work for Epic. So, that's my
16 disclosure is I am an employee of Epic and we are
17 a health IT provider.

18 DR. JONES: Jason Jones. I hadn't
19 really thought about the disclosures that
20 broadly. I mean I guess my job is to try to
21 oversee the implementation of point of care
22 decision support. So, if it doesn't work, I

1 guess I will have to look for another career or
2 something.

3 At the same time, reading through the
4 background, it was sort of inspiring, again, to
5 see how weak the evidence is in this regard. I
6 am looking forward to trying to find ways to
7 either make things effective or find alternate
8 paths to improving patient safety.

9 MR. MARELLA: Good morning. I'm Bill
10 Marella. I'm here from the Pennsylvania Patient
11 Safety Authority and we run a large population-
12 based safety surveillance system. So, that is
13 one of my biases.

14 I also work for ECRI Institute, which
15 has had a number of contracts with ONC. We do a
16 lot of work for AHRQ and, going back a few years
17 in my career, actually with Eric, was part of the
18 team that developed the National Quality Measures
19 Clearinghouse, which informed some of my quality
20 measure perspective.

21 DR. ALEXANDER: Hi, I'm Greg
22 Alexander. I'm from the University of Missouri.

1 I am a professor at the Sinclair School of
2 Nursing. I am a researcher. My disclosures are
3 I have funding from the Centers for Medicare and
4 Medicaid on their hospital readmissions project.
5 I also have funding from AHRQ for patient safety.
6 My background is in long-term care, as well as I
7 have worked in ICUs and other settings around
8 where nurses work.

9 DR. SCHNEIDER: Hi. I'm Eric
10 Schneider. I am the third week into a new
11 position as Senior Vice President for Policy and
12 Research at the Commonwealth Fund in New York,
13 which is a health policy research foundation.

14 Until the end of last year, I was
15 Director of RAND's Boston Office and worked on
16 several projects with ECRI Institute related to
17 patient safety and health IT issues. I also was
18 a professor at Harvard School of Public Health
19 and a general internist, seeing patients at
20 Brigham and Women's Hospital where I probably
21 caused several health IT safety events, if not,
22 participated in them.

1 So, I am delighted to be here with all
2 of you.

3 DR. HRIPCSAK: Hi, George Hripcsak,
4 Chair of Biomedical Informatics at Columbia
5 University. I serve on workgroups at ONC related
6 to HIT and I have funding from AHRQ and NIH,
7 mostly on quality improvement but some elements
8 of patient safety. And I am also on a board for
9 RHIO, but I don't think that is relevant.

10 DR. ZIMMER: My name is Karen Zimmer.
11 I am currently an independent consultant in
12 Health IT and Patient Safety and Quality. For
13 disclosure, I formerly was the Medical Director
14 for ECRI Institute PSO and integral in the
15 development of that. And also was the past ECRI
16 lead for the HIT projects.

17 DR. ADELMAN: Good morning. I'm Jason
18 Adelman. I am the Patient Safety Officer for the
19 Montefiore Health System in the Bronx, New York.

20 As far as disclosure, I developed one
21 HIT safety measure about wrong patient errors and
22 I have some funding from AHRQ to further my

1 research in wrong patient errors.

2 DR. SEGAL: Good morning. Mark Segal
3 with GE Healthcare IT. Like Jim, one disclosure
4 is I work for a health IT company where I am
5 involved both internally in helping our teams
6 deal with both quality measures and also patient
7 safety policy issues and then, externally in a
8 number of public policy and industry settings.

9 I am currently chair of the EHR
10 Association and then serve on or am lead on a
11 number of industry policy committees, such as
12 with eHI and HIMSS.

13 DR. HEERMANN-LANGFORD: I'm Laura
14 Heermann-Langford and I work for Intermountain
15 Healthcare. So, I think I am representing the
16 provider organizations here.

17 I also work a lot with the standards
18 organizations, HL7 and IHE. I co-chair several
19 committees within both of those. And I have a
20 nursing background, mostly with emergency care
21 and care coordination across the different
22 venues.

1 DR. KHUNLERTKIT: Hi, I'm Nana
2 Khunlertkit. I'm a human factors specialist from
3 the Johns Hopkins' Armstrong Institute. My role
4 over there is to make sure the transition between
5 two electronic medical records go as smoothly as
6 possible. So, I may have bias toward how it
7 works and how it is not being worked very well.

8 And in the past, I have done several
9 research on the barriers and the facilitators
10 that providers may have when we implement the
11 electronic medical record.

12 DR. CLASSEN: Hi, I'm David Classen.
13 I am an infectious disease physician from the
14 University of Utah and I am funded there from
15 AHRQ to look at waste and measure the safety of
16 EHRs in actual operation.

17 In addition, I chair the NQF Common
18 Formats Panel, which advises AHRQ on how to do a
19 standardized common format for PSO reporting.
20 And I also work part-time for a patient safety
21 organization called Pascal Metrics.

22 And so my disclosures, probably all of

1 those areas.

2 DR. BURSTIN: Thank you. Any members
3 on the telephone? Tejal, good morning.

4 DR. GANDHI: Hi, this is Tejal Gandhi.
5 I am currently the President and CEO of the
6 National Patient Safety Foundation and formerly
7 did quite a bit of research on HIT safety based
8 out of Brigham and Women's and Partners
9 Healthcare. I was also the Quality and Safety at
10 the Brigham for about ten years and then Chief
11 Quality and Safety Officer for Partners
12 Healthcare.

13 And I am hoping to be there in person
14 tomorrow, if my flight actually leaves today.

15 In terms of disclosures, I also serve
16 on some ONC workgroups in particular, a health
17 policy subcommittee on safety interoperability
18 and usability. I also am on the RTI ONC-funded
19 project to create the roadmap for an HIT safety
20 center that Linda mentioned.

21 I am on the advisory panel for the
22 ECRI Partnership on Health IT Safety. And

1 finally, the national patient safety foundation
2 does receive funding via sponsorship for things
3 like our annual meetings from certain EHR
4 vendors. So, I just wanted to mention that as
5 well.

6 DR. BURSTIN: Thanks, Tejal. Anybody
7 else on the line?

8 MS. FREEMAN: Yes, Lisa Freeman. I am
9 an independent patient advocate. I am currently
10 the Executive Director of the Connecticut Center
11 for Patient Safety. I have been doing this for
12 many, many years. I came to it because of a
13 family member who had extensive medical issues
14 over an 18-year period. And I don't think I have
15 any conflicts.

16 DR. BURSTIN: Great. Anybody else on
17 the line? Hopefully some other folks that may be
18 coming with weather delays. I apologize for
19 those of you from the northeast or the mid-west
20 who are astounded by how D.C. shuts down with a
21 flake. Yes, school was closed yesterday for four
22 fluffy inches of snow. It was basically a day to

1 play and sled, according to our children. They
2 could have easily gone to school.

3 But anyway, that being said, welcome.
4 It is still pretty hard to get into this city a
5 day past the snowstorm of the year, so far, for
6 us. But I am delighted to have you here.

7 The one question I will ask you is if
8 anybody has any questions of each other. This is
9 also an opportunity to -- you know you have now
10 heard everybody's disclosures. If you have any
11 questions of each other or if at any point during
12 the course of this meeting if you feel like there
13 is bias or any other issues, please feel free to
14 come to me or anyone else. It is always better
15 to deal with those issues in real-time than to
16 find out later that somebody was concerned there
17 was a sense of a bias on the committee or
18 something along those lines.

19 So, with that, I will turn it back
20 over to Andrew. Thank you.

21 MR. LYZENGA: Yes, and before I launch
22 into some of the background and other items, I

1 figure I should take care of a bit of
2 housekeeping.

3 The bathrooms are out this door,
4 actually out of either of these doors, past the
5 desk there and to the right, once you hit the
6 wall.

7 We do have a transcriber here. We
8 will be trying to get a transcription of the
9 meeting. It is also being recorded. But we
10 would ask you to state your name before speaking.
11 That will help both our transcriber and us
12 identify who has been speaking, as we try to
13 record the proceedings of this meeting.

14 We do have internet access, if anybody
15 would like that. The log-in is "guest" and the
16 password is "NQF guest". I believe the wireless
17 network is also called "NQF guest". Just let us
18 know if you have questions about that. It is up
19 here if you need to see it.

20 Also, we would ask that if you would
21 like to speak, just raise your placard up, set
22 its end and we will call on you as we go around.

1 It is just an easy way to identify who would like
2 to speak.

3 And everybody has been doing a great
4 job of this so far, but just push the button when
5 you want to speak into the microphone. Again,
6 that will also help our transcriber record
7 everything that is going on here.

8 And with that, we will get started.
9 I will talk a little bit about background first
10 on NQF.

11 NQF is a private, nonprofit, voluntary
12 consensus standard setting organization. We
13 operate under a three-part mission to improve the
14 quality of American healthcare. The aim is to
15 build consensus on national priorities and goals
16 for performance improvement and working in
17 partnerships in order to achieve them, endorsing
18 national standards for measuring and publicly
19 reporting on performance and promoting the
20 attainment of national goals through education
21 and outreach programs.

22 We have a variety of activities and

1 programs that advance those goals. Among them,
2 our endorsement process, where we do sort of a
3 detailed review and evaluation of performance
4 measures submitted to us, put them through our
5 endorsement process and give them sort of a stamp
6 of approval of endorsement.

7 We also have the Measures Application
8 Partnership, which makes recommendations around
9 potential use of the measures. It makes those
10 recommendations to the federal government and
11 also to other stakeholders. We have had some
12 activities with the National Priorities
13 Partnership, in terms of identifying overarching
14 priorities for healthcare improvement for the
15 nation and then a few other activities as well.

16 Just a quick note on our measure
17 evaluation criteria, again, just for a bit of
18 context as we think about measurement in this
19 area. We have got some additional guidance, sort
20 of more in-depth guidance on what our evaluation
21 process is, what our criteria are, some of the
22 things we look at when we are evaluating measures

1 but we will probably get into that a little later
2 on, as we sort of dig into the more detailed
3 measure analysis and prioritization activities.

4 But from a high-level perspective, our
5 criteria for evaluating measures for endorsement
6 are importance to measure and report. Those
7 really relate to the evidence around the measure;
8 its priority within the sort of healthcare
9 landscape; the scientific acceptability of the
10 measure, which relates to its reliability, the
11 ability to reliability collect data and report
12 data; the validity of the measure; whether it is
13 accurately reflecting quality performance and
14 quality issues of a provider or a hospital;
15 feasibility, whether it is feasible to use,
16 whether it can be done with a relatively low
17 burden on providers and at low cost, whether it
18 is done with readily available data, and so on;
19 and use and usability, which relates to the
20 extent to which a measure is being used or could
21 potentially be used for accountability purposes,
22 including public reporting, payment, or quality

1 improvement or other purposes. We have some
2 other sort of goals around endorsement, which
3 relate to harmonization and selection of measures
4 that are best-in-class with sort of the objective
5 of achieving a parsimonious set of national
6 quality measures to the extent that we can.

7 In terms of this project, again, in
8 terms of background, there has been a lot of
9 activity trying to encourage and incentivize the
10 adoption of HIT. I am sure you all know about
11 meaningful use and a number of the other programs
12 going on and that has increased in adoption to a
13 great degree. And with that increased adoption,
14 has come increased interest in the impact of HIT
15 on patient safety. The Office of the National
16 Coordinator has developed and supported a number
17 of policies, programs, tools, and resources, to
18 help address these issues, including the Health
19 IT Patient Safety Action and Surveillance Plan,
20 some strategy and recommendations for a risk-
21 based framework for regulation of health IT; some
22 other programs, including certification of health

1 IT products; and as Dr. Singh mentioned, the
2 SAFER Guides, which are assigned to help
3 healthcare organizations conduct self-assessments
4 to optimize the safety and safe use of EHRs.
5 This work is, in some ways, building on that and
6 continuing that work and extending it
7 specifically into the area of measurement of HIT-
8 related safety issues.

9 The description of this project, under
10 the guidance of this committee, NQF will assess
11 the current environment related to measurement of
12 HIT-related safety events, help to create or
13 adopt an existing conceptual framework, for
14 identifying, assessing, and prioritizing measures
15 of HIT safety. The end-deliverable will be a
16 report that includes that framework, that
17 conceptual framework, and also an analysis of the
18 measure gaps that exist, recommendations for
19 filling those gaps, and recommendations for
20 future measure development, as well as some
21 recommendations around best practices and
22 challenges in measurement of HIT safety issues to

1 date.

2 In terms of scope, we would like to
3 synthesize the current evidence around health IT
4 and safety. Identify, to the extent that we can,
5 all relevant and meaningful health IT patient
6 safety measures, again, provide input on the
7 conceptual framework, identify priority
8 measurement areas for the greatest potential for
9 improving safety of HIT and using HIT to improve
10 patient safety.

11 And then to identify challenges and
12 barriers to effective performance measurement,
13 such as limited infrastructure information
14 exchange, lack of data, or lack of evidence.

15 The time line we have already seeded
16 the multi-stakeholder committee, as you know. We
17 have got the committee here. The sort of first
18 phase of this project is the environmental scan
19 and then preliminary development of the
20 conceptual framework. This phase of the project
21 will be running through August of this year. We
22 have sort of conducted our preliminary

1 environmental scan to this point and we will be
2 continuing that again in the next several months
3 with input from the members of this committee,
4 guidance from you on how we shape the rest of
5 that environmental scan and pursue different
6 priorities. We will be trying to draft a
7 conceptual framework again or adapt or modify an
8 existing framework.

9 We will try to finalize the
10 environmental scan by the time of around the
11 second in-person meeting, which I believe will be
12 in August or September of this year. And we, at
13 some point, will be bringing our conceptual
14 framework that is developed and some other
15 findings to the AHRQ Common Formats Panel to
16 review, just to see what their take on it is, to
17 see if they see any opportunities for alignment
18 or have any input into that framework, in terms
19 of its usefulness in identifying measures and
20 reporting patient safety events.

21 The sort of third phase of the project
22 will be, again, really digging into the

1 prioritization of measures and measure gaps,
2 identifying of best practices and challenges. We
3 will incorporate your feedback and revisions into
4 the environmental scan, into the conceptual
5 framework, submit that draft for CMS review,
6 draft up a written report and final conceptual
7 framework and final environmental scan.

8 As I mentioned, part of all NQF
9 projects is public and member comment. So, we
10 will be having several opportunities for the
11 public to comment and provide input on our
12 recommendations and findings. We will, again,
13 ask you to sort of adjudicate that and help us
14 respond to those comments and incorporate the
15 feedback of the public and stakeholders into our
16 recommendations and our report.

17 And I'm going to keep talking. So, I
18 will start by just giving a quick overview of the
19 environmental scan. I don't think I have a ton
20 of time for this. So, I will try to move through
21 fairly quickly. The purpose of this
22 environmental scan is really to provide committee

1 members and other stakeholders and the public
2 with a view of the current landscape with respect
3 to evaluation and measurement of HIT-related
4 safety issues; to lay the groundwork for the
5 development, modification or use of a conceptual
6 framework for analyzing, and identifying, and
7 prioritizing measures of HIT safety and then to
8 inform the committee's recommendations around
9 those areas, the prioritization, identification,
10 and recommendations around gap filling and
11 measure development with respect to HIT safety.

12 Our preliminary methodology and what
13 we have sort of carried out so far was a
14 literature review to identify relevant literature
15 in this area, as well as HIT safety-related
16 measures, measure concepts, or current or
17 emerging evidence-based practices. We have done
18 a review of NQF's portfolio of endorsed measures,
19 a review of AHRQ's National Quality Measures
20 Clearinghouse and the Guidelines Clearinghouse,
21 and review of the Health Indicators Warehouse.
22 That has sort of provided the basis for our scan

1 results so far. We will be continuing that with
2 input from the committee and our committee
3 members. We plan to refine our methodology and
4 our search strategy and sort of extend that
5 preliminary literature review with feedback from
6 the committee. We have already identified some
7 areas where we do feel like there is a need to
8 sort of revise the strategy, including extending
9 it back a little bit to -- we had initially
10 limited it to the studies published in the last
11 five years and we think we need to push that a
12 little bit back to incorporate some of the more
13 foundational work in this area and some of the
14 evidence that is very pertinent to the issue.

15 Let's see. We will be doing some key
16 informant interviews. Again, we would love to
17 have your feedback on that on some people who
18 would be useful to talk to. We would maybe like
19 to do some interviews with the committee members
20 themselves. We will be doing some targeted and
21 general outreach to our membership, using our
22 membership team and the broader public. We will

1 be doing, on one of our conference calls, we will
2 be sort of opening that up to the public to do a
3 sort of crowd sourcing of best practices and
4 insights into HIT safety-related issues, best
5 practices, and challenges. We will be reviewing
6 the CMS measures inventory, including measure
7 under development. And again, soliciting some
8 recommendations and guidance from you as
9 committee members on how we can best refine and
10 direct and target our search to identify the most
11 relevant information that will be useful for you
12 and the public in terms of identifying and
13 prioritizing measures in this area and
14 identifying the frame for analyzing and thinking
15 through these issues.

16 Our preliminary results, we identified
17 and reviewed around 200 articles, identified a
18 total of 42 measure concept-related to HIT
19 safety. A number of those were sort of
20 duplicative. So, accounting for those
21 duplicates, there were 32 distinct measure
22 concepts that we identified and seven conceptual

1 frameworks that were, in some way, related to HIT
2 safety or assessing or evaluating HIT safety or
3 HIT safety research.

4 We focused some of our analysis of the
5 literature on the effect of HIT on patient
6 safety. And as others have found, including the
7 IOM committee that studied this issue, the
8 evidence of HIT's impact on patient safety is
9 fairly limited. There are studies suggesting
10 that elements of HIT can be helpful in improving
11 patient safety, particularly medication safety,
12 while others have found that there is little
13 discernable effect of HIT systems and
14 implementation of HIT systems on the safety of
15 patient care. But there is quite a few
16 limitations of the published evidence in this
17 area, which kind of preclude us from making any
18 definitive conclusions about the effect of HIT on
19 patient safety, including that harm or adverse
20 effects are often inadequately reported in the
21 research literature, poorly indexed in medical
22 databases and, generally, difficult to identify.

1 The studies of HIT's impact on patient
2 safety are often fairly narrowly focused,
3 sometimes around a particular element of HIT, a
4 particular care setting, or a particular
5 application of some sort of HIT. There is a
6 fairly high degree of variability in the results,
7 which prevents us from, again, drawing any firm
8 conclusions.

9 And then the just complexity of HIT's
10 effects on safety really sort of complicate our
11 ability to draw conclusions from, again, fairly
12 narrowly focused studies, in general, on what the
13 effects of HIT on patient safety are.

14 So, despite the equivocal nature of
15 the published evidence, it is well-acknowledged
16 among clinicians that there are a variety of
17 risks and benefits associated with HIT. And it
18 is a major issue of great interest and importance
19 among practicing clinicians. I know Helen heard
20 that loud and clear when she was at the ONC
21 annual meeting recently.

22 There is increasing concern over what

1 is sometimes called HIT-induced error or HIT-
2 facilitated error, e-iatrogenesis. Dean Sittig
3 and Hardeep Singh have provided the following
4 definition of HIT-related error, which would be:
5 instances where the HIT system is unavailable for
6 use, malfunctions during use, is used
7 incorrectly, or when HIT interacts with another
8 system component incorrectly, resulting in data
9 being lost or incorrectly entered, displayed, or
10 transmitted.

11 So, in terms of HIT-related safety
12 events and errors, that is kind of the scope of
13 what we are looking at here.

14 Obviously, there again with the
15 complexity of this issue, there are factors
16 across the spectrum of design, implementation,
17 use, and other domains that impact patient
18 safety. The design considerations include
19 ensuring the reliability of hardware and
20 software, ensuring interface usability,
21 interoperability of systems, the reliability of
22 data, the integrity of that data, its

1 accessibility, ensuring it remains confidential.
2 There are many challenges related to
3 implementation of HIT as well. Organizations
4 need to customize their hardware, software for
5 their organization's specific needs. They need
6 to integrate that new HIT into their existing
7 clinical work flows or redesign work flows to
8 accommodate that HIT. They need to train their
9 staff in appropriate use of that HIT and ensure
10 that the organizational culture is amenable to
11 using the HIT in the most appropriate and optimal
12 way.

13 And, obviously, also challenges
14 related to use of HIT, ensuring appropriate use
15 in response to alarms or warnings, inappropriate
16 use of copy and paste functionality, trying to
17 avoid work-arounds, features and functions that
18 clinicians may view as inefficient or sort of
19 barriers to getting their work done, and then
20 preventing errors in entry or interpretation of
21 information for a variety of reasons, including
22 interface issues and other factors.

1 Just a few notes on some sort of areas
2 of increasing interest in HIT safety, human
3 factors in ergonomics approaches appear to be of
4 increasing interest in this area, acknowledging
5 the cognitive, physical, and organizational
6 limitations that inevitably influence human
7 behavior and work system performance. Accounting
8 for those limitations allows you to work
9 solutions into the design and implementation in
10 use of HIT systems.

11 And then we have seen that principles
12 of sociotechnical theory have also been very
13 useful in analyzing these issues, recognizing
14 that work systems and HIT systems are imbedded in
15 broader organizational and social contexts, and
16 then focus on improving the interactions among
17 those various sociotechnical domains and factors
18 involved in an enterprise like HIT design
19 implementation and use to optimize the
20 performance across all those different domains
21 and meet the needs of all the players among those
22 domains.

1 We did identify, again, various
2 conceptual models and frameworks that have been
3 used to analyze HIT safety issues. We have got a
4 preliminary inventory of those and in the
5 document that we sent out just before the
6 weekend, some of the key frameworks that we
7 identified and have been focusing our attention
8 on specifically are Dr. Singh and his colleague,
9 Dean Sittig's, eight-dimensional sociotechnical
10 model, the three-phase framework for EHR safety
11 that was used as a basis for the SAFER Guides;
12 and then a combination of those two models that
13 was used to analyze patient safety issues, sort
14 of layering them on top of each other, which has
15 been the direction we have been at least
16 tentatively moving toward in terms of a
17 conceptual framework for this project in
18 identifying and prioritizing measures and
19 measurement areas. And I won't say too much
20 about that because I know Dr. Singh is going to
21 present on frameworks and conceptual models for
22 addressing HIT safety in just a few moments.

1 Again, we identified a number of
2 distinct measure concepts, not any sort of fully
3 defined, fully specified in tested measures to
4 the extent that they would warrant NQF
5 endorsement, although that is a fairly high bar,
6 requires, again, a lot of specification, testing
7 for reliability and validity, feasibility of use.
8 But there were some measure concepts out there,
9 many not even developed so far as to have a
10 numerator and denominator but just sort of a
11 conceptual statement around the measure or
12 measure concept. Most of those were, or a large
13 proportion of those were structural measures as
14 you might imagine in this area, when you are
15 dealing with a technological system, a
16 computerized system. Examples of those are the
17 rate at which EHRs are up and running. Also,
18 some process measures like alert override rate.
19 There were some measures that, and this is just
20 sort of a tentative classification at this point.
21 We would welcome your input on this. Some
22 measures that might appear to be structural

1 measures that sort of reflect a characteristic of
2 a system, for example, the rate at which they
3 return test results, inaccurate test results can
4 maybe be viewed as a structural characteristic of
5 the system. But to the extent that they do imply
6 an adverse impact on patients, again, with
7 incorrect reporting of test results, those are,
8 in some sense, an intermediate outcome. But
9 again, we would welcome your feedback on how we
10 have sort of classified those.

11 A number of outcome measures as well,
12 mostly related to measuring patient outcomes
13 before and after an HIT implementation to assess
14 the impact of those HIT systems.

15 Some of the most common themes, we
16 found, were a number of measures and measure
17 concepts related to alert appropriateness, for
18 example, interruptive alerts that have fired more
19 than a 100 times with 100 percent override rate;
20 the response of clinicians to alerts, such as
21 alert override rate; and then measures of system
22 availability, either EHR system uptime rate, EHR

1 system downtime rate, or other sort of related
2 issues.

3 And we kind of mapped the measures
4 that we found to a variety of models and
5 frameworks, just to give you a glance here. I
6 won't walk through this in too much detail. But
7 again, using these two frameworks that we have
8 been focusing on so far, we broke out the
9 measures into how they map to these various
10 domains.

11 There is a bit of overlap, as you
12 might expect. Measures may apply to various
13 different categories. So, these totals don't add
14 up to 32 but just to give you a sense of how
15 these measures that we found kind of map to the
16 sociotechnical model and the three-phase EHR
17 safety model. And we can discuss that a little
18 bit further as we move through the project and
19 sort of come up with a more systematic way of
20 analyzing the measures and measure concepts we
21 come up with in prioritizing those.

22 So, any questions, initially on those

1 preliminary results or just reactions or
2 feedback?

3 DR. PINES: Thanks, Andrew. This is
4 Jesse Pines.

5 Just to make a few comments on sort of
6 what we want from the committee here. As
7 everyone knows, this is a very tough area for a
8 variety of reasons that we went through the
9 environmental scan, where a lot of the same type
10 of evidence that underlies NQF measures,
11 particularly in disease-specific areas, process
12 measures, outcome measures, is really sort of not
13 there in the health IT space but we know that
14 there is health IT and patient safety is a real
15 issue. As a practicing provider and for folks
16 who are practicing providers, this is a major
17 issue, although, the evidence and particularly
18 the way that the National Quality Forum Standards
19 for Evidence is applied now when it comes to
20 approving measures and endorsing measures, some
21 of that may not necessarily fit exactly into the
22 current state of the evidence for health IT.

1 Just also, I know that there is a
2 number of ongoing projects in this area.
3 Tomorrow, we will actually be hearing from
4 several of the groups who are working on other
5 projects and we will be explicitly trying to
6 harmonize this project with some of the other
7 ongoing projects, just to make sure we are not
8 really duplicating the work of other groups.

9 And thinking about your role here,
10 really the focus of today is getting from these
11 health IT safety issues to measure concepts and
12 how we can measure this, both through the NQF
13 standard endorsement process and also, more
14 broadly, what are some of the other mechanisms
15 that we can take on where we can really get to
16 public accountability for EHR safety?

17 And my last comment is we have talked
18 a lot about EHR safety and sort of what that
19 means, health IT safety. I want to think about
20 not only sort of preventing harm but also trying
21 to promote a lot of the elements of health IT
22 that have really helped us in clinical practice.

1 So, when we think about preventing safety events,
2 I want people to think more broadly about how we
3 can promote some of those elements, such as
4 certainly handwriting issues are gone with health
5 IT for the most part. And health IT really has
6 solved several issues in clinical practice. So,
7 when we think about this from a harm perspective
8 and also promoting how health IT has really
9 helped us in clinical practice, and, again, what
10 we want from you all today, is think of today as
11 a multi-disciplinary group coming together to
12 help brainstorm issues in health IT, patient
13 safety that can ultimately really sort of move
14 the ball down field when it comes to measurement
15 in this area, both through the NQF process and
16 also we are going to be hearing from our co-
17 chairs who have done a lot of great work in this
18 area. Hardeep is going to tell us a lot about
19 his work conceptually with health IT and patient
20 safety. And also Elisabeth is going to be
21 telling us about some of the other mechanisms to
22 potentially consider, beyond just the standard

1 NQF process.

2 So, I would like to thank you all
3 today for participating and I will turn it over
4 to the co-chairs for the discussion.

5 DR. BURSTIN: And maybe you could just
6 introduce some of the folks who came late before
7 we do that, too. I think we had a couple, Kevin
8 and Andrea.

9 DR. GELZER: Hi, I'm Andrea Gelzer.
10 I am Corporate Chief Medical Officer for the
11 AmeriHealth Caritas Family of Companies.

12 We do primarily managed Medicaid and
13 dual-eligible managed care.

14 DR. HAYNES: Hi, I'm Kevin Haynes with
15 HealthCore, which is a research arm of Anthem.

16 MS. GRACE: Good morning. My name is
17 Erin Grace. I am with the Agency for Healthcare
18 Research and Quality, formerly with the Health IT
19 Team and now Director of the Patient Safety
20 Program.

21 CO-CHAIR SINGH: Okay, great. Thanks,
22 Andrew. So any quick reflections -- is there

1 somebody else?

2 DR. ALEXANDER: I just had a question
3 about the presentation. So, and this may be too
4 granular at this point, but I was curious about
5 the good work and the areas in which these
6 occurred, so you know, these sort of safety
7 issues. Are all of these issues applicable in
8 acute care, long-term care, ambulatory care,
9 those kinds of places? I am wondering if they
10 are consistent across all those areas. Have
11 these models been used in all of those areas? Is
12 this a pretty good swath of information from
13 across the continuum? That is the question.

14 MR. LYZENGA: We found some
15 information that was specific to some different
16 care settings, not a ton. That is, I think,
17 something that we would like to get, again, some
18 feedback and input from the committee on, how we
19 can kind of expand our search to incorporate some
20 of those broader questions of what the specifics
21 of HIT safety issues are in different settings.

22 CO-CHAIR SINGH: Yes, and this is

1 Hardeep Singh and I would like to reflect a
2 little bit on that.

3 I think you are right. I think there
4 is some difference between sort of long-term,
5 ambulatory, and inpatient care. For instance, if
6 you have a big downtime, if you are in a small
7 practice, you might actually shut down the
8 practice for the day, cancel the patients and
9 everybody goes home.

10 If you are a big hospital, you are
11 losing a million dollars an hour and you have got
12 a huge operation to run. So, some of the
13 concepts might be a bit different and your risk
14 might be a bit different, depending on the safety
15 measure you are looking at.

16 Similarly, a follow-up of test
17 results, for instance. Andrew brought up sort of
18 the test results reporting would be maybe more
19 important in the distributed environment of the
20 outpatient setting in maybe long-term care but in
21 the hospital, you know, the patients are being
22 monitored every day. It may not be as relevant

1 because they are there. Then you can get the
2 test results right away.

3 So, I think that there is a bit of a
4 difference. We have got to think of broadly of
5 the practices and then we maybe we can think
6 about narrowing some of these concepts in terms
7 of risk or some areas maybe more than the others.

8 CO-CHAIR SINGH: Karen? I think Bill
9 had it before. I'm not sure who went first but I
10 saw Bill's.

11 DR. ZIMMER: This is Karen Zimmer.
12 Just to help establish the framework, I hear a
13 lot when I hear about environmental scans,
14 either, of course, historic or present issues. I
15 am assuming we are supposed to be forward-
16 thinking. So whatever we come up with is not
17 just for today but would actually help us a few
18 years from now so we can be forward-thinking
19 here.

20 MR. LYZENGA: Yes, absolutely.

21 CO-CHAIR SINGH: Bill.

22 MR. MARELLA: Hi. Bill Marella.

1 Well, first of all, I just wanted to compliment
2 the NQF staff on, I think, synthesizing really
3 concisely a lot of the nuances around why this
4 area is unique, in terms of quality measurement.

5 One of the things that I think might
6 be missing potentially is, there was not anything
7 said about the quality of clinical documentation.
8 And in the studies that we have done, that is
9 always a very large category of health IT events.
10 It does fit within Hardeep's definition of health
11 IT safety. And I think to the extent that
12 clinicians either don't feel the information in
13 the EHR is reliable, that degrades clinical
14 communication and it also limits the usefulness
15 of clinical decision support because if that
16 information isn't in the EHR or it is in the
17 wrong patient record, those things are problems.
18 So, I think there are ways that we can measure
19 that because those are also compliance issues and
20 there are audits that have to be done for Joint
21 Commission compliance.

22 So, I mean those are the things that

1 could potentially be captured as well.

2 MR. LYZENGA: Thank you.

3 DR. GELZER: Andrea Gelzer. I agree
4 with those comments wholeheartedly.

5 I just wanted to mention the downtime.
6 If we are looking to develop concepts for patient
7 safety and for measures, hopefully in the future,
8 of eHealth-related measures or electronic health
9 record-related measures, it would seem to me that
10 the downtime is inevitably going to occur at some
11 time. So, from a patient safety perspective, the
12 backup plan is what is most important to measure.
13 Does the institution, does the practice have an
14 adequate backup plan? Obviously, we all have
15 systems in hospitals, in plans, and we all have
16 disaster recovery plans. And we all have backup
17 plans, if there is a hurricane. So, to me, it is
18 what do you do in response to that inevitable
19 event that is going to occur?

20 CO-CHAIR SINGH: I agree with your
21 point. And the SAFER Guides actually help with
22 that.

1 DR. HRIPCSAK: George Hripcsak.

2 First, a high-level comment. First of all, thank
3 you for the excellent environmental scan or draft
4 of it.

5 One slight comment is the tone of it
6 severely discounts the literature on the benefits
7 of HIT on safety but assumes that the risks are
8 real. And I think if someone were to take this
9 -- because remember what we are doing is a
10 utility analysis to say is this drug, HIT drug,
11 safe or not. We need to treat them both equally.

12 So, I just in the tone of the report,
13 don't discount the benefits too much. I mean I
14 think it is good to point out that it is not
15 really totally solid but then don't turn around
16 two pages later and say but of course there are
17 risks and everyone knows it. Because we think
18 there are benefits also and everyone knows it
19 also.

20 Then there are specific comments but
21 I think you don't want to do that now. Right? I
22 mean I think structure process outcome, I have

1 some thoughts about that and I have thoughts
2 about the phases. But we are going to wait until
3 later for that?

4 MR. LYZENGA: Yes, we will kind of dig
5 into that a little bit later, including in the
6 breakout sessions.

7 DR. HRIPCSAK: Okay.

8 MR. LYZENGA: Dena?

9 MS. MENDELSON: Yes and this might be
10 a comment for later but I was just struck by the
11 lack of literature on patient use of health IT.
12 And if you are thinking of patients as a partner
13 in their healthcare and an important part of what
14 the outcome is going to be, then you have to look
15 at how patients are using the health IT and
16 whether there is literacy issues or what is going
17 on in that component of it.

18 DR. JONES: Jason Jones. Just a
19 process question because there is a lot coming
20 forward in the day. Can we get the presentations
21 ahead of time, even briefly, so we can sort of
22 flip back and forth? Because even this was

1 really helpful, even interpreting the document
2 that was sent out before. I just think it might
3 facilitate discussion a little.

4 MR. LYZENGA: Yes, we will do.

5 DR. KHUNLERTKIT: Hi, this is Nana.
6 I just wonder to the point that Dena just
7 mentioned about patient using the patient portal,
8 probably. We have to also look into the
9 interactions between how provider interact with
10 the patient before and after the implementation
11 of the EHR.

12 CO-CHAIR SINGH: Jason, did you have
13 another comment? Did you have another comment,
14 Jason? Okay.

15 So, the other sort of maybe
16 discussion, Jesse, would this be a good time to
17 sort of discuss what is our scope of -- Eric, I'm
18 sorry.

19 DR. SCHNEIDER: I jumped in at the
20 last minute there. I was wrestling with how to
21 pose the question. I do think it is an excellent
22 synthesis.

1 I think one of the things I am going
2 to struggle with and I think we will all struggle
3 with is the use of these measures, where they are
4 going to end up and how we should be thinking
5 about that. And actually, that can be a helpful
6 constraint sometimes in this sort of a situation.
7 So, maybe if you could comment a little more.
8 And when I say use of measures, are these going
9 to go to CMS value-based purchasing programs?
10 Are they going to go to public reporting? What
11 is the unit that is going to be evaluated? Is it
12 an Epic systems versus somebody else's systems?
13 Is it settings, health plans?

14 And there may be not be answers to
15 this but it is sort of one of the things that I
16 am going to be trying to navigate as we talk
17 through this.

18 DR. BURSTIN: It is a great question,
19 Eric. So, I honestly don't know that we know but
20 I think this is such a nascent area, I think, and
21 I am glad David Hunt joined us from ONC. He will
22 be happy to chime in on that as well.

1 But I think the idea would just to be
2 figure out what measures there are at all. And
3 then I think the uses, perhaps will follow that.

4 NQF is also doing some work this
5 spring moving away from a yes/no endorsement but
6 more endorsement for intended use. So, I think
7 there are potentially ways to kind of think about
8 measures differently, depending on how they might
9 be used. But for this exercise, I would just
10 keep it very broad and think about what measures
11 can best be used to drive improvement. By having
12 this information, what could be done to
13 understand the current situation and make care
14 safer?

15 DR. HUNT: Hi, sorry I am late. And
16 I would just reiterate what Helen said. We are
17 not really sure where we will go but we have some
18 very strong allies and partners in CMS and in
19 AHRQ. So, the first question is to find out what
20 we have and then HHS, as a whole, will take a
21 look and see what we can do with those measures.

22 DR. SCHNEIDER: Just one other thing

1 to add. I think this is an area that will lend
2 itself to the sort of industrial quality
3 management perspective, thinking in terms of
4 industrial improvement cycles. There is a lot of
5 engineering flavor to the things that we have
6 been reading about that isn't always apparent in
7 the more traditional quality improvement --
8 healthcare quality improvement literature. So
9 just something to put on the table.

10 DR. GELZER: I just want to add that
11 I would also hope that from a plan perspective,
12 entities like NCQA would also look at these
13 measures and they might help better inform what a
14 Level 3 patient-centered medical home is and
15 different accreditation status.

16 DR. SCHNEIDER: I'm sorry. I just
17 realized I should have made some other
18 disclosures. Thank you.

19 I am a co-chair of NCQA's Committee on
20 Performance Measurement and that is an ongoing
21 role. And also I'm on the Editorial Board of the
22 National Quality Measures Clearinghouse,

1 something that I have worked with for several
2 years. So I just wanted to make sure everyone
3 knew about those potential conflicts.

4 DR. CLASSEN: Andrew, the only thing
5 I might post on the website is, this is the
6 second environmental scan I have seen in this
7 area. We did this at the IOM in the same area.
8 I would post that report online for everyone.

9 MR. LYZENGA: Okay.

10 DR. CLASSEN: And Chapter 6 is how we
11 thought about measures. So you might as well
12 repost that so people can see that because we did
13 have a view about measures.

14 MR. LYZENGA: Yes.

15 DR. CLASSEN: But all I would say is
16 having been through this now the second time, the
17 literature hasn't really changed much. And I
18 think, Jesse and Andrew, your comments are there
19 isn't really a lot of good solid science behind
20 measures in this area and tell them instead, this
21 is in its infancy. Right?

22 But I would argue that as a practicing

1 clinician, IT has invaded my life in a way now
2 that it hadn't even five years ago. And so ----
3 right? When I see patients now, I spend a couple
4 hours at night doing all my documentation. And I
5 get 50 alerts every day. I'm overwhelmed.

6 CO-CHAIR SINGH: Fifty is low,
7 actually.

8 DR. CLASSEN: Yes, I know. So, just
9 from the perspective of having done that work
10 back in 2009, 2010, and 2011 at the IOM, it has
11 really invaded my life much more. And I think
12 you heard this, too, right?

13 DR. BURSTIN: Yes, the context
14 changed.

15 DR. CLASSEN: The context has changed.
16 So, the issues become more and more acute. The
17 evidence base hasn't really changed. That is
18 what is concerning.

19 CO-CHAIR BELMONT: So just a reminder.
20 If individuals could state their name before you
21 make your comment, that would be helpful later
22 when we go back and do the transcript. Thanks.

1 CO-CHAIR SINGH: I think we have one.
2 Gerry just joined us. Gerry, you want to just do
3 a quick introduction and disclosure, if any?

4 DR. CASTRO: Great, thanks. My name
5 is Gerry Castro. I am Project Director for
6 Patient Safety Initiatives at the Joint
7 Commission. I apologize for being late. My
8 flight out of Chicago was canceled, so ----
9 unexpectedly. But I managed to wake up at 3:30
10 this morning and catch the first flight here.

11 So I am here. Thank you for having
12 me. I really appreciate this opportunity to be
13 here.

14 So, I have no disclosures but in the
15 context of today's meeting, what I do is I manage
16 our Sentinel Event Database. So, if you are not
17 familiar with that, that is the voluntarily
18 reported sentinel events to the Joint Commission.
19 So, I am the one that analyzes the data and runs
20 the reports.

21 We also received a contract from the
22 Office of the National Coordinator to analyze

1 those sentinel events and to do some other
2 educational activities. And I have no
3 disclosures.

4 CO-CHAIR SINGH: So one sort of
5 question, which will probably come up later --
6 this is Hardeep Singh again -- is the scope of
7 what people think is health IT.

8 I think we are mostly talking about
9 electronic health records here, and I think
10 probably personal health records, patient portals
11 could probably be encompassed within that. Does
12 anybody have any questions, concerns, comments
13 regarding the scope?

14 Okay, I see three going up. Let's go.
15 All right.

16 DR. ALEXANDER: Greg Alexander. Most
17 of my research -- my background in nursing is
18 critical care, but most of my research is in
19 long-term care, and have worked in long-term care
20 for a number of years. I know the concept of a
21 fully-integrated electronic health record in
22 long-term care is not a very common concept.

1 They use a lot of disparate systems
2 that aren't connected with one another. And so,
3 as I think about these measures and the way you
4 presented them in the environmental scan, I asked
5 that previous question with that experience in
6 mind. You know do the quality measures for HIT
7 safety, are they just for a fully integrated
8 electronic record or do we need a subset of those
9 for specific disparate sets of information
10 systems that are used every day to collect NDS
11 measures and patient safety kinds of issues?

12 So, I just question that a little bit,
13 about what is the scope of the EHR that we are
14 looking at.

15 CO-CHAIR SINGH: Okay, let's keep
16 going around because I think this is an important
17 sort of shared mental model that we need to agree
18 upon.

19 Karen?

20 DR. ZIMMER: Karen Zimmer. The
21 thoughts I am about to say may be beyond the
22 scope but even if they are beyond the scope, I

1 think they need to be addressed in our document.

2 One is we do need to talk about phones
3 because today phones are mini-computers. It is
4 not just laptops or what we record in but we have
5 to keep that in mind or at least address that, if
6 it is not within the scope.

7 The other part of documentation, we
8 need to also consider texting. That is a form of
9 communication with this generation and that will
10 become even more apparent in our professional
11 world. So, again, it may be beyond our team's
12 scope but we should at least address it that it
13 is.

14 Security, we need to again think about
15 cyber security somewhere in there. And again, if
16 that is beyond, our health systems are getting
17 hit over 100,000 times a month. So we need to at
18 least address it, even if it is beyond our scope.

19 DR. SEGAL: Yes, I'm Mark Segal. I
20 think there is two dimensions to that. One is
21 just from the standpoint of clinical health IT,
22 there is much clinical health IT beyond the EHR's

1 specialty focus systems, cardiology, pathology,
2 radiology, labor/delivery. So I think we really,
3 at minimum it seems to me, we want to focus on
4 safety risks involving clinical health IT, not
5 just EHRs. And I certainly agree with everything
6 that was just said.

7 I think we also, doing that, need to
8 be mindful -- and I will touch on it briefly when
9 I talk a bit later, let's have the HIT, let's
10 have the EHR measure things as well. You know
11 EHRs may be set up, although I think there are
12 limitations to measure certain things, but other
13 clinical health IT may not be as amenable. So, I
14 think we need to be careful about the old thing
15 of why is the guy looking for his key that he
16 lost under the light, well because it is dark
17 where I think I lost it.

18 But then the other is -- and I think
19 it was David or maybe Hardeep, you talked about
20 downtime and costing. Well we also, just from a
21 risk and importance standpoint, need to think
22 about non-clinical health IT as well. So in a

1 hospital, if their scheduling system is down,
2 that could also have substantial costs.

3 So I think, again, thinking about what
4 measures are important and where the safety risks
5 lie, I can imagine that certain aspects of non-
6 clinical health IT, including the fact that often
7 demographic data, for example, is actually ported
8 or interfaced into let's say the EHR from a
9 registration system and then that demographic
10 data can be very important in terms of clinical
11 care.

12 So I would urge us to take kind of a
13 broad look and then prioritize having done that.

14 CO-CHAIR SINGH: David.

15 DR. CLASSEN: Yes, so I would just add
16 and sort of emphasize Mark's comments. And I
17 think, Hardeep, this is a critical question for
18 us. How do you define it?

19 CO-CHAIR SINGH: Yes.

20 DR. CLASSEN: And at the IOM, when we
21 went through our process, we really struggled
22 with this. And I was just going to read you how

1 we defined it after a long-term of struggling
2 with it.

3 I think we viewed health IT as
4 ubiquitous, almost like the aviation system. You
5 can't define it as something in a box. It has
6 already spread so far beyond what we originally
7 defined as EHRs, that it is much broader. So I
8 will just read you what we eventually, after
9 wrangling with this for a long time, came up
10 with.

11 In this IOM report, health IT includes
12 a very broad range of products, including EHRs,
13 patient engagement tools, PHRs, secure patient
14 portals, health information exchanges. The only
15 thing we excluded was medical devices.

16 And we felt that clinicians expect
17 health IT to support a lot of functions in
18 healthcare, including storing comprehensive
19 health data, providing clinical decision support,
20 facilitating communications, and reducing errors.

21 Health IT is not a single product. It
22 encompasses a technical system of computers and

1 software that operates in the context of a much
2 larger sociotechnical system. So, we took a very
3 expansive view, if you will. And that played a
4 big role in our recommendations to not regulate
5 health IT as a medical device. That is one of
6 the many manifestations that came out of what we
7 did.

8 So, it was very broad. So, I would
9 support what Mark said. Thank you.

10 CO-CHAIR SINGH: We have Kevin and we
11 will come back to this discussion again. Kevin.

12 DR. HAYNES: Thanks. Kevin Haynes.
13 So I would add one other area of health
14 information technology that is sort of missing
15 from both sort of the environmental scan and even
16 the IOM report but the payer.

17 So, if you start doing quality
18 performance metrics with regard to 30-day
19 readmission and you don't know what happened down
20 the street because your EHR system, even if it is
21 an Epic-based system to another Epic-based
22 system, you have absolutely no clue that they got

1 admitted down the street but the payer does. So
2 I would keep that in the forefront.

3 And then of course, the disruptive
4 nature of the healthcare system. When people hit
5 65 and we throw away all that administrative
6 data, they become Medicare and we sort of -- as a
7 pharmaco-epidemiologist, the most under-studied
8 population in America is the 65 to the 65 and
9 one-half year old because we are waiting for them
10 to accrue all of these diagnoses because you wake
11 one morning and go today is the day I am going to
12 have all of this go wrong with me.

13 So I would keep the payer perspective
14 in mind from a longitudinal perspective as people
15 traverse a diverse range of healthcare systems.

16 CO-CHAIR SINGH: Elisabeth, did you
17 have a comment?

18 CO-CHAIR BELMONT: This is Elisabeth
19 Belmont and I wondered what folks thought about
20 taking the IOM definition and potentially
21 building and expanding on that.

22 CO-CHAIR SINGH: Well, Karen, I think

1 your point about keeping sort of mobile devices
2 and phones -- I mean it looks like IOM sort of
3 did not --

4 DR. CLASSEN: But just to clarify, we
5 sort of excluded medical devices because that was
6 not in our charge from ONC. And ONC project
7 officer Kathy Kenyon is here, who sponsored it.
8 So that was the reason, just because of our
9 charge, that we excluded it. I don't know that
10 it should be excluded.

11 CO-CHAIR SINGH: Do we need to go back
12 to the charge, Andrew? We have got ONC
13 representatives here. I mean, this is the time
14 we need to sort of make sure.

15 MR. LYZENGA: I would welcome any
16 thoughts from David on this issue and Helen as
17 well.

18 DR. HUNT: Well the first thing I
19 would say is that there is so much to do and so
20 many possibilities in terms of just the small
21 world of EHRs, I think we have to make sure we at
22 least get that right first.

1 But I do hear and I do agree that at
2 ONC you all know we are thinking beyond the idea
3 that things are just in EHR and if we are
4 actually successful in what we plan on doing, you
5 won't be able to necessarily tell the device or
6 the object that you are working with. So to that
7 extent, we should be very, very cognizant of the
8 other areas where clinical information is
9 traversing.

10 So, I would say yes because a mobile
11 phone is just -- nowadays a mobile phone is
12 another name for a small computer in your pocket.
13 So I have functions on my phone that I don't even
14 have yet on my practice management system. So I
15 would say we have to make sure that we don't
16 limit ourselves to what is obviously the next
17 step up.

18 DR. SEGAL: Just one quick follow-on
19 to that. As we develop measures that are, let's
20 say product relevant, I think that -- we may want
21 to prioritize or users may want to prioritize in
22 terms of how they deploy the measures, but it

1 seems to me that particularly as definitions of
2 what is an EHR? What are other things, are
3 blurring, that as much as possible as measures
4 are developed, they ought to be agnostic to a
5 particular type of product. And I think that, to
6 me, is sort of a separate issue from where you
7 prioritize in terms of use.

8 CO-CHAIR SINGH: I think, Mark, you
9 are right. Some of these concepts, models,
10 measures, actually could be broadly applicable
11 across, but I think also -- sort of Gregory's
12 point, that some of them may have to be sort of
13 narrowed down for that specific area and that we
14 may have to come up with some additional
15 measures, for instance, for long-term care.

16 Jason and then Bill.

17 MR. MARELLA: So Elisabeth, I think
18 you asked the question about how do people feel
19 about the IOM definition versus the one that was
20 in the environmental scan. I mean I support the
21 IOM definition because I think it is expanded and
22 I think it would also encompass something that I

1 don't think we have addressed which is the
2 interfaces between all these systems.

3 So it isn't just about the EHR but a
4 lot of the errors that we see are essentially
5 happening between two systems that don't talk to
6 each other. So the decision to exclude medical
7 devices from that definition might have made
8 sense maybe from a regulatory perspective a year
9 or two ago. Wait another two years, it may make
10 less sense because that is where a lot of the
11 problems we are seeing are occurring.

12 I hear some physicians talking about
13 voodoo vitals as being those vitals that are
14 pushed into the EHR from physiologic monitors and
15 things like that. So they don't trust it. And I
16 think in order for clinicians to feel supported,
17 I think we need to get to a place where they can
18 trust it.

19 CO-CHAIR SINGH: Jason Jones and then
20 David.

21 DR. JONES: Jason Jones. I was
22 curious about the -- I tend to be a more

1 expansive person but as I look at the weakness in
2 the evidence that we have now, I wonder if that
3 is going to help us strive towards improvement,
4 if we are too expansive.

5 I was interested in the -- I think,
6 Helen, you mentioned it -- that we should focus
7 on -- not worry so much about the use but think
8 more about the measures.

9 That worries me a little bit because,
10 one, we are not short on measures. Two, the
11 number watched behaves and often behaves in ways
12 we don't anticipate because we set up conflicts
13 where we thought we were helping things.

14 And in particular, in the HIT space,
15 when I think about when we tried to implement
16 something at Kaiser Permanente. Many of the
17 practices that we have put in place on the IT
18 side to protect us, end up causing far more harm
19 simply because we set up so many blocks along the
20 way that -- David, the reason you get harassed so
21 much, is because if you could just pick up the
22 phone and tell someone this was a stupid alert,

1 can you fix it? That is like a 12-month process
2 because we have put so many measures in place to
3 try to ensure -- maybe not borrowing enough from
4 the industrial practices that you mentioned Eric.

5 But I just worry, and maybe it is
6 absolutely the right approach, but should we
7 think about really how will this measure improve
8 the system? How will it lead to better
9 processes? How will it lead to a better provider
10 experience? We might walk away with something a
11 little bit different. So I just throw that out
12 for suggestion.

13 DR. BURSTIN: Just a quick
14 clarification. That is actually a very helpful
15 point, Jason. I didn't mean to imply that sure
16 let's just have as many measures as we need. I
17 think the real question is which measures we
18 think would actually drive and help improvement.
19 I think we are saying the same thing.

20 I was mainly responding to Eric's
21 concern of should we be worried that some of
22 these may immediately go into value-based

1 purchasing for hospitals and I think we are not
2 even close. I think, at this point, let's just
3 think about the best possible approaches and
4 measures and then that could be way down the
5 line, if there is a few useful ones. I think
6 more than anything else, I suspect this is more
7 about driving internal system improvement than it
8 is about accountability, per se, at this point.

9 CO-CHAIR SINGH: David, Eric, and then
10 Jason.

11 DR. HUNT: David Hunt here. I really
12 appreciate Bill's comment because all of us who
13 have worked in safety recognize hand-offs are a
14 time of great danger and interfaces are the
15 virtual equivalent of hand-offs in the regular
16 clinical world.

17 But I also want to say something that
18 -- I'm not sure if it was expressed earlier, but
19 it is something we should all keep in mind is
20 that ---- and my colleagues Erin and Helen, and
21 all of you, in the measured space know this,
22 measures are never finished. Okay?

1 It is not as though we will do this
2 job and do this work and say, wow, boy, that's
3 it. We just nailed that. We will look at this
4 ten years from now. You know Leonardo da Vinci
5 said, art is never finished, it is just
6 abandoned. It is almost the same for measures.
7 They are always going to be a constant cycle with
8 this.

9 So I don't think we should worry that
10 we got every single thing perfectly right because
11 there is going to be a natural evolution to
12 these, and part of the natural evolution will be
13 identifying exactly where these measures find a
14 good place within the larger context of HHS and
15 the private sector also.

16 So yes, they may be considered for
17 value-based purchasing models, for other types of
18 models, but it is going to be something that is
19 continually evolving.

20 DR. SCHNEIDER: I agree with
21 everything that has been said here, and I just
22 wanted to add -- or suggest a possibility, so we

1 can have our cake and eat it too.

2 Which is to use the broad definition,
3 the IOM definition, and acknowledge that the
4 potential for medical devices and monitoring
5 devices and patient-generated data and lots of
6 sort of movements that are underway, where we
7 can't predict where it will be three to five
8 years from now. It would make sense to broaden
9 our definition now and sort of acknowledge that,
10 that we can't foresee the future here.

11 At the same time, then bringing it
12 back and saying this committee is going to focus
13 on the EHR and interfaces, or something of that
14 sort. Because otherwise, I worry that we are
15 into a space where it just becomes intractable.
16 There are so many possibilities. There are so
17 many dimensions to it that we'll not even be able
18 to get off the ground.

19 I'm all for exploring but at a certain
20 point, you are just lost in the wilderness but
21 that may be a way out of the thicket.

22 DR. ADELMAN: So, I guess my comment

1 follows nicely with what Eric just said in that
2 when David read the definition -- the IOM's
3 definition of HIT and there was an exclusion for
4 medical devices, I was ---- it made me think well
5 then what is the definition of medical devices.

6 Because I could see clearly like it
7 would be tough to think about HIT safety and
8 pacemakers, but what about like IV pumps when the
9 EHR system figures out the dose and the
10 concentration and the amount of volume, and then
11 sends it all to a smart pump. And then the smart
12 pump has to figure out the rate and then the
13 nurse enters some information there, and an error
14 happens there, is that not HIT safety? Or very
15 simply attaching a bar code reader to almost
16 anything to prevent doing something on the wrong
17 patient, like a radiation oncology medical
18 equipment or device?

19 So ---- but following with what Eric
20 said, I think having a broader definition as
21 these lines get blurred makes ---- there will be
22 software everywhere very soon, if it is not

1 already, that will connect to the ultimate EHR
2 with a lot of communication. So I favor keeping
3 a broad definition.

4 MS. MENDELSON: Yes, and just to
5 reiterate that point, I like the idea of a broad
6 definition because what is available is
7 constantly evolving and seems to be going so
8 quickly that when you form a committee like this
9 and we make a definition, by the time the
10 committee is done in 15 months, the definition is
11 going to be out of date.

12 So with the medical devices, part of
13 the question is ---- like you was saying, where
14 do you draw the line, what is a medical device?
15 And going along with the telephone, people ----
16 you know, diabetics are going to be able to take
17 their sugar reading on their device and they are
18 going to be able to send the record to their
19 physician and put it into their patient portal
20 and put it into their EHR.

21 So the question is, at what point do
22 you draw the line and you say, well, this is what

1 we are talking about now and this what we are
2 going to talk about later. Or do we want to
3 leave the door open and say, anything that has IT
4 in it is health IT, if it relates to your health
5 and if it has IT. So that is one part.

6 The other part is just talking about
7 the measures. When I see 32 measures, it does
8 look like a lot, but then when I see that only
9 four of them talk about outcomes, it doesn't even
10 look like I am looking at 32 measures. It looks
11 like I am looking at four measures.

12 There is a lot of different ways to
13 measure the process that goes into healthcare but
14 really matters to the consumer is what happens to
15 them at the end of the day and what their
16 outcomes are. So what I would like to see more
17 is more to talk about what the outcomes are using
18 the health IT and, like I said before, what the
19 patients are doing with it.

20 And then the final thing on that is
21 whether there are even benchmarks set. So when
22 you want to have an outcome measure, you want to

1 say what your benchmark goals are, and what the
2 floor is, and where you want to be eventually.

3 So my question for this committee, and
4 also just for creating measures in the future, is
5 how can we look at the outcomes and how consumers
6 are experiencing their healthcare, and where do
7 we want to set our benchmark, and then where do
8 we want to go from there.

9 DR. KHUNLERTKIT: Hi, this is Nana.
10 I actually come from a different perspective --
11 from another angle of looking at things from the
12 processing structure standpoint to make things a
13 little bit more proactive, rather than looking at
14 the outcome and moving back to improve the
15 structure in the process.

16 So I think what we lack in the
17 framework of measuring HIT or EHR is the design
18 of the equipment. Like usability evaluation,
19 usability testing to begin with, or even the
20 implementation process, how much you engage a
21 user into the process. So, that is where I am
22 coming from.

1 CO-CHAIR SINGH: George?

2 DR. HRIPCSAK: I think the answer to
3 Karen's question about the unexpected future,
4 what we have been talking about is just having a
5 good framework so that you can categorize because
6 we can't handle everything that is to come. But
7 you know if it is a system, it is going to be
8 down. It is going to have uptime and downtime.
9 Is it going to be accurate or not? So if we have
10 a good framework, I think that helps us.

11 And then I think it is okay, then to
12 limit our first measures to be more EHR focused.
13 And I would handle the phone only probably
14 insofar as it is a terminal to be used to get to
15 an EHR, but not use it for texting that doesn't
16 touch an EHR database, as an example of where we
17 should start in scope.

18 CO-CHAIR SINGH: And I want to hear --
19 Linda, I think since you are sort of leading the
20 effort on the HIT safety center, are there any
21 types of sort of scope activators you are looking
22 at that would sort of help us think about these

1 things?

2 DR. DIMITROPOULOS: Well one of the
3 tests under the contract for the Roadmap is to
4 identify measures and do a gap analysis. So
5 there was some overlap in the scope. So what we
6 are trying to do is look at the work this
7 committee is doing and identify an area that we
8 may be able to carve out and contribute.

9 So, we haven't defined that yet. So,
10 we are working on that. You know Mark Graber and
11 I are working on that. So that is something we
12 should be considering today. If there something
13 that comes up that is not quite fitting in but we
14 feel it is really important to do, then we can
15 talk to ONC and see if that is something that we
16 could contribute to this process externally.

17 CO-CHAIR SINGH: Any other comments?

18 So what we are hearing is sort of a
19 broad agreement on keeping a broad overview and
20 then, perhaps, having a shared sort of
21 frameworks, conceptual models, shared
22 understanding, and then maybe narrowing down and

1 keeping our focus tightly on electronic health
2 records and related.

3 And again, EHRs are becoming very
4 broad and a lot of the interface issues are going
5 to come up anyway in discussions about EHRs. So
6 we are not going to be that limited, even if we
7 focus just on EHRs and PHRs and related
8 information technologies.

9 And the idea would be to keep the
10 measures broad. I think some of the things are
11 very applicable across multiple settings and
12 multiple pieces of information technologies. You
13 know, things like downtime and broken tables, and
14 so on and so forth.

15 Andrew, over to you.

16 MR. LYZENGA: All right. Well, I
17 think -- if there are no more comments or
18 questions, we might as well take a quick break at
19 this point and come back. We will do a bit of --
20 we will have some thoughts from Dr. Singh and
21 Elisabeth on conceptual models, legal and
22 regulatory environment. Some thoughts from Mark

1 Segal on the vendor perspective.

2 So let's take a break for 15 minutes.
3 Come back at 10:15 and we will jump back into the
4 agenda then. Thanks.

5 (Whereupon, the above-entitled matter
6 went off the record at 9:58 a.m. and resumed at
7 10:20 a.m.)

8 MR. LYZENGA: All right, thanks,
9 everybody. So we again, have a few presentations
10 here from our co-chairs, among others. And I
11 also wanted to just note that Helen, I believe,
12 just sent out a version -- all right. And we
13 have posted a number of materials on the
14 committee's SharePoint site, include the slides,
15 the IOM report, and the rest of the slides that
16 are a part of the presentations today and
17 tomorrow. So if you want to go and check that
18 out, they are available to you.

19 With that, I will hand it back over to
20 Dr. Singh.

21 CO-CHAIR SINGH: Welcome back,
22 everybody.

1 So I was going to use this
2 presentation time in mostly trying to make sure
3 we are all on the same page about measurement and
4 definitions and all that. But also, I would like
5 to make it interactive. So if you want to sort
6 of stop me at any given time, please do so. We
7 will definitely have a chance to debrief after I
8 finish the presentations as well.

9 So okay, do I need to -- okay. Now it
10 is working. All right, great.

11 So I think this is the reason why we
12 are here. This slide sort of specifically says
13 that we cannot actually improve what we can't
14 measure and we can't measure what we can't
15 define. So I think we have a really tough task
16 ahead of us, a challenging but I think it will be
17 a rewarding task to make sure that what we come
18 up with leads to patient safety improvement, like
19 Helen said this morning as well.

20 But also at the same time, we have a
21 very good opportunity to sort of define what
22 Health IT safety is. I see so many papers now

1 where everybody sort of uses their own
2 definition, their own conceptual model of sort of
3 what is a health IT safety event, health IT
4 safety concern, iatrogenesis, technology failure.
5 We have got all of these terms floating around.
6 So I think we should sort of come up with a
7 consensus around what is it that we are actually
8 studying here.

9 Why do we need this measurement
10 approach? Why are we all here? I don't think we
11 are doubting that health IT has tremendous long-
12 term benefits and will, in long-term lead to good
13 patient care. But we do have implementation and
14 use challenges. And inherently, HIT
15 implementation use is complex and prone to
16 failure. And we have to be able to measure these
17 failures in order to make our progress in patient
18 safety.

19 There is emerging evidence -- so I
20 think all of you probably have seen reports from
21 the ECRI Institute. The Pennsylvania State
22 Authority has had a report. There has been a

1 number of papers. Australia, National Health
2 Service has had ---- there was a recent paper
3 from NHS in sort of these safety events.

4 But recently, Joint Commission has
5 done -- and Gerry is here and we can sort of talk
6 about this again later, but Joint Commission
7 actually looked at 120 of the health IT-related
8 sentinel events. And what they found was the
9 three most frequent type of events were
10 medication errors, wrong site procedure, or wrong
11 patient, and delays in treatment, in that order.

12 This is, I think, important because I
13 think that is probably the first time Joint
14 Commission has sort of dug deeper into their
15 Sentinel Event Database to look for health IT-
16 related issues and, again, has sort of come up
17 with this very informative report that I think --
18 Gerry is it going to be released soon, the report
19 as well? I know there is a lot of information on
20 the web but the report is about to be released as
21 well. And they will have a sentinel event alert
22 coming out as well with the report in the next

1 month or so.

2 They actually use our eight-
3 dimensional sociotechnical model of safe and
4 effective health IT use in their analysis. What
5 they did, from what I understand, is they sort of
6 picked the dimension or one of these eight
7 dimensions that was sort of most closely related
8 as a contributing factor to the sentinel event.
9 That often is a very hard challenge because it is
10 almost never that one of these dimensions is the
11 only one involved in causing a health IT-related
12 failure or event.

13 The eight dimensions here, most of you
14 have probably seen this framework, but a couple
15 of important things I wanted to sort of bring
16 out. In their analysis, the user interface or
17 the human-computer interaction was the number one
18 reason for the sentinel event. The number two in
19 their analysis was workflow and communication,
20 and actually number three was content.

21 So content basically is in the
22 knowledge, the rules, the algorithms, the alerts,

1 the reminders, the decision support in the EHR,
2 all of that is what we call content. If you want
3 to read about the framework, we have a full paper
4 on that.

5 One important neglected component of
6 this framework for safe and effective health IT
7 use is the external rules and regulations. We
8 often don't take those into account and I think
9 this is really important because things like
10 meaningful use drove a lot of the EHR
11 implementation. I think the role of NQF and
12 Joint Commission, itself, probably can be
13 construed as a part of that dimension.

14 One of the things we have learned in
15 our work is all of these dimensions have to be
16 thought through in any health IT-related patient
17 safety analysis, project, evaluation. And so we
18 actually walked through each of these dimensions
19 in our work. So I sort of compliment Joint
20 Commission for doing such a thorough analysis and
21 we look forward to reading their report when it
22 comes out.

1 What are the emerging evidence? This
2 is a survey we all did. Actually, Elisabeth is
3 also one of the authors on this paper. We
4 actually asked the ASHRM members and the AHLA
5 Association Members -- the American Health
6 Lawyers Association Members, are you having any
7 EHR-related serious safety events. And we asked
8 many people, in fact 4,000 or 5,000.

9 We didn't get a great response of 369
10 respondents, which I think is pretty good because
11 the lawyers don't kind of tell you a lot. So the
12 lawyers are telling you this. I really think
13 that it really means a lot.

14 So you know they said -- about half of
15 them said, they admitted to at least one safety
16 event in the previous five years and ten percent
17 experienced more than twenty events in the last
18 five years. So, I think, again, emerging
19 information from all across the country that we
20 have some issues we need to deal with.

21 I'm sure people have seen headlines
22 such as electronic health records system

1 crashing. There was actually a more a more than
2 14-hour crash in Australia just yesterday. It
3 affected a lot. And you know we actually asked
4 Scottsdale Institute members, which is I would
5 say the health IT -- the enthusiastic group.

6 So it is people who have been doing
7 health IT implementations for a very long time.
8 There is about 60 members, institutional members,
9 across the country -- Scottsdale Institute has.
10 And around 95 percent said they had had an
11 unplanned downtime. 80 percent said they had an
12 unplanned downtime of at least 8 hours and
13 several of them had a downtime for more than 24
14 hours and we talked about downtime a little
15 earlier as well.

16 We actually did a study in the VA. It
17 came out just about last year, late last year,
18 and the VA has had an Informatics and Patient
19 Safety Office where they evaluate -- they have
20 sort of a broad human factors, cognitive science
21 informatics approach. They have a team of
22 individuals who investigates reports that are

1 submitted from across the VA hospitals around the
2 country.

3 They have been in existence for a good
4 number of years, about maybe 70 to 80 years. VA
5 has actually implemented the EHR in late '90s.
6 So, they have been doing this a while. They
7 looked at 344 incidents and then we further
8 evaluated 100 of these incidents in detail. And
9 what we found was most of these safety concerns
10 are related to either unmet data display needs in
11 the EHR, which I think meshes well with the Joint
12 Commission analysis of sort of the human-computer
13 interface being an important one.

14 We have also found safety concerns
15 where there are software upgrades and
16 modifications. So this typical example is where
17 you have an upgrade, something that was working
18 really well, doesn't work very well. So in one
19 instance in our facility, we found the test
20 results that were being transmitted to referring
21 docs suddenly were not being transmitted to the
22 referring docs after the upgrade.

1 The third one was data transmission
2 between EHR components. We talked about this
3 this morning, as well. So this is the system-
4 system interfaces. So, the lab information
5 system communicating with the EHR and the CPOE
6 with the EHR, so on and so forth.

7 What did we learned from the VA study?
8 I think this is the key point. VA has had the
9 EHR system for a very long time, monitoring it.
10 It has a very good sophisticated infrastructure.
11 And despite those monitoring, we are still having
12 safety concerns long after we went live.

13 It really sort of tells us that we
14 need to be paying attention to these issues. And
15 again, this is passive reporting and so there
16 were not a whole lot of events over the last five
17 years. So you could think that, oh well, not a
18 lot is going on but as most of you know, only
19 about one to five percent of these things ever
20 get reported. So, really we're at the tip of the
21 iceberg. There is a lot more that is going on in
22 these EHR systems that we don't know about.

1 So as a researcher we kind of try to
2 break things down so that we could understand
3 them and figure out what we can do. So over the
4 last few years, Dean Sittig and I have actually
5 come up with this hierarchy, if you will, of
6 three phases of health IT and I think some of you
7 have heard about this this morning.

8 And the first phase we say is we have
9 got to have health information technology that is
10 safe. That means we can't have computer bugs and
11 malfunctions and all that. And the reason we
12 like sort of these phases is it just helps you
13 sort of think through the broad dimensions of the
14 things that we need to be thinking about as a
15 group in what types of measure we are going put
16 in and what type of events are we going to be
17 sort of looking at for improvement.

18 So this phase is ---- you know, the
19 classic example I like to use. You know this is
20 a National Health Service, this is BBC News 2006,
21 where 900 patients actually got a prescription of
22 Viagra instead of Wellbutrin. And the reason

1 they found is women started showing up in the
2 pharmacy with Viagra prescriptions and this was
3 because of a computer glitch. And so in our
4 model, this was a phase one, it was clearly a
5 technology problem. So again, what we need to be
6 thinking about is how do we make sure that the
7 technology is safe. So this is all about safe
8 technology.

9 The second phase in our model, or our
10 hierarchy, is using health IT safely. So again,
11 we could have the best health IT in the world, we
12 could have the best EHR in the world and we would
13 still sort of mess it up in some way or the other
14 and that is because either we don't use the
15 technology appropriately or we use it, sort of --
16 the use is unsafe. Also, unsafe changes in the
17 workflow that can emerge from technology use.

18 And I think a perfect example of
19 something like this happening is the Ebola case
20 in Dallas, Texas, where it was a constellation of
21 a lot of things that was going on. If you know
22 the case in detail, this is our analysis on the

1 paper. The doc actually spent more time with
2 electronic health record and looking at data than
3 with the patient and there were a lot of issues.
4 You know the patient presented with a fever and
5 lots of other symptoms.

6 The doc had written in the note --
7 talking about documentation, Bill, as you said
8 this morning. The note said no fever, and so why
9 do you think the note said no fever? Because the
10 doc was probably using templates. The doc also
11 wrote ---- wrote, quote, unquote -- instructions
12 in the note which were gender neutral. They will
13 follow up. They will do this. And clearly, it
14 was using some kind of macros and templates to
15 create these documentations.

16 So I think, again, it gets to the
17 point why are we documenting so much in the ER
18 and a lot of it is sort of reimbursement
19 pressures and so on and so forth. We could go on
20 and on. But this is, again, a case where
21 something which probably should have been
22 communicated verbally was not communicated. I

1 think the nurse had sort of got a history of
2 travel to West Africa documented in the note but
3 did not communicate it to the doctor and the
4 doctor never asked the patient either.

5 So, there was a lot of complex issues
6 about technology that came up as far as this case
7 was concerned. But we have got others, so many
8 examples. So we have the potential of the EHRs
9 to sort of interfere with our decision-making,
10 which was sort of well seen by this case.

11 Copy/paste issues were mentioned.
12 There is also instances in which templates have
13 been used and docs have sort of signed labs that
14 are clearly abnormal because they are using
15 templates. And we have seen patients who are
16 anemic, hemoglobin is eight, it is signed in the
17 note. And nobody has taken any action on it
18 because the labs were imported into the record by
19 automatic sort of population of the note through
20 templates and so on.

21 So again, reviews physician
22 efficiency. Why is that important? If you can't

1 spend time with patients, not going to be really
2 good care. And so David, I think, many members
3 of my family circle, I have the same problem as
4 you, sitting and documenting until 11:00.

5 The next issue is sort of there are
6 data disparity issues that can lead to ambiguity.
7 We have got plenty of examples of people are
8 missing important information in the EHR,
9 critical results are sitting at the bottom,
10 nobody can look at them. They are beyond the EHR
11 screen.

12 We have a paper sort of coming out
13 where we actually compare the graphical sort of
14 interface of test results displayed in the EHRs.
15 We named the EHR but we didn't say which one we
16 used. We actually ranked them in terms of
17 appropriateness of the graph. And you have one
18 EHR where the graph is going from ---- instead of
19 going from left to right, it is actually going
20 the other way, from right to left. So we have
21 got lots of data disparities we need to be
22 thinking about.

1 We talked about iPatient a little bit.
2 People are spending sort of more time with the
3 computer than talking to the patients, and I
4 think we are going to have to think through some
5 of these issues. How are we going to be able to
6 measure these things? How are we going to make
7 sure these things are addressed so we can go
8 towards improvement?

9 We also have a lot of electronic
10 communication breakdowns. So with EHRs it is now
11 possible to transmit information from point A to
12 point B, but that doesn't mean it is going to
13 lead to action. We actually looked at almost
14 more than a thousand abnormal results related to
15 labs, almost a thousand abnormal results related
16 to abnormal imaging. And we still have things
17 getting lost to follow-up in the EHR, even when
18 we transmit information from point A to point B.

19 So we found that docs would open up
20 the alert and, David, you said you get 50 alerts.
21 You open up the alert, you read the alert but you
22 didn't take any action on it. And we looked

1 into why is this happening? And the reason we
2 found out this was happening was because if the
3 test result was ordered by somebody else, you
4 would think well, the other guy is going to take
5 action on it. It is abnormal. It is my patient
6 as a PCP, but the specialist ordered the test so
7 it is his responsibility to follow-up. And the
8 specialists thinks, oh, well, I ordered the test.
9 It is a PCP's issue.

10 DR. CLASSEN: In my system, when I
11 click on that alert, it disappears and I never
12 see it again. I can't find it again.

13 CO-CHAIR SINGH: Yes, correct. So,
14 that, again, is a software issue.

15 So again, so we have lots of issues.
16 And then again, we also found, as David said this
17 morning, we are getting too many of these alerts.
18 And these are the asynchronous in-basket alerts.
19 I think most of the people have heard about pop-
20 up alerts that show up when you order
21 medications. Yes, that has been a problem for
22 the last decade. Ninety-nine percent of them are

1 ignored.

2 But we have got a different problem
3 now, which we sort of investigated in the VA many
4 years ago. And the moment the EHR started
5 getting implemented, we knew this would sort of
6 also spill over to the rest of the U.S. And now,
7 docs are saying they have got so many in-basket
8 alerts that are popping up as messages for
9 patient care that they can't handle them.

10 So we did this survey and we found
11 that almost a third of the providers said they
12 have missed abnormal test results because of too
13 many alerts in the EHR system. So we are going
14 to have to sort of deal with that too.

15 In phase three of our health IT safety
16 hierarchy, that is when we actually -- this is
17 why we actually use technology, right? We use
18 health IT, or we wanted to use electronic health
19 records, because we want to improve patient
20 safety.

21 So in this phase we really want to try
22 leverage health IT to identify the unsafe care,

1 the potential patient safety concerns, before
2 they cause harm. So you want to prevent the
3 harm. You want to identify the near misses. You
4 want to try to use health IT to improve every
5 aspect of patient safety and maybe even quality
6 of care in this phase.

7 And so what is an example of that? I
8 think a good example is you have got lots and
9 lots of data in the EHR and now it is going to
10 get integrated. In our case, we study abnormal
11 test results a lot. In the VA we have a fairly
12 innovative EHR, which is comprehensive. So, we
13 have our patient data across systems of care,
14 outpatient, inpatient, ER, sometime even between
15 hospitals.

16 So we have actually tried to leverage
17 that to identify instances in which the test
18 result was abnormal but there was no follow-up
19 action. So if you go to a doc and you have an
20 abnormal x-ray or an abnormal fecal occult blood
21 test or thyroid-stimulating hormone and you don't
22 get follow-up in 30 days or 60 days, depending on

1 the predefined criteria, we have actually
2 identified those instances.

3 So we call this sort of phase three,
4 when we are trying to build triggers in the EHR
5 to identify a potential -- either delays in care,
6 unsafe care, potential harm, and even harm
7 because you can learn from harm and go and fix
8 it. So anytime you are using technology to
9 improve patient safety and improve patient care,
10 this could be within the phase three purview.

11 This is a model that I like to spend
12 a minute on because I think it has been really
13 helpful for us to think through all the work that
14 we have done in the last eight or ten years, and
15 for Dean Sittig, even longer. So, Dean and I
16 sort of have been working on this. And it is,
17 again, work under progress, where we think
18 through how can we use a framework to help
19 measurement of health IT-related patient safety.

20 So, we started with our sociotechnical
21 eight-dimensions and we said all of what we sort
22 of think through in our sociotechnical health

1 system, all of those dimensions are applicable to
2 our entire -- we call it sort of the HITS
3 Framework. And again, if you look at this
4 closely, it has CQIs based on the continuous
5 quality improvement framework.

6 So on the left side of the framework,
7 we sort of have our health IT safety hierarchy,
8 and I just sort of walked you through this. So
9 the foundation has to be safe EHR, safe health
10 IT. You have got to have safe use of health IT
11 on top of that and then we have to use health IT
12 to improve safety.

13 Now if you look at these principles --
14 so the italicized text here to know it is the
15 hierarchy principles, these principles are
16 described in the SAFER guides. These are the
17 exact same principles we used in the SAFER
18 guides. And again, I am not going to walk you
19 through all of these because we have written
20 about them before, but in general, this is what
21 the health IT safety hierarchy sort of does.

22 And then we build measures, and I

1 think Andrew sort of gave this list this morning
2 of the NQF criteria. We have got to build both
3 retrospective systems of measurements as well as
4 prospective measurement systems. So I think
5 somebody said this morning we have got to be more
6 proactive. We can't always rely on harm to occur
7 or an error to occur. How can we do this more
8 prospectively, more proactively?

9 So we ought to have measures that are
10 both retrospective as well as more proactive or
11 more prospective. And these are exact criteria,
12 except for maybe transparency, but Andrew, maybe
13 transparency is a part of your criteria, maybe.

14 MR. LYZENGA: Yes, usability to some
15 degree and incorporate the extent to which a
16 measure's results are publicly available,
17 publicly reported.

18 CO-CHAIR SINGH: Yes. And the reason
19 we thought transparency is important is because
20 we have heard the stories when physicians get
21 measures and they are wrong and they try to sort
22 of say, this is wrong. We often don't have the

1 transparency of these measures to understand what
2 is right about them and what is wrong about them.

3 So, again, we are going into a very
4 complex territory. We have got to have measures
5 that not only we agree upon but also whatever we
6 are trying to measure, know exactly what our
7 measure looks like and how do we get to that
8 measure? How do we ---- what is the numerator,
9 what is the denominator, and everything. And I
10 think NQF already has some of that built-in.

11 All of this then, would lead to
12 organizational learning, including the sort of
13 the shared responsibility that I think many
14 people sort of have heard. I think there is
15 multiple stakeholders involved. It is not just
16 the EHR developer or the physician or the
17 hospital or the Board. We have got to be
18 thinking about broadly sort of the accountability
19 and the shared responsibility.

20 We have risk management and quality
21 management ---- sort of some standards that we
22 could think about in this type of learning from

1 measure development. This is, again, going to be
2 an iterative process. David mentioned this
3 morning we are never going to be sort of
4 finished, per se. We are going to be on a
5 constant evolution. So the measures are going to
6 get better. The definitions are going to get
7 better. The strategies are going to get better.
8 And then again, at some point in time, we could
9 probably use them for some benchmarking.

10 And then what we learned from all of
11 this could go to change standards, regulations,
12 policy and practice, but also inform the
13 developers in healthcare organizations so they
14 can change. And somebody was asking, well, how
15 are we going to use this? Is it going to be for
16 value-based purchasing and all of that? I think
17 we are going to at least start from the learning
18 at the local organizational level.

19 So, healthcare institutions should be
20 able to run some measure. And I think Jason
21 Adelman has developed one measure that I am going
22 to show you in a minute that can be used. And I

1 think, Jason, are you actually using that in the
2 institution about the order tracking order?

3 DR. ADELMAN: Yes.

4 CO-CHAIR SINGH: Absolutely. So, the
5 question is can other institutions use such a
6 measure in their institution to identify patients
7 of misidentification. S

8 So again, not necessarily used for
9 value-based purchasing or changing policy. But
10 again, at one institutions, it has had pretty
11 good success and I think we have got to learn
12 from these cases.

13 And so as long as these measures are
14 even being used for some local quality
15 improvement, local patient safety improvement
16 efforts and not necessarily being used for sort
17 of reimbursement, or penalties especially, that
18 would be fine. And all of this would lead to
19 safer health IT-enabled care. And again, we have
20 got a feedback loop, so it is sort of following
21 the CQI model.

22 Let's talk about definition. Any

1 questions, by the way? We are going to talk
2 about this later but any quick reflections on the
3 HITS Framework before I move on to the
4 definition?

5 George.

6 DR. HRIPCSAK: I like the
7 sociotechnical. I like the hierarchy but do we
8 have to call them phases? Because I got
9 confused. I was trying to figure out well, when
10 did I want to start this and do these have to be
11 finished and they will never be finished. And
12 they are kind of levels in this diagram, rather
13 than phases.

14 CO-CHAIR SINGH: Yes.

15 DR. HRIPCSAK: Because otherwise,
16 people are going to ask, well, why do I have to
17 wait to start using HIT.

18 CO-CHAIR SINGH: Yes, you know we
19 actually when we wrote the paper originally, we
20 actually used the word phases. This was like
21 four years ago. This thinking is constantly
22 evolving. And over the last year we realized we

1 had the same question. We said does phase really
2 mean that I actually can't get to it while I am
3 in phase one? Well, not really, you can do any
4 of these anywhere. So we have been moving away
5 from that. So, maybe that is a good sort of a
6 thought. Maybe we just use the word hierarchy.
7 Is that going to be better? Yes, we should
8 remove the word phases.

9 Okay. Any other quick reflections?

10 Okay, so talking about definitions.
11 This is where you know things get very confusing.
12 What is a health IT-related safety event and a
13 concern?

14 So, David Classen, Dean Sittig, and I
15 actually had this paper where we actually built
16 on the definition that Andrew showed, which was
17 again, written about five years ago. And we
18 expanded that definition and said we are not
19 calling it errors because we can't even agree on
20 what a medical error is. We are not calling it
21 an event because you know event means that maybe
22 some adverse event has happened. And we want to

1 be broad. We want to be not only looking at
2 outcomes. We want to be looking at some
3 structure process issues like, Nana, you
4 mentioned this morning.

5 So we want to call it safety concerns
6 because it broadly encompasses a lot of the
7 things that we were talking about -- and actually
8 that was consistent with the AHRQ common format
9 because, as probably David Classen will tell you,
10 that is a term that we didn't invent this.

11 Somebody else thought of this. Great. So we can
12 now sort of define what we want to sort of do in
13 their sort of language.

14 So we have five of these concerns.
15 Again, I want you to sort of read them and sort
16 of think through them because I think this
17 pattern will keep emerging through the rest of
18 the next couple of days and through probably the
19 report as well.

20 So the first safety concern that we
21 say is -- a type of HIT safety concern is when
22 HIT fails during use or is not working. So you

1 know downtime or broken hardware or software bug,
2 so that the computer glitch that I talked about
3 from NHS, that would all be in sort of this first
4 category.

5 The second category is instances in
6 which HIT is working as designed, but the design
7 does not meet the user's need or expectations.
8 So these are all the usability issues. This is
9 where a lot of the physician concerns lie. This
10 is not useable for me. This doesn't work the way
11 I want it to be or how I expected it to.

12 Number three is instances in which HIT
13 is well-designed and working correctly. So
14 remember the first two. It is sort of working
15 correctly, well-designed, but it is not
16 configured, implemented, or used in a way planned
17 for by the system designer or developer.

18 So remember all those duplicate
19 alerts? So if you just configure all of your
20 patients who are taking aspirin, 81 milligrams to
21 also get an alert on the Tylenol that they will
22 get. Well that is a configuration issue. So,

1 that would be an example of three in here,
2 duplicate PRN medicines and all of that. So any
3 configuration type issue or implementation issue
4 could be within this category.

5 So the fourth category is instances in
6 which HIT was working as designed, configured and
7 used correctly, but interactive with an external
8 system. So the data got lost or incorrectly
9 transmitted or displayed. So remember we talked
10 about sort of system to system communication this
11 morning. The lab information system to EHR, EHR
12 to CPOEs, all of that.

13 So, if a medication converts from
14 long-acting morphine to a short-acting morphine,
15 when it crosses over because either a table
16 mismatch or interface ---- a problem with
17 interface translation table, that would be an
18 example of number four.

19 Number five is instances where you can
20 actually use HIT to fix things. So this is where
21 you know we want to try to implement those alerts
22 and reminders and improve care, and all of that

1 will fall into this. So when HIT could prevent a
2 safety concern, that would be an instance in
3 which -- and the reason we sort of put that in
4 there is because we thought -- sort of balancing,
5 I think that George was mentioning this morning.
6 We want to balance the risk part with sort of the
7 safety benefits part. We want to try to make
8 sure that people understand that all of these
9 patient safety events and harm that is occurring
10 could be prevent us from using HIT. So, it would
11 make people think through some of these issues.

12 So if you don't have an alert for the
13 maximum daily dose, for instance, as an example
14 here, you know somebody receives five grams of
15 Tylenol, so that would not be good. But you
16 could prevent that if you had a maximum daily
17 dosing alerting.

18 Any questions on these sort of five
19 levels or five categories? Mark.

20 DR. SEGAL: I have a question on the
21 last one, how broadly do you define that? So, it
22 is one thing, let's say if they had maximum dose

1 alerting and it wasn't turned on or that is a
2 common industry approach and a particular product
3 didn't implement it, but there is also this
4 almost infinite set of potential things that can
5 be done with technology.

6 I was talking with Kathy Kenyon
7 earlier about this with cars. You know if you
8 spend twice as much on a car, you can probably
9 exponentially increase the safety.

10 So how are you sort of bounding that
11 last one to what is sort of realistic to expect
12 or is that even a concern of yours?

13 CO-CHAIR SINGH: Well, I mean this is
14 all conversations open for discussion. I mean
15 this is I think a lot of it would depend on
16 organizations, sort of what they want, how
17 important it is to them, and their tolerance.

18 And if you do some sort of assessment,
19 for instance, in SAFER guides you can actually
20 look at some of the categories to see is this
21 important to you. And if you realize, well, this
22 is really important to us and we want to invest

1 in this, it is good. But I don't think anybody
2 is sort of expected to sort of -- I think you are
3 right, there is an infinite number of things we
4 can do. We haven't sort of put any boundaries to
5 it yet.

6 DR. CLASSEN: I just might add to
7 that. In the IOM Committee, clearly we were very
8 focused on instances where health information
9 technology led to harm, but we were also very
10 focused on instances where HIT could have
11 prevented harm and did not.

12 The reason we are so focused on that
13 is because in the sociotechnical environment that
14 these systems get implemented in, people come to
15 expect a safety net from the EHR system that
16 drives their behavior and how they react to
17 things.

18 So case in point, people come to
19 accept that the EHR system will intercept
20 important drug allergies and cross-allergies.
21 And so when a medication gets ordered and the
22 nurse is getting ready to give it, she assumes

1 that it has been through the system and the
2 allergy and cross-allergies have already been
3 checked so she doesn't have to be the safety net.
4 Twenty years ago, she would have rechecked to
5 make sure that the cross-allergies and allergies.
6 Now she or he doesn't have to.

7 The reason that is so important is I
8 view these systems as complex adaptive systems.
9 They are changing all the time. And upgrades can
10 dis-inactivate previous safety checks and nobody
11 knows about it. And we, with the EHR flight
12 simulator, documented this endless times that an
13 upgrade will inactivate a critical drug cross-
14 allergy check but the people who are actually
15 taking care of the patients assume it is still in
16 effect.

17 And so at the IOM, we were very
18 concerned about that sort of baseline safety net
19 we all assumed is there. It gets turned off by
20 an upgrade and nobody knows.

21 So you know, Mark, I think your point
22 is a great one. The question is, should there be

1 sort of a floor that these are the minimal safety
2 functions of the system and we have to have a way
3 to measure that they actually are still working
4 on a daily basis.

5 DR. SEGAL: I guess I totally get
6 that. I think it is that sort of could have
7 because absolutely if it is something that got
8 turned off in an upgrade, inadvertently, and
9 particularly when people are relying on it. But
10 then there is also the could have, if you had a
11 really smart designer putting something in.

12 So, I think it is just that kind of
13 bound of the could have.

14 CO-CHAIR SINGH: Yes, and we thought
15 this would foster innovation. So you know find
16 that you didn't have it today, but could this
17 make a difference in the future. So it would
18 stimulate people to think about reporting or
19 whatever on events that could be improved for the
20 future.

21 So here is where we can get down to
22 specifics, again, you know this adjusts some

1 strawmen examples of what we can measure. This
2 is not a be all, end all list. I just wanted you
3 to sort of fuel everybody just to sort of think
4 about.

5 In each of those phases, what are some
6 of the things you could measure? These are not
7 maybe the exact measures but these are the things
8 you could think about.

9 So if you have an unexpected EHR
10 downtime, if an institution has it more than an
11 eight hours, we could sort of measure those
12 things. We could also measure mean EHR response
13 time. We have been to places where it is slow,
14 so slow, slow, it is like functionally it is like
15 a downtime. We could measure EHR response time.
16 We could measure erroneous displays of lab
17 results on medications. Software bugs reported
18 of the EHR vendor could be another type of area
19 of measurement we could be thinking about.

20 In phase two, which is sort of using
21 health IT, we could measure all the interruptive
22 alerts, which have close to 100 percent override

1 rate. I mean the alert is being overridden 99.99
2 percent of the time. We have got to be thinking
3 about why do we have it.

4 Another one could be -- I think Andrew
5 mentioned this morning as well, is the number of
6 EHR users that are being trained and passed a
7 competency test before getting a log-in. There
8 are so many times you would hear from clinicians
9 I don't know how to use this and you go from
10 systems -- you know, they are using three or four
11 different systems. It is just impossible for
12 them to sort of all know all of those systems in
13 great detail without undergoing their training
14 and many people don't show up for training, they
15 don't get enough training. So we could be
16 thinking about a measure about training.

17 We could think about a measure about
18 CPOE entry use, CPOE use, and that is because if
19 you have a partial CPOE system in the hospital,
20 it is always more dangerous and there has been
21 plenty of literature around that.

22 CPOE helps sort of close the loop

1 between an ordered test or an ordered medication
2 and you just can't do that if you have sort of a
3 halfway use system.

4 The next one is order-retract-reorder
5 trigger that I was mentioning. Jason can tell
6 you a lot more about this. Jason, do you want to
7 give like a ten-second overview of what you are
8 doing with this?

9 DR. ALEXANDER: Sure. We developed an
10 automated metric to look for when providers place
11 orders on the wrong patient and it works very
12 simply. It looks for when a doctor places
13 Tylenol and x-ray on patient A. That doctor
14 cancels that order and then very quickly orders
15 it on another patient. The programmer who wrote
16 it used to call it the oops query. Like, oops, I
17 am on the wrong patient. But we give it a more
18 professional term of retract and reorder.

19 CO-CHAIR SINGH: I actually kind of
20 like oops measurement.

21 DR. ALEXANDER: Well, we use that now
22 as an outcome measure in multiple studies,

1 different interventions to prevent wrong patient
2 errors. With more time, I can tell you about
3 some of them.

4 CO-CHAIR SINGH: Sure. All right, and
5 then maybe the number of duplicate patients.
6 This has been a real problem in several systems.

7 In phase three what we could measure,
8 we could look at the abnormal results that have
9 not received follow-up. We could look at the
10 benefits of some decision support interventions,
11 such as the sepsis alert. We could also think
12 about just automating measures of the current
13 sort of hospital-acquired conditions or even
14 early warning signs for those hospital-acquired
15 conditions.

16 And again, no, Mark, to your point, we
17 can't even sort of imagine right now some of the
18 things we could be thinking about because we
19 know, we haven't even started measuring patient
20 safety accurately. But when we start to do that,
21 we can figure out oh, we can actually use some
22 health IT to prevent this. So, I think the list

1 would be growing a long way quickly.

2 One of our proactive measurements when
3 we talked about mostly sort of retrospective
4 things, one of our proactive measurements as
5 well, I would like to just spend a couple of
6 minutes on the ONC SAFER Guides, which I think
7 most of you may be familiar with but we consider
8 them as a proactive risk assessment and a
9 guidance instrument, which just sort of tells you
10 here are some ways you could assess how your EHR
11 is working or not working in your institution.

12 We call this sort of a self-
13 assessment. This is not policy. It is not
14 guidelines. It is not a regulation. It is not
15 accreditation. It is not certification. And so
16 I think even though we had our sort of nice
17 critique from the vendor community -- I must say
18 it was 27 pages long -- but it was very sort of
19 informative to see that they actually agreed with
20 a lot of the practices of the SAFER Guides, but
21 it was just the examples that we had sort of
22 given where they would say you know it would be

1 hard to this in our system. And we totally
2 agree.

3 An example is like banana, apples, and
4 oranges are fruits. So, if you say you have got
5 to have a fruit every day, just pick any one of
6 them. And so we could think of an innumerable
7 number of examples to meet those practices that
8 we recommended.

9 So, we would say you must have this in
10 your system. That would be the practice. And
11 then we would give three or four examples of how
12 you could implement that practice or what types
13 of features you could have to make your system
14 better.

15 And I think as long as you use and do
16 a self-assessment on the practice I think in the
17 next slide -- one of the next slides, I will show
18 you the practice and you can go through it.

19 We have nine guides. Seven of them are
20 on high-risk areas. And if you look, the
21 foundational guides are high priority practices
22 and organizational responsibilities. We think

1 every hospital and every institution in the
2 country ought to be doing this if you are using
3 an EHR. I actually just came from a conference
4 in Tucson and there were two people who knew
5 about SAFER Guides in the audience and everybody
6 is like well, how come we never heard of this?

7 So anyway, they have been out a year
8 and there are some guides that are a bit more
9 technical, like the infrastructure guides, but a
10 lot of them are clinical process guides in high-
11 risk areas, so IED, CPOE, and CDS test results
12 reporting and communication we think are really
13 high-risk.

14 And I think the one we missed and we
15 kind of thought that it was kind of too late
16 because we were almost halfway there is the one
17 on documentation I think Bill mentioned this
18 morning. But ACP just came out with a nice
19 documentation-related guidelines. I don't know
20 if they call them guidelines but it is a pretty
21 nice, it is an Annals of Internal Medicine. It
22 is a recommendation for improving EHR

1 documentation and we called them pretty close to
2 what we would have done, all of them are written
3 as a SAFER Guide but it is pretty good.

4 This is what a SAFER Guide looks like.
5 It is just a self-assessment, an example being
6 you have got to have allergies that are entered
7 or stored using standard coded data. So, all our
8 practices were those that you could not argue
9 with. In fact, I think we have had very little
10 critique or criticism about any of our practices
11 because they are broadly applicable and everybody
12 starts to agree, yes, we have got to be doing
13 this. Well, if you don't code your allergies,
14 the next time the patient with ACE inhibitor
15 angioedema where the throat just shuts off
16 because of allergic reaction comes into your
17 system and if you entered that as a free text
18 allergy, the computer cannot recognize V-tach.
19 So, nobody argues when we say we have got to have
20 coded data in the EHR for allergies. So, they
21 are fairly sort of high-level practices.

22 This is the page that shows you the

1 worksheet where there are some examples. Who can
2 you ask whether you are doing the practices or
3 you want to do the practice or who do you go talk
4 to? So, we have suggested sources of input. We
5 also give rationale for every practice. And
6 again, the examples are where we got some sort of
7 feedback from the EHR developer.

8 So, the take-home, I think it is
9 essential to have robust definitions and shared
10 mental models of our frameworks. We have got to
11 be on the same page as to what we are talking
12 about. So, when I say health IT-related safety
13 event, you understand that to be the same thing
14 as I understand it to be. And again, it doesn't
15 have to be mine, I am just making sure that we
16 all have to be on the same page on our models.

17 The second take-home point is I think
18 we have got some risk areas that are clearly
19 defined and are amenable to local measurement. I
20 think Jason's is a great example of what other
21 institutions are already doing in terms of
22 putting like an example of sort of a trigger for

1 automated measurement of patient ID issues.

2 And the third is we really need to
3 make sure -- I think there is lots of
4 infrastructure for patient safety improvement
5 across hospitals, but we need to go and talk to
6 these people. They are mostly focused on the
7 general patient safety issues. You know, the
8 bedsores, the readmission, the falls, medication
9 errors, they are now thinking health IT-related
10 patient safety. And I really, again, Joint
11 Commission is coming up with a very nice,
12 actually they just released it, training module
13 where they talk about safety, health IT-related
14 patient safety. I hope that, Gerry you can sort
15 of correct me, I think you are going to encourage
16 every organization to sort of try to do that so
17 they can get information as to how do you fit
18 this into the regular patient safety activities
19 of that institution. We are not there yet. They
20 are not sort of thinking about these issues.
21 They know what these issues -- I think SAFER
22 Guides are a help for them, but they really need

1 to try to push the ball further. And this group
2 could really help with that -- pushing the ball
3 further.

4 That is all I have for the slides but
5 we still have time for more reflection and
6 questions.

7 MR. LYZENGA: Lisa, you are on the
8 phone. Did you have a question?

9 MS. FREEMAN: Yes, thank you. I am
10 just a little bit concerned and kind of jumping
11 back to something that was touched upon earlier.
12 It seems that the framework that you are
13 referring to where it is talking about user
14 training and user interface and things like that
15 is implying that the user is on the provider side
16 of things.

17 My concern is that we are missing a
18 very, very important user, and that is the
19 patient. In all of my years interfacing with
20 hospitals in personal situations, in the
21 situations where I am in an advocate role, it
22 seems to me that the patient is that one person

1 who has been through everything all along and is,
2 perhaps, the only one who has the complete
3 picture. And when they are not given the access
4 to the information, many opportunities for
5 avoiding errors before they happen are missed.
6 And I know it is really hard to measure missed
7 opportunities, but it would be great if somehow
8 that can be built into this.

9 CO-CHAIR SINGH: Yes, Lisa, this is
10 Hardeep, again. This is a great point and I
11 should have actually mentioned I have actually
12 taken everybody back to the sociotechnical model
13 picture, patients are right there with the
14 personnel. So, we are not sort of ignoring
15 patients and I think but this discussion this
16 morning of being sort of broad and looking at
17 portals and patient-centered sort of technology,
18 it is really important and points are really well
19 taken.

20 I am going to say I have heard in many
21 conversations that it is obviously good that
22 patients are getting access to this information

1 and I think it will be very good for patient
2 engagement but also of instances in which
3 patients have received somebody else's test
4 results and somebody else's records in the
5 patient portal that they were using.

6 So, again, we have got to be including
7 those instances in which this unintended
8 consequence of health IT is happening as well.

9 MS. FREEMAN: Yes, I am actually an
10 example of that. There are two Lisa Freemans in
11 my community, so we have shared records often.

12 Yes, okay. I appreciate your
13 addressing it then. Thank you.

14 CO-CHAIR SINGH: Thank you. Eric and
15 Jason.

16 MR. LYZENGA: There were several
17 people --

18 CO-CHAIR SINGH: Oh, sorry. I was
19 looking at this. Just follow --

20 DR. HAYNES: So, Kevin Haynes. So, a
21 question about framing the definition. So, is a
22 health IT event also considered once something is

1 entered into any information system? Right, so
2 in your ACE allergy example, if that is
3 documented over at Temple and then I come over to
4 the hospital at the University of Pennsylvania
5 and they are not interoperable, is that a
6 breakdown of the system? Because I didn't see
7 interoperability as a component to the piece.
8 And the same thing with your five milligrams of
9 APAP. If I go to Baylor and in the ED I get a
10 couple milligrams of APAP and then I go over to
11 the VA and I get more, those two systems aren't
12 talking to one another right now. And that could
13 easily be within the 24-hour period.

14 There is not that just sort of Excel
15 spreadsheet that just sort of follows me around
16 that is interoperable. But yet, through TC/IP
17 protocol, I can send everybody in this room an
18 email whether you are Gmail or Outlook.

19 So, where is the interoperability
20 piece with regards to the communication?

21 CO-CHAIR SINGH: I'm thinking should
22 we include that in our sort of broader conceptual

1 framework. I think that is what you are getting
2 at. We need to be thinking about broadly, not
3 just within one system but could other system --
4 I mean we could go on and on. This same example
5 could hold between Texas and California, for
6 instance.

7 DR. HAYNES: Well, yes. So, what I
8 mean and this is really forward thinking but if
9 we all carry phones around with us, if those
10 phones are also our own personal record, at least
11 knows that other things was touched to us, this
12 whole world could change very quickly if we all
13 had a smart card that you plugged in and
14 everything that has happened to me over the past
15 seven days is available. The ambulance picks me
16 up and knows that I have a codeine allergy and
17 doesn't give me codeine on the way in.

18 Where do we draw the line with regards
19 to once something is in an information system is
20 it then mandated that is now available for all
21 information systems? And this is a huge broader
22 question in maybe this community, but it is

1 important.

2 CO-CHAIR SINGH: No, I mean I agree.
3 I don't know, David, did IOM sort of think about
4 these things?

5 DR. CLASSEN: Yes, we did, exactly.
6 We felt that this was going to move so quickly
7 that you really couldn't think of the system as
8 just an EHR system. If you looked at aviation,
9 how quickly it moved there, we would go in the
10 same direction closely. So, that is why we took
11 the broad definition of EHRs, and we thought
12 patient engagement was absolutely critical. So,
13 we wrote a whole chapter in the report, Chapter 5
14 on patient engagement.

15 So, when you post the report, Andrew,
16 people might look at Chapters 5 and 6. They are
17 very relevant to this discussion.

18 But I would agree. And we said you
19 know maybe we should think that if you are
20 allergic to penicillin, wherever you go in the
21 system, it should be interoperable enough to
22 transmit that basic safety information.

1 CO-CHAIR SINGH: And I think the topic
2 of patient engagement is really critical here.
3 And I still remember there is, in a non-CPOE
4 system, we told the patient, you know sort of as
5 a team, you are allergic to Lisinopril. Don't
6 take Lisinopril in your entire life. This was 25
7 years ago. And the patient went in, went to
8 another doctor and the doctor gave Fosinopril.
9 And the patient thought well, this isn't
10 Lisinopril, and I don't have to tell the doctor.
11 And she came back with another angioedema.

12 So, I think this is where I think
13 patients can play also a big role, going now to
14 Lisa's point that could they have the information
15 that could prevent such harm.

16 MS. FREEMAN: This is Lisa again. Can
17 I just jump in for a moment?

18 CO-CHAIR SINGH: Yes.

19 MS. FREEMAN: With regard to that, the
20 one problem is that very often the patient is not
21 either conscious or they are not cognitively able
22 to participate actively in their care. So, it is

1 necessary to rely on the other system and the
2 patient should just be one part of the input.
3 But we really can't say -- you know we certainly
4 want to encourage the patient engagement and
5 support it in every way possible, but we can't
6 rely on that.

7 CO-CHAIR SINGH: Yes, good point.
8 Kevin, did you want to add something?

9 DR. HAYNES: So, the only other point
10 that I was going to make is that the payer has a
11 lot of information about a patient across
12 healthcare systems, which I made that point
13 earlier.

14 Medication reconciliation can be done
15 very quickly based on payer data because you know
16 what was paid and those types of things. So,
17 there is a lot of interoperability that a payer
18 might bring to a table. And I will keep pounding
19 that pavement here.

20 DR. JONES: Jason Jones. Your slide
21 I really, really appreciate. That is the sort
22 of visual one and it is not just because I am

1 illiterate.

2 (Laughter.)

3 DR. JONES: But it gets to the value
4 and the outcomes, which I think is great. I was
5 wondering if, as you were generating these
6 frameworks, you had attempted and rejected the
7 notion of taking a process-based approach, where
8 the process is either delivering HIT. So, I
9 start with a problem I am trying to solve and I
10 end up with a solution that I think solves the
11 problem, which then gets disseminated and used,
12 the actual process of producing HIT, or the
13 process of delivering care and ensuring health,
14 you know, diagnosis, prognosis, treatment
15 strategy selection, implementation sort of thing.

16 Did you try those and find those not
17 helpful or did you find -- because often that
18 helps me in trying to say okay well, now I am
19 going to identify a measure that looks from the
20 software development perspective, identifies a
21 potential weakness, which is often not including
22 clinicians in the process until 12 months later

1 or, gosh, I am trying to make a prognosis. And
2 to get back to the payer thing, we try it at both
3 Intermountain and at Kaiser Permanente to
4 leverage problem lists to identify something like
5 readmission risk totally useless, not because
6 there weren't problems but because they were so
7 differently used by different providers they were
8 completely useless, that claims data, which
9 everyone knows ICDs are wrong 25 to 50 percent of
10 the time is the single best predictor that we
11 have of readmission.

12 So, I was just wondering, again, back
13 to the picture which I love, especially with the
14 stuff on the right, did you jettison the approach
15 of a process?

16 CO-CHAIR SINGH: So, yes. So,
17 disclosure. So, we recently just published a
18 framework which the picture looks a little
19 different than this for diagnosis, for diagnostic
20 error. So, errors later, like anything but
21 misdiagnosis.

22 And we did think a lot about structure

1 process outcome type issues in that framework.
2 We couldn't really fit it so well within this
3 sort of the process but if you will look at and
4 think through design and development of HIT, for
5 instance, that is covered under the safe health
6 IT because you really want to make sure that the
7 technology is safe. And so we thought that maybe
8 like the implementation and use could be covered
9 under safe use of IT. So, we thought that maybe
10 that would probably solve it. But I see your
11 point and maybe that is another area that we
12 could -- again, this is evolution. The framework
13 is under evolution so, happy to sort of know that
14 comment. Thanks.

15 DR. ALEXANDER: Greg Alexander. I
16 wanted to go back to your sociotechnical work
17 system slide, where the personnel was. And I
18 just wanted to -- this may be just semantics and
19 it is probably described better in your article
20 but I am wondering -- I don't consider a patient
21 to be personnel. And I really think they need to
22 be separated out because there is a different set

1 of relationships associated with personnel than
2 would be expected of patients. And patients are
3 going to have a different interaction and a
4 different set of reasons for interacting than a
5 person in personnel would.

6 So, I would encourage you to call that
7 out specifically and I would be thinking of it
8 differently in this committee, each of those
9 individually.

10 CO-CHAIR SINGH: A very good point and
11 I must add that in our SAFER book that I just
12 mentioned, we actually have patient in the center
13 as a separate entity. So, thank you.

14 DR. SCHNEIDER: So, thank you, Greg.
15 I was going to make that point, too. I really
16 think it is important to distinguish the
17 patient's role here and to push us hard to think
18 about where we want to be in terms of direct harm
19 to the patient versus re-engineering, a process
20 which may function really well but we still may
21 find other ways to harm patients, and measures in
22 both of those two categories may end up being

1 useful. And maybe I can elaborate on that a
2 little later.

3 But I did also want to say the five
4 contributors I think is a really helpful way of
5 distinguishing IT-related design issues from the
6 clinician workflow issues. And I have to confess
7 that as I heard you describe it, it did seem it
8 was coming from the perspective of the clinician,
9 the workflow, as kind of the dominant
10 perspective. And the designers either get it
11 right or get it wrong in terms of trying to
12 respond to those clinical workflow needs.

13 A couple of years ago we published a
14 paper called the IT Productivity Paradox and why
15 it might be important in thinking about health
16 IT. And one of the insights from that paper for
17 me was that industries tend to hold onto
18 dysfunctional workflow because it is habitual and
19 not be able to take advantage of the capabilities
20 that IT systems create to reimagine their
21 workflow or redesign their workflow.

22 So, we could design really elegant IT

1 solutions that support really lousy workflow.
2 And the workflow is the part that is dangerous.
3 So, I am wrestling with, in this context, how we
4 want to think about measurement. Because if we
5 took the very broad safety perspective, we would
6 actually say well, there is actually dangerous
7 workflow, there is dangerous IT. There are all
8 these different sources of danger. And we would
9 be fairly agnostic to which of them was primarily
10 responsible. We would say they are all
11 contributing.

12 And then we might also be more, I
13 don't know, cognizant of measures that wouldn't
14 necessarily point the finger at one or the other
15 but would actually talk about how the mismatch
16 between workflow and IT is creating a problem.

17 And I apologize if this seems sort of
18 like a philosophical point, but it is one of the
19 profound aspects of IT that it does change the
20 way we think about the way we would do our work.

21 CO-CHAIR SINGH: Good points. And I
22 think the Joint Commission's analysis, they

1 looked at the eight dimensions separately after
2 they identified these events. So, looking at
3 sort of from the contributing factors point of
4 view, so you could sort of look at the eight-
5 dimension model as the workflow being sort of the
6 problem. And I think, Gerry, that is kind of
7 what you all did. So, point well taken.

8 Karen?

9 DR. ZIMMER: This is Karen Zimmer. I
10 wanted to focus on, going back to that personnel,
11 sort of the stakeholders, and who are the
12 stakeholders here? We have talked about the
13 payer. We have talked about physician, nursing.

14 I am going to bring up pharmacist.
15 And the example I am going to give is in our
16 clinic we have Epic and we actually know which
17 patients pick up their prescriptions and which
18 ones don't because of e-prescribing. So, it
19 suddenly changes our management. It changes our
20 workflow and that is also additional information.

21 So, I just -- when we talk about
22 personnel, I don't think we have thought about

1 the pharmacy as well.

2 CO-CHAIR SINGH: Nana?

3 DR. KHUNLERTKIT: I actually have a
4 comment on that sociotechnical model as well. I
5 think the personnel, when they look at that with
6 the workflow and communication, I think personnel
7 kind of depends on where in the process are you
8 looking at.

9 So, just like the pharmacy example, if
10 you look into the workflow process, it may be
11 towards the end where the patient is picking up
12 the medication. So, the personnel in the middle
13 is actually incorporating everyone in the
14 workflow process, not only care providers but
15 also patient.

16 And so the next comment I have is on
17 the mixed model under the sociotechnical model,
18 the other one that you have.

19 CO-CHAIR SINGH: The framework?

20 DR. KHUNLERTKIT: Yes, the framework.
21 So, this one, I think what is missing on that one
22 is the evaluation of end-user satisfaction and

1 the use of the technology because satisfaction
2 also drives how much they are going to be using
3 the technology and how well they are going to be
4 using it.

5 Patient satisfaction and also workload
6 for the provider.

7 CO-CHAIR SINGH: So, do you think
8 those could be sort of encompassed within the
9 measures?

10 DR. KHUNLERTKIT: Right. Right. I
11 think it could be in the big white arrow in the
12 middle in there.

13 CO-CHAIR SINGH: Yes, good point.
14 Thanks.

15 Helen, last word?

16 DR. BURSTIN: Last word? Oh, I don't
17 think it is quite that important.

18 It's just we spent a lot of time
19 talking about the definition of health IT, but we
20 haven't spent a lot of time talking about the
21 definition of safety. And I keep coming back to
22 feeling like it is the old iceberg analogy again

1 of patient safety events. What we are talking
2 about identifying and putting in the model are
3 the things we can see above the surface. And I
4 feel like there is just a whole lot we haven't
5 really talked about in terms of our definitions
6 of what safety means that lies below the water
7 and not just near misses, either.

8 Just as an example, some of my
9 residents recently were, I asked them what their
10 issues were with health IT and then my issues
11 with the way they use health IT were completely
12 different. So, for example, back to Jason's
13 comment about problem lists, one of my residents
14 had a patient that said unexplained weight loss
15 on their problem list. I am like whoa, that is a
16 pretty major diagnosis. I mean has that been
17 worked up? And he said well, I don't even know
18 how that got there; I didn't put it there.

19 And so from his perspective, that was
20 a non-issue, a non-safety event. In fact, that
21 was a pretty significant event and he gave me a
22 lot of grief when I made him sit down and in fact

1 do the chart biopsy to find out in fact it was
2 all done. But he had no idea how to take
3 anything off a problem list.

4 So, there are so many of those
5 underlying issues that particularly some of your
6 model assumes clinicians know how it should work
7 and what is important. And I think part of the
8 problem is: I'm not sure we do.

9 CO-CHAIR SINGH: Yes, Helen, I agree.
10 All models are wrong and some are more useful
11 than others.

12 (Laughter.)

13 CO-CHAIR SINGH: Thank you all for the
14 feedback and conversations.

15 DR. HEERMANN-LANGFORD: I have a
16 comment --

17 CO-CHAIR SINGH: Oh, sorry.

18 DR. HEERMANN-LANGFORD: -- this is
19 Laura Heermann, to what Helen just said.

20 I think that we set our clinicians up,
21 though with policies and practices because not
22 only may they not know how to do it but who is

1 allowed to. Who can change a problem list? Who
2 can take something off?

3 Because I think we let things get
4 cluttered at times because everybody feels like
5 in the shared record, we don't know who owns it
6 and if I am allowed to take that off. And so we
7 have a lot of policy or practice things set up
8 that are contributing to this.

9 CO-CHAIR SINGH: Absolutely. Great
10 segue to Elisabeth's talk now because taking data
11 out and also changing stuff in the EHR, once you
12 enter some wrong information, and how you do
13 that?

14 So, over to Elisabeth.

15 CO-CHAIR BELMONT: Thanks, Hardeep.
16 I think Hardeep provided us with a great overview
17 of the landscape and some examples of where our
18 technology can go wrong.

19 I am going to provide you with a brief
20 overview of the legal and regulatory
21 considerations that I think it is important that
22 we keep in mind as we think about patient safety

1 framework.

2 And I want to make a couple of general
3 points. I think all of us are aware that
4 healthcare is a highly regulated environment and
5 the law has been, and I believe it will continue
6 to trail advances in technology. And when we
7 think about some of the consequences, I have done
8 medical malpractice work for the past 25 years
9 and it has been interesting to me to see the
10 number of increasing cases that are coming up
11 that is involving some aspect of health
12 information technology. And there is not
13 necessarily a good standard of care for that.
14 And when you look at the consequences of a
15 patient safety event and one that's technology is
16 involved, you look at the consequences that can
17 arise in a medical malpractice perspective, not
18 only the cost but I have seen the emotional toll
19 that it takes on the practitioners involved or
20 even the clinical engineering folks when try and
21 figure out what went wrong to try and explain to
22 the family and, equally importantly, to try and

1 prevent it from happening again.

2 So, moving forward, I just want to set
3 the stage by providing an overview of the sources
4 of legal and regulatory authority that we are
5 going to look at. Both the federal government as
6 well as state government has engaged in some
7 regulation, which is pertinent. I mentioned a
8 moment ago that the law is trailing advances in
9 technology. So, some of the things I am going to
10 refer to are more generally stated and
11 technology-related issues can fit in there. Some
12 of the more current federal developments are
13 becoming more specific with technology.

14 As Hardeep mentioned, the Joint
15 Commission has done some great work in this area.
16 I will touch on that.

17 There is another source of authority
18 relating to the fiduciary duty of governing
19 boards for ensuring the quality of care and
20 patient safety within their organizations. And I
21 think that that is another lever that we can use
22 here.

1 And last, one of my favorite topics,
2 challenges that providers and vendors have in
3 contracts with respect to limiting liability,
4 indemnifying other parties and some non-
5 disclosure provisions, all of which can affect
6 health IT safety.

7 So, beginning back in 2003 I have done
8 a little time line for you, if we look at the
9 HIPAA security standards, there was language
10 actually in the HIPAA security standards which
11 relates to patient safety. The security
12 standards require covered entities to take
13 appropriate administrative, technical and
14 physical safeguards to ensure the
15 confidentiality, integrity, and availability of
16 electronic protected health information. And of
17 course it is important from a safety perspective
18 that health information be complete, that it be
19 accurate, so that goes to data integrity. There
20 has been comments around the table this morning
21 about availability of data and the
22 interoperability issues to ensure that it is

1 available.

2 So, we start from that place. In
3 2011, we had the IOM's report on health IT and
4 patient safety, building safer systems for better
5 care. And David has talked with us about that
6 this morning, so I am not going to go into detail
7 about it.

8 Then, in more recent years, ONC
9 funded, actually it was a joint HHS and AHRQ
10 project. It was the Health Information
11 Technology Safety Action and Surveillance Plan.
12 And the goals of that was to promote the use of
13 HIT to make care safer and to continuously
14 improve the safety of HIT itself. And as you can
15 see with the progression, we are becoming more
16 specific on health IT safety as more of these
17 federal initiatives are coming to fruition.

18 And last year we had the ONC SAFER
19 Guides, which Hardeep talked about in some
20 detail, so I am not going to do that.

21 In 2014, we also had the FDASIA
22 report, which is a joint FDA, ONC, and FCC

1 project. And that was a really interesting
2 report. It focused on a risk-based framework for
3 the management of health information technologies
4 functionalities. And for the framework, they
5 wanted to one, promote the use of quality
6 management principles; also, identify, develop,
7 and adopt standards and best practices; three, it
8 wanted to focus on leveraging conformity
9 assessment tools; and fourth, it wanted to create
10 an environment of learning and continual
11 improvement.

12 And particularly with respect to item
13 four, I think the measures that we are talking
14 about creating are very important to that
15 learning environment and continual improvement.

16 The FDASIA report also called for ONC
17 to create a health IT safety center in
18 collaboration with the FDA, FCC, and AHRQ to
19 develop a sustainable, integrated health
20 information technology learning system that
21 avoids regulatory duplication and leverages and
22 complements existing and ongoing efforts.

1 I think that that was really helpful.
2 I, in particular, was glad to see the different
3 agencies coming together, not only to avoid
4 duplication in regulation but also conflict. And
5 mobile health technology is a great area where we
6 were beginning to see some duplication and
7 conflict.

8 And then there is also a focus on the
9 safety of EHRs and portions of the stage two
10 meaningful use requirements, which were adopted
11 for the Medicare and Medicaid EHR Incentive
12 Program.

13 So, I think the net effect of all of
14 those federal initiatives is to bring safety to
15 the forefront and have healthcare providers,
16 payers, vendors, all focusing on safety. From a
17 state perspective, we haven't had as much focus.
18 In the hospital licensing provisions that most
19 states have, there is typically a reference to
20 the Medicare conditions of participation. And I
21 want to read you a section of the Medicare
22 conditions of participation.

1 The relevant section states: The
2 hospital must develop, implement, and maintain an
3 effective ongoing hospital-wide, data-driven
4 quality assessment and performance improvement
5 program. The hospital's governing body must
6 ensure that the program focuses on indicators
7 related to improved health outcomes and the
8 prevention and reduction of medical errors.

9 This condition of participation was
10 enacted a number of years ago. It doesn't
11 specifically mention health IT but again, when
12 the language relating to indicators, relating to
13 improved health outcomes, again, I think that
14 that justification for our focusing on the
15 measures.

16 There are actually, according to the
17 National Academy for State Health Policy, there
18 are 27 states, as well as the District of
19 Columbia, who have hospital mandatory reporting
20 of sentinel events.

21 And we have been talking about
22 definitions this morning. And what is

1 interesting with these state statutes is that the
2 definition of the sentinel or adverse events,
3 typically focuses on patient outcomes. So, they
4 are looking at death or they are looking at major
5 permanent loss of function, as opposed to the
6 mechanism of injury. So, in these statutes or
7 regulations, there is no specific focus on health
8 IT-related events.

9 As a lawyer representing a provider
10 organization, I am generally not a fan of more
11 regulation, but I have to really compliment the
12 Joint Commission for what it has done in this
13 area because way back in 2008, the Joint
14 Commission developed the Sentinel Event Alert
15 Number 42: Safely Implementing Health
16 Information and Converging Technologies. And I
17 thought that that was a great way to start
18 focusing the provider community on steps it could
19 take toward safe implementation.

20 And SEA 42 actually suggested 13
21 actions ranging from early examination of work
22 flows and involving clinicians in planning to

1 monitoring systems after implementation to track
2 errors and close calls.

3 So, today, the reporting of sentinel
4 events is voluntary. And while there aren't a
5 lot of statistics on SEA 42, I think that the
6 standard is very helpful. And what we are seeing
7 with some of the federal regulation that has been
8 in this phase, there are more pressures for
9 reporting and equally more pressures to have more
10 transparency in this area.

11 Hardeep had talked a little bit about
12 the fact that ONC has contracted with the Joint
13 Commission to do some research in terms of
14 investigations at both hospitals and ambulatory
15 sites to look at the source of health IT safety
16 events. And since Hardeep talked a bit about
17 that, I am not going to repeat that.

18 So, let's take a look at the fiduciary
19 duty of healthcare governing boards. Healthcare
20 governing boards have a fiduciary duty to oversee
21 the quality of care and patient safety rendered
22 within their institutions. And I think that

1 given the increasing importance of health IT and
2 the delivery of patient care, as well as the
3 occasional errors and unintended consequences
4 that are arising from health IT use, it is clear
5 that governing body oversight should include a
6 review of certain EHR and health IT metrics. As
7 part of the ASHRM study, I actually looked to see
8 what healthcare providers across the country was
9 using for those metrics, and I actually only
10 found one hospital that had a metric relating to
11 EHR use, which I found interesting.

12 And I think that developing
13 appropriate metrics and interpreting them for
14 governing board directors, who might have a
15 variety of technical and clinical expertise,
16 presents new challenges. So, when we think about
17 the measures that we are developing to the extent
18 there are some for governing boards, I think we
19 need to take into consideration that there might
20 be a learning curve for certain governing and
21 board members, who may not have the technical
22 background for them.

1 So, there is, if folks are looking for
2 some potential metrics for governing boards, the
3 result of the joint AHLA/ASHRM study was a
4 publication called Minimizing ERH Serious Safety
5 Events. It is available free of charge through
6 the American Health Lawyers Association, and we
7 came up with some sample EHR-related metrics not
8 only for the governing board, but we thought that
9 the Chief Information Officer in the Health IT
10 Department should be looking at some metrics too.
11 So, I give you that for your consideration.

12 And in terms of the comment that was
13 made earlier this morning about having some
14 emergency preparedness plan for health IT, in the
15 same document we also have an emergency
16 preparedness checklist for health IT
17 infrastructure and applications.

18 So, if you have an interest in that,
19 I would recommend this document for you.

20 As further support that the governing
21 boards of healthcare institutions have a
22 responsibility to oversee quality of care, JACHO,

1 again, has been helpful. And JACHO actually has
2 a leadership standard that states the governing
3 body is ultimately accountable for the safety and
4 quality of care, treatment, and services. And on
5 top of that, I had mentioned earlier and read you
6 a section of the Medicare conditions of
7 participation, which also reinforces that point.
8 And I think part of the challenge is: where is
9 quality on the governing board's agenda, and to
10 what extent does the entire board look at quality
11 issues? Governing boards usually have a quality
12 committee and, from some of the research we did,
13 there was a large variation in the amount of time
14 and in the detail that governing boards had.

15 So again, to the extent we develop
16 measures that we want the governing board to look
17 at, we need to take these factors into
18 consideration.

19 So, one of the interesting things
20 about the federal and state developments are the
21 impact that they have had on the standard of
22 care. And I think that the increasing amount of

1 safety data, studies, and tools can affect the
2 standard of care that may be applied to courts in
3 negligent cases.

4 For example, plaintiffs' attorneys
5 might use information to argue that healthcare
6 providers should be liable for health IT-related
7 patient harm, if they fail to select a safe
8 system or they didn't report, monitor, or take
9 appropriate action regarding health IT-related
10 patient safety events.

11 Additionally, there are tools like the
12 SAFER Guides that might be cited by plaintiffs'
13 lawyers who are trying to establish that there is
14 a higher standard of care. The SAFER self-
15 assessment guides states that they are for
16 informational purposes only and are not intended
17 to be exhaustive or a definitive source. But to
18 the extent the SAFER Guides are adopted into
19 wider use, then I think a plaintiff can make a
20 compelling argument that why didn't XYZ hospital
21 take the time to do this type of self-assessment.

22 So, I think what we have here is an

1 evolving area that is going to need to be
2 evaluated on an ongoing basis, both in light of
3 industry developments and governmental
4 regulation, as well as new case law that may
5 exist.

6 So, another source of legal issues
7 that we need to deal with relate to vendor
8 contractual limitations that you see in
9 contracts. Probably all of you around the table
10 are familiar with these. You have hold harmless
11 clauses that require health IT purchasers to
12 indemnify vendors for errors, injuries, or
13 malpractice claims arising from the use of that
14 technology. And what is interesting about a hold
15 harmless or an indemnity clause is that it shifts
16 responsibility to the purchasers, without regard
17 to the cause of the problem or without regard to
18 whose acts or omissions may have given rise to
19 the claim. And indemnity provisions,
20 essentially, change basic principles of tort law,
21 which require that each party should be
22 responsible for their own acts and omissions.

1 So, it is a source of liability that
2 both providers and venders need to be concerned
3 about.

4 A related provision that you typically
5 see in contracts are the limitation of liability
6 provisions and those, essentially, have two
7 components. There is typically a limit as to the
8 total dollar amount or cap on damages for which a
9 vendor could be held responsible. Secondly, it
10 is not unusual for a vendor to disclaim certain
11 types of liability entirely.

12 For example, vendors may seek to
13 disclaim liability for consequential, special,
14 incidental, or punitive damages. And I think the
15 notion of apportioning liability is a difficult
16 one, especially where the healthcare delivery is
17 such a complex area. And it actually may be more
18 productive to engage vendors in a discussion on
19 how to reduce risk associated with health IT,
20 rather than negotiating relative liability and
21 limits of liability.

22 And what the parties could potentially

1 agree to do is participate in a shared risk
2 environment. Because at the end of the day,
3 whichever party can best mitigate the risk
4 arguably is the one who should bear
5 responsibility for that particular risk.

6 Another clause that has come under
7 scrutiny are the nondisclosure provisions, which
8 prohibits users, open disclosures of identified
9 product glitches, defects, or hazards. And
10 health IT vendors often cite their right to
11 protect their intellectual property and their
12 right to manage processes by which problems are
13 reported and adjust as the basis for such
14 clauses. Such clauses, however, are often so
15 broadly drafted that they actually prohibit users
16 from discussing and sharing patient-related
17 safety events in appropriate venues. And I think
18 it would be possible to define appropriate
19 venues, such as patient safety organizations,
20 risk management committees, user groups, and to
21 allow the sharing of information but allay some
22 of the concerns the vendors have about their

1 intellectual property protections.

2 So, Hardeep had provided a potential
3 framework that we could use for thinking about
4 measures and I wanted to take a similar approach
5 in the legal environment. And what I would like
6 the committee to think about in developing
7 measures is to consider developing some measures
8 for a shared risk environment. And we are going
9 to be thinking about measures that healthcare
10 providers can use. And why not think about and
11 identify measures for both vendors and users?
12 And I think that what we could look at is develop
13 safety measures for vendors that are consistent
14 with the ISO, IEC standard for risk management.
15 And if we are successful in doing that, then,
16 arguably, we could include vendor performance
17 standards based on health IT safety measures and
18 software license and purchase agreements.

19 And again, I think it is a shared risk
20 environment. We each play a part, and it would
21 be helpful if vendors would notify users if they
22 identify or become aware of software, hardware,

1 or other issues that materially affect patient
2 safety and not only notify us, but offer
3 solutions to identified issues to all users, such
4 as workflow guidance, features that shouldn't be
5 used, software updates.

6 I am personally aware of at least a
7 dozen instances where there has been a software-
8 related safety issue with some EHR vendor. And
9 I, frankly, have heard of these things via word
10 of mouth. And in over half the cases, I had to
11 follow-up with the vendor before the vendor
12 notified us. And rather than have a serious
13 safety event occur, if the vendor first becomes
14 aware of something, why not send out a blast to
15 all current users of the system, so everyone is
16 notified at the same time?

17 And again, I end with the thought that
18 I made earlier: whichever party can best mitigate
19 the risk is the one who should bear particular
20 risk.

21 So, let me stop there and let me throw
22 the discussion open to the committee for your

1 thoughts and questions.

2 David?

3 DR. CLASSEN: Yes, thank you. That is
4 sort of elucidating a number of issues that I
5 think about. There have been calls that
6 governing boards should commission not only
7 audits of financial performance but audits of
8 quality and safety performance. And I think it
9 is a very interesting idea.

10 If they did, what kind of metrics
11 would we want to think about that they might look
12 at at the governing board level in this
13 particular area? So, that is where I was.

14 And are you aware of any such audits
15 that people have commissioned by healthcare
16 organizations at the board level?

17 CO-CHAIR BELMONT: When we did our
18 project with ASHRM two years ago, there weren't
19 any audits I could find. But I think you raised
20 a really important point about what is the right
21 level of metrics to take to the governing board,
22 given the governing boards' responsibilities and

1 the differences in their background, and we
2 struggled with that.

3 And I can share with the committee, I
4 can give you a couple of examples now, we though
5 EHR system uptime rate might be an appropriate
6 metric. Alert override and adjustment rates,
7 laboratory and other diagnostic test results
8 incorrectly reported. And so I think it is
9 important to have the right level. And then in
10 the course of working on those, that is why we
11 came to the conclusion that the CIO and the
12 health information technology department also
13 should have metrics that they are measuring to
14 keep some of the minutiae off the board's plate.

15 Kim? Oh, Karen. Sorry.

16 DR. ZIMMER: It still goes back to
17 that question of: who are these metrics for and
18 do we need to come up with different metrics for
19 the different stakeholders? This sounds like
20 there could be a metric of how often are vendors
21 providing solutions when they hear about errors,
22 I mean what percentage or something for them and

1 not have everything be hospital or organization-
2 based.

3 So, again, it is unclear to me when we
4 talk about metrics, who are these metrics for?

5 CO-CHAIR BELMONT: Okay, that is a
6 good point. Thank you.

7 Eric?

8 DR. SCHNEIDER: Elisabeth, Eric
9 Schneider.

10 This is a fantastic presentation.
11 Actually in a report we did with ECRI, where we
12 worked with seven systems to try to have them
13 identify and mitigate risks, this came up as one
14 of the real Achilles heels of this type of
15 effort, that there didn't seem to be any
16 mechanism for a dialogue between vendors and
17 providers about what was going wrong or what
18 problems that they had identified. So, I think
19 this is really important.

20 Also, it illustrates for me one of the
21 principles of quality measurement that sometimes
22 is forgotten, that measurement is not a camera.

1 It doesn't just take a picture and give you a
2 representation of what is in front of it. It
3 actually changes what people are doing, how they
4 -- actually, it is like a camera in that sense.
5 People change their positions and their dress and
6 everything else.

7 But the idea that we would develop
8 measures or select measures that reinforce this
9 joint responsibility for health IT safety
10 problems that are shared between the providers
11 and the vendors could be a very powerful tool for
12 reinforcing that dialogue between those two
13 parties.

14 I have to say I was also surprised
15 when I learned that these contracts included
16 these clauses. And I wondered who regulates such
17 contracts. Do the states play a role in that?
18 How much variability is there amongst states in
19 terms of what can be in contracts like this, or
20 is that a federal responsibility? I just don't
21 know the answer, but I would be curious to hear a
22 little bit more about how much variation there is

1 in state regulation in this area.

2 CO-CHAIR BELMONT: Well, contracts by
3 their very terms are negotiable between the
4 parties. There has been some comment at the
5 federal level that the total shifting of
6 liability is arguably against public policy on
7 that. And you know right now -- and this sort of
8 goes back to when software was new -- at the time
9 software vendors made the argument that they
10 couldn't be subjected to unlimited liability
11 because it would put limits on their future
12 developments. And that view has kind of
13 persisted, and I think we are way past that. And
14 I think if you really want to partner with
15 someone, there are ways to do it.

16 I will give you an example. About 14
17 years ago, my institution put in a new PACS
18 system. And of course, they wanted to have all
19 the usual provisions in there about indemnities,
20 limitations of liability. And I was concerned
21 when we did it because once you got a PACS, if
22 PACS went down, we then would have to retool up

1 and go back to the x-ray system. And while I
2 understood that they didn't want to have
3 unlimited liability, I said look, we are going to
4 be in this with you for the long-run. And for
5 that reason, we need to share the risk here. So,
6 I actually carved out certain damages to their
7 usual disclaimer. And so in the event it was
8 necessary for us to retool up, I persuaded them
9 to pay that all. And I think that we really need
10 to change what the framework is with vendors and
11 view it as a partnership, because at the end of
12 the day, I think that the providers can teach the
13 vendors certain things about how their software
14 and hardware works in a clinical system and vice-
15 versa.

16 And so, I think it will take some
17 education on folks. And because we have
18 different jurisdictions among the states and
19 different contracting practices, it might be
20 difficult to get a uniform approach. But in
21 terms of the key concept, if people would
22 consider their shared risk environment, I think

1 it would move the dialogue along.

2 DR. SCHNEIDER: That's great. And are
3 there any examples from other industries where
4 those models have been developed? Because I
5 could imagine this comes up all the time in
6 customer-supplier relationship.

7 CO-CHAIR BELMONT: I can't think of
8 one off the top of my head, but I will tell you,
9 in the hospital supply chain, the relationships
10 we tend to have with software and hardware
11 vendors are more contentious than some of the
12 others. I mean I think of some of the radiology
13 equipment that we have, and if there is a
14 problem, the vendors are always willing to come.
15 They are very willing to talk about what the
16 nature of the risk is.

17 DR. ALEXANDER: So that last statement
18 you made was a good segue for what I am about to
19 say. I have a background in occupational health
20 and worked as an ergonomic manager for a large
21 poultry plant, managing a medical area where
22 nurses worked and the employees worked with lots

1 of technology as they processed Butterball
2 turkeys.

3 And so what my job was was to do
4 ergonomic analysis and risk assessment of the
5 technologies that they used to prevent injuries
6 to the people that were dissecting the birds.

7 So, at the time that I did that, many,
8 many years ago, I didn't realize that all that
9 work with engineers and ergonomic specialists and
10 human factors experts would apply later in my
11 life, when I am doing this kind of safety
12 research. And you don't find those kinds of
13 models and those kinds of things being discussed
14 in MEDLINE or in PubMed because they are not
15 published in medical journals. They are
16 published in the Industrial Journal of
17 Ergonomics, where I have published some of my
18 work.

19 And so my comment is that there are
20 examples of that out there but they are not in
21 the main medical literature. They are in other
22 sources. And the ideas and the things that come

1 from that type of work are very applicable to the
2 use of technology and ergonomic assessment, risk
3 assessment, and level of harm and injury that can
4 occur, and even dollars and how to evaluate
5 dollars. To us, the dollar amount was related to
6 harm to our workers and subsequent disability and
7 things like that. But those kinds of areas are
8 very applicable, I think, to what can occur with
9 technology, and we should be looking at those.

10 CO-CHAIR BELMONT: And perhaps you can
11 assist me, then, in identifying some of those
12 areas.

13 DR. ALEXANDER: Sure, I can do that.

14 CO-CHAIR BELMONT: That would be very
15 helpful. Thank you.

16 David?

17 DR. HUNT: Yes, I don't want to put
18 Linda on the spot, but I just want to ask: have
19 discussions like this come up -- and obviously
20 you can't give a definitive answer -- but
21 discussions come up like this in the context of
22 the work in developing the roadmap for the health

1 IT safety center?

2 DR. DIMITROPOULOS: Discussions about
3 the vendor?

4 DR. HUNT: The relationship and how
5 you carve a space because -- well, like all
6 doctors, I am scared to death of lawyers.

7 (Laughter.)

8 DR. HUNT: Is there any place below
9 that lawyerly legal radar space that those
10 discussions can go on? And how would that
11 actually happen?

12 DR. DIMITROPOULOS: It's a really good
13 question. And within the context of the project,
14 I don't know if we have had a lot of those
15 discussions because there are so many discussions
16 going on. But I think, I mean what I have heard
17 in the past is basically work it out. Work out
18 some of these issues with the clinicians. And
19 then once you figure out sort of what you think
20 you want to do, then bring in the lawyers and
21 have them sort of make it happen for you.

22 And that is just one approach but I

1 think it is an important discussion and
2 conversation.

3 DR. HUNT: And I would also just ask,
4 again, I don't want to put folks on the spot, but
5 Mark, within the context of your -- do you have
6 or have you thought of internal measures within
7 your company or other companies to talk about how
8 can this feedback happen, particularly given the
9 real pressure on the development cycle?

10 DR. SEGAL: Yes, I was going to save
11 some of what I was going to respond to, some of
12 the issues Elisabeth did because I am up next,
13 but I will deal with it now.

14 So, a couple things. One, at an
15 individual company level, and ultimately that is
16 all I can speak to, we talk to our customers all
17 the time. We talk to them in terms of what they
18 want from our products. We talk to them about
19 what they don't like about our products. Our
20 lawyers talk to their lawyers.

21 So, at a company level, there is very
22 active engagement on these kinds of issues. At

1 an industry level to address a couple of the
2 items that Elisabeth about, the issue of what is
3 often called gag clauses came up. The
4 indemnification. And I am not a lawyer so, I
5 just entirely stay away from that. But the gag
6 clause issues come up, the issue of notification,
7 which I think is up on the screen there. And one
8 of the things we did, the EHR association, I
9 think actually your former boss, Farzad helped
10 spur us to it, was develop an EHR Developer Code
11 of Conduct, which I think know has been adopted
12 by 25 companies, most our members, some not.

13 A few of the items that specifically
14 were addressed there, and parenthetically in
15 developing that and in going through drafts, we
16 collaborated, consulted pretty actively with
17 provider groups with ONC, with AHRQ, I believe,
18 and took that feedback. We have provisions
19 encouraging companies to use quality management
20 systems, QMS and user-center design. As part of
21 the code, it also references notification of
22 vendors when there is a material, it is almost

1 word for word what you have there.

2 And then on the issue of the
3 contractual limits on disclosure, which again,
4 one of the things as a trade association you
5 certainly can't see other companies' contracts.
6 And since I am not a lawyer, I don't typically
7 see our own. But that has always struck me a
8 little bit of an urban legend about exactly sort
9 of what these clauses both say and what they mean
10 in practice. I know from a GE perspective, our
11 view is, again, with IP protections, which is
12 mostly not going to be the issue, full discussion
13 of safety issues. You know EMRs have user groups
14 that these things are discussed openly on
15 Listservs and what have you.

16 Within the context of the EHRA as part
17 of the code specifically indicates that companies
18 will not have contractual limits on discussion of
19 safety-related issues. We used the terminology
20 and it was a little controversial but it was
21 almost exactly what you cited, Elisabeth,
22 appropriate venues, which was, in an FAQ, we

1 construed pretty broadly. So, we had PSOs. We
2 had state regulatory. We had user groups.

3 You know, again, in the context of
4 protecting IP, which that is going to be a narrow
5 slice of what could come up when you are talking
6 about safety issues. So, in developing that, we
7 talked pretty extensively with groups
8 representing providers. And then again, each
9 company sort of has to implement those within the
10 context of their own procedures.

11 CO-CHAIR BELMONT: Let me respond to
12 both of you briefly, if I can.

13 In terms of how to implement this,
14 after the IOM report came out with the call to
15 safety, I thought wow, this is a great catalyst
16 for me to start putting a safety provision in our
17 EHR contracts that had some of these points on
18 it. And I received a tremendous amount of
19 pushback on it but I persisted. And I think in
20 terms of the EHR developer code, it is a
21 suggested code of conduct so folks can choose to
22 follow it or not.

1 One of the things I started doing,
2 which helped me get my safety provision in
3 contracts, was start putting certain principles
4 in the RFP that went out there. And again, what
5 I included was very similar to what I had on the
6 last two slides. So, I didn't think I was asking
7 for anything unreasonable.

8 I think part of it is a culture shift
9 that we need to work on with the providers. And
10 again, it goes back to the shared risk
11 environment and that this is a shared
12 responsibility.

13 So, Bill?

14 MR. MARELLA: Yes, I want to make two
15 seemingly contradictory points but they are
16 actually both true, I think, in different places
17 and for different people.

18 So, we are talking about these gag
19 clauses and the vendor contracts, which I have
20 heard some people they are real, others say they
21 are not real. It is sort of everyone's
22 experience seems to be different with that.

1 But if we are asking for providers to
2 communicate safety information outside the walls
3 of their institution, it sort of requires that A,
4 they recognize the health IT contribution, I
5 guess, to those safety issues and that they be
6 comfortable communicating it. Now, I know a lot
7 of you are involved in the health IT partnership
8 that ECRI has stood up and we brought vendors and
9 providers together with patient safety
10 organizations to work on these things.
11 Generally, and apologies to the vendors in the
12 room, it usually doesn't take much to get unhappy
13 providers to complain about their technology, and
14 they are more than willing to do that. And I
15 know there are a lot of PSOs that have data like
16 that. So, that is one issue. The other is the
17 recognition issue. And a lot of the safety
18 issues associated with health IT use, especially
19 at the use end. They come through to those of us
20 working in safety as something else. They don't
21 necessarily call themselves out as IT-related but
22 you know that if you are getting medication

1 errors for something that should have been caught
2 in an alerting system at a HIMSS level 6 or 7
3 hospital, you know that there has got to be
4 either an IT contribution or an IT omission that
5 had some role in that.

6 So, I think that information is there
7 to be mined and I am not sure the gag clauses are
8 even visible or understood by the people who are
9 usually communicating the safety information.
10 So, I am not sure how much of a restriction that
11 is.

12 CO-CHAIR BELMONT: Well, it can be a
13 restriction with regard to sharing certain
14 details like screen shots as the example.

15 James.

16 MR. RUSSELL: So, I am Jim Russell
17 from Epic and just want to comment on a couple
18 things. Mark actually put almost all my comments
19 out there already.

20 As we do have a lot of the things that
21 you have already talked about here with the very
22 strong, if we identify or if customers notify us

1 of problems, we have a very strong process for
2 dealing with those and getting those back out to
3 all our customers and notification processes for
4 that and offer solutions and guidance.

5 I think one of the things that happens
6 to us when a vendor community is under the
7 patient safety organization legislation is
8 vendors aren't protected under that. And because
9 we are not protected under that, for us to be
10 able to really be open and share everything we
11 can, that makes it very difficult for us, under
12 that framework, to do so. And so that would be
13 something for us, as a group, to look at as where
14 it can be put some protections and maybe for
15 vendors to be able to share data and information
16 a lot more openly than we can right now.

17 DR. CASTRO: So actually, yes, Jim,
18 that was exactly going to be my point. And that
19 was one of the discussions we had in our health
20 IT safety center small workgroups. You know, is
21 a protected space required for that type of
22 conversation? And is federal legislation

1 necessary? That is something that the patient
2 safety law provided for PSOs. Is that same type
3 of provision required for this? We don't know.

4 And so we were looking at different
5 mechanisms for how to best facilitate that
6 discussion. Of course, the ECRI group was
7 mentioned as well. So, do we need more of that?
8 Do we need the legislation? Do we need those
9 protections?

10 I will also comment on you brought up
11 the issue of governance and bringing these issues
12 to the governance. And that is actually a major
13 push of the Joint Commission. It is something
14 that we look at daily, trying to push the quality
15 and safety discussion up to the boards and having
16 them really push out that idea that safety is a
17 shared responsibility throughout the
18 organization. And to the extent that we could
19 push the idea of health IT safety, that would be
20 supportive of that.

21 CO-CHAIR BELMONT: Any other last
22 thoughts or comments? Yes, Karen.

1 DR. ZIMMER: I just want to highlight
2 the importance of the shared responsibility but
3 also a caveat to that. Which is, I have also
4 seen with shared responsibility a dilution of
5 efforts. And what I mean by that is in a lab
6 follow-up, for example, if a number of providers
7 are notified, nobody knows exactly who is going
8 to act. And the same way when it comes to
9 reporting issues on health IT, is it the vendors,
10 is it the providers? So, while we have that
11 shared responsibility, I think we also need to
12 identify who, ultimately, should be reporting
13 what, so we don't just all look at the screen.

14 CO-CHAIR BELMONT: I think that is a
15 good point and I think the way to address that is
16 to have clearly defined responsibilities as to
17 who is responsible for what. Again, it goes back
18 to my point that whichever party can best
19 mitigate the risk should have the responsibility
20 for that particular risk. So, I think spending
21 more time identifying that would be helpful.

22 CO-CHAIR SINGH: Yes, I just want to

1 add that we had the same similar sort of thoughts
2 while we were developing SAFER Guides because it
3 is not always only the vendor who can fix this.
4 It is often other sort of institutional members
5 and other people also involved. So the lab
6 service has to be involved or the urologist or
7 the pharmacy has to be involved.

8 So, I think as we develop these
9 measures, which could include measures of sort of
10 interaction of the communications. Mark, you
11 mentioned that a lot of things are already
12 happening. So, I think probably it would be a
13 good idea for this group to think about how can
14 we measure those things that Epic, you guys are
15 already doing, that it is in the Code of Conduct,
16 how do you measure that at the institutional
17 level that this collaboration and this
18 communication and this sort of positive
19 relationship is actually happening and we are
20 sort of transforming the way we communicate with
21 the vendors in addition to thinking who is
22 responsible for doing this measure or leading the

1 measure.

2 CO-CHAIR BELMONT: Right. And when I
3 designed the last two slides, I really did want
4 it to be a positive experience because, again, I
5 think both vendors and providers can learn from
6 each other, others. And as we think about
7 measures, measures could lead to some universal
8 safety performance measures that if we could put
9 in in contracts, that would be helpful.

10 DR. ALEXANDER: So, you just triggered
11 a thought in my brain that as I am listening and
12 I just realized this, maybe it is just my
13 interpretation that we are really talking about
14 these safety measures after an event has already
15 occurred. We should really focus on safety --
16 well, usability that might have something prior
17 to the implementation, so the testing of these
18 technologies and the things that occur prior to
19 their implementation should be part of our
20 purview in a big way, I think.

21 CO-CHAIR SINGH: Yes.

22 CO-CHAIR BELMONT: Right. You know in

1 the design implementation and use phases.

2 CO-CHAIR SINGH: Yes, I totally agree.
3 I don't think we should be thinking of only sort
4 of retrospective, oh, harm happened, let's just
5 measure that. I think we have got to be forward
6 thinking, prospective, proactive. You know I
7 think the term they have in sort of human factors
8 is requisite imagination. So, you can predict
9 what is going to go wrong in the future when you
10 are building these systems. So, how can we have
11 measures that can help you do that better?

12 DR. ALEXANDER: So, that leads me to
13 another point that is really critical that we
14 look at other types of literature, too, as we are
15 thinking about this because those design things
16 are not published in PubMed and MEDLINE. They
17 are published in engineering journals and other
18 things.

19 CO-CHAIR SINGH: Absolutely.

20 CO-CHAIR BELMONT: And Nadine Sarter
21 has done some work in this area, which might be
22 useful and I can provide that to the NQF staff.

1 So, we are finishing five minutes
2 early. You actually ran over.

3 CO-CHAIR BELMONT: Oh, okay. Sorry.

4 CO-CHAIR SINGH: That was before they
5 fixed the schedule.

6 MR. LYZENGA: Yes, Mark, I don't know
7 how much we have covered of what you wanted to
8 talk about but there are some other things.
9 Okay. We are thinking maybe we could just take a
10 break for lunch at this point, return to the
11 discussion immediately thereafter and then sort
12 of segue into the breakout groups after that.

13 DR. SEGAL: I have got a problem. I
14 actually have a call during the breakout.

15 MR. LYZENGA: Can we postpone lunch a
16 little bit? All right, let's do that. So, why
17 don't we just go ahead and move on.

18 DR. SEGAL: Thank you.

19 MR. LYZENGA: Not a problem.

20 DR. SEGAL: So, from the vendor
21 perspective and, again, you know I am here as a
22 member of the committee and as an employee of GE.

1 And so, you know I am involved in other industry
2 groups but I am not representing the industry and
3 certainly not the EHR Association. But I think I
4 can characterize, based on observation both how
5 our company and how the industry that I am
6 familiar with are approaching patient safety.

7 And you know I think one of the key
8 points, we are all, companies doing things, view
9 ourselves as part of the healthcare community.

10 And so as such, we are absolutely committed to
11 patient safety. And then, again, looking at how
12 things have evolved, I think we have been very
13 much convinced and taken with the notion, you
14 know the concepts, and taken to hear about the
15 culture of safety, about particularly a non-
16 punitive culture of safety, some of the work that
17 has gone on with PSOs, and about the
18 sociotechnical view that they are really both
19 from a lifecycle standpoint, in terms of the
20 lifecycle of the use of health IT and the various
21 participants that there are multiple participants
22 in that lifecycle that have, to Elisabeth's point

1 in terms of sharing risk, sharing responsibility
2 at different times.

3 You know certainly from a GE
4 perspective, we are focused on products and
5 services, first and foremost, that enhance
6 safety, whether it is CPOE, or e-prescribing, or
7 other kinds of medication items, and that also
8 are developed and deployed in a safe manner. And
9 both of those are really critical, both sort of
10 the engineering usability part and how they are
11 deployed.

12 And we are a bit unique in that we
13 have a mix of both FDA-regulated and non-
14 regulated products. And in general, kind of the
15 approach of being an FDA-regulated company in
16 terms of things like quality management systems
17 and how customers are notified. That really sort
18 of dominates our perspective.

19 I think my colleagues and I have been
20 really convinced that, and this is relevant to
21 some of the discussions of how much you should
22 have HIT-specific safety approaches. Obviously,

1 here we are talking about HIT-specific measures
2 but in general you don't want to have HIT silos
3 that really are looking at patient safety.

4 And as I think a number of folks have
5 said, it is often not at all clear when reports
6 initially come in or even later evaluated what
7 the role of HIT is. And it is typically not the
8 sole piece anyhow. So, it is one of the reasons
9 we have liked the PSO approach for reporting
10 because, again, focused on safety generally with
11 HIT as a component.

12 You know I think we are also
13 convinced, and I sort of had a similar response,
14 honestly, in reviewing the environmental scan,
15 that I thought it was maybe a bit tougher on the
16 studies that found benefit from health IT, in
17 terms of linkages to safety and maybe not so much
18 easier on the others but well, there aren't a lot
19 of studies that show negatives but we are going
20 to sort of view that as the tip of the iceberg.

21 But again, from a positive standpoint,
22 I think we are pretty passionate about the

1 ability among other things of health IT whether
2 it is EHRs or PACs or perinatal systems to
3 enhance safety.

4 And I think we have seen --
5 unfortunately, I don't have the citation. I am
6 not sure if it is in here, a recent study that
7 came out of the Pennsylvania data experience that
8 showed some pretty substantial increases on some
9 key patient safety metrics. You know Bill, I am
10 sure you are familiar with it in terms of usages
11 of Health IT.

12 We have been working as an industry,
13 and again, I am most familiar with the EHR part
14 of that industry, with a range of both federal,
15 not so much state and private sector partners.
16 What my colleagues, some of my colleagues
17 testified at one of the hearings of the original
18 IOM study, and I was involved in some of those
19 discussions and follow-up meetings, we have been
20 working pretty closely with folks like Bakul
21 Patel and FDA, colleagues at ONC and AHRQ have
22 been working on suggested enhancements to the

1 AHRQ, common formats around health IT, and
2 particularly for them be relevant in an
3 ambulatory setting.

4 A number of our folks were heavily
5 engaged in various parts of the FDASIA process,
6 both in terms of the sort of stakeholder
7 workgroup and then testifying at sort of a
8 meeting that they had, I think a three-day
9 meeting, out at the NIST headquarters.

10 And then, I think, Hardeep, you talked
11 about the input we gave, pretty voluminous on the
12 SAFER Guides.

13 CO-CHAIR SINGH: Twenty-eight pages.

14 DR. SEGAL: Twenty-eight pages.

15 That's short for us.

16 And then more recently, and it has
17 been kind of interesting seeing how things have
18 been processed up on Capitol Hill, where you have
19 a variety of bills that are looking to deal
20 legislatively with patient safety issues.

21 We were very involved with, a number
22 of colleagues and I, with the Bipartisan Policy

1 Center that had worked on this sort of three-
2 tiered approach, which I think actually became
3 quite influential and sort of processed through
4 the ultimate FDASIA process.

5 And then I have also been involved in
6 discussions with ECRI, with AQIPS, which I think
7 is sort of the trade association of PSOs and with
8 individual PSOs on reporting. And a number of
9 our companies, including GE, are formerly members
10 and participating in the ECRI pilot.

11 And I did mention the EHRA Code of
12 Conduct. So, again, we are trying to kind of
13 listen to the issues that come up and really kind
14 of factor that in. I think it was very important
15 what Elisabeth said about the sort of request for
16 a proposal as an important vehicle for things.

17 And one of the things we are actually
18 sort of suggesting as a use of that code is to
19 have our purchasers actually reference the code
20 as part of their solicitations. We think that is
21 absolutely not only a fair thing to do, an
22 appropriate thing to do.

1 We are also working on a series of
2 white papers on patient safety-related topics
3 that relate to health IT. The ones that I am
4 aware of now are med management, best practices,
5 reuse of data, and usability. And usability has
6 been sort of a crossover issue that we have been
7 very engaged with, including some active
8 collaboration with the American College of
9 Physicians and the AMA in particular.

10 And I think somebody mentioned the
11 recent ACP. That was just a terrific study on
12 clinical documentation. And I think both we took
13 that to heart. I know when that came out I
14 circulated that within GE to my colleagues and
15 within the EHRA. And I think some of the
16 concepts in that actually reflected some of the
17 extensive discussions we had where there were a
18 lot of aha moments. You know when you lock
19 people together in a room for a full day and will
20 be together for two days where we were setting,
21 we were seeing things from the other's
22 perspective that we wouldn't necessarily have

1 coming in.

2 The last thing I would like to just
3 kind of highlight is really what we are here all
4 about, which is the measurement piece. And you
5 know from a GE standpoint, kind of a stereotype,
6 which I think is also a true stereotype, which
7 the best ones are, is the philosophy that you
8 can't manage if you can't measure. And so I mean
9 everything is measured there. Everything is
10 about metrics and rigor. And I am all for that
11 but I would also say that thinking about from a
12 public policy standpoint and the experience of
13 now being in a second stage of meaningful use, I
14 think we have actually learned a lot, an awful
15 lot about when you put extensive measurement in
16 federal programs, particularly when you are
17 attaching financial incentives or financial
18 penalties to that and the consequences there, and
19 I think we have seen that both on the measurement
20 of what we often call the functional measures
21 around meaningful use, how much CPOE are you
22 doing, how much e-prescribing? And then also

1 just the challenges that I don't think people
2 really expected in rolling out electronic
3 clinical quality measures in EHRs.

4 Again, mostly, although it is shifting
5 in the context of really sort of focusing on
6 almost pay for reporting as opposed to a pay for
7 performance, but on the meaningful use measures,
8 the financial incentives are directly tied to how
9 you do.

10 And I think we have seen that a lot of
11 the -- and this came up in the conversations with
12 the AMA and ACP that a lot of what we are seeing
13 In the trade press and you see it in the Boston
14 Globe now, the Wall Street Journal yesterday that
15 dissatisfaction around EHRs and particularly kind
16 of in recent years, really in part is the
17 consequence of both people having to use them to
18 do certain things and really that shift from I am
19 going to use my iPhone to do what I want to if I
20 used my iPhone to meet a whole series of specific
21 tasks. But also what we have found is that
22 engineering the products, again, there is a real

1 interest in well, let's use the EHR, or other
2 health IT to do the measurement. Right? The
3 data is there. It sounds great.

4 We have seen situations where the
5 amount of engineering work to support the
6 measurement around a meaningful use item really
7 exceeds the incremental work that let's say had
8 to be done with CPOE to make it appropriate for
9 certification.

10 You have to think about, okay, so what
11 are the work flows that can actually measure it
12 objectively. And that may, in fact, be a subset
13 of the workflows that people may want to actually
14 use the health IT with. You know we are hearing
15 from physicians and hospitals that it is being
16 measured, the act of what they have to contribute
17 to measurement, the fact that products are
18 configured to do measurement that can be a
19 challenge.

20 So, I think it is really important as
21 we kind of boil down where we are, ultimately.
22 And I think it was definitely up in the NQF kind

1 of hierarchy of criteria for selecting measures
2 that this issue of the usability of the measures,
3 whether they can actually draw on data that is
4 already being collected for other purposes.

5 Because again, we still have that with sort of
6 EHR-based collection where initially it was well,
7 it is so much better to do quality measure from
8 an EHR rather than to have to do paper
9 abstraction, because we have already got the data
10 there. And then that quickly shifts to oh, gosh,
11 we can add new data elements to the EHR to
12 support the measure we are interested in. And
13 there is a temptation there. And I think we just
14 need to be aware of that.

15 So, I guess I would just urge us, as
16 we move along, to really be cognizant not only of
17 the important benefits which we have talked about
18 about measurement, but the cost that can occur in
19 general, as you get a lot of measures, and then
20 with specific kinds of measures.

21 And so just, I think, as a
22 consideration as we are moving through, I would

1 kind of highlight that.

2 And then again, I am happy to answer
3 any questions or hear any feedback on what I have
4 outlined.

5 DR. PINES: And before we start with
6 a general discussion, thanks, Mark, I wanted to
7 let James, if you have any comments from Epic, we
8 didn't want to have this whole new vendor
9 perspective, but if you have any comments before
10 we start the general discussion, that would be
11 great.

12 MR. RUSSELL: No, that was actually
13 well done. So, I only have one comment and that
14 goes back to measures and things like that of
15 pushing the burden of collecting the data
16 upstream on clinicians and adding more and more
17 things they have to do to meet the needs of the
18 quality people, the safety people, the back end,
19 so they can put that stuff together to report.

20 Alan Flynn is a pharmacist, did a
21 great presentation of it is putting the helmet
22 on, the elbow pads, everything else, the body

1 armor on the kid so he can go on a skateboard, so
2 the people who will get the quality stuff can
3 just ride free.

4 And then the second one being is we
5 run into all the time is having all these
6 different quality measures and different things
7 have to be reported. And they are so different
8 between all the different agencies and all the
9 different player and all the different states.

10 So, anything that can be done to
11 harmonize those things would be a huge benefit.
12 I mean there are some easy examples where CMS
13 requirements for some of the infectious disease
14 reporting and the ones for CDC are completely --
15 they are not even close to being in agreement. I
16 know there is some work on that but it just makes
17 it hard for us on the vendor side to have to be
18 able to things together for every single, you
19 know, 51 different jurisdictions. And then in
20 some states you go down to county level and
21 things like that.

22 CO-CHAIR SINGH: Yes, I would just

1 like to echo what James said in terms of the
2 measure of harmonization. And I know that is
3 something that has been of a real priority for
4 NQF and CMS is focusing on that harmonization
5 across their programs.

6 But perhaps as the environmental scan
7 goes forward and as we identify measures, we also
8 kind of look at situations where there may be
9 measures that may be appropriate but are kind of
10 ripe for harmonization because that really crowds
11 out. If you are spending money and time all
12 across the ecosystem supporting multiple ways of
13 measuring the same thing, that is basically
14 detracting from the number of other things that
15 you can measure.

16 DR. PINES: Any additional questions
17 or comments?

18 Okay, I think everyone is hungry. So,
19 why don't we go ahead and break for lunch now?
20 And we are going to come back at one o'clock to
21 start up again. And we have got a short
22 presentation about how the afternoon sessions are

1 going to go. So, everyone, thanks for a great
2 discussion this morning and enjoy lunch.

3 (Whereupon, the above-entitled matter
4 went off the record at 12:28 p.m. and resumed at
5 1:07 p.m.)

6 MR. LYZENGA: And I'm going to
7 actually -- well, I will go through a quick
8 presentation first but then I am going to ask for
9 another show of hands to try to split us out into
10 these breakout sessions.

11 First, I will kind of give a little
12 bit of background and context to set out what we
13 are going to be doing in these breakout groups.
14 Do we have the breakout slides available to pull
15 up?

16 So, as we mentioned, we have kind of
17 tentatively been leaning toward using a sort of
18 hybrid of the three-phase safe EHR framework and
19 the eight-dimensional sociotechnical model.

20 So, for this exercise, for the
21 breakout group, we are using this for a few
22 purposes. One just to really brainstorm a bunch

1 of ideas around issues, challenges, concerns
2 related to HIT safety, barriers to addressing
3 those issues, and then maybe some measurement
4 concepts associated with those issues.

5 We have sort of structured the
6 discussion according to this framework. We are
7 going to break you out into three groups. One,
8 according to each phase of EHR safety. And then
9 within each of those groups, we will sort of be
10 going domain by domain across the sociotechnical
11 dimensions to address what concerns exist within
12 that dimension and within that phase and sort of
13 moving through the dimensions that way so we can
14 have some sort of systematic way of categorizing
15 the feedback and input we get from you.

16 So, you know, again, taking that as
17 guidance and input into our further environmental
18 scan into the conceptual framework and also sort
19 of using this as a test case of sorts to see if
20 this framework is, in fact, useful for thinking
21 about these issues and sort of talking them
22 through and categorizing issues and identifying

1 issues. So, at the end, we will kind of ask you
2 to reflect a bit on how this exercise has gone
3 and whether it is, in fact, a useful framework
4 for analyzing these issues. So, those are kind
5 of what we want to get out of these sessions.
6 Again, some brainstorming, just generally, around
7 issues and concerns and potential measurement
8 concepts. And then sort of test use case of the
9 framework.

10 So, to just prepare us here, I will
11 walk us through these different framework
12 dimensions.

13 The first group is Phase 1, Safe
14 Health IT and Dr. Singh has walked through these
15 a little bit but I will just briefly cover them
16 again. Several principles involved in this
17 phase: data availability, data quality and
18 integrity, data confidentiality, and this is
19 really about systems. The actual each IT systems
20 themselves, hardware and software, issues related
21 to technology, specifically.

22 Now, the second group, Using IT

1 Safely, is about optimizing the safe use of EHRs,
2 complete and correct use, usability of the
3 system, having features and functionality that
4 are designed correctly, implemented correctly.

5 And then the third phase is Using IT
6 to Improve Safety, surveillance optimization,
7 reporting of safety events, safety issues or
8 hazards, and finding ways to optimize the use of
9 EHRs to improve quality and safety.

10 And I sort of view, I don't know if I
11 am mischaracterizing this and Dr. Singh can
12 correct me if I am wrong, but I sort of view this
13 phase as addressing what some of the committee
14 members and others have raised as wanting to make
15 sure we address that positive side of HIT, the
16 ability of HIT to improve safety and to improve
17 the quality of care and the safety of patient
18 care. And this phase kind of speaks to those
19 issues, I think largely.

20 And then going through the
21 sociotechnical domains. Again, we will split you
22 into those three groups and then within each of

1 those three groups, we will walk through each of
2 these sociotechnical domains, trying to identify
3 issues and barriers, and potential measures
4 within each domain. The first domain is hardware
5 and software; the second, clinical content; the
6 third, human computer interface issues. And I
7 think maybe we can make these available.

8 We will have these slides available in
9 each of the groups, if you need to refer back to
10 it to sort of clarify what we mean by each of
11 these domains: people, workflow and
12 communication, internal organizational policies
13 and procedures; external rules, regulations and
14 pressures; sort of legal and regulatory concerns
15 or issues or factors; and then issues related to
16 system measurement and monitoring.

17 And there is a great deal of overlap
18 between each of the phases, among each of the
19 domains. None of them have distinct sort of
20 walls. Most measurement issues or each HIT
21 safety issues can likely be mapped to any number
22 of these domains or phases of safety or have

1 factors that influence them along the spectrum of
2 EHR safety in the sociotechnical domains.

3 So we will obviously have some overlap
4 here and you will probably have some discussion
5 about where some particular issue fits into the
6 domains and all of that, I think, is open for
7 discussion and something we can talk through.
8 And I don't think it is a problem if we have some
9 duplication there, et cetera.

10 CO-CHAIR SINGH: Thank you Andrew.
11 So, I was just going to say I think if you want
12 to add sort of a patient dimension as a ninth
13 dimension, just so that if you don't feel
14 comfortable putting it into the personnel sort of
15 dimension, that would be fine, too. I mean just
16 modify whatever you feel is appropriate for
17 patient, patient-generated data or patient-
18 centered care.

19 MR. LYZENGA: Great. And we have sort
20 of set up the slides here. Each of the groups
21 will have the slide. We have gone by each of the
22 domains, again, within the phase of HIT safety

1 that which group you are in, Group A, B, or C,
2 what are the major safety issues and challenges
3 related to, then the sociotechnical domain,
4 hardware and software, where the potential
5 solutions, barriers, potential measures. And
6 move on to the next sociotechnical domain, same
7 questions, and then just kind of move through in
8 that same way.

9 And we can feel free to skip around,
10 just have some free discussion. We will have
11 some people trying to record the discussion and
12 we can kind of flip around, depending on where
13 the discussion goes and assign issues and
14 insights, as appropriate, wherever they go. And
15 we will look to the committee members to give us
16 some feedback on that as well.

17 So, having said that, we -- go ahead,
18 Jesse.

19 DR. PINES: Just one comment. So,
20 also, to see where this fits in the broader
21 context of this project. So, this is primarily a
22 brainstorming session. What we want from you all

1 is general ideas, sort of everything on the
2 table. That is why we left two hours for these
3 groups. These are going to be relatively small
4 groups. There are only going to be four or five
5 people and then our co-chairs are going to be
6 floating around, along with a staff in each
7 group. So, again, this is going to be sort of a
8 brainstorming session where we want to get
9 everything on the table. And then later, we are
10 going to be doing prioritization.

11 So, really sort of get everything out
12 there as much as we can, even if there is a lot
13 of overlap, which we expect there to be.

14 MR. LYZENGA: And again, we will take
15 that into consideration as we move forward with
16 the project, as we prepare for the next meeting,
17 during which we will be kind of digging more into
18 more detail in the measure identification and
19 prioritization and those sorts of exercises, as
20 well as informing our remaining environmental
21 scan activities.

22 So, we actually would like to just get

1 a show of hands, try to see if we can sort of
2 self-select into groups. Could we see who would
3 like to participate in Group 1, the Safe HIT
4 group, the first phase? Does anybody want to
5 raise their hand for that. If we get a really
6 unequal distribution, we are going to have to
7 think about assigning people to groups here. We
8 may have to volunteer some people.

9 And how about the second group, Phase
10 2, Using Health IT Safely? Six people there.

11 And then how about the third group?
12 All right, a little heavier on that last group, a
13 little light on the first group. Maybe we will
14 try to reassign some people. You can go to B,
15 fair enough.

16 DR. HAYNES: I'll go to A.

17 MR. LYZENGA: You will go to A? All
18 right. Thanks, Kevin.

19 Well, I think that gives us actually
20 a fairly even distribution. I think we have got
21 about five to six people in each group. So,
22 based on which one you self-identified for, we

1 will break out into groups now.

2 I think, Adeela, do you want to tell
3 us where we are going?

4 CO-CHAIR SINGH: So, hang on. Will
5 they have access to the slides?

6 MR. LYZENGA: Yes.

7 CO-CHAIR SINGH: Okay.

8 MS. KHAN: So, Group 1 is going to be
9 led by Jason Goldwater over here and we are going
10 to be going down to 8 Small.

11 Group 2 is Jesse and they will be in
12 8 Large. So, we will take you down to those
13 conference rooms.

14 And then the third group will just
15 stay here. And that will be led by Andrew.

16 MR. LYZENGA: So come find staff and
17 we will lead you to the right place.

18 (Whereupon, the above-entitled matter
19 went off the record at 1:19 p.m. and resumed at
20 3:28 p.m.)

21 CO-CHAIR SINGH: Okay. Welcome back,
22 everybody. I'm sure all of us had a very

1 fruitful discussion. I want to make a quick
2 comment, and then I'll hand it back to Andrew.

3 So, over one of the groups -- by the
4 way, the discussions were wonderful in all
5 groups. And one comment I -- sort of I heard in
6 Group 2 and -- was can we also look at some types
7 of Health IT safety events just so that we can
8 get ideas as to, you know, are we thinking about
9 the right things? Are we thinking about the
10 right measures? Is talking about efficiency
11 issues important enough for safety, and things
12 like that.

13 So, just as an example, National
14 Health Service had a nice document that Andrew is
15 going to send around. And on Page 38, there's
16 lots of good examples of Health IT-related
17 areas.

18 Remember, they'll mostly be in Phase
19 1 and 2. They're mostly technology-induced
20 issues, but it will just be an example.

21 And then there was another paper that
22 came out from the National Health Service again

1 in the UK which was in, I think, International
2 Journal of Medical Informatics. Maybe we can
3 send that paper -- that also has examples again
4 mostly in Phase 1 and Phase 2 issues. And we've
5 had some other papers, but I think with these
6 two, people will get an idea.

7 And then we have the definition of
8 Health IT that people were talking about this
9 morning. And the best, I think, was circulated
10 to everybody tonight along with that PDF
11 document.

12 So, Page 38 of the PDF document and
13 look at the definition tonight which was
14 modified. And I think, Helen, we did a first
15 stab and we could use some more edits on this
16 tomorrow. Okay.

17 MR. LYZENGA: So, are we going with
18 the report-outs? Did we -- have you guys
19 assigned somebody to do a report-out on your
20 session? I think we actually didn't get to that.

21 MR. GOLDWATER: So, I had a very
22 introverted group, apparently, because they

1 nominated me to do it.

2 (Laughter.)

3 MR. GOLDWATER: Which is ironic given
4 the level of discussion in the session. You
5 would certainly not think introverted --
6 "introverted" would not be the first word that
7 would come to mind, but we did have a very
8 spirited and very thoughtful and very engaged
9 discussion that really led to a lot of very good
10 content about these three issues with the first
11 domain.

12 So, I thank the group for their work
13 and their efforts and thoroughly enjoyed the
14 conversation, absolutely.

15 So, with hardware and software, the
16 first was really what are the major safety issues
17 and challenges specific to hardware and software
18 required to run HIT applications taking into
19 account data availability, data quality and
20 integrity and data confidentiality.

21 Some of the issues that we talked
22 about were system architecture, how that system

1 is set up whether it is a client server which is
2 where, according to the President of the EHR
3 Vendor's Association is where most of the
4 architectures are, whether it was remotely hosted
5 or whether it was cloud-based, which is where a
6 lot of them are moving towards; how many times a
7 system is upgraded in the course of a year and
8 what kind of upgrades they are; the issues of
9 cybersecurity which are ever present, you know,
10 viruses or hacks; compatibility issues within
11 healthcare systems, a system-to-system interface
12 particularly when there are diverse systems even
13 within a hospital where there is an EHR and then
14 a different practice management system, for
15 example; potential data loss; and then the issue
16 of health information exchange, particularly the
17 lack of interoperability between disparate
18 systems.

19 What are some of the potential
20 solutions for these? One, I think obviously is
21 having a very comprehensive backup plan. An
22 enterprise-wide backup contingency plan,

1 enterprise-wide testing plan that accounts for
2 testing of the entire enterprise, and then
3 particular units of that enterprise such as a
4 pharmacy system if that were to drop.

5 And then testing the system. And
6 there are various types of tests, I know. So,
7 David Hunt and I worked at CMS together longer
8 than we would care to admit a hundred years ago.
9 So, he is as familiar with these tests as I am.

10 But some of the tests like end-to-end
11 testing or load balancing or stress testing,
12 which are pretty common in the industry and
13 really help you prevent some of these problems if
14 tested effectively, having a contingency plan
15 that incorporates these tests to be applied as
16 needed.

17 What are some of the barriers to
18 addressing these issues? Really having a
19 comprehensive readiness assessment; when do you
20 engage these testing plans, and at what time?

21 And so, a potential measure is really
22 looking at the availability of critical hardware

1 and software as well as, again, being able to
2 have an enterprise-wide testing and contingency
3 plan again that accounts for the entire
4 architecture, as well as for individual units as
5 needed.

6 For clinical content. So, within this
7 phase of HIT safety, what are the major safety
8 issues and challenges related to clinical
9 content? Again, focusing on availability of
10 data, integrity and quality of data and
11 confidentiality.

12 Templates that are commonly used in
13 systems can create noise, quote/unquote, where
14 some of that clinical context could be lost.

15 There's differing sets of
16 documentation standards among care settings such
17 as long-term care, home health, hospitals.

18 How do we ensure that the treatments
19 that are up to date are reflected in current
20 clinical decision support? The issue of alert
21 fatigue. Proprietary issues of clinical data
22 particularly those where -- that come from these

1 large organizations. And then a lack of
2 reconciliation when you receive data from
3 differing sources.

4 What are some potential solutions?
5 Make sure the source is credible and updated
6 regularly. Making sure alerts occur at the
7 correct time in the workflow process in the hopes
8 of eventually reducing that sort of alert
9 fatigue.

10 What are the barriers? Quality
11 control, lack of comprehensive quality control,
12 proprietary control of the data, and data as
13 often seen in one source which sometimes will
14 lack context.

15 Measures, is the alert in the right
16 place at the workflow? If data is being brought
17 in from other systems, is it being incorporated
18 into the patient's record accurately to be used
19 for decision-making?

20 Human-computer interface. This was
21 fun, because it deals with usability which we all
22 had opinions on.

1 Within the phase of HIT safety, what
2 are the major issues regarding -- with respect to
3 human-computer interface?

4 Really, how the information is
5 displayed, how the information is retrieved, how
6 the information is inputted and then work-arounds
7 when a usability problem is identified.

8 Usually when there is a usability
9 issue as it was told to me, clinicians are not
10 like, oh, it's a usability issue, I know how to
11 deal with this. They usually work around the
12 issue, which sometimes can lead to challenges and
13 there being consistent use of the application.

14 What are some of the barriers to
15 addressing these issues? Testing doesn't
16 actually occur in a clinical setting.

17 If you read sort of the industry
18 standards for how testing should be conducted,
19 the use of kind of the current tools that could
20 be used for usability that a lot of very large
21 software corporations use, is they actually watch
22 users interacting with the system, look and see

1 what the issues are, and then rectify those.

2 That is very rarely, if ever, done in a clinical
3 setting.

4 So, the testing doesn't occur in that.
5 It occurs in a laboratory. It occurs in a
6 development environment. And so, they're not
7 watching people actually interact with a system
8 directly.

9 What are some potential measures
10 addressing this dimension? Are you using human
11 factor experts in the development of your system?
12 Are you really looking at building usability into
13 the life cycle? Are you using common industry
14 practices and tools?

15 There is a -- one of our discussions
16 was there's a lot of different ways of doing
17 testing for usability and no one person does it
18 the same way. NIS has standards. AHRQ has
19 standards. CDC has standards.

20 There's standards at Apple, which is
21 probably one of the most usable systems in the
22 world has actually promulgated and who's using

1 what? I don't know.

2 You can pretty much choose the kind of
3 standards that you want to be using. So, is
4 there a consistent application of industry
5 standards and tools, and are you doing risk
6 stratified usability assessment? The higher the
7 risk, how great is the usability of the system
8 based on what you're doing?

9 So, for example, if you're an ER doc,
10 there's a higher risk. So, there's obviously the
11 system needs to be considerably more -- the
12 system always needs to be usable, but usability
13 is higher there.

14 And so, we only got to Four. That's
15 how spirited the discussion was. If I kept them
16 longer, they would have started throwing things
17 and it would have been bad.

18 So, people was the last one. Within
19 this phase of HIT safety, what are the issues
20 involving design, development, implementation and
21 use?

22 The biggest issue was training the

1 support staff for both providers and patients.

2 That was key with patients as well as providers.

3 There's a scarcity of people that are
4 trained to actually provide key support. And the
5 different job roles that people play in the
6 course of a clinical environment, each of that
7 role has a different interface and are they
8 trained all identically, or are they trained
9 specifically on that interface?

10 What are some potential solutions?
11 Identify training needs for every stakeholders
12 and then developing proper support in case there
13 are issues like a help desk and making sure those
14 tickets are open and closed within an expeditious
15 fashion.

16 What are some barriers for addressing
17 those issues? The end user is not necessarily
18 part of the development. They're not really
19 looking at front-line staff.

20 I remember I mentioned this story that
21 several years ago I visited Texas Health
22 Resources. I'm sure a lot of you are familiar

1 with that. It's a very large Epic shop. They
2 have, I think, spent \$750 million on Epic.

3 And they did -- we interviewed many
4 doctors, many nurses and they all generally said
5 the same thing that they were never involved --
6 the testing was -- the testing was not -- the
7 system was done in a lab. It was not actually
8 done in the hospital.

9 So, what they were doing in a
10 laboratory environment or a training environment
11 was not what they normally do when they're
12 actually in the hospital setting itself.

13 What are some potential measures for
14 addressing this dimension? What are your FTE
15 requirements for training? How many hours of
16 training are actually required? What is the
17 ticket response time for the help desk? Are you
18 doing appropriate simulation testing and are you
19 doing competence testing?

20 And we have to sort of define what
21 "competence" means, but are you developing a
22 threshold of competence to make sure you have an

1 understanding of the system and how the system
2 should be used.

3 And that is, unfortunately, as far as
4 we got, but I thought we got a lot done. So,
5 again, I thank the group very much.

6 Is that okay? Mark, are you alright
7 with that? You're sure? All right.

8 (Comments off mic.)

9 MR. GOLDWATER: I've known Mark for a
10 while. So, I have no reservations about saying
11 ---

12 DR. HUNT: I just have one question.

13 MR. GOLDWATER: Sure.

14 DR. HUNT: You used one phrase, and I
15 want to make sure that I understand it correctly
16 and clearly.

17 You said "proprietary issues of
18 clinical data."

19 MR. GOLDWATER: Uh-huh.

20 DR. HUNT: Proprietary issues of ---
21 so, there's clinical data that is proprietary.
22 It is almost an oxymoron that someone would say

1 that my data as a patient is their proprietary
2 information.

3 Is that what you were saying?

4 DR. SEGAL: (Comments off mic.)

5 MR. LYZENGA: Use the mic.

6 DR. SEGAL: Oh, sorry. Mark Segal.

7 When we're talking about clinical
8 content, we talk broadly about anything from the
9 physician note in the record or labs that were
10 entered, to the content that might be used to
11 support things like clinical decision support.
12 And the proprietary involve that external
13 content, drug-drug interaction databases.

14 DR. ALEXANDER: Just an example we
15 talked about was the INTERACT tool. So, we have
16 implemented the INTERACT in several facilities
17 and another research project I'm involved in and
18 there have been questions about how much we could
19 change the details of that tool, which is a
20 clinical document, sort of an architecture way to
21 document, and it's a proprietarily-owned
22 document.

1 And so, you know, that's a good
2 question that you sort of pose there, you know,
3 how much can you change and if it's clinical data
4 and who owns the clinical data and that kind of
5 thing.

6 CO-CHAIR SINGH: So, Jason, Greg, to
7 sort of recap, and I can on behalf of you pick on
8 the rest of 15 members who have not spoken as
9 yet, to see what else they would like to add
10 specifically in terms of sort of the third
11 bullet, right?

12 So, what are the few key areas that
13 you would then say for, you know, Level 1, you
14 know, safe technology? What would be the areas
15 we would focus on in terms of measure
16 development?

17 I don't think we need exact measure,
18 you know, X percentage of this and X percent of
19 that.

20 Just let's just think through five,
21 ten, eight, seven, come up with maybe some areas
22 that we can say concretely these are the eight to

1 ten areas which will help the group move forward.

2 And if you want to think through this
3 and have a discussion until later, we could do
4 that, but I think I'm going to challenge every
5 group to try to do that in order to move us
6 forward.

7 MR. LYZENGA: We'll also have an
8 opportunity tomorrow morning to ---

9 CO-CHAIR SINGH: Yeah, and you could
10 do that tomorrow after you've ---

11 MR. LYZENGA: Marinated on it
12 overnight.

13 CO-CHAIR SINGH: But they'll get a
14 chance to ---

15 MR. GOLDWATER: So, I mean, I think
16 that my observation was the issues that really
17 brought up the most discussion, the ones that we
18 were really involved with really had to do with
19 human-computer interface with people and then, I
20 think, with clinical content.

21 I mean, we spent a lot of time with
22 hardware and software, but I think we --- and I

1 think that's always an issue and it's an issue
2 that we can focus on, but those were really the
3 three domains that a substantial amount of time
4 and feedback was getting --- was circulating
5 throughout the group.

6 And, I mean, does anybody else want to
7 sort of comment on this? That's where I thought
8 most of our discussion was centered around those
9 three issues.

10 DR. ZIMMER: This is Karen Zimmer.

11 The only thing I was going to say is
12 we struggled a little bit initially of what was
13 meant by clinical content. So, we took the more
14 general view of both clinical decision support as
15 well as actual information.

16 But by the time we finished what we
17 thought belonged in there, it was a rather large
18 area.

19 CO-CHAIR SINGH: Yeah, I think
20 knowledge, rules, logic, alerts, reminders, all
21 of that should be --- that's my documentation.

22 DR. ZIMMER: And that's the approach

1 we took.

2 CO-CHAIR SINGH: Yeah. So, what would
3 be the areas that you would then say, here's the
4 certain types of measures we could look at?

5 I mean, this morning, I projected a
6 slide that said, you know, software bugs reported
7 to EHR vendor. So, did you talk about that kind
8 of a relationship between ---

9 MR. GOLDWATER: We did. I mean, I
10 think, you know, what was really great about ---
11 I know I feel like I'm bragging about my group,
12 but I will.

13 What I really think was great about it
14 was we would have these discussions. And if they
15 didn't think it could be measured, we would
16 either rethink it through in a way that could be
17 measurable, or we would drop it and move on to
18 another more relevant topic.

19 I mean, I think that really measuring
20 how we do usability, I think, is fairly
21 important, you know.

22 There's a million different ways of

1 doing this and there's a lot of different
2 standards out there about how you test the
3 usability of software and systems.

4 And I think what we all discussed was
5 is that it's not being uniformly applied. It's
6 not, you know, nobody is saying these are the
7 standards. If you have an EHR, this is what you
8 need to test for in terms of usability and this
9 is how you have to do it and here are the tools
10 that are accessible for you to do it.

11 And it's sort of more open-ended than
12 that. And I think that's --- we sort of
13 discovered that's what led to problems, because
14 it's not --- there are ways of doing this that
15 are effective that are being used in industry
16 that are not necessarily being applied within the
17 clinical setting. I think that was a big, you
18 know, particular issue.

19 I think the types of training that are
20 involved, measuring the types of training, the
21 hours of training, how that training is being
22 done, you know, that really will make a

1 difference in how people are using the system and
2 how that system is being used effectively.

3 Mark.

4 DR. SEGAL: Yeah, I guess, to go on
5 record on the usability piece, I think that
6 absolutely there is a major opportunity for
7 companies to enhance their use of user-centered
8 design, but at the same time recognizing that
9 it's really a toolkit that needs to be
10 situationally applied that --- from the
11 standpoint of sort of imposing standards that are
12 translated into hard measures about did you do
13 UCD right, or not?

14 At least I would be hesitant about
15 that. And I think most of the industry
16 colleagues I work with who are committed to UCD
17 would be. So, I think we need to be careful
18 about what kind of measures we would design to
19 measure kind of the process part of UCD use.

20 CO-CHAIR SINGH: Jason, did you have
21 a comment?

22 DR. JONES: Jason Jones. I just had

1 a question.

2 So, the usability piece, how did you
3 --- did you have trouble --- I was trying to keep
4 that separate from safe HIT.

5 We struggled in our group, which is
6 the next group, actually, to figure out how to
7 fit things in the bucket. So, that was something
8 we kind of acknowledged and said we're having a
9 hard time putting things into buckets.

10 Did you attempt to separate the safe
11 HIT from the safe use of HIT? No? Or do you
12 think ---

13 MR. GOLDWATER: I think we viewed
14 human-computer interaction as usability. I mean,
15 that was --- they're pretty much tied into one
16 another. So, if you're going to be effective in
17 human-computer interaction, the system in and of
18 itself has to be usable.

19 It has to be, you know, accessible to
20 the nurse or the physician or, you know, some
21 other sort of clinical worker that is inputting
22 data, and then taking that data out and using it

1 to make decisions with respect to a patient.

2 So, I don't think we separated out the
3 issues; I think we looked at this as being
4 intertwined with one another that if you make a
5 system that is usable, that is comprehensible and
6 that provides ease of use to the end user,
7 eventually that will, in theory, at least, lead
8 to safe and effective use of Health IT.

9 It will prevent some of the errors
10 that come from bad usability design.

11 DR. JONES: Did you guys have any
12 thoughts on the --- specifically around
13 competence that you had mentioned about how that
14 could be measured and ---

15 MR. GOLDWATER: So, I will leave that
16 to my colleagues to answer.

17 DR. ZIMMER: We talked about a few
18 things. We did say to apply different industry
19 tools and that's nice jargon, but what does that
20 really mean?

21 So, sometimes for usability it could
22 be a survey. There are actually tools out there

1 that actually see how people's eyes follow the
2 screens. There's actually a possibility --- it's
3 a bit labor-intensive -- but obviously someone
4 could watch you in the work environment to see
5 how you're interacting.

6 And then we also did talk about if you
7 did some either form of simulations, since a lot
8 of places do have simulation centers now that you
9 could do simulations there, or if you are in a
10 lab. Either way there would be some form of
11 competency where you might have case studies and
12 things where you have to sort of work through it
13 to show that you have some form of competency as
14 part of your credentialing.

15 DR. ALEXANDER: The only other thing
16 I wanted to add was about content. And we did
17 have some discussions around the differences in
18 the types of contents between different
19 healthcare organizations and, you know, how would
20 you be able to develop a measure for different
21 organizations that collect different content, but
22 they're caring for the same patients.

1 And so, that's an issue that was hard
2 to think about, but -- so, I think from the
3 standpoint of standards and looking at the way
4 standards have been developed and are being used
5 that there's still some need for content to be
6 more standardized so that systems are more
7 useable.

8 CO-CHAIR SINGH: Karen.

9 DR. ZIMMER: I Just want to continue
10 on with what Greg said, because you've brought up
11 a very good point especially with long-term care
12 facilities look at data very differently than the
13 inpatient setting. And more and more
14 particularly as we move towards ACOs and more
15 care being done in the outpatient setting, we all
16 have to increase our education about how other
17 people use information in other settings.

18 CO-CHAIR SINGH: Okay. I'm going to
19 ask one more sort of question to your group and
20 then it will also be relevant for the others, and
21 maybe we can move on and then come back, because
22 some of these discussions will need to be sort of

1 built one on top of the other.

2 But when I was having a brief
3 discussion about, you know, are some of these
4 measures or measurements going to be more at sort
5 of the enterprise level organization-wide, which
6 is sort of clinicians, patients, units, you
7 wanted to speak to that about what you all sort
8 of finally decided or thought? Because I think
9 the other groups will also speak to that.

10 MR. GOLDWATER: Sure. This is Jason
11 Goldwater.

12 You know, what was decided was -- and
13 this really came out of the hardware and software
14 issue.

15 So, when you do a testing, a
16 contingency plan, you know, the first thought was
17 you do it for the entire system. And that way if
18 the system goes down or if there's an upgrade
19 that doesn't necessarily work or, you know,
20 there's a hack or there's a virus that's inserted
21 itself into the enterprise, what do you do? What
22 steps do you go through? What testing do you

1 need to do to retain the system integrity and to
2 ensure that it is working appropriately in the
3 quickest time possible.

4 What Karen brought up was there are
5 times when such as the pharmacy system goes down.
6 The system itself doesn't go down, but the
7 pharmacy system drops. But when that drops, it
8 affects everything. And so, what kind of
9 contingency plan do you have to have for that?

10 Now, most CIOs I would hopefully ---
11 I don't want to necessarily go on record, but I
12 would think all CIOs would develop a plan, a
13 contingency plan and a testing plan that would
14 accommodate that -- that would look at
15 comprehensive enterprise testing as well as unit
16 testing as needed, but I think the point was
17 brought up that that really needs to be
18 specified.

19 If we're going to measure that, that
20 we really have to look at developing an
21 enterprise plan, but also really looking at
22 individual unit plans and how that would be

1 tested, because the testing might be different
2 for some of the systems.

3 And I think that was a point well
4 made, because there are some systems that will
5 drop and that will, you know, if a practice
6 management system drops, that also affects
7 everything. So, how are you going to do that
8 appropriately?

9 So, that's sort of what we decided
10 that it's sort of a combination of both.

11 CO-CHAIR SINGH: Jason.

12 DR. JONES: Jason Jones again.

13 So, I think the question was --- at
14 least how we had discussed it if you mentioned
15 the competency thing, which I had asked about
16 earlier -- you could have a system or enterprise
17 measure. Do you have competency testing? Yes,
18 no. Answer the question for the entire
19 organization.

20 Or you could have sort of individual
21 clinician or unit measurements. Does the ED have
22 competency testing? Does ICU have competency

1 testing? Does nursing? Does pharmacy? Or that
2 could go all the way down to an individual. What
3 chunk of your clinicians of a particular type
4 have undergone competency testing, and what was
5 their level of competency?

6 I think was that sort of ---

7 CO-CHAIR SINGH: Yes. Yes. 80
8 percent --

9 DR. JONES: Yes.

10 CO-CHAIR SINGH: -- of our users have
11 competency testing for some, you know, or could
12 that be a measure or something like that. Just
13 putting numbers is hard, but coming up with some
14 concrete measure.

15 DR. JONES: So, it wasn't really ---
16 so, the system like if the pharmacy system goes
17 down or not, that sort of --- that is an
18 enterprise level. Do you have a backup strategy
19 for a system?

20 You're not going to have a backup
21 strategy for a small component to the system, but
22 competency could be measured at many levels with

1 an organization.

2 So, if there was a measure out there
3 that existed, if NQF was going to say you should
4 have a measure of competency, would that be
5 measured at the institute, entire institution
6 level, or at some granular level?

7 How would you even have something like
8 that?

9 DR. ZIMMER: When we were talking
10 about competency just based on that discussion, I
11 took it as that we were talking about it at an
12 individual level.

13 To be fair, we didn't spend enough
14 time on the competency to address all of the
15 different levels, but that's a good point.

16 DR. PINES: If I could comment on how
17 NQF approaches that in terms of the measure
18 specification, so each of the measures that goes
19 through the NQF process actually does have
20 recommendations about at what level a measure
21 would be deployed.

22 So, for example, from clinician all

1 the way up to health plan being sort of the
2 widest measure.

3 So, that would be something that
4 would, you know, I think should be addressed and
5 should, you know, potentially go into the report
6 as, you know, sort of who's accountable for what
7 elements of this, be it competency, usability, et
8 cetera.

9 MR. RUSSELL: Jim Russell.

10 One question on there would be
11 competency is really great at the beginning, but
12 I think what you really want to be measuring is
13 proficiency over time -- how are users really
14 using the system over time?

15 So -- because competency is a pretty
16 basic level. You want to make sure that they're
17 actually progressing over time.

18 DR. SCHNEIDER: Yeah, I actually was
19 going to say the same thing, but I was going to
20 say for a different reason which is that
21 clinicians prefer the word "proficiency" to the
22 word "competency."

1 (Laughter.)

2 DR. HUNT: A couple of things that
3 come to mind, I remember a conference with a
4 pharmacy group. And one member pointed out that
5 useable is a little bit broad and it should be
6 useful, useable and used. They are the three
7 areas it really hit.

8 But in listening to some of the topics
9 that came on, could it be fair --- and, Hardeep,
10 I'll ask you -- would it be fair to characterize
11 a lot of the things as the high outline of the
12 contingency and the organizational or high
13 priorities guide and the SAFER guides?

14 I'm hearing the topics that were hit
15 really seem to be outlined in that and if that
16 might be a way to think about a lot of this work.

17 And one more question, because I can't
18 really get a sense from the group. Jason uses a
19 lot of euphemisms. Is it a crime scene down
20 there? Is there blood on the wall?

21 Will we have to, you know, provide ---

22 MR. GOLDWATER: If it had gone on for

1 another 15 minutes maybe, but, no, I'm kidding.

2 It was very engaging.

3 Very --- I started to use the word
4 "provocative," and then I was like, well, that's
5 not really the right word to be using. Nothing
6 provocative that would ---

7 (Comments off mic.)

8 CO-CHAIR SINGH: So, yeah, David, you
9 know, I think at the risk of getting tomatoes
10 shot at me, I would love for people to get a
11 little bit of homework and I think just after
12 this conversation, sort of revisit the SAFER
13 guide.

14 Especially the high priority and maybe
15 the organizational, the big picture ones because
16 a lot of these issues that we're discussing today
17 are already there, but they are not written
18 specifically in terms of their measures or
19 measurements, but they could easily be converted.

20 So, just to sort of give you guys more
21 homework to do, just think about doing that in
22 addition to the things that we're saying.

1 DR. ZIMMER: Hardeep, maybe put them
2 on our site. The website.

3 CO-CHAIR SINGH: Yeah. The website,
4 yeah. Yeah.

5 DR. ZIMMER: It seems like a good
6 place.

7 CO-CHAIR SINGH: Yes, we'll put it.

8 DR. ZIMMER: Okay. And then can that
9 be part of tomorrow's discussion when we break up
10 in groups?

11 CO-CHAIR SINGH: Yeah, that will be
12 great.

13 Moving to Group 2, I think. Anybody
14 else have anything else? David and Jason, you're
15 done, right? Okay.

16 All right. So, are you doing the ---

17 DR. PINES: Yes. So, I'm going to be
18 doing the report-out for Group 2. So, Group 2
19 focused on usability and use. And there were ---
20 I think there was a fair amount of overlap in
21 terms of some of our discussions in terms of the
22 need for usability testing and competency

1 testing.

2 One of the --- one comment that I
3 thought was very interesting came from --- sort
4 of from a high-level perspective.

5 We've got, you know, the sort of
6 system components that we can measure that lead
7 to process measures, that lead to the ultimate
8 outcomes of Health IT. Some of those being sort
9 of positive outcomes such as, you know, are we
10 getting the right, accurate information, are we
11 communicating effectively, or is there a good
12 decision support to negative outcomes such as
13 errors.

14 And we spend a fair amount of time
15 sort of talking at those different levels what
16 sort of goes into those --- what sort of goes
17 into those buckets.

18 And so, you know, one of the big
19 factors that we talked about sort of towards the
20 end and also interspersed throughout is sort of
21 the impact of how Health IT on the workflow as
22 people are putting in information into the

1 system, one of the what were called work-arounds,
2 which are called "scribes," you know.

3 Because the interface is not
4 particularly easy to use, user-friendly, we have
5 this work-around called scribes, where scribes
6 enter the information for us. And we may not
7 necessarily be leveraging the full --- the best
8 aspects of Health IT, particularly when scribes,
9 you know, may not have the same medical training
10 as the person who's sort of the intended user.

11 We also talked about specifically when
12 it came to scribes, there could be a measure
13 around making sure that when there are work-
14 arounds like scribes put into place, that they
15 are used appropriately.

16 The clinical example I gave is that
17 our scribes in the ED are only put in the history
18 of present illness and the past medical history.
19 And then the physicians do the -- put in the
20 physical exam and the orders, and so that when
21 you do have these work-arounds, you do have to
22 sort of use them appropriately.

1 There was an example of sort of use of
2 Health IT and for --- to facilitate care that
3 came from out of Kaiser, you know. Specifically
4 one of the measures that they use is do patients
5 understand --- or did the physician understand my
6 medical problem and, you know, some of the
7 physicians at Kaiser are actually trained to
8 actually input the information in conjunction
9 with the patient to ensure that that question
10 gets answered in the affirmative.

11 So, this was an example of sort of a
12 positive way that health IT was used in a
13 positive way.

14 We also spent a fair amount of time
15 talking about alerts as one of the process
16 measures and whether a certain number of alerts
17 was too many, you know.

18 Everyone sort of knows that alert
19 fatigue is a major issue. It was mentioned that
20 some clinicians get 50 to a hundred alerts in a
21 day, and that's just too much.

22 And then, you know, sort of zooming

1 out from that we talked a little bit about
2 whether or not --- when we talk about holding the
3 organizations, clinicians, vendors accountable --
4 whether or not we want to use, you know, these
5 outcome measures. So, sort of the ultimate
6 measures of usability, for example, how do
7 clinicians actually rank the usability of the
8 system versus the sort of system component such
9 as do we actually want to, you know, measure
10 alerts as --- and use that as the ultimate
11 measure, you know.

12 My perspective on that coming out of
13 another patient safety committee through NQF is
14 that the --- specifically when it comes to the
15 NQF criteria, there are algorithms that have been
16 --- that were developed about --- I think about a
17 year and a half ago that are applied to structure
18 and process measures that require a pretty high
19 level of evidence in order to sort of get through
20 the evidence criteria for NQF, where you've got
21 to really sort of definitively link a process to
22 an outcome in order to pass that measure.

1 So, you know, and I think that that's
2 sort of a good thing to keep in mind for the
3 group as we move forward with this is that, you
4 know, there are certain mechanisms that if we do
5 want to use the NQF mechanism for endorsement, it
6 does have to sort of get through those standards.

7 And the focus more lately has been on
8 these outcome measures and the, again, one of the
9 great comments that came out of the group, sort
10 of an a-ha moment for me is that when it comes to
11 usability if we can think about where we want to
12 end up and sort of how to measure as close as we
13 can what usability actually means and who can
14 best sort of, you know, give their assessment of
15 how usable a system is, that that may be
16 ultimately where we want to go.

17 We talked a lot about, you know, a lot
18 of measures of patient experience being, you
19 know, quality metrics these days, you know. Can
20 we think about potentially developing some
21 measures of clinician experience as a target for
22 usability because the, you know, there was a lot

1 of discussion about the, you know, sort of the
2 complexity of what it really takes, you know,
3 when it comes to the system components and how
4 well the system components perform to the
5 ultimate usability experience.

6 And, you know, we had, you know, a lot
7 of different opinions about whether or not we
8 should be focusing on system components or the
9 outcomes or, you know, whether or not we can do a
10 combination of the two.

11 Some of the other areas we talked
12 about, I think, were similar to Group 1. We
13 talked a lot about the --- messed up my slides
14 here.

15 (Pause.)

16 (Comments off record.)

17 DR. PINES: Thanks.

18 So, we also spent some time talking
19 about sort of two areas of sort of how you ---
20 what usability testing looks like. And Nana had
21 a lot of good examples of what they do at Hopkins
22 and, you know, had a description of the --- of

1 sort of pre-usability testing that would be the
2 responsibility of the vendor.

3 And actually we found out from George
4 that actually part of the meaningful use criteria
5 is actually to do usability testing, you know, in
6 order to be certified as a vendor.

7 But the sort of three levels would be
8 the usability testing before you implement
9 something, the usability during implementation,
10 and then ongoing usability testing and thinking
11 from a measurement perspective how we can
12 potentially create measures about sort of who's
13 responsible for what during those various phases.

14 You know, certainly the vendor would
15 be responsible for creating the product and maybe
16 that pre-usability testing. And that as a ---
17 over time that that responsibility would become
18 shared because, you know, certainly you can
19 create the best product in the world, but that
20 product will need to be adapted locally to ---
21 for --- to make sure it's interconnected and
22 actually is locally usable.

1 We also spent some time, similar to
2 the other group, talking about training and what
3 training would look like. Training on two
4 separate levels. One, the initial training
5 getting people up to speed in terms of how --- in
6 terms of whether or not they actually can
7 effectively use the system, but also ongoing
8 training as new system upgrades come into play
9 and particularly through big system upgrades to
10 make sure that people sort of stay up to speed in
11 terms of, you know, making sure that they can
12 continue to use the system.

13 And also to bring up something that
14 David Hunt said that, you know, when it comes to
15 particularly the interoperability, I think this
16 is --- there was a discussion about the three
17 levels of, you know, is the information there?
18 Is it actually usable? And then is it actually
19 used?

20 And the example --- I gave some
21 examples sort of locally here in the D.C. area
22 what our regional health information exchange

1 looks like. It's called CRISP. And also how
2 that's been deployed in Washington state after --
3 - there was a threat in Washington state where
4 the --- Washington state Medicaid threatened to
5 not pay for more than three ED visits for
6 Medicaid beneficiaries in the emergency
7 department.

8 And the emergency physicians at a
9 number of the hospital organizations got together
10 to really put a pretty effective health
11 information exchange where they could sort of see
12 metadata.

13 And it was, you know, and the --- at
14 least some of the feedback from the physicians
15 there was it's actually very useful to know, you
16 know, that someone just left the hospital down
17 the street with a similar diagnosis.

18 And actually if you, you know, you can
19 log into the system and you can actually see some
20 of the metadata regarding those visits.

21 Let me see here.

22 CO-CHAIR SINGH: Should we have other

1 people reflect by the time you ---

2 DR. PINES: Sure. Thank you.

3 CO-CHAIR SINGH: Anybody else from the
4 group want to sort of chime in while Jesse pulls
5 up his slides? Do you want to walk through the
6 system that you have at Hopkins as you were
7 telling us about the usability?

8 (Comments off mic.)

9 DR. KHUNLERTKIT: The three different
10 types of usability testing.

11 CO-CHAIR SINGH: And actually also the
12 reports based off of --- I think you were talking
13 about sort of ticket --- you were talking about
14 some experiences at Hopkins that you guys are
15 doing differently.

16 Prioritization of tickets ---

17 DR. KHUNLERTKIT: Oh, I gotcha.

18 CO-CHAIR SINGH: Yes.

19 DR. KHUNLERTKIT: So, when there is a
20 problem with the system, usually clinician will
21 put in a ticket to get the system fixed or
22 enhance the function of the system.

1 And I found that we have a
2 communication gap or lack of understanding
3 between vendors and clinicians of what may be the
4 priority on the list of what to fix.

5 So, what we ended up doing is forming
6 a group within our healthcare organization based
7 on the area of expertise and have the right
8 people at the table and prioritize the problems
9 for the vendor. And then send that list to the
10 vendor so they can fix it in a timely manner.

11 CO-CHAIR SINGH: Yes, so we were just
12 sort of talking briefly that could a measure then
13 be developed which would say, do you have such a
14 prioritization mechanism for patient safety-
15 related tickets, for some reason.

16 DR. KHUNLERTKIT: Yes.

17 CO-CHAIR SINGH: Something along those
18 terms.

19 DR. KHUNLERTKIT: And there are
20 actually multiple points of prioritization
21 criteria. So, we put like patient safety and we
22 have the weighting criteria the highest for that

1 one, productivity of clinicians, financial effect
2 and also some other things.

3 We roughly have about probably like
4 eight factors for prioritizing the problems, but
5 I don't quite remember all of them.

6 CO-CHAIR SINGH: So, Jesse, are you
7 ready or -- I mean, I was going to ask our, you
8 know, vendor representative, do you have some
9 sort of an established standard way of
10 prioritizing sort of tickets as you get them?

11 Is it the same across the --

12 DR. SEGAL: I'll go from what I know
13 about, which is that -- and, again, we're -- I
14 think I might have mentioned this. We're doing
15 more and more work in an agile framework where I
16 don't really fully understand this, but you comb
17 backlogs or something.

18 But I think the patient safety issue
19 gets prioritized first, and then, you know, then
20 you're going to be looking at things like how
21 many customers were asking for it, you know.

22 So, I think it's -- the main thing I

1 would know about is that if it's a patient
2 safety-related issue, that goes to the top of the
3 queue.

4 CO-CHAIR SINGH: Even if it's from one
5 person?

6 DR. SEGAL: Oh, yes.

7 And, again, one of the things you have
8 to look at, and we find this, is sometimes people
9 identified something as a patient safety issue
10 because they know it will get to the top of the
11 queue. So, you have to review it and see what
12 the situation is. But, yes, even with one person
13 we'll take that seriously.

14 Now, it may or may not lead to a
15 change in the software. There are other kinds of
16 solutions. It could be something very specific.
17 It could be a training thing or it could be
18 they're giving us an early alert on something
19 that might be more widespread.

20 CO-CHAIR SINGH: And I'm going to add
21 on a question to that which I would like Jim also
22 to reflect is if you find something substantive,

1 then how do you communicate that information to
2 all of your other organizations that are using,
3 for instance, like the same version or same
4 system?

5 DR. SEGAL: Two customers?

6 CO-CHAIR SINGH: Yes.

7 DR. SEGAL: I think -- and, again, not
8 every issue that gets raised will necessarily go
9 to every customer, but I think -- I think it's
10 generally going to be done by some combination of
11 mail or email sort of depending on the
12 seriousness of the issue and also what, you know,
13 if there's a fix or if there's something you want
14 the customers to do.

15 So, I think it's somewhat situational,
16 but I think nowadays it tends to be a mix of
17 email and mail in some cases.

18 CO-CHAIR SINGH: So, the other thing
19 that I've heard sort of from sort of the field is
20 they're going into these user groups which I
21 don't know if they're monitored or not. And
22 they're trying to like, you know, at the user

1 group or -- I'm not sure how formal/informal
2 these are and they're exchanging we had this
3 problem and --

4 DR. SEGAL: So, I can tell you on
5 that, for example, because we've just -- and,
6 Jim, you should weigh in.

7 So, our user -- like our ambulatory
8 EMR user group is an independent organization.
9 They're not like part of us, they're not staffed
10 by us, but we provide them support.

11 They have a Listserv that's theirs.
12 And if they post and they share things, we, with
13 their permission, moderate it. And if we see an
14 issue raised that we have something to
15 contribute, our folks will weigh in, but it's
16 basically kind of, you know, an open forum for
17 people to exchange their own experiences.

18 And, you know, that gets to the
19 earlier questions about gag clauses and all that,
20 but we're trying to monitor those more
21 systematically so we can do really rapid reach-
22 outs.

1 A lot of times it's more about --
2 increasingly it's not just about the technology
3 or what the application does, but an
4 interrelationship with services, you know. The
5 ability to send or receive data or submit quality
6 measures.

7 And so, often it's something that, you
8 know, you need to talk to the customer, assess
9 what's going on, maybe get a field engineer
10 involved.

11 And we're trying to monitor those
12 closely and do quick, personal reach-outs.

13 CO-CHAIR SINGH: Thanks. Jim.

14 MR. RUSSELL: Sure.

15 DR. SEGAL: You do it entirely
16 differently, right?

17 MR. RUSSELL: Of course. Same thing,
18 different verse. So, what we do is if anybody
19 calls in and says this is a patient safety issue,
20 that goes through a very rigorous process
21 internally to make sure that we're assessing
22 right away with that customer what's going on

1 with them and make sure that we understand the
2 problem, one, and number two is that if there's
3 mitigation already.

4 I think the next thing we do is we
5 really run through the whole process internally
6 and then there's a push-out to all our customers.

7 And typically what it is, at the
8 customer site they'll have a dedicated people
9 that we will be reaching out to either by email
10 or by phone.

11 If we can't reach them within certain
12 amounts of time, we have all sorts of escalations
13 that go through making sure we reach them in a
14 certain amount of time.

15 With what is the problem, this has
16 been found in other customers. We do searches to
17 make sure -- see who it affects based on version,
18 based on the module, things like that. And then
19 send out updates as we learn more information,
20 pushing out that information as we hear it's a
21 new mitigation we maybe discovered in the next
22 last, first day, 24 hours, 48 hours, et cetera,

1 and move those things through.

2 And then the same thing like I guess
3 what Mark was saying is we go very active users
4 groups who do work with one another and we have
5 listservs where people post a lot of questions, a
6 lot of things out there.

7 We moderate. We answer when we have
8 to get an answer to -- moderate and answer those,
9 too.

10 So, very similar, little different
11 flavor, it's all the same thing.

12 CO-CHAIR SINGH: Quick, David, and
13 then back to Jesse.

14 DR. CLASSEN: I just had a question
15 for James and Mark. One of the things we start
16 with the IOM is it didn't appear that people were
17 reporting these issues to the FDA.

18 And do you guys report these issues to
19 the FDA? And how do you decide if you do,
20 whether you do?

21 DR. SEGAL: My understanding is for
22 non-FDA-regulated products we don't report to the

1 FDA, but that the internal processes we have in
2 terms of assessing them, in terms of notifying
3 externally are more or less the same for FDA and
4 non-FDA-regulated products, but I don't believe
5 we report to the FDA on things that we don't have
6 to.

7 MR. RUSSELL: And having looked at mod
8 data just very recently, it's something we're
9 actually look at whether it's really a value to
10 do it to the mod database.

11 I would hesitate to say that non-FDA-
12 regulated are really reported to the extent that
13 people may say --

14 DR. SEGAL: I think the other issue
15 that's come up and I think it goes back to the
16 IOM study and the desire to use sort of a PSO
17 model or what have you is, again, if I'm
18 understanding the FDA requirement in general
19 death and serious injury and that there are a lot
20 of safety-related events that fall below that
21 threshold. And so, you know, I think that the
22 death and serious injury, my guess, happens very

1 rarely in health IT and is probably a very small
2 subset of the broader set of things that one
3 wants to be tracking.

4 DR. CLASSEN: The only reason I say
5 that is we struggled with this issue.

6 We struggle with this issue a lot.
7 And there's a lot of skepticism on the Committee
8 that any system on the FDA was going to set up
9 was going to be very valuable for learning.

10 So, a big part of our report was on
11 alternate reporting systems or the PSOs rather
12 than the FDA, just so you know that.

13 DR. HUNT: David Hunt.

14 Very much along those same lines of
15 questioning, how would a general user that may
16 not necessarily have one reported this issue to
17 you or that you may not know has a similar
18 configuration, is there a general, broad way that
19 is your average user might find out about things
20 that you've corrected, fixed or have issued
21 tickets on that; one, I might not have reported,
22 or; two, you might not know that this will be a

1 problem for me, but I would love to say, wow,
2 there's a little pearl right there. This is how
3 you do that.

4 Is there a way that I could -- that
5 you generally make available information that
6 people could -- your users could then benefit
7 from?

8 MR. RUSSELL: So, the short answer --
9 that's one of those that there's a really, really
10 long answer.

11 Short answer, yes. Long answer is
12 typically at the organizational level they have
13 their hierarchy of how things get pushed off to
14 us and how things come back in to them and how
15 they spread those out to their end user and to
16 their community within the organization.

17 Rather than us blasting Kaiser and I
18 don't even know how many users you have, it
19 normally gets communicated to the organization.
20 The organization makes the decision on how to
21 disseminate that information.

22 DR. SEGAL: I'd say the one other

1 thing we have is where we send out notices to
2 customers. And well send out issues on bugs that
3 have nothing to do with, say, I mean, as we
4 communicate, as we put in place, I think, in the
5 last year a services portal. And, again, there's
6 that again, because that's -- it's the services
7 people that typically are the ones who are
8 customer facing that I think basically sort of
9 archives and organizes those kinds of customer
10 communications.

11 So, Somebody who might not have
12 received it on sort of the push or might not be a
13 designated contact would be able to go to that
14 and, I believe, search and find issues.

15 DR. HUNT: You know, a few years back
16 to use an analogy from a car company, Mercedes-
17 Benz made a big deal about a pushing out
18 information on a lot of their patent ideas that
19 they knew they could keep as proprietary. But
20 they also realized, wow, if other people knew how
21 to do this, it would actually save some lives.
22 Little things like having the engine drop down

1 and go under the car instead of into the
2 passenger seat.

3 Do either of you know of any occasions
4 where you said, wow, this may affect Cerner or
5 something else, just the general metaphor that
6 this is something that we should probably let
7 other people know this is the way to do
8 something.

9 Have you ever -- can you think of any
10 occasion where you saw something that the general
11 community might benefit from beyond just your
12 users?

13 CO-CHAIR SINGH: And, David, maybe the
14 question is, if not, then should we be thinking
15 about this as a group that that could be some
16 sort of a measure that we could --

17 MR. RUSSELL: And, Mark, you probably
18 have a comment on it, too.

19 DR. SEGAL: Yes.

20 MR. RUSSELL: I would say it usually
21 goes through some sort of third party kind of
22 brokerage.

1 It's usually not a direct
2 communication, but we would do that through EHRA
3 would be one vehicle for doing some of those
4 things. I can't think of specific examples.

5 DR. SEGAL: I mean, I don't think
6 there's anything organized for that. I think
7 that's one of those things that as folks have
8 talked about the Safety Center or working with
9 PSOs and ways for PSOs to share with each other,
10 there's just -- I don't think there's, you know,
11 or perhaps, again, I can imagine, but don't have
12 any firsthand, that an issue might get shared in
13 Amy or something like that.

14 But; A, one has to be not from
15 firsthand experience, but just my sense is
16 there's going to be a natural desire to be
17 careful about wildly sharing things that are
18 company specific, in part, because how that could
19 be misinterpreted, but I think there's also a
20 recognition that being able to participate where
21 we can learn in a, quote/unquote, safe
22 environment, you know, from others would be

1 beneficial.

2 Again, this is one of those in terms
3 of the scope of the group. I think that's a
4 really important idea.

5 Whether it's something that one wants
6 to attach measurement to, that's another issue.
7 But as we've looked at opportunities for the
8 Safety Center, for example, having that
9 opportunity to share things and where it's really
10 not an issue about one product, but something
11 that people may be seeing with CPOE. I think
12 there's definitely value there.

13 MR. RUSSELL: And just to finish that,
14 I think one of the problems we run into
15 consistently is Mark doesn't know how our system
16 works, we don't know how their system works and
17 that makes --

18 We work really hard not to know, to be
19 honest with you.

20 DR. JONES: Do you know how your
21 system works?

22 MR. RUSSELL: I barely know.

1 (Laughter.)

2 MR. RUSSELL: And I almost retorted
3 back to you I barely do.

4 DR. JONES: It's harder than you
5 think.

6 MR. RUSSELL: It is.

7 CO-CHAIR SINGH: So, do -- should we
8 have a discussion? Should Jesse finish up and
9 then you guys keep your cards up and then we can
10 start back?

11 Okay. Go ahead.

12 DR. HEERMANN: This is Lori Heermann
13 from Intermountain.

14 I just -- we tried at Intermountain
15 Healthcare about 15, 20 years ago to export some
16 of our ventilator protocols to 11 hospitals
17 across the nation. And it was done into three
18 different EHRs, but it was very challenging.

19 And a lot of that had to do with
20 terminology differences, but also the practice of
21 medicine and doctors wanting to take knowledge
22 developed from a different hospital.

1 It took a lot of effort. But, like I
2 said, it was done, but I don't think it was
3 sustained after the study.

4 CO-CHAIR SINGH: Yes, but I think,
5 Laura, I think if you look at the big picture and
6 maybe not getting down to granular level, if Epic
7 discovers especially after meeting -- well,
8 anybody, Epic, NexGen or any other system
9 discovers after reading about sort of the graphs
10 were not done correctly, right?

11 So, that's something then you learned
12 that then you can pass on to not just your own
13 sort of system, but to other systems as well, you
14 know, that we have a problem with graphing.

15 So, I think maybe, David, your point
16 still sort of applies to some high-level things.
17 I think you're looking for here's a great catch
18 that other systems have to know.

19 That's what you're looking for, right,
20 David?

21 DR. HUNT: David Hunt.

22 Everyone will say, oh, my system is

1 different. God knows I heard that so many times
2 when I was developing surgical quality measures.
3 It's just absolutely amazing. I'm special. I'm
4 different, but there really has to be, has to be
5 some generalizable cases of safety issues that I
6 think the community would really benefit from.

7 DR. HEERMANN: So, I can tell you with
8 the experience I had on this protocol study is
9 that it came down to really three things to make
10 them successful.

11 And that is the community taking from
12 Intermountain had to value it, trust it and
13 actually know how to use it. And if they
14 couldn't do those three things, it didn't work.

15 CO-CHAIR SINGH: Okay. All right.
16 We'll go back to Jesse.

17 DR. PINES: Sure. I can finish up
18 quickly and I do want to -- we've got about 15
19 more minutes here. I do want to have a lot more
20 discussion here.

21 But just to touch on some of the high-
22 level areas that Group 2 hit on, we did spend a

1 fair amount of time discussing the process by
2 which clinician has issue and sort of where that
3 goes and sort of the train of how that gets
4 reported within an organization back to the
5 vendor and how responsive that feedback loop is
6 and whether or not we can actually quantify that
7 in some way and put some measurement concepts
8 around the feedback loop and whether that's
9 happening in a timely or in an effective way.

10 We also talked about using Health IT
11 to not only to prevent harm or sort of the
12 negative aspects, but also using measurement to
13 think about how Health IT can be used in positive
14 ways such as clinical decision support and sort
15 of what information is coming out of Health IT
16 and how that's being trended over time.

17 And Laura had a lot of good examples
18 from Intermountain how they trend a lot of the
19 information that comes out of the system over
20 time and how that's fed back to the clinicians.

21 We also have discussion about sort of
22 how, not only sort of what clinical decision

1 support is used particularly to implement things
2 like guidelines, but also how often it's updated,
3 how it's updated and how clinicians are actually
4 notified when actually something changes.

5 And also to get back to David's point
6 about the, you know, it is, you know, if you have
7 -- you can have clinical decision support in your
8 system, but is someone using it?

9 You can have an interoperable EHR, but
10 is it actually giving you useful information and
11 are you actually using it? So, to sort of think
12 at those levels.

13 We also had interesting discussion
14 about the HL7 EHR functional model. And maybe,
15 Laura, you can give us sort of a brief
16 description of that at Intermountain.

17 DR. HEERMANN: Well, I can't say
18 Intermountain uses it, but I know from the HL7
19 hat that I wear that there is a subgroup that has
20 created a document called the EHR Functional
21 Model 2.0. And it is a document that really
22 lists requirements at a very granular level with

1 the should, shall and may of what systems should
2 incorporate and use in their systems.

3 DR. PINES: Let me think if there are
4 any other high-level areas that we hit in our
5 group.

6 There were a lot of specific examples
7 of very specific EHR-related safety issues and
8 how those could potentially be facilitated with
9 measurement, you know, trying to figure out
10 particularly when it comes to safety information
11 and specific information where that information
12 is coming from.

13 For example, you know, allergy
14 information taken by a registration person may
15 not be considered as relevant to allergy
16 information taken by a caregiver.

17 Again, we talked a lot about ongoing
18 training and also sort of how that training
19 actually happens in practice. And actually how
20 the change in management occurs to actually get
21 people to actually engage in, you know, using EHR
22 in a useful way -- using EHRs in a useful way.

1 So, we talked about some potential measures for
2 training.

3 We also spent a fair amount of time
4 talking about sort of from the perspective of the
5 end user. And there was a lot of discussion
6 about the two hours people spend at the end of
7 their shift charting and how that -- how an
8 organization sort of either facilitates that,
9 rewards that or doesn't and sort of an
10 organization's response to the additional work
11 load on the clinicians related to EHR and whether
12 or not that's actually taken into account.

13 In terms of other measurement issues
14 we talked about, you know, measuring adverse
15 events related to EHR and sort of where that
16 information sits.

17 And I think that that's -- that will
18 ultimately be an important quality metric is
19 adverse events related to EHR.

20 One of the major limitations there at
21 least while putting the patient safety and
22 complications hat on from another committee is

1 that some of that complication information NQF-
2 endorsed or, you know, a lot of the patient
3 safety indicators stems from ICD-9 information.
4 And the question is, how do we sort of get the
5 more proximal information that comes directly
6 from the clinician where the clinician knows or
7 has a hunch that this error is actually from an
8 EHR-related or design issue and actually sort of
9 being able to measure and quantify that and
10 assure that that information gets addressed in a
11 timely manner.

12 We also from an external regulations
13 point of view, we talked a little bit about the
14 Joint Commission. And the Joint Commission
15 actually does have some standards associated with
16 accreditation that could potentially translate to
17 measures.

18 I think was it, Laura, did you talk
19 about that? I forget what the specific comment
20 was about the Joint Commission. I think it was
21 Bill.

22 MR. MARELLA: So, we were talking

1 about the accuracy of clinical documentation.

2 And Gerry made this point before you came in this
3 morning that, you know, there's a whole section
4 of the accreditation standards that deals with
5 the accuracy, timeliness of medical information
6 that applies to electronic documentation as much
7 as paper.

8 So, some of that not regulatory, but
9 some of that expectation was sort of already set
10 in the industry, I think.

11 DR. PINES: And the final area, and I
12 we've touched on this a little bit throughout the
13 discussion, has been on workflow and ensuring
14 that systems are designed with workflow in mind,
15 you know, in a particularly -- and that the
16 various clinicians within an organization
17 understand each other's workflow, you know.

18 The EHR that I use, I can see the
19 physician view. I can't see the nursing view and
20 the medical technician view.

21 So, we're really to, you know, to
22 improve our -- broader understanding of sort of

1 how EHR fits into workflow, you know, with a
2 potential role for human factors engineering and
3 simulation and, you know, and really ensuring
4 that it's sort of optimized in a way that
5 minimizes clicks and that when somebody does
6 figure out a better way to do it, you know,
7 figure out how to reduce your 11 clicks to four
8 clicks, that that information is really
9 disseminated back as a best practice. And that
10 really gets sort of taken up in as a cultural
11 change within an organization.

12 CO-CHAIR SINGH: Great. Shall we move
13 on for the rest of the time? All right. Who's
14 Level 3 representatives?

15 DR. PINES: So, I think we only have
16 a few more minutes. Do we want to --

17 CO-CHAIR SINGH: Do we have public
18 comments?

19 DR. PINES: Yes, I think we have until
20 4:45. So, maybe --

21 CO-CHAIR SINGH: 4:45 is public
22 comments.

1 Do we have any?

2 DR. PINES: So, we'd have to open the
3 phone lines for public comments, but maybe what
4 we could do is sort of have a short discussion of
5 Group 2. Then move into public comment. And
6 then we can have Group 3 go tomorrow morning.

7 Does that sound good?

8 MR. LYZENGA: If there is any
9 discussion of Group 2 additionally. Were there
10 any more comments or thoughts?

11 CO-CHAIR SINGH: A couple of people
12 here had their cards turned up.

13 DR. JONES: Just one thing, David,
14 based on what you said about how do we -- how
15 does Epic share information -- or actually this
16 was a question to Mark as well -- if there's an
17 event that's identified?

18 So, again, yes, patient safety event
19 it's, you know, stop everything, big call, well
20 organized.

21 We actually struggle with all the
22 information that we get from our vendors. It's

1 too much.

2 Even with standard upgrades, we really
3 struggle with trying to figure out, okay, which
4 of these do we want to accept? How do we
5 integrate it with everything else?

6 And I think it's somehow true of just
7 data and healthcare more broadly. It's not a
8 problem of too little information. It's a
9 problem of what to focus upon.

10 So, I really like the idea of best
11 practices, but trying to figure -- sharing those
12 whether they be pertinent solely within safety or
13 more broadly, but we do have to think about how
14 it is that that gets through the noise that's out
15 there because, again, we really struggle with TMI
16 from Epic now and others. We do have Cerner in
17 the lab -- too much information, sorry. That's
18 my daughter. I'm channeling my daughter.

19 (Laughter.)

20 DR. JONES: Every time I get a text,
21 I'm like, oh, no, I need a dictionary.

22 (Laughter.)

1 DR. JONES: But we do and it's -- the
2 volume of information has actually become for us
3 a problem in and of itself.

4 So, I totally love the idea, would
5 love to figure out if we can have a measure --
6 maybe, Laura, you had mentioned with the
7 Intermountain experience and the ventilator
8 protocols, you know, how do you have measures
9 that help you figure out how something goes from
10 useful to used on the basis of trust, for
11 instance.

12 It would be really terrific. I don't
13 know how to do that.

14 DR. ZIMMER: Jason, thank you for that
15 point. That's actually interesting to me as well.

16 One thing I would ask is we venture
17 forward and we try to come up with new measures
18 and new mechanisms. Try to look at what's
19 already in place.

20 So, for example, I don't know the
21 politics here. But if EHR is the place to do it,
22 then maybe that is what you do because I think

1 creating one more siloed venue to handle
2 something like this, I mean, part of -- we're
3 already complaining that the government agencies
4 have too many -- too many conflicting measures
5 and regulations and things like that and they're
6 not talking.

7 So, I just, I think we all agree that
8 would be great if we could share at a higher
9 level and find something applicable in a
10 generalizable way. I just question how we go
11 forward with that and to be thoughtful on that.

12 DR. HUNT: David, just along those
13 lines and I wrote down your note that you're
14 struggling with, you know, so much information
15 from the vendors.

16 Is the information from the vendors,
17 is it categorized? I'm thinking about -- and I
18 hate to use this as an example, Microsoft OS
19 updates, you know.

20 You'll get a notice updates are
21 available. You have 116 updates that should be
22 available, you know. 18 are critical and 106 are

1 perhaps useful. And you can actually click on
2 each one and say, no, yes, and, no, nobody really
3 does it, but you actually could if you wanted to.

4 Is the information sorted in any way,
5 or is it -- is there a way -- is it given in a
6 way that could be prioritized particularly around
7 issues of safety?

8 Because one thing I'll point out,
9 things that are -- a lot of times the glaring
10 safety issues don't really knock on your door and
11 say, hey, I'm a safety issue. Sometimes they
12 knock on your door as, you know, oh, something
13 strange just happened, but never happened before.
14 And the next thing you know, Toyota says their
15 cars are on fire.

16 So, is there a way that you can -- I'm
17 hyperbolic. I'm sorry.

18 (Laughter.)

19 DR. HUNT: But is there a way to
20 prioritize some of that?

21 CO-CHAIR SINGH: Jason Jones.

22 DR. JONES: Yes, I think there is and

1 I think we get that information. The challenge
2 is that so many of our systems -- we talk about
3 interoperability between -- I can't remember --
4 Texas and California or something like that, but
5 we have interoperability between the ED and med
6 surg.

7 So, it's very difficult for any one
8 vendor to be able to say, oh, you know, here's
9 how it's going to be critical in your
10 organization. So, it is prioritized. It is
11 bucketed. Still very difficult to consume.

12 And if I might just say one other
13 thing where we were so happy with regulatory
14 government organizations coming together in the
15 past, I think we actually have a precedent for
16 this, the readmission measures totally unrelated
17 in a way to Health IT, but, my gosh, when CMS
18 adopted the HEDIS readmission measure, that
19 solved so many problems for us.

20 Believe it or not within Kaiser
21 Permanente for the three years prior, every
22 discussion about reducing readmission was, well,

1 what counts as a discharge and what counts as a
2 readmission? I mean, it was silly. What if they
3 were only in obs, you know? What if they were in
4 obs with a discharge, but then they come back to
5 obs later?

6 So many discussions. But that simple
7 act of CMS saying we're going to adopt the HEDIS
8 definition was transformative for us. It removed
9 the barriers. It removed the prior discussions
10 that we could not make progress on.

11 So, I think, you know, to your point,
12 we have precedent for having to -- for merging
13 measures and actually seeing the tremendous
14 benefit that could result.

15 It allows us to focus on what were we
16 really trying to achieve here? Really everyone
17 agrees, you know, it's bad to be readmitted. But
18 we spent so much time arguing over the measure,
19 we couldn't get there. And then, you know,
20 people came up and made it that much easier and I
21 think we have that opportunity here as well.

22 CO-CHAIR SINGH: Eric.

1 DR. SCHNEIDER: It was a great
2 discussion in the group. And Jason is reminding
3 me and Laura had mentioned the EHR functional
4 model 2.0 as a potential guideline from which one
5 could build measures.

6 And I don't know maybe there are
7 others in the room that are familiar with that
8 functional model 2.0, and I'd be curious of your
9 reactions to that possibility.

10 It would also be interesting just to
11 know what percentage of the statements in that
12 functional model actually would have a direct
13 relationship to patient safety.

14 Any reactions?

15 CO-CHAIR SINGH: David.

16 DR. CLASSEN: Yes, like Laura I was
17 involved in HL& and building that model. So, and
18 we spent a lot of time on that model hoping that
19 it would be used in certification, which it was
20 for a while and then dropped out.

21 I would say probably 15 to 25 percent
22 of the stuff in there is somehow related to

1 patient safety and we've worked on it for a
2 number of years.

3 And so, I do think it's not a bad
4 place to look for a way to measure things. I
5 agree with what's been said.

6 In addition, I was going to ask --
7 NIS, I think, has done a lot of work in this area
8 and could some of the NIS stuff be harvested for
9 measures as well?

10 We haven't talked much about that.

11 (Off the record comments.)

12 MR. LYZENGA: So, operator, are you on
13 the line?

14 THE OPERATOR: Yes, sir.

15 MR. LYZENGA: Could we see if there is
16 any public comment?

17 THE OPERATOR: Okay. At this time if
18 you have a public comment, please press * and the
19 number one.

20 (Pause.)

21 THE OPERATOR: There are no public
22 comments at this time.

1 MR. LYZENGA: Okay. Thank you. Now,
2 we can move on to our next agenda item. I
3 actually don't have one in front of me.

4 Well, we're adjourning then. I don't
5 know if anybody has any sort of wrap-up thoughts
6 for the day. We are going to as Jesse mentioned,
7 we'll present the third group's sort of findings
8 and discussions tomorrow morning and just do some
9 general wrap-up of the breakout report-outs.
10 Sort of synthesize that a bit, see if we can find
11 some common themes and, you know, conclusions
12 that we can draw from that, directions we can
13 take.

14 So, again, we've got dinner after
15 this. What time is dinner? Six o'clock at a
16 place called Catch 15 right around the corner.

17 Do you guys have any closing remarks?

18 CO-CHAIR SINGH: Elisabeth, do you
19 want to say something now?

20 CO-CHAIR BELMONT: Sure. Well, just
21 to remind everyone, we do have a couple of small
22 homework assignments for you tonight.

1 If you would take a look at the
2 revised definition of Health IT. If you would
3 also take a look at the SAFER guides.

4 Then in terms of cross-pollinization
5 on the breakout groups that we have, for those of
6 you who weren't participating in a particular
7 breakout group, if you have additional comments
8 to share, please bring those tomorrow.

9 And after we have the comments on
10 Breakout 3 if there are any other additional
11 comments, we can catch those at the time if we
12 have a few extra minutes.

13 CO-CHAIR SINGH: And, again, I would
14 encourage everybody to think about, you know, a
15 bit more sort of after having this broad
16 discussion and, Jesse, maybe putting you on the
17 spot for a couple of minutes, too, what would be
18 the five or ten areas that you think are, you
19 know, key or ripe for moving this measurement
20 agenda forward?

21 You can talk about it now or tomorrow.
22 Whatever you want to do.

1 DR. PINES: Sure. So, also just for
2 the process here, you know, the way that we were
3 conceptualizing this is that we're still very
4 much in the brainstorming phase and really are --
5 the goal for tomorrow is to again get everything
6 out on the table, get all the different concepts.

7 The team and the -- with the help of
8 the Committee will go back to organize that
9 information.

10 And then I really sort of see the --
11 our next in-person meeting as the time that we
12 really prioritize.

13 So, essentially we're going to take a
14 lot of these ideas, lay them out, you know, in
15 some useful way and then we'll use sort of our
16 next one to prioritize and then come up with
17 specific recommendations.

18 So, I think at this point if we want
19 to hold on specifically saying which works at the
20 top --

21 CO-CHAIR SINGH: I just want to make
22 sure that you didn't sort of already think about,

1 okay, we have to have, you know, measures related
2 to, you know, X, Y, Z.

3 MR. LYZENGA: Catch 15 is -- let's
4 see. Can we put that up on the -- I got it on my
5 -- let me see if I can find it here.

6 DR. PINES: It's 1518 K Street.

7 MR. LYZENGA: 1518 K Street. And
8 here's the address for the dinner up on the
9 screen right now if you want to take that down.

10 And just to let you know, we will do
11 separate checks for that and we'll reimburse you
12 up to \$36 plus one alcoholic beverage is our
13 constraint imposed by our contract. Not our rule.

14 CO-CHAIR SINGH: It's better than zero.

15 MR. LYZENGA: It's better than zero.

16 CO-CHAIR SINGH: Well, thank you,
17 everybody.

18 MR. LYZENGA: Yes, thanks, everybody,
19 and we'll see you tomorrow morning if not
20 tonight.

21 (Whereupon, the above-entitled matter
22 went off the record at 4:48 p.m.)

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In the matter of: HIT Safety Committee

Before: NQF

Date: 02-18-15

Place: Washington, DC

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