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 MENDELSOHN, JD, MPH, Consumers Union/Consumer Reports
JAMES RUSSELL, RPh, Epic
ERIC SCHNEIDER, MD, MSc, RAND Corporation
MARK SEGAL, PhD, GE Healthcare
KAREN PAUL ZIMMER, MD, MPH, FAAP, Independent Consultant, Health IT, Patient Safety and Quality

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

(8:34 a.m.)

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

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

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

in making the SAFER Guides.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MS. MENDELSOHN: Hi. This is Dena Mendelsohn. I am here from Consumers

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

research in wrong patient errors.

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

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

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

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

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

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

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

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

And so my disclosures, probably all of

those areas.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

figure I should take care of a bit of housekeeping.

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

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

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

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

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

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

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

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

We have a variety of activities and

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

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

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

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

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

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

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

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

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

date.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

There is increasing concern over what

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

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

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

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

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

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

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

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

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

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

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

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

system downtime rate, or other sort of related issues.

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

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

So, any questions, initially on those

preliminary results or just reactions or feedback?

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

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

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

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

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

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

NQF process.

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

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

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

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

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

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

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

somebody else?

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

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

CO-CHAIR SINGH: Yes, and this is

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

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

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

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

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

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

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

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

MR. LYZENGA: Yes, absolutely.

CO-CHAIR SINGH: Bill.

MR. MARELLA: Hi. Bill Marella.

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

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

So, I mean those are the things that

could potentially be captured as well.

MR. LYZENGA: Thank you.

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

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

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

DR. HRIPCSAK: George Hripcsak. First, a high-level comment. First of all, thank you for the excellent environmental scan or draft of it.

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

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

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

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

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

DR. HRIPCSAK: Okay.

MR. LYZENGA: Dena?

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

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

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

MR. LYZENGA: Yes, we will do.

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

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

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

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

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

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

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

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

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

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

DR. SCHNEIDER: Just one other thing

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

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

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

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

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

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

MR. LYZENGA: Okay.

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

MR. LYZENGA: Yes.

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

But I would argue that as a practicing

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

CO-CHAIR SINGH: Fifty is low, actually.

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

DR. BURSTIN: Yes, the context changed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Karen?

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

think they need to be addressed in our document.

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

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

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

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

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

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

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

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

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

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

CO-CHAIR SINGH: David.

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

CO-CHAIR SINGH: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CO-CHAIR SINGH: Well, Karen, I think

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

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

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

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

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

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

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

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

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

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

Jason and then Bill.

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

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

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

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

CO-CHAIR SINGH: Jason Jones and then David.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

can have our cake and eat it too.

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

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

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

DR. ADELMAN: So, I guess my comment

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CO-CHAIR SINGH: George?

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

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

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

things?

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

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

CO-CHAIR SINGH: Any other comments?

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

keeping our focus tightly on electronic health records and related.

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

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

Andrew, over to you.

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

Segal on the vendor perspective.

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

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

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

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

CO-CHAIR SINGH: Welcome back, everybody.

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

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

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

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

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

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

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

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

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

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

month or so.

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

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

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

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

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

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

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

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

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

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

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

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

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

submitted from across the VA hospitals around the country.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ignored.

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

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

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

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

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

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

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

the predefined criteria, we have actually identified those instances.

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

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

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

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

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

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

And then we build measures, and I

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

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

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

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

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

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

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

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

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

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

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

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

DR. ADELMAN: Yes.

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

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

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

Let's talk about definition. Any

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

George.

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

CO-CHAIR SINGH: Yes.

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

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

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

Okay. Any other quick reflections?

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

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

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

So we want to call it safety concerns because it broadly encompasses a lot of the things that we were talking about -- and actually that was consistent with the AHRQ common format because, as probably David Classen will tell you, that is a term that we didn't invent this. Somebody else thought of this. Great. So we can now sort of define what we want to sort of do in their sort of language.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CPOE helps sort of close the loop

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

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

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

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

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

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

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

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

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

would be growing a long way quickly.

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

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

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

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

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

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

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

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

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

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

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

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

This is the page that shows you the

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

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

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

automated measurement of patient ID issues.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. LYZENGA: There were several people --

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

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

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

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

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

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

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

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

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

important.

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

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

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

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

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

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

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

CO-CHAIR SINGH: Yes.

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

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

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

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

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

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

illiterate.

(Laughter.)

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

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

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

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

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

And we did think a lot about structure

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

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

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

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

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

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

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

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

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

So, we could design really elegant IT

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

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

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

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

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

Karen?

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

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

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

the pharmacy as well.

CO-CHAIR SINGH: Nana?

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

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

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

CO-CHAIR SINGH: The framework?

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

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

Patient satisfaction and also workload for the provider.

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

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

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

Helen, last word?

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

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

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

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

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

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

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

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

(Laughter.)

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

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

CO-CHAIR SINGH: Oh, sorry.

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

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

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

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

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

So, over to Elisabeth.

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

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

framework.

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

prevent it from happening again.

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

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

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

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

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

available.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

monitoring systems after implementation to track errors and close calls.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

So, I think what we have here is an

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

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

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

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

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

And what the parties could potentially

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

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

intellectual property protections.

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

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

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

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

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

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

thoughts and questions.

David?

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

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

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

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

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

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

Kim? Oh, Karen. Sorry.

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

not have everything be hospital or organization-based.

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

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

Eric?

DR. SCHNEIDER: Elisabeth, Eric Schneider.

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

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

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

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

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

in state regulation in this area.

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

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

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

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

it would move the dialogue along.

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

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

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

of technology as they processed Butterball turkeys.

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

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

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

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

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

DR. ALEXANDER: Sure, I can do that.

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

David?

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

IT safety center?

DR. DIMITROPOULOS: Discussions about the vendor?

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

(Laughter.)

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

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

And that is just one approach but I

think it is an important discussion and conversation.

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

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

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

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

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

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

word for word what you have there.

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

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

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

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

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

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

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

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

So, Bill?

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

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

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

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

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

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

James.

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

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

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

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

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

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

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

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

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

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

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

CO-CHAIR SINGH: Yes, I just want to

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

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

measure.

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

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

CO-CHAIR SINGH: Yes.

CO-CHAIR BELMONT: Right. You know in

the design implementation and use phases.

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

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

CO-CHAIR SINGH: Absolutely.

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

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

CO-CHAIR BELMONT: Oh, okay. Sorry.

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

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

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

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

DR. SEGAL: Thank you.

MR. LYZENGA: Not a problem.

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

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

And you know I think one of the key points, we are all, companies doing things, view ourselves as part of the healthcare community. And so as such, we are absolutely committed to patient safety. And then, again, looking at how things have evolved, I think we have been very much convinced and taken with the notion, you know the concepts, and taken to hear about the culture of safety, about particularly a non-punitive culture of safety, some of the work that has gone on with PSOs, and about the sociotechnical view that they are really both from a lifecycle standpoint, in terms of the lifecycle of the use of health IT and the various participants that there are multiple participants in that lifecycle that have, to Elisabeth's point

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CO-CHAIR SINGH: Twenty-eight pages.

DR. SEGAL: Twenty-eight pages. That's short for us.

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

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

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

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

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

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

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

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

coming in.

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

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

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

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

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

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

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

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

of hierarchy of criteria for selecting measures that this issue of the usability of the measures, whether they can actually draw on data that is already being collected for other purposes. Because again, we still have that with sort of EHR-based collection where initially it was well, it is so much better to do quality measure from an EHR rather than to have to do paper abstraction, because we have already got the data there. And then that quickly shifts to oh, gosh, we can add new data elements to the EHR to support the measure we are interested in. And there is a temptation there. And I think we just need to be aware of that.

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

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

kind of highlight that.

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

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

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

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

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

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

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

CO-CHAIR SINGH: Yes, I would just

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

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

DR. PINES: Any additional questions or comments?

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

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

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

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

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

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

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

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

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

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

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

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

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

Now, the second group, Using IT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

So, we actually would like to just get

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

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

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

DR. HAYNES: I'll go to A.

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

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

will break out into groups now.

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

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

MR. LYZENGA: Yes.

CO-CHAIR SINGH: Okay.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

nominated me to do it.

(Laughter.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

what the issues are, and then rectify those. That is very rarely, if ever, done in a clinical setting.

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

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

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

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

what? I don't know.

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

So, for example, if you're an ER doc, there's a higher risk. So, there's obviously the system needs to be considerably more -- the system always needs to be usable, but usability is higher there.

And so, we only got to Four. That's how spirited the discussion was. If I kept them longer, they would have started throwing things and it would have been bad.

So, people was the last one. Within this phase of HIT safety, what are the issues involving design, development, implementation and use?

The biggest issue was training the

support staff for both providers and patients. That was key with patients as well as providers.

There's a scarcity of people that are trained to actually provide key support. And the different job roles that people play in the course of a clinical environment, each of that role has a different interface and are they trained all identically, or are they trained specifically on that interface?

What are some potential solutions? Identify training needs for every stakeholders and then developing proper support in case there are issues like a help desk and making sure those tickets are open and closed within an expeditious fashion.

What are some barriers for addressing those issues? The end user is not necessarily part of the development. They're not really looking at front-line staff.

I remember I mentioned this story that several years ago I visited Texas Health Resources. I'm sure a lot of you are familiar

with that. It's a very large Epic shop. They have, I think, spent $750 million on Epic.

And they did -- we interviewed many doctors, many nurses and they all generally said the same thing that they were never involved -- the testing was -- the testing was not -- the system was done in a lab. It was not actually done in the hospital.

So, what they were doing in a laboratory environment or a training environment was not what they normally do when they're actually in the hospital setting itself.

What are some potential measures for addressing this dimension? What are your FTE requirements for training? How many hours of training are actually required? What is the ticket response time for the help desk? Are you doing appropriate simulation testing and are you doing competence testing?

And we have to sort of define what "competence" means, but are you developing a threshold of competence to make sure you have an

understanding of the system and how the system should be used.

And that is, unfortunately, as far as we got, but I thought we got a lot done. So, again, I thank the group very much.

Is that okay? Mark, are you alright with that? You're sure? All right.

(Comments off mic.)

MR. GOLDWATER: I've known Mark for a while. So, I have no reservations about saying ---

DR. HUNT: I just have one question.

MR. GOLDWATER: Sure.

DR. HUNT: You used one phrase, and I want to make sure that I understand it correctly and clearly.

You said "proprietary issues of clinical data."

MR. GOLDWATER: Uh-huh.

DR. HUNT: Proprietary issues of --- so, there's clinical data that is proprietary. It is almost an oxymoron that someone would say

that my data as a patient is their proprietary information.

Is that what you were saying?

DR. SEGAL: (Comments off mic.)

MR. LYZENGA: Use the mic.

DR. SEGAL: Oh, sorry. Mark Segal.

When we're talking about clinical content, we talk broadly about anything from the physician note in the record or labs that were entered, to the content that might be used to support things like clinical decision support. And the proprietary involve that external content, drug-drug interaction databases.

DR. ALEXANDER: Just an example we talked about was the INTERACT tool. So, we have implemented the INTERACT in several facilities and another research project I'm involved in and there have been questions about how much we could change the details of that tool, which is a clinical document, sort of an architecture way to document, and it's a proprietarily-owned document.

And so, you know, that's a good question that you sort of pose there, you know, how much can you change and if it's clinical data and who owns the clinical data and that kind of thing.

CO-CHAIR SINGH: So, Jason, Greg, to sort of recap, and I can on behalf of you pick on the rest of 15 members who have not spoken as yet, to see what else they would like to add specifically in terms of sort of the third bullet, right?

So, what are the few key areas that you would then say for, you know, Level 1, you know, safe technology? What would be the areas we would focus on in terms of measure development?

I don't think we need exact measure, you know, X percentage of this and X percent of that.

Just let's just think through five, ten, eight, seven, come up with maybe some areas that we can say concretely these are the eight to

ten areas which will help the group move forward.

And if you want to think through this and have a discussion until later, we could do that, but I think I'm going to challenge every group to try to do that in order to move us forward.

MR. LYZENGA: We'll also have an opportunity tomorrow morning to ---

CO-CHAIR SINGH: Yeah, and you could do that tomorrow after you've ---

MR. LYZENGA: Marinated on it overnight.

CO-CHAIR SINGH: But they'll get a chance to ---

MR. GOLDWATER: So, I mean, I think that my observation was the issues that really brought up the most discussion, the ones that we were really involved with really had to do with human-computer interface with people and then, I think, with clinical content.

I mean, we spent a lot of time with hardware and software, but I think we --- and I

think that's always an issue and it's an issue that we can focus on, but those were really the three domains that a substantial amount of time and feedback was getting --- was circulating throughout the group.

And, I mean, does anybody else want to sort of comment on this? That's where I thought most of our discussion was centered around those three issues.

DR. ZIMMER: This is Karen Zimmer.

The only thing I was going to say is we struggled a little bit initially of what was meant by clinical content. So, we took the more general view of both clinical decision support as well as actual information.

But by the time we finished what we thought belonged in there, it was a rather large area.

CO-CHAIR SINGH: Yeah, I think knowledge, rules, logic, alerts, reminders, all of that should be --- that's my documentation.

DR. ZIMMER: And that's the approach

we took.

CO-CHAIR SINGH: Yeah. So, what would be the areas that you would then say, here's the certain types of measures we could look at?

I mean, this morning, I projected a slide that said, you know, software bugs reported to EHR vendor. So, did you talk about that kind of a relationship between ---

MR. GOLDWATER: We did. I mean, I think, you know, what was really great about --- I know I feel like I'm bragging about my group, but I will.

What I really think was great about it was we would have these discussions. And if they didn't think it could be measured, we would either rethink it through in a way that could be measurable, or we would drop it and move on to another more relevant topic.

I mean, I think that really measuring how we do usability, I think, is fairly important, you know.

There's a million different ways of

doing this and there's a lot of different standards out there about how you test the usability of software and systems.

And I think what we all discussed was is that it's not being uniformly applied. It's not, you know, nobody is saying these are the standards. If you have an EHR, this is what you need to test for in terms of usability and this is how you have to do it and here are the tools that are accessible for you to do it.

And it's sort of more open-ended than that. And I think that's --- we sort of discovered that's what led to problems, because it's not --- there are ways of doing this that are effective that are being used in industry that are not necessarily being applied within the clinical setting. I think that was a big, you know, particular issue.

I think the types of training that are involved, measuring the types of training, the hours of training, how that training is being done, you know, that really will make a

difference in how people are using the system and how that system is being used effectively.

Mark.

DR. SEGAL: Yeah, I guess, to go on record on the usability piece, I think that absolutely there is a major opportunity for companies to enhance their use of user-centered design, but at the same time recognizing that it's really a toolkit that needs to be situationally applied that --- from the standpoint of sort of imposing standards that are translated into hard measures about did you do UCD right, or not?

At least I would be hesitant about that. And I think most of the industry colleagues I work with who are committed to UCD would be. So, I think we need to be careful about what kind of measures we would design to measure kind of the process part of UCD use.

CO-CHAIR SINGH: Jason, did you have a comment?

DR. JONES: Jason Jones. I just had

a question.

So, the usability piece, how did you --- did you have trouble --- I was trying to keep that separate from safe HIT.

We struggled in our group, which is the next group, actually, to figure out how to fit things in the bucket. So, that was something we kind of acknowledged and said we're having a hard time putting things into buckets.

Did you attempt to separate the safe HIT from the safe use of HIT? No? Or do you think ---

MR. GOLDWATER: I think we viewed human-computer interaction as usability. I mean, that was --- they're pretty much tied into one another. So, if you're going to be effective in human-computer interaction, the system in and of itself has to be usable.

It has to be, you know, accessible to the nurse or the physician or, you know, some other sort of clinical worker that is inputting data, and then taking that data out and using it

to make decisions with respect to a patient.

So, I don't think we separated out the issues; I think we looked at this as being intertwined with one another that if you make a system that is usable, that is comprehensible and that provides ease of use to the end user, eventually that will, in theory, at least, lead to safe and effective use of Health IT.

It will prevent some of the errors that come from bad usability design.

DR. JONES: Did you guys have any thoughts on the --- specifically around competence that you had mentioned about how that could be measured and ---

MR. GOLDWATER: So, I will leave that to my colleagues to answer.

DR. ZIMMER: We talked about a few things. We did say to apply different industry tools and that's nice jargon, but what does that really mean?

So, sometimes for usability it could be a survey. There are actually tools out there

that actually see how people's eyes follow the screens. There's actually a possibility --- it's a bit labor-intensive -- but obviously someone could watch you in the work environment to see how you're interacting.

And then we also did talk about if you did some either form of simulations, since a lot of places do have simulation centers now that you could do simulations there, or if you are in a lab. Either way there would be some form of competency where you might have case studies and things where you have to sort of work through it to show that you have some form of competency as part of your credentialing.

DR. ALEXANDER: The only other thing I wanted to add was about content. And we did have some discussions around the differences in the types of contents between different healthcare organizations and, you know, how would you be able to develop a measure for different organizations that collect different content, but they're caring for the same patients.

And so, that's an issue that was hard to think about, but -- so, I think from the standpoint of standards and looking at the way standards have been developed and are being used that there's still some need for content to be more standardized so that systems are more useable.

CO-CHAIR SINGH: Karen.

DR. ZIMMER: I Just want to continue on with what Greg said, because you've brought up a very good point especially with long-term care facilities look at data very differently than the inpatient setting. And more and more particularly as we move towards ACOs and more care being done in the outpatient setting, we all have to increase our education about how other people use information in other settings.

CO-CHAIR SINGH: Okay. I'm going to ask one more sort of question to your group and then it will also be relevant for the others, and maybe we can move on and then come back, because some of these discussions will need to be sort of

built one on top of the other.

But when I was having a brief discussion about, you know, are some of these measures or measurements going to be more at sort of the enterprise level organization-wide, which is sort of clinicians, patients, units, you wanted to speak to that about what you all sort of finally decided or thought? Because I think the other groups will also speak to that.

MR. GOLDWATER: Sure. This is Jason Goldwater.

You know, what was decided was -- and this really came out of the hardware and software issue.

So, when you do a testing, a contingency plan, you know, the first thought was you do it for the entire system. And that way if the system goes down or if there's an upgrade that doesn't necessarily work or, you know, there's a hack or there's a virus that's inserted itself into the enterprise, what do you do? What steps do you go through? What testing do you

need to do to retain the system integrity and to ensure that it is working appropriately in the quickest time possible.

What Karen brought up was there are times when such as the pharmacy system goes down. The system itself doesn't go down, but the pharmacy system drops. But when that drops, it affects everything. And so, what kind of contingency plan do you have to have for that?

Now, most CIOs I would hopefully --- I don't want to necessarily go on record, but I would think all CIOs would develop a plan, a contingency plan and a testing plan that would accommodate that -- that would look at comprehensive enterprise testing as well as unit testing as needed, but I think the point was brought up that that really needs to be specified.

If we're going to measure that, that we really have to look at developing an enterprise plan, but also really looking at individual unit plans and how that would be

tested, because the testing might be different for some of the systems.

And I think that was a point well made, because there are some systems that will drop and that will, you know, if a practice management system drops, that also affects everything. So, how are you going to do that appropriately?

So, that's sort of what we decided that it's sort of a combination of both.

CO-CHAIR SINGH: Jason.

DR. JONES: Jason Jones again.

So, I think the question was --- at least how we had discussed it if you mentioned the competency thing, which I had asked about earlier -- you could have a system or enterprise measure. Do you have competency testing? Yes, no. Answer the question for the entire organization.

Or you could have sort of individual clinician or unit measurements. Does the ED have competency testing? Does ICU have competency

testing? Does nursing? Does pharmacy? Or that could go all the way down to an individual. What chunk of your clinicians of a particular type have undergone competency testing, and what was their level of competency?

I think was that sort of ---

CO-CHAIR SINGH: Yes. Yes. 80 percent --

DR. JONES: Yes.

CO-CHAIR SINGH: -- of our users have competency testing for some, you know, or could that be a measure or something like that. Just putting numbers is hard, but coming up with some concrete measure.

DR. JONES: So, it wasn't really --- so, the system like if the pharmacy system goes down or not, that sort of --- that is an enterprise level. Do you have a backup strategy for a system?

You're not going to have a backup strategy for a small component to the system, but competency could be measured at many levels with

an organization.

So, if there was a measure out there that existed, if NQF was going to say you should have a measure of competency, would that be measured at the institute, entire institution level, or at some granular level?

How would you even have something like that?

DR. ZIMMER: When we were talking about competency just based on that discussion, I took it as that we were talking about it at an individual level.

To be fair, we didn't spend enough time on the competency to address all of the different levels, but that's a good point.

DR. PINES: If I could comment on how NQF approaches that in terms of the measure specification, so each of the measures that goes through the NQF process actually does have recommendations about at what level a measure would be deployed.

So, for example, from clinician all

the way up to health plan being sort of the widest measure.

So, that would be something that would, you know, I think should be addressed and should, you know, potentially go into the report as, you know, sort of who's accountable for what elements of this, be it competency, usability, et cetera.

MR. RUSSELL: Jim Russell.

One question on there would be competency is really great at the beginning, but I think what you really want to be measuring is proficiency over time -- how are users really using the system over time?

So -- because competency is a pretty basic level. You want to make sure that they're actually progressing over time.

DR. SCHNEIDER: Yeah, I actually was going to say the same thing, but I was going to say for a different reason which is that clinicians prefer the word "proficiency" to the word "competency."

(Laughter.)

DR. HUNT: A couple of things that come to mind, I remember a conference with a pharmacy group. And one member pointed out that useable is a little bit broad and it should be useful, useable and used. They are the three areas it really hit.

But in listening to some of the topics that came on, could it be fair --- and, Hardeep, I'll ask you -- would it be fair to characterize a lot of the things as the high outline of the contingency and the organizational or high priorities guide and the SAFER guides?

I'm hearing the topics that were hit really seem to be outlined in that and if that might be a way to think about a lot of this work.

And one more question, because I can't really get a sense from the group. Jason uses a lot of euphemisms. Is it a crime scene down there? Is there blood on the wall?

Will we have to, you know, provide ---

MR. GOLDWATER: If it had gone on for

another 15 minutes maybe, but, no, I'm kidding. It was very engaging.

Very --- I started to use the word "provocative," and then I was like, well, that's not really the right word to be using. Nothing provocative that would ---

(Comments off mic.)

CO-CHAIR SINGH: So, yeah, David, you know, I think at the risk of getting tomatoes shot at me, I would love for people to get a little bit of homework and I think just after this conversation, sort of revisit the SAFER guide.

Especially the high priority and maybe the organizational, the big picture ones because a lot of these issues that we're discussing today are already there, but they are not written specifically in terms of their measures or measurements, but they could easily be converted.

So, just to sort of give you guys more homework to do, just think about doing that in addition to the things that we're saying.

DR. ZIMMER: Hardeep, maybe put them on our site. The website.

CO-CHAIR SINGH: Yeah. The website, yeah. Yeah.

DR. ZIMMER: It seems like a good place.

CO-CHAIR SINGH: Yes, we'll put it.

DR. ZIMMER: Okay. And then can that be part of tomorrow's discussion when we break up in groups?

CO-CHAIR SINGH: Yeah, that will be great.

Moving to Group 2, I think. Anybody else have anything else? David and Jason, you're done, right? Okay.

All right. So, are you doing the ---

DR. PINES: Yes. So, I'm going to be doing the report-out for Group 2. So, Group 2 focused on usability and use. And there were --- I think there was a fair amount of overlap in terms of some of our discussions in terms of the need for usability testing and competency

testing.

One of the --- one comment that I thought was very interesting came from --- sort of from a high-level perspective.

We've got, you know, the sort of system components that we can measure that lead to process measures, that lead to the ultimate outcomes of Health IT. Some of those being sort of positive outcomes such as, you know, are we getting the right, accurate information, are we communicating effectively, or is there a good decision support to negative outcomes such as errors.

And we spend a fair amount of time sort of talking at those different levels what sort of goes into those --- what sort of goes into those buckets.

And so, you know, one of the big factors that we talked about sort of towards the end and also interspersed throughout is sort of the impact of how Health IT on the workflow as people are putting in information into the

system, one of the what were called work-arounds, which are called "scribes," you know.

Because the interface is not particularly easy to use, user-friendly, we have this work-around called scribes, where scribes enter the information for us. And we may not necessarily be leveraging the full --- the best aspects of Health IT, particularly when scribes, you know, may not have the same medical training as the person who's sort of the intended user.

We also talked about specifically when it came to scribes, there could be a measure around making sure that when there are work-arounds like scribes put into place, that they are used appropriately.

The clinical example I gave is that our scribes in the ED are only put in the history of present illness and the past medical history. And then the physicians do the -- put in the physical exam and the orders, and so that when you do have these work-arounds, you do have to sort of use them appropriately.

There was an example of sort of use of Health IT and for --- to facilitate care that came from out of Kaiser, you know. Specifically one of the measures that they use is do patients understand --- or did the physician understand my medical problem and, you know, some of the physicians at Kaiser are actually trained to actually input the information in conjunction with the patient to ensure that that question gets answered in the affirmative.

So, this was an example of sort of a positive way that health IT was used in a positive way.

We also spent a fair amount of time talking about alerts as one of the process measures and whether a certain number of alerts was too many, you know.

Everyone sort of knows that alert fatigue is a major issue. It was mentioned that some clinicians get 50 to a hundred alerts in a day, and that's just too much.

And then, you know, sort of zooming

out from that we talked a little bit about whether or not --- when we talk about holding the organizations, clinicians, vendors accountable -- whether or not we want to use, you know, these outcome measures. So, sort of the ultimate measures of usability, for example, how do clinicians actually rank the usability of the system versus the sort of system component such as do we actually want to, you know, measure alerts as --- and use that as the ultimate measure, you know.

My perspective on that coming out of another patient safety committee through NQF is that the --- specifically when it comes to the NQF criteria, there are algorithms that have been --- that were developed about --- I think about a year and a half ago that are applied to structure and process measures that require a pretty high level of evidence in order to sort of get through the evidence criteria for NQF, where you've got to really sort of definitively link a process to an outcome in order to pass that measure.

So, you know, and I think that that's sort of a good thing to keep in mind for the group as we move forward with this is that, you know, there are certain mechanisms that if we do want to use the NQF mechanism for endorsement, it does have to sort of get through those standards.

And the focus more lately has been on these outcome measures and the, again, one of the great comments that came out of the group, sort of an a-ha moment for me is that when it comes to usability if we can think about where we want to end up and sort of how to measure as close as we can what usability actually means and who can best sort of, you know, give their assessment of how usable a system is, that that may be ultimately where we want to go.

We talked a lot about, you know, a lot of measures of patient experience being, you know, quality metrics these days, you know. Can we think about potentially developing some measures of clinician experience as a target for usability because the, you know, there was a lot

of discussion about the, you know, sort of the complexity of what it really takes, you know, when it comes to the system components and how well the system components perform to the ultimate usability experience.

And, you know, we had, you know, a lot of different opinions about whether or not we should be focusing on system components or the outcomes or, you know, whether or not we can do a combination of the two.

Some of the other areas we talked about, I think, were similar to Group 1. We talked a lot about the --- messed up my slides here.

(Pause.)

(Comments off record.)

DR. PINES: Thanks.

So, we also spent some time talking about sort of two areas of sort of how you --- what usability testing looks like. And Nana had a lot of good examples of what they do at Hopkins and, you know, had a description of the --- of

sort of pre-usability testing that would be the responsibility of the vendor.

And actually we found out from George that actually part of the meaningful use criteria is actually to do usability testing, you know, in order to be certified as a vendor.

But the sort of three levels would be the usability testing before you implement something, the usability during implementation, and then ongoing usability testing and thinking from a measurement perspective how we can potentially create measures about sort of who's responsible for what during those various phases.

You know, certainly the vendor would be responsible for creating the product and maybe that pre-usability testing. And that as a --- over time that that responsibility would become shared because, you know, certainly you can create the best product in the world, but that product will need to be adapted locally to --- for --- to make sure it's interconnected and actually is locally usable.

We also spent some time, similar to the other group, talking about training and what training would look like. Training on two separate levels. One, the initial training getting people up to speed in terms of how --- in terms of whether or not they actually can effectively use the system, but also ongoing training as new system upgrades come into play and particularly through big system upgrades to make sure that people sort of stay up to speed in terms of, you know, making sure that they can continue to use the system.

And also to bring up something that David Hunt said that, you know, when it comes to particularly the interoperability, I think this is --- there was a discussion about the three levels of, you know, is the information there? Is it actually usable? And then is it actually used?

And the example --- I gave some examples sort of locally here in the D.C. area what our regional health information exchange

looks like. It's called CRISP. And also how that's been deployed in Washington state after -- - there was a threat in Washington state where the --- Washington state Medicaid threatened to not pay for more than three ED visits for Medicaid beneficiaries in the emergency department.

And the emergency physicians at a number of the hospital organizations got together to really put a pretty effective health information exchange where they could sort of see metadata.

And it was, you know, and the --- at least some of the feedback from the physicians there was it's actually very useful to know, you know, that someone just left the hospital down the street with a similar diagnosis.

And actually if you, you know, you can log into the system and you can actually see some of the metadata regarding those visits.

Let me see here.

CO-CHAIR SINGH: Should we have other

people reflect by the time you ---

DR. PINES: Sure. Thank you.

CO-CHAIR SINGH: Anybody else from the group want to sort of chime in while Jesse pulls up his slides? Do you want to walk through the system that you have at Hopkins as you were telling us about the usability?

(Comments off mic.)

DR. KHUNLERTKIT: The three different types of usability testing.

CO-CHAIR SINGH: And actually also the reports based off of --- I think you were talking about sort of ticket --- you were talking about some experiences at Hopkins that you guys are doing differently.

Prioritization of tickets ---

DR. KHUNLERTKIT: Oh, I gotcha.

CO-CHAIR SINGH: Yes.

DR. KHUNLERTKIT: So, when there is a problem with the system, usually clinician will put in a ticket to get the system fixed or enhance the function of the system.

And I found that we have a communication gap or lack of understanding between vendors and clinicians of what may be the priority on the list of what to fix.

So, what we ended up doing is forming a group within our healthcare organization based on the area of expertise and have the right people at the table and prioritize the problems for the vendor. And then send that list to the vendor so they can fix it in a timely manner.

CO-CHAIR SINGH: Yes, so we were just sort of talking briefly that could a measure then be developed which would say, do you have such a prioritization mechanism for patient safety-related tickets, for some reason.

DR. KHUNLERTKIT: Yes.

CO-CHAIR SINGH: Something along those terms.

DR. KHUNLERTKIT: And there are actually multiple points of prioritization criteria. So, we put like patient safety and we have the weighting criteria the highest for that

one, productivity of clinicians, financial effect and also some other things.

We roughly have about probably like eight factors for prioritizing the problems, but I don't quite remember all of them.

CO-CHAIR SINGH: So, Jesse, are you ready or -- I mean, I was going to ask our, you know, vendor representative, do you have some sort of an established standard way of prioritizing sort of tickets as you get them?

Is it the same across the --

DR. SEGAL: I'll go from what I know about, which is that -- and, again, we're -- I think I might have mentioned this. We're doing more and more work in an agile framework where I don't really fully understand this, but you comb backlogs or something.

But I think the patient safety issue gets prioritized first, and then, you know, then you're going to be looking at things like how many customers were asking for it, you know.

So, I think it's -- the main thing I

would know about is that if it's a patient safety-related issue, that goes to the top of the queue.

CO-CHAIR SINGH: Even if it's from one person?

DR. SEGAL: Oh, yes.

And, again, one of the things you have to look at, and we find this, is sometimes people identified something as a patient safety issue because they know it will get to the top of the queue. So, you have to review it and see what the situation is. But, yes, even with one person we'll take that seriously.

Now, it may or may not lead to a change in the software. There are other kinds of solutions. It could be something very specific. It could be a training thing or it could be they're giving us an early alert on something that might be more widespread.

CO-CHAIR SINGH: And I'm going to add on a question to that which I would like Jim also to reflect is if you find something substantive,

then how do you communicate that information to all of your other organizations that are using, for instance, like the same version or same system?

DR. SEGAL: Two customers?

CO-CHAIR SINGH: Yes.

DR. SEGAL: I think -- and, again, not every issue that gets raised will necessarily go to every customer, but I think -- I think it's generally going to be done by some combination of mail or email sort of depending on the seriousness of the issue and also what, you know, if there's a fix or if there's something you want the customers to do.

So, I think it's somewhat situational, but I think nowadays it tends to be a mix of email and mail in some cases.

CO-CHAIR SINGH: So, the other thing that I've heard sort of from sort of the field is they're going into these user groups which I don't know if they're monitored or not. And they're trying to like, you know, at the user

group or -- I'm not sure how formal/informal these are and they're exchanging we had this problem and --

DR. SEGAL: So, I can tell you on that, for example, because we've just -- and, Jim, you should weigh in.

So, our user -- like our ambulatory EMR user group is an independent organization. They're not like part of us, they're not staffed by us, but we provide them support.

They have a Listserv that's theirs. And if they post and they share things, we, with their permission, moderate it. And if we see an issue raised that we have something to contribute, our folks will weigh in, but it's basically kind of, you know, an open forum for people to exchange their own experiences.

And, you know, that gets to the earlier questions about gag clauses and all that, but we're trying to monitor those more systematically so we can do really rapid reach-outs.

A lot of times it's more about -- increasingly it's not just about the technology or what the application does, but an interrelationship with services, you know. The ability to send or receive data or submit quality measures.

And so, often it's something that, you know, you need to talk to the customer, assess what's going on, maybe get a field engineer involved.

And we're trying to monitor those closely and do quick, personal reach-outs.

CO-CHAIR SINGH: Thanks. Jim.

MR. RUSSELL: Sure.

DR. SEGAL: You do it entirely differently, right?

MR. RUSSELL: Of course. Same thing, different verse. So, what we do is if anybody calls in and says this is a patient safety issue, that goes through a very rigorous process internally to make sure that we're assessing right away with that customer what's going on

with them and make sure that we understand the problem, one, and number two is that if there's mitigation already.

I think the next thing we do is we really run through the whole process internally and then there's a push-out to all our customers.

And typically what it is, at the customer site they'll have a dedicated people that we will be reaching out to either by email or by phone.

If we can't reach them within certain amounts of time, we have all sorts of escalations that go through making sure we reach them in a certain amount of time.

With what is the problem, this has been found in other customers. We do searches to make sure -- see who it affects based on version, based on the module, things like that. And then send out updates as we learn more information, pushing out that information as we hear it's a new mitigation we maybe discovered in the next last, first day, 24 hours, 48 hours, et cetera,

and move those things through.

And then the same thing like I guess what Mark was saying is we go very active users groups who do work with one another and we have listservs where people post a lot of questions, a lot of things out there.

We moderate. We answer when we have to get an answer to -- moderate and answer those, too.

So, very similar, little different flavor, it's all the same thing.

CO-CHAIR SINGH: Quick, David, and then back to Jesse.

DR. CLASSEN: I just had a question for James and Mark. One of the things we start with the IOM is it didn't appear that people were reporting these issues to the FDA.

And do you guys report these issues to the FDA? And how do you decide if you do, whether you do?

DR. SEGAL: My understanding is for non-FDA-regulated products we don't report to the

FDA, but that the internal processes we have in terms of assessing them, in terms of notifying externally are more or less the same for FDA and non-FDA-regulated products, but I don't believe we report to the FDA on things that we don't have to.

MR. RUSSELL: And having looked at mod data just very recently, it's something we're actually look at whether it's really a value to do it to the mod database.

I would hesitate to say that non-FDA-regulated are really reported to the extent that people may say --

DR. SEGAL: I think the other issue that's come up and I think it goes back to the IOM study and the desire to use sort of a PSO model or what have you is, again, if I'm understanding the FDA requirement in general death and serious injury and that there are a lot of safety-related events that fall below that threshold. And so, you know, I think that the death and serious injury, my guess, happens very

rarely in health IT and is probably a very small subset of the broader set of things that one wants to be tracking.

DR. CLASSEN: The only reason I say that is we struggled with this issue.

We struggle with this issue a lot. And there's a lot of skepticism on the Committee that any system on the FDA was going to set up was going to be very valuable for learning.

So, a big part of our report was on alternate reporting systems or the PSOs rather than the FDA, just so you know that.

DR. HUNT: David Hunt.

Very much along those same lines of questioning, how would a general user that may not necessarily have one reported this issue to you or that you may not know has a similar configuration, is there a general, broad way that is your average user might find out about things that you've corrected, fixed or have issued tickets on that; one, I might not have reported, or; two, you might not know that this will be a

problem for me, but I would love to say, wow, there's a little pearl right there. This is how you do that.

Is there a way that I could -- that you generally make available information that people could -- your users could then benefit from?

MR. RUSSELL: So, the short answer -- that's one of those that there's a really, really long answer.

Short answer, yes. Long answer is typically at the organizational level they have their hierarchy of how things get pushed off to us and how things come back in to them and how they spread those out to their end user and to their community within the organization.

Rather than us blasting Kaiser and I don't even know how many users you have, it normally gets communicated to the organization. The organization makes the decision on how to disseminate that information.

DR. SEGAL: I'd say the one other

thing we have is where we send out notices to customers. And well send out issues on bugs that have nothing to do with, say, I mean, as we communicate, as we put in place, I think, in the last year a services portal. And, again, there's that again, because that's -- it's the services people that typically are the ones who are customer facing that I think basically sort of archives and organizes those kinds of customer communications.

So, Somebody who might not have received it on sort of the push or might not be a designated contact would be able to go to that and, I believe, search and find issues.

DR. HUNT: You know, a few years back to use an analogy from a car company, Mercedes-Benz made a big deal about a pushing out information on a lot of their patent ideas that they knew they could keep as proprietary. But they also realized, wow, if other people knew how to do this, it would actually save some lives. Little things like having the engine drop down

and go under the car instead of into the passenger seat.

Do either of you know of any occasions where you said, wow, this may affect Cerner or something else, just the general metaphor that this is something that we should probably let other people know this is the way to do something.

Have you ever -- can you think of any occasion where you saw something that the general community might benefit from beyond just your users?

CO-CHAIR SINGH: And, David, maybe the question is, if not, then should we be thinking about this as a group that that could be some sort of a measure that we could --

MR. RUSSELL: And, Mark, you probably have a comment on it, too.

DR. SEGAL: Yes.

MR. RUSSELL: I would say it usually goes through some sort of third party kind of brokerage.

It's usually not a direct communication, but we would do that through EHRA would be one vehicle for doing some of those things. I can't think of specific examples.

DR. SEGAL: I mean, I don't think there's anything organized for that. I think that's one of those things that as folks have talked about the Safety Center or working with PSOs and ways for PSOs to share with each other, there's just -- I don't think there's, you know, or perhaps, again, I can imagine, but don't have any firsthand, that an issue might get shared in Amy or something like that.

But; A, one has to be not from firsthand experience, but just my sense is there's going to be a natural desire to be careful about wildly sharing things that are company specific, in part, because how that could be misinterpreted, but I think there's also a recognition that being able to participate where we can learn in a, quote/unquote, safe environment, you know, from others would be

beneficial.

Again, this is one of those in terms of the scope of the group. I think that's a really important idea.

Whether it's something that one wants to attach measurement to, that's another issue. But as we've looked at opportunities for the Safety Center, for example, having that opportunity to share things and where it's really not an issue about one product, but something that people may be seeing with CPOE. I think there's definitely value there.

MR. RUSSELL: And just to finish that, I think one of the problems we run into consistently is Mark doesn't know how our system works, we don't know how their system works and that makes --

We work really hard not to know, to be honest with you.

DR. JONES: Do you know how your system works?

MR. RUSSELL: I barely know.

(Laughter.)

MR. RUSSELL: And I almost retorted back to you I barely do.

DR. JONES: It's harder than you think.

MR. RUSSELL: It is.

CO-CHAIR SINGH: So, do -- should we have a discussion? Should Jesse finish up and then you guys keep your cards up and then we can start back?

Okay. Go ahead.

DR. HEERMANN: This is Lori Heermann rom Intermountain.

I just -- we tried at Intermountain Healthcare about 15, 20 years ago to export some of our ventilator protocols to 11 hospitals across the nation. And it was done into three different EHRs, but it was very challenging.

And a lot of that had to do with terminology differences, but also the practice of medicine and doctors wanting to take knowledge developed from a different hospital.

It took a lot of effort. But, like I said, it was done, but I don't think it was sustained after the study.

CO-CHAIR SINGH: Yes, but I think, Laura, I think if you look at the big picture and maybe not getting down to granular level, if Epic discovers especially after meeting -- well, anybody, Epic, NexGen or any other system discovers after reading about sort of the graphs were not done correctly, right?

So, that's something then you learned that then you can pass on to not just your own sort of system, but to other systems as well, you know, that we have a problem with graphing.

So, I think maybe, David, your point still sort of applies to some high-level things. I think you're looking for here's a great catch that other systems have to know.

That's what you're looking for, right, David?

DR. HUNT: David Hunt.

Everyone will say, oh, my system is

different. God knows I heard that so many times when I was developing surgical quality measures. It's just absolutely amazing. I'm special. I'm different, but there really has to be, has to be some generalizable cases of safety issues that I think the community would really benefit from.

DR. HEERMANN: So, I can tell you with the experience I had on this protocol study is that it came down to really three things to make them successful.

And that is the community taking from Intermountain had to value it, trust it and actually know how to use it. And if they couldn't do those three things, it didn't work.

CO-CHAIR SINGH: Okay. All right. We'll go back to Jesse.

DR. PINES: Sure. I can finish up quickly and I do want to -- we've got about 15 more minutes here. I do want to have a lot more discussion here.

But just to touch on some of the high-level areas that Group 2 hit on, we did spend a

fair amount of time discussing the process by which clinician has issue and sort of where that goes and sort of the train of how that gets reported within an organization back to the vendor and how responsive that feedback loop is and whether or not we can actually quantify that in some way and put some measurement concepts around the feedback loop and whether that's happening in a timely or in an effective way.

We also talked about using Health IT to not only to prevent harm or sort of the negative aspects, but also using measurement to think about how Health IT can be used in positive ways such as clinical decision support and sort of what information is coming out of Health IT and how that's being trended over time.

And Laura had a lot of good examples from Intermountain how they trend a lot of the information that comes out of the system over time and how that's fed back to the clinicians.

We also have discussion about sort of how, not only sort of what clinical decision

support is used particularly to implement things like guidelines, but also how often it's updated, how it's updated and how clinicians are actually notified when actually something changes.

And also to get back to David's point about the, you know, it is, you know, if you have -- you can have clinical decision support in your system, but is someone using it?

You can have an interoperable EHR, but is it actually giving you useful information and are you actually using it? So, to sort of think at those levels.

We also had interesting discussion about the HL7 EHR functional model. And maybe, Laura, you can give us sort of a brief description of that at Intermountain.

DR. HEERMANN: Well, I can't say Intermountain uses it, but I know from the HL7 hat that I wear that there is a subgroup that has created a document called the EHR Functional Model 2.0. And it is a document that really lists requirements at a very granular level with

the should, shall and may of what systems should incorporate and use in their systems.

DR. PINES: Let me think if there are any other high-level areas that we hit in our group.

There were a lot of specific examples of very specific EHR-related safety issues and how those could potentially be facilitated with measurement, you know, trying to figure out particularly when it comes to safety information and specific information where that information is coming from.

For example, you know, allergy information taken by a registration person may not be considered as relevant to allergy information taken by a caregiver.

Again, we talked a lot about ongoing training and also sort of how that training actually happens in practice. And actually how the change in management occurs to actually get people to actually engage in, you know, using EHR in a useful way -- using EHRs in a useful way.

So, we talked about some potential measures for training.

We also spent a fair amount of time talking about sort of from the perspective of the end user. And there was a lot of discussion about the two hours people spend at the end of their shift charting and how that -- how an organization sort of either facilitates that, rewards that or doesn't and sort of an organization's response to the additional work load on the clinicians related to EHR and whether or not that's actually taken into account.

In terms of other measurement issues we talked about, you know, measuring adverse events related to EHR and sort of where that information sits.

And I think that that's -- that will ultimately be an important quality metric is adverse events related to EHR.

One of the major limitations there at least while putting the patient safety and complications hat on from another committee is

that some of that complication information NQF-endorsed or, you know, a lot of the patient safety indicators stems from ICD-9 information. And the question is, how do we sort of get the more proximal information that comes directly from the clinician where the clinician knows or has a hunch that this error is actually from an EHR-related or design issue and actually sort of being able to measure and quantify that and assure that that information gets addressed in a timely manner.

We also from an external regulations point of view, we talked a little bit about the Joint Commission. And the Joint Commission actually does have some standards associated with accreditation that could potentially translate to measures.

I think was it, Laura, did you talk about that? I forget what the specific comment was about the Joint Commission. I think it was Bill.

MR. MARELLA: So, we were talking

about the accuracy of clinical documentation. And Gerry made this point before you came in this morning that, you know, there's a whole section of the accreditation standards that deals with the accuracy, timeliness of medical information that applies to electronic documentation as much as paper.

So, some of that not regulatory, but some of that expectation was sort of already set in the industry, I think.

DR. PINES: And the final area, and I we've touched on this a little bit throughout the discussion, has been on workflow and ensuring that systems are designed with workflow in mind, you know, in a particularly -- and that the various clinicians within an organization understand each other's workflow, you know.

The EHR that I use, I can see the physician view. I can't see the nursing view and the medical technician view.

So, we're really to, you know, to improve our -- broader understanding of sort of

how EHR fits into workflow, you know, with a potential role for human factors engineering and simulation and, you know, and really ensuring that it's sort of optimized in a way that minimizes clicks and that when somebody does figure out a better way to do it, you know, figure out how to reduce your 11 clicks to four clicks, that that information is really disseminated back as a best practice. And that really gets sort of taken up in as a cultural change within an organization.

CO-CHAIR SINGH: Great. Shall we move on for the rest of the time? All right. Who's Level 3 representatives?

DR. PINES: So, I think we only have a few more minutes. Do we want to --

CO-CHAIR SINGH: Do we have public comments?

DR. PINES: Yes, I think we have until 4:45. So, maybe --

CO-CHAIR SINGH: 4:45 is public comments.

Do we have any?

DR. PINES: So, we'd have to open the phone lines for public comments, but maybe what we could do is sort of have a short discussion of Group 2. Then move into public comment. And then we can have Group 3 go tomorrow morning.

Does that sound good?

MR. LYZENGA: If there is any discussion of Group 2 additionally. Were there any more comments or thoughts?

CO-CHAIR SINGH: A couple of people here had their cards turned up.

DR. JONES: Just one thing, David, based on what you said about how do we -- how does Epic share information -- or actually this was a question to Mark as well -- if there's an event that's identified?

So, again, yes, patient safety event it's, you know, stop everything, big call, well organized.

We actually struggle with all the information that we get from our vendors. It's

too much.

Even with standard upgrades, we really struggle with trying to figure out, okay, which of these do we want to accept? How do we integrate it with everything else?

And I think it's somehow true of just data and healthcare more broadly. It's not a problem of too little information. It's a problem of what to focus upon.

So, I really like the idea of best practices, but trying to figure -- sharing those whether they be pertinent solely within safety or more broadly, but we do have to think about how it is that that gets through the noise that's out there because, again, we really struggle with TMI from Epic now and others. We do have Cerner in the lab -- too much information, sorry. That's my daughter. I'm channeling my daughter.

(Laughter.)

DR. JONES: Every time I get a text, I'm like, oh, no, I need a dictionary.

(Laughter.)

DR. JONES: But we do and it's -- the volume of information has actually become for us a problem in and of itself.

So, I totally love the idea, would love to figure out if we can have a measure -- maybe, Laura, you had mentioned with the Intermountain experience and the ventilator protocols, you know, how do you have measures that help you figure out how something goes from useful to used on the basis of trust, for instance.

It would be really terrific. I don't know how to do that.

DR. ZIMMER: Jason, thank you for that point. That's actually interesting to me as well.

One thing I would ask is we venture forward and we try to come up with new measures and new mechanisms. Try to look at what's already in place.

So, for example, I don't know the politics here. But if EHR is the place to do it, then maybe that is what you do because I think

creating one more siloed venue to handle something like this, I mean, part of -- we're already complaining that the government agencies have too many -- too many conflicting measures and regulations and things like that and they're not talking.

So, I just, I think we all agree that would be great if we could share at a higher level and find something applicable in a generalizable way. I just question how we go forward with that and to be thoughtful on that.

DR. HUNT: David, just along those lines and I wrote down your note that you're struggling with, you know, so much information from the vendors.

Is the information from the vendors, is it categorized? I'm thinking about -- and I hate to use this as an example, Microsoft OS updates, you know.

You'll get a notice updates are available. You have 116 updates that should be available, you know. 18 are critical and 106 are

perhaps useful. And you can actually click on each one and say, no, yes, and, no, nobody really does it, but you actually could if you wanted to.

Is the information sorted in any way, or is it -- is there a way -- is it given in a way that could be prioritized particularly around issues of safety?

Because one thing I'll point out, things that are -- a lot of times the glaring safety issues don't really knock on your door and say, hey, I'm a safety issue. Sometimes they knock on your door as, you know, oh, something strange just happened, but never happened before. And the next thing you know, Toyota says their cars are on fire.

So, is there a way that you can -- I'm hyperbolic. I'm sorry.

(Laughter.)

DR. HUNT: But is there a way to prioritize some of that?

CO-CHAIR SINGH: Jason Jones.

DR. JONES: Yes, I think there is and

I think we get that information. The challenge is that so many of our systems -- we talk about interoperability between -- I can't remember -- Texas and California or something like that, but we have interoperability between the ED and med surg.

So, it's very difficult for any one vendor to be able to say, oh, you know, here's how it's going to be critical in your organization. So, it is prioritized. It is bucketed. Still very difficult to consume.

And if I might just say one other thing where we were so happy with regulatory government organizations coming together in the past, I think we actually have a precedent for this, the readmission measures totally unrelated in a way to Health IT, but, my gosh, when CMS adopted the HEDIS readmission measure, that solved so many problems for us.

Believe it or not within Kaiser Permanente for the three years prior, every discussion about reducing readmission was, well,

what counts as a discharge and what counts as a readmission? I mean, it was silly. What if they were only in obs, you know? What if they were in obs with a discharge, but then they come back to obs later?

So many discussions. But that simple act of CMS saying we're going to adopt the HEDIS definition was transformative for us. It removed the barriers. It removed the prior discussions that we could not make progress on.

So, I think, you know, to your point, we have precedent for having to -- for merging measures and actually seeing the tremendous benefit that could result.

It allows us to focus on what were we really trying to achieve here? Really everyone agrees, you know, it's bad to be readmitted. But we spent so much time arguing over the measure, we couldn't get there. And then, you know, people came up and made it that much easier and I think we have that opportunity here as well.

CO-CHAIR SINGH: Eric.

DR. SCHNEIDER: It was a great discussion in the group. And Jason is reminding me and Laura had mentioned the EHR functional model 2.0 as a potential guideline from which one could build measures.

And I don't know maybe there are others in the room that are familiar with that functional model 2.0, and I'd be curious of your reactions to that possibility.

It would also be interesting just to know what percentage of the statements in that functional model actually would have a direct relationship to patient safety.

Any reactions?

CO-CHAIR SINGH: David.

DR. CLASSEN: Yes, like Laura I was involved in HL& and building that model. So, and we spent a lot of time on that model hoping that it would be used in certification, which it was for a while and then dropped out.

I would say probably 15 to 25 percent of the stuff in there is somehow related to

patient safety and we've worked on it for a number of years.

And so, I do think it's not a bad place to look for a way to measure things. I agree with what's been said.

In addition, I was going to ask -- NIS, I think, has done a lot of work in this area and could some of the NIS stuff be harvested for measures as well?

We haven't talked much about that.

(Off the record comments.)

MR. LYZENGA: So, operator, are you on the line?

THE OPERATOR: Yes, sir.

MR. LYZENGA: Could we see if there is any public comment?

THE OPERATOR: Okay. At this time if you have a public comment, please press * and the number one.

(Pause.)

THE OPERATOR: There are no public comments at this time.

MR. LYZENGA: Okay. Thank you. Now, we can move on to our next agenda item. I actually don't have one in front of me.

Well, we're adjourning then. I don't know if anybody has any sort of wrap-up thoughts for the day. We are going to as Jesse mentioned, we'll present the third group's sort of findings and discussions tomorrow morning and just do some general wrap-up of the breakout report-outs. Sort of synthesize that a bit, see if we can find some common themes and, you know, conclusions that we can draw from that, directions we can take.

So, again, we've got dinner after this. What time is dinner? Six o'clock at a place called Catch 15 right around the corner.

Do you guys have any closing remarks?

CO-CHAIR SINGH: Elisabeth, do you want to say something now?

CO-CHAIR BELMONT: Sure. Well, just to remind everyone, we do have a couple of small homework assignments for you tonight.

If you would take a look at the revised definition of Health IT. If you would also take a look at the SAFER guides.

Then in terms of cross-pollinization on the breakout groups that we have, for those of you who weren't participating in a particular breakout group, if you have additional comments to share, please bring those tomorrow.

And after we have the comments on Breakout 3 if there are any other additional comments, we can catch those at the time if we have a few extra minutes.

CO-CHAIR SINGH: And, again, I would encourage everybody to think about, you know, a bit more sort of after having this broad discussion and, Jesse, maybe putting you on the spot for a couple of minutes, too, what would be the five or ten areas that you think are, you know, key or ripe for moving this measurement agenda forward?

You can talk about it now or tomorrow. Whatever you want to do.

DR. PINES: Sure. So, also just for the process here, you know, the way that we were conceptualizing this is that we're still very much in the brainstorming phase and really are -- the goal for tomorrow is to again get everything out on the table, get all the different concepts.

The team and the -- with the help of the Committee will go back to organize that information.

And then I really sort of see the -- our next in-person meeting as the time that we really prioritize.

So, essentially we're going to take a lot of these ideas, lay them out, you know, in some useful way and then we'll use sort of our next one to prioritize and then come up with specific recommendations.

So, I think at this point if we want to hold on specifically saying which works at the top --

CO-CHAIR SINGH: I just want to make sure that you didn't sort of already think about,

okay, we have to have, you know, measures related to, you know, X, Y, Z.

MR. LYZENGA: Catch 15 is -- let's see. Can we put that up on the -- I got it on my -- let me see if I can find it here.

DR. PINES: It's 1518 K Street.

MR. LYZENGA: 1518 K Street. And here's the address for the dinner up on the screen right now if you want to take that down.

And just to let you know, we will do separate checks for that and we'll reimburse you up to $36 plus one alcoholic beverage is our constraint imposed by our contract. Not our rule.

CO-CHAIR SINGH: It's better than zero.

MR. LYZENGA: It's better than zero.

CO-CHAIR SINGH: Well, thank you, everybody.

MR. LYZENGA: Yes, thanks, everybody, and we'll see you tomorrow morning if not tonight.

(Whereupon, the above-entitled matter went off the record at 4:48 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: HIT Safety Committee

Before: NQF

Date: 02-18-15

Place: Washington, DC

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

Neal R Gross

Court Reporter