

NATIONAL QUALITY FORUM

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IMPROVING DIAGNOSTIC QUALITY AND SAFETY  
IN-PERSON MEETING

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TUESDAY  
JANUARY 10, 2017

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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 9:00 a.m., Missy Danforth and Mark Graber, Co-Chairs, presiding.

PRESENT:

MISSY DANFORTH, Vice President, Hospital Ratings,  
The Leapfrog Group, Co-Chair  
MARK GRABER, MD, FACP, President, Society to  
Improve Diagnosis in Medicine, RTI  
International, Co-Chair  
JENNIFER CAMPISANO, JD, Attorney and Patient  
Advocate, Booby and the Beast Blog  
MICHAEL DUNNE, PhD, Vice President, Research and  
Development North America, bioMerieux, Inc.  
DAVID GRENACHE, PhD, Professor of Pathology/  
Laboratory Medical Director, University of  
Utah  
HELEN HASKELL, MA, President, Mothers Against  
Medical Error  
CARLOS HIGUERA-RUEDA, MD, Vice Chair of Quality  
and Patient Safety, Orthopaedic and  
Rheumatologic Institute; Assistant Professor  
of Surgery, Cleveland Clinic  
MARILYN HRAVNAK, RN, PhD, ACNP-BC, FCCM, FAAN,  
Professor of Nursing, University of  
Pittsburgh

MIRA IRONS, MD, Senior Vice President, Academic Affairs, American Board of Medical Specialties

NICHOLAS KUZMA, MD, Attending Physician, Section of Hospital Medicine; Assistant Professor, St. Christopher's Hospital for Children

PRASHANT MAHAJAN, MD, MPH, MBA, Vice-Chair, Department of Emergency Medicine, Section Chief, Pediatric Emergency Medicine, University of Michigan

KATHRYN MCDONALD, PhD, Senior Scholar and Executive Director, Center for Health Policy and Center for Primary Care and Outcomes Research

LAVINIA MIDDLETON, MD, Deputy Chief Medical Officer and Professor, Department of Pathology, The University of Texas MD Anderson Cancer Center

DAVID E. NEWMAN-TOKER, MD, PhD, Professor of Neurology; Director, Armstrong Institute Center for Diagnostic Excellence, Johns Hopkins University School of Medicine

MARTHA RADFORD, MD, MA, Chief Quality Officer, NYU Langone Medical Center

DAVID SEIDENWURM, MD, Quality & Safety Director, Sutter Health

THOMAS SEQUIST, MD, Chief Quality and Safety Officer, Partners Healthcare System (via telephone)

HARDEEP SINGH, MD, MPH, Physician Researcher, Veterans Affairs Center of Innovation and Baylor College of Medicine

NQF STAFF:

JOHN BERNOT, MD, Senior Director

HELEN BURSTIN, MD, MPH, Chief Scientific Officer

TRACY LUSTIG, DPM, MPH, Senior Director

ANDREW LYZENGA, MPP, Senior Director

VANESSA MOY, MPH, Project Analyst

CHRISTY SKIPPER, MS, Project Manager

ALSO PRESENT:

PAUL EPNER, MBA, MEd, Society to Improve  
Diagnosis in Medicine

KERM HENRIKSEN, PhD, Agency for Healthcare  
Research and Quality

DAVID HUNT, MD, Department of Health and Human  
Services

JEFFREY JOPLING, MD, Gordon and Betty Moore  
Foundation

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

2 9:03 a.m.

3 MR. LYZENGA: All right, everybody.

4 I think we are going to get started. Thanks to  
5 everyone for coming. We are really pleased that  
6 you could join our committee and participate in  
7 this meeting. I think we've got a good meeting  
8 planned out here in terms of agenda. We should  
9 have some good discussion. I will hand it over  
10 to our co-chairs to say a few remarks and  
11 welcome. And I think maybe Helen wants to say a  
12 few opening remarks as well.

13 So, go ahead, guys.

14 CO-CHAIR DANFORTH: Good morning,  
15 everyone. I'm Missy Danforth. I'm the Vice  
16 President for Hospital Ratings at Leapfrog and so  
17 excited to be here with all of you today. I  
18 worked with some of you in the past on this  
19 particular topic and other related topics, but  
20 very excited about the work that this committee  
21 is going to be doing over the coming year. So,  
22 thank you.

1 CO-CHAIR GRABER: Good morning,  
2 everyone. My name is Mark Graber. It is a  
3 pleasure to be here. This is a landmark day for  
4 me and I think everybody interested in doing  
5 something about diagnostic error. We have been  
6 talking about diagnostic error now for several  
7 years, but we have a weakest link, and our  
8 weakest link is measurement. Everybody says,  
9 well, how can we start to measure it? And it is  
10 amazing to me we have been practicing medicine  
11 for 2,000 years, and there has never been this  
12 kind of discussion, discussion at this level  
13 about, shouldn't we measure diagnosis? And can't  
14 we measure? And how should we measure? And how  
15 can we improve through measurement?

16 So this is an incredibly important  
17 day. I think what we're doing is really  
18 important work. And I thank you all for your  
19 interest in participating, and a huge thanks to  
20 Helen and the NQF and the NQF staff for hosting  
21 this event and to David for -- thank you David,  
22 for getting this whole thing going. So this is

1 an amazing event, and we really look forward to  
2 working with you.

3 DR. BURSTIN: I'd just add my thank  
4 you as well. Helen Burstin. I am the Chief  
5 Scientific Officer here. It has been a wonderful  
6 -- this is one of the most enjoyable committees  
7 to empanel because it was truly an amazing array  
8 of you who applied. So thank you all for joining  
9 us.

10 Do you want me to just go ahead and do  
11 the script for disclosures as long as we are at  
12 it? Okay.

13 What we are going to do next is we are  
14 going to go around the room and ask each of you  
15 to introduce yourself. Each of you has already  
16 completed a disclosures of interest form that you  
17 shared with NQF. So what we would like you to do  
18 as we go around the room. In addition to  
19 introducing yourself, say where you are from.  
20 Please indicate if you have got any disclosures.  
21 We recognize we picked you because of your  
22 expertise. Expertise does not equal bias or

1 conflict in any way. So, you don't need to share  
2 your full CVs, or we won't ever get any work  
3 done. Because I have seen them. They are great.  
4 They will take a very long time.

5 So just give us the highlights, and  
6 let us know if you have anything in particular, a  
7 financial interest, anything that what you think  
8 would be an important consideration for your  
9 other committee members to know as we have this  
10 discussion over the next couple of days.

11 And with that, why don't we begin with  
12 the chairs? And then we will walk around the  
13 room.

14 CO-CHAIR GRABER: So Mark Graber. I  
15 am an internist. I live in Massachusetts and  
16 California. I have no financial conflicts to  
17 disclose. My day job is through a group called  
18 RTI International, and I am the unpaid volunteer  
19 President of the Society to Improve Diagnosis.

20 CO-CHAIR DANFORTH: Missy Danforth,  
21 again, Vice President for Hospital Ratings at the  
22 Leapfrog Group. Nothing to disclose.



1                   MEMBER CAMPISANO: Jen Campisano. I  
2 am a patient advocate, and I don't have any  
3 disclosures.

4                   MEMBER SINGH: Hi, I am Hardeep Singh.  
5 I'm a patient safety researcher and a general  
6 internist at Baylor College of Medicine and the  
7 Houston VA Center for Innovation. I have  
8 received funding from AHRQ, the Department of  
9 Veterans Affairs, and Office of the National  
10 Coordinator for the work that I may be discussing  
11 in the committee, as well as I have provided  
12 expertise to several healthcare organizations for  
13 giving advice on ambulatory safety.

14                  MEMBER HIGUERA RUEDA: I'm Carlos  
15 Higuera. I am an orthopedic surgeon at the  
16 Cleveland Clinic and their Vice Chair of Patient  
17 Quality and Safety. And I have a particular  
18 interest in research. I have a significant  
19 amount of conflicts because I receive funding  
20 from industry, and I am a consultant for Pfizer  
21 and CD Diagnostics.

22                   I have a particular interest in

1 infection diagnosis, and I have been involved in  
2 their development of new technologies for  
3 diagnosis of infection.

4 MEMBER SEIDENWURM: Hi. My name is  
5 David Seidenwurm. I am a neuroradiologist at  
6 Sutter Health in Sacramento, California. I have  
7 been interested in performance measurement and  
8 appropriateness for quite a long time, and  
9 quality and safety is part of my day job.

10 My principal conflicts of interest are  
11 that I am a radiologist, and I also do a  
12 substantial amount of medical-legal work, much of  
13 which concerns actual medical error, in my  
14 opinion, or accusations of it that are not actual  
15 instances of medical error, in my opinion.

16 MEMBER HRAVNAK: I'm Marilyn Hravnak.  
17 I am a professor at the School of Nursing at the  
18 University of Pittsburgh. I understand I may be  
19 the only nurse on the group. So I am standing in  
20 for Florence Nightingale, I guess.

21 In terms of disclosures, I'm PI on two  
22 R01 grants from NIH. Probably the most

1 interesting relative to the work of this group is  
2 that we are looking at ways to enable nurses to  
3 better detect patient deterioration and  
4 instability at the bedside in order to prevent  
5 failure to rescue.

6 MEMBER NEWMAN-TOKER: David Newman-  
7 Toker, Johns Hopkins, Director of the Center for  
8 Diagnostic Excellence there. And I have  
9 disclosures related to federal grant support for  
10 the work we do related to diagnostic errors and  
11 improving diagnosis from the NIH, AHRQ, and  
12 private foundations, as well as some research  
13 equipment has been loaned to us by device  
14 manufacturers to help us with our stroke  
15 diagnosis research work. I have no other  
16 financial interest in those companies.

17 And I am an unpaid Board member of the  
18 Society to Improve Diagnosis in Medicine. And I  
19 guess my academic conflict of interest is I care  
20 about that.

21 MEMBER MIDDLETON: Good morning. I'm  
22 Lavinia Middleton. I'm a pathologist with sub-

1 specialty expertise in breast diseases. I am  
2 coming from Houston, Texas, where I am the Deputy  
3 Chief Medical Officer of the Medical Affairs for  
4 the Anderson Cancer Center. My area of expertise  
5 is in diagnostic errors and also hardwiring  
6 improvement and measures and accountability in  
7 annual performance evaluations of our faculty.

8 MEMBER MAHAJAN: Good morning. My  
9 name is Prashant Mahajan. I am a pediatric  
10 emergency physician and the Vice Chair of  
11 Emergency Medicine at University of Michigan.

12 My interest in diagnostic errors has  
13 been simulated when I first attended the DEM  
14 Conference five or six years ago. And my  
15 conflicts of interest are I am funded by the AHRQ  
16 for improving diagnosis in the pediatric  
17 emergency medicine realm.

18 DR. HENRIKSEN: Good morning. I'm  
19 Kerm Henriksen with the Agency for Healthcare  
20 Research and Quality. I'm trained as an  
21 experimental psychologist. Most of my working  
22 life, I have worked in the area of human factors

1 and systems engineering. I'm glad to be here.

2 DR. HUNT: Good morning. I'm David  
3 Hunt. I am a general surgeon, and I am Medical  
4 Director for Patient Safety at the Office of the  
5 National Coordinator. I am incredibly happy that  
6 this meeting has actually started. I am thrilled  
7 to see each and every one of you.

8 MEMBER KUZMA: Good morning. I am  
9 Nick Kuzma. I am a pediatric hospitalist in  
10 Philadelphia. I don't have any conflicts of  
11 interest to disclose, and I am equally excited to  
12 be here. So, welcome, everybody.

13 MEMBER HASKELL: I'm Helen Haskell.  
14 I am a patient advocate with Mothers Against  
15 Medical Error and Consumers Advancing Patient  
16 Safety. And I am also co-chair of the Patient  
17 Engagement Committee of the Society to Improve  
18 Diagnosis in Medicine.

19 MEMBER RADFORD: Good morning. I'm  
20 Martha Radford. I am Chief Quality Officer at  
21 NYU Langone Medical Center in New York. Other  
22 than my day job, I have no conflicts of interest,

1       which makes me probably living below the  
2       Manhattan poverty line.

3               I just want to mention also that I am  
4       an active participant in the AMA-sponsored  
5       Physicians' Consortium for Performance  
6       Improvement, who asked me to nominate myself, I  
7       guess, on their behalf. So I am representing  
8       them.

9               MEMBER GRENACHE: I'm David Grenache.  
10       I am a professor of pathology at the University  
11       of Utah and a medical director at ARUP  
12       Laboratories. It is a large national referral  
13       lab that is owned by the University of Utah.

14              I guess that's it. I am very happy to  
15       be here and looking forward to the next few days  
16       of work we have to do.

17              Oh, not conflicts of interest.

18              MEMBER DUNNE: Hi. I am Mike Dunne.  
19       My training, I am a country clinical  
20       microbiologist. I am a professor of pathology  
21       and immunology at Washington University School of  
22       Medicine, a professor of pediatrics at Duke

1 University.

2 My interests are human microbiome,  
3 next-gen sequencing, and metagenomic diagnostics.  
4 And my conflict of interest is that I am  
5 currently Vice President of DMRU, which is an  
6 infectious diseases diagnostic company.

7 MEMBER IRONS: Good morning. I'm Mira  
8 Irons. I am Senior Vice President of Academic  
9 Affairs at the American Board of Medical  
10 Specialties. I am also a pediatrician and  
11 medical geneticist.

12 Before coming to ABMS, I was the  
13 Clinical Chief of Genetics and the Training  
14 Program Director for the Harvard Genetics  
15 Programs at Boston Children's Hospital.

16 My interest in this area is both as a  
17 clinician -- over the years I was involved in  
18 genetic diagnosis of children with rare diseases  
19 and how neurotesting can actually helped with  
20 that. I have lived experienced in how that  
21 neurotesting can also lead to misdiagnosis with  
22 people who don't know how to use that.

1                   On the ABMS side, my interest is how  
2 we can use certification, continuing  
3 certification to help in this area to reach  
4 800,000 physicians.

5                   MEMBER MCDONALD: Hi. I'm Kathy  
6 McDonald, and I am at Stanford University as a  
7 health services researcher, focusing on safety  
8 and quality in measurement.

9                   In terms of conflicts of interest, I  
10 am also a non-paid volunteer at SIDEM on the  
11 Patient Engagement Committee, co-chairing that.  
12 I have funding from AHRQ and the Moore  
13 Foundation, and both of those are related  
14 measurement and quality and safety. So that is  
15 where I come from.

16                  DR. BURSTIN: Great. And I know we  
17 have got Tom Sequist, who is sadly in Boston with  
18 a fever, with us on the phone. Tom, can you do  
19 your introduction and disclosures?

20                  MEMBER SEQUIST: Hello, everyone. I'm  
21 sorry I'm not there with you. My name is Tom  
22 Sequist. I'm the Chief Quality and Safety



1 Officer for Partners HealthCare in Boston. And I  
2 don't believe I have any conflicts but I am  
3 really excited to be part of this. Thanks.

4 DR. BURSTIN: Great. Thank you much.  
5 And we have two guests joining us today, if you  
6 would like to introduce yourselves.

7 MR. EPNER: I'm so glad I don't have  
8 to do disclosures. I'm Paul Epner. I am the  
9 paid Executive Vice President of the Society to  
10 Improve Diagnosis in Medicine and the Chair of  
11 the Coalition to Improve Diagnosis, which is a  
12 32-organization coalition focused on this  
13 problem, and NQF is, hopefully, today signing the  
14 paper to be -- actually, we have 30 now. So  
15 hopefully you will be our 31st. And Gordon and  
16 Betty Moore are going to be our 32nd. So, we are  
17 up to 32 organizations.

18 DR. JOPLING: Good morning. My name  
19 is Jeff Jopling. I am a fellow at the Gordon and  
20 Betty Moore Foundation and a general surgery  
21 resident at Stanford.

22 I have no conflicts of interest

1       because I am here for an alignment of interest.  
2       The Foundation is interested in supporting the  
3       achievement of diagnostic excellence. And in  
4       general, the Foundation is extremely passionate  
5       about measurement and then, specifically, in this  
6       issue, doubly passionate as well so is thankful  
7       to be here.

8                   DR. BURSTIN: Thank you so much for  
9       joining us.

10                   So one quick comment. Thank you for  
11       those disclosures. Obviously, we have assembled  
12       an amazing cast for this discussion.

13                   A couple of you have indicated on here  
14       representing X. You are actually not. You are  
15       representing yourselves. You may have been  
16       nominated by somebody else, but you sit as an  
17       individual. You don't necessarily bring an  
18       organizational perspective. You can bring a  
19       perspective, but you are not speaking on behalf  
20       of anyone else.

21                   And lastly, as you heard those  
22       comments and disclosures, it is also an

1 opportunity if you have any questions of anybody  
2 who has given their disclosures, this would be an  
3 opportunity -- I will leave an open opportunity  
4 for anyone to ask questions. But really, through  
5 the course of the next two days, if you have any  
6 concerns that someone is potentially being biased  
7 or trying to -- in this instance, it's different.  
8 It is not about endorsing or approving measures.  
9 It is really more of a conceptual piece. So it  
10 is less of an issue, but please feel free to come  
11 forward to us or the chairs. It is always easier  
12 to kind of deal with those concerns in real-time,  
13 rather than after the fact.

14 So I will just stop there. If anybody  
15 has any questions of each other based on  
16 disclosures, otherwise, I will turn it back over  
17 to the chairs.

18 Oh, actually, I also want to have the  
19 staff introduce themselves if nobody has any  
20 other questions.

21 Great. All right, well let's do staff  
22 intros, if we could. Go ahead.

1 MR. LYZENGA: Hi. I'm Andrew Lyzenga.  
2 I'm a senior director here at NQF. I have been  
3 here since about 2009. I have worked on a number  
4 of our consensus development projects and MAP  
5 projects and a couple of these types of framework  
6 projects as well. I am very excited to be  
7 working on this.

8 MS. SKIPPER: Good morning, everyone.  
9 My name is Christy Skipper. I am the Project  
10 Manager on this project. I have been with NQF  
11 for almost a year now. I can't believe how  
12 quickly time has flown. But in addition to this  
13 project, I have also done a couple of measure-  
14 endorsement projects related neurological and  
15 surgical topic areas. And I am currently working  
16 on an infectious disease project.

17 But I welcome you all here, and I look  
18 forward to the next two days.

19 MS. MOY: Hello. Good morning,  
20 everyone. My name is Vanessa Moy. I am a  
21 Project Analyst here at NQF, and I have been here  
22 for about four months, and I look forward to

1 hearing your feedback. And I am very excited to  
2 learn more about the NASEM framework and just  
3 hear everyone's feedback. Welcome.

4 DR. BERNOT: Hi. I'm John Bernot,  
5 also relatively new to the NQF. I have been here  
6 for about four months myself. I am a family  
7 physician, and I am really interested in this  
8 project from both a clinician perspective, as  
9 well as a patient perspective.

10 And I just want to thank you all again  
11 for making the trip here to Washington in the  
12 cold.

13 DR. LUSTIG: Hi. I'm Tracy Lustig.  
14 I am also a senior director here. I had a first  
15 career as a podiatrist. I, after that, was at  
16 the Institute of Medicine for 12 years. I was  
17 there when the Report on Diagnostic Accuracy was  
18 happening, but I was not working on it. And then  
19 I came here about nine months ago. So new but  
20 that new.

21 DR. BURSTIN: Thanks. I will turn it  
22 back over to Christy.

1 MS. SKIPPER: Okay, next slide. All  
2 right, and we have kind of already covered this.  
3 Keep going.

4 All right, I will start with the  
5 project objectives. So we have been asked to  
6 convene a committee to develop a measurement  
7 framework to help identify and prioritize  
8 measures of diagnostic accuracy, diagnostic  
9 error. And we are trying to identify and  
10 conceptualize structures, processes, and outcomes  
11 related to this topic. And a measurement  
12 framework is a tool that will help us do that.  
13 The framework will help us organize our thinking  
14 and have a shared understanding of the conceptual  
15 structural for doing our work over the next few  
16 months.

17 As you all know, the National  
18 Academies of Science, Engineering, and Medicine  
19 did a lot of expansive work for thinking about  
20 diagnosis and diagnostic accuracy, and it was  
21 created with a broad acceptance and consensus  
22 among the healthcare stakeholders. But we do

1 have an opportunity to refine this framework just  
2 a bit for our purposes, but we do want to retain  
3 the overall framework. Next slide.

4 So this slide restates a bit of what  
5 I just said, clarifying that we will be  
6 identifying a measurement framework that can help  
7 us identify measures or concepts, identify any  
8 significant gaps, and set priorities for  
9 measurement around diagnostic accuracy.

10 In this project, we will not be  
11 developing a new conceptual framework, nor will  
12 we develop any measures or endorse measures.

13 So over the next two days, we will  
14 hear more about the NASEM framework, and we will  
15 hear from other professionals in the field this  
16 morning about other models or concepts related to  
17 the topic. On Day 2, we will do a deeper  
18 discussion of some of the measures that we have  
19 already identified and then also break you all  
20 into groups for some group work to help us  
21 identify any measures, measure concepts, and  
22 domains. Next slide.

1                   Just a couple of ground rules. If you  
2 would like to be acknowledged, we ask that you  
3 turn your tent card into the vertical position,  
4 and one of the co-chairs will call on you to  
5 speak. And please always use your microphone and  
6 lean in like I am doing now so that you can be  
7 heard. The meeting is being recorded. And also  
8 note that only three microphones can be on at a  
9 time. So once you are done speaking, click the  
10 speak button so that the red button turns off.

11                   And then also throughout the day, just  
12 please openly share and respect differing points  
13 of view. There are no wrong answers. We  
14 appreciate every viewpoint that is represented  
15 around this table, and we definitely want to hear  
16 from you, but we ask that you also avoid  
17 dominating the discussion, and please allow your  
18 colleagues to be heard.

19                   So I will stop right there. Are there  
20 any questions or anything that any members of the  
21 team would like to add? If not, we will jump  
22 right in to -- I'll stop right there.



1 Are there any questions? Okay.

2 MR. LYZENGA: And just to sort of set  
3 the stage here, we have asked a few of your  
4 colleagues on the committee to, and they have  
5 kindly agreed to, present a bit of work that they  
6 have done or been involved in just to sort of  
7 reinforce the background and context within which  
8 we are doing this work and sort of get everybody  
9 up to date to the extent that we aren't.

10 So thanks to our colleagues here who  
11 have agreed to say a bit.

12 Do you want to get started, Kathy?

13 MEMBER MCDONALD: Hi, everybody. Yes,  
14 I was asked to speak a little bit about the  
15 framework that was developed during the  
16 NASEM/IOM/NAM work by the Diagnostic  
17 Accuracy/Diagnostic Error/Improving Diagnosis  
18 Committee. We have been called all those  
19 different things.

20 And as you will remember from the  
21 phone call that we all had together, we were  
22 shown the framework in the state that is up here

1 on the screens in front of us, where failures are  
2 at the top. But this framework was built sort of  
3 in pieces by the committee, and what I wanted to  
4 do is to acquaint you with those pieces, in case  
5 you haven't read every word and page and looked  
6 at every figure in the tome that was that report.

7 So we will start with this, and we  
8 will end up coming back to it. So let's take it  
9 apart. Go ahead.

10 The important pieces are right here.  
11 The definition of diagnostic error, and again, on  
12 our phone call, we talked about that some, but I  
13 will show it to you again. And then the  
14 diagnostic process.

15 So these are the components of the  
16 conceptual model. The work system and factors  
17 that influence the process. And finally, the  
18 outcomes of the diagnostic process.

19 So conceptually, these four bullets  
20 are the parts that we want to drill into and  
21 understand if we are going to think conceptually  
22 about improving diagnosis and diagnostic error.

1 The next one.

2 Again, this was the definition that  
3 you saw as we had the committee call. It is  
4 patient-centered. It draws from other  
5 definitions, but it was a new definition at the  
6 time. It gives a certain primacy to the second  
7 part, to communicate that explanation of what is  
8 known at the time to be as accurate and timely as  
9 possible an explanation of the patient's health  
10 problem. So it has these two components and it  
11 is an Or. It would be a diagnostic error not to  
12 communicate that explanation. It would be a  
13 diagnostic error not to provide an accurate  
14 enough and timely enough explanation of the  
15 patient's health problem, given what is known at  
16 the time.

17 I mentioned on that phone call that it  
18 is worth reading the material around this  
19 definition because no short definition can  
20 capture the nuance of at least what was discussed  
21 by the committee. And I know what we started to  
22 discuss on that last phone call. But I just

1 wanted to point out that the more unique aspects  
2 of this definition are the idea of communication  
3 and the notion that there is sort of a process  
4 and outcome element to this within the idea of  
5 accurate and timely, the process being a little  
6 bit more on the timely side, that there is a  
7 process, and accurate being again constrained by  
8 what is known at the time or what could be known  
9 at the time. Next.

10 So the second big component of the  
11 conceptual thinking and framework is the idea of  
12 a diagnostic process. Again, building on a lot  
13 of other work. The process in these committees  
14 is to look at the evidence that exists and work  
15 from that.

16 The committee spent a lot of time  
17 developing this particular picture, and there is  
18 a lot of words behind this picture, but what I  
19 want to emphasize in terms of understanding this  
20 part of the conceptual thinking is that at the  
21 very bottom, in the smallest of print, but with a  
22 long line, it says time. And time is very

1 important, obviously, in diagnosis. So, in some  
2 ways, that probably should be larger and easier  
3 to see. But I want you all to know that we  
4 shouldn't forget that that's a big part of how we  
5 need to think about diagnosis based on what the  
6 committee was talking about at that stage, that  
7 that mattered. So even though it is small at the  
8 bottom, it is very much part of the conceptual  
9 thinking.

10 Another part of this diagram that I  
11 want to highlight is, before you even get to --  
12 it is easy to sort of look at that big circle in  
13 the middle, which is the idea that there is kind  
14 of a flow of information and integration of that  
15 information and coming up with a working  
16 diagnosis, and it can kind of keep circling  
17 around. So that middle circle, you can sort of  
18 focus in on that and get a lot of attention, and  
19 clinically, that is where a lot of the action is.  
20 It has got the diagnostic testing. It has got  
21 the physical exam, the history. It has got  
22 everything that is in that kind of bull's eye of

1 clinical work, but it doesn't say that it is  
2 clinical work by a team. So I am going to get to  
3 that.

4 It also can attract your attention and  
5 make it harder to see that coming into that  
6 circle is the patient experiencing their health  
7 problem or being concerned that they need to be  
8 checked for something and the patient engaging in  
9 the healthcare system.

10 And then on the other side, you have  
11 this idea of the communication to the patient.  
12 You have some treatment, and you have outcomes.  
13 The treatment can feed back, of course, into the  
14 process. So if you try to sort of dissect each  
15 piece of this, you will see that it follows a  
16 view that would be combining the view of every  
17 member of the team, all the participants who  
18 would be involved in any sort of diagnostic  
19 occurrence.

20 Let's see the next piece of the  
21 conceptual framework, which is the idea that this  
22 process occurs within a work system. And that

1 work system is, again, this is another visual way  
2 of seeing it. The entire external environment  
3 could be affecting that process.

4 Right in the middle of these four  
5 circles is the diagnostic team members, so the  
6 actual people who are involved in the diagnostic  
7 work and the diagnostic process.

8 Around those team members, supporting  
9 them, enabling them, are organizations. There is  
10 the physical environment. There is actual tasks  
11 that are being done, and there is tools and  
12 technologies that can be involved. So this is a  
13 fairly stylized picture, but it is the idea that  
14 the diagnostic process isn't occurring all by  
15 itself.

16 So the next piece, let's drill into  
17 the work system. So right in the middle was that  
18 diagnostic team. And we have two different  
19 visuals in the report about the diagnostic team,  
20 and I think that is -- I'm not sure, actually, as  
21 it was being put together, what the exact sort of  
22 decision-making on it was about in terms of why

1       there were two visuals. So, I am kind of backing  
2       it out from my own thinking and what I recall in  
3       terms of the committee conversations.

4               I think this diagram is there because  
5       of the idea of the centrality of the patient and  
6       family members. So by putting together a diagram  
7       that has sort of the circles within circles,  
8       within circles, it helps us remember that  
9       critical aspect of the conceptual work reflecting  
10      what the committee felt was important.

11             The patients and family members then  
12      are sort of surrounded by diagnosticians. And  
13      again, the word diagnosticians was the idea that  
14      anybody involved in diagnosing is part of a  
15      diagnostic team. And then around that are other  
16      healthcare professionals who are supporting that  
17      diagnostic process. They are not making the  
18      diagnosis, but they are supporting it.

19             So this is one way of thinking about  
20      the diagnostic team. And for measurement I have  
21      to say I think this is pretty important because  
22      it is easy to sort of zero in on the particular



1 conditions that don't get diagnosed correctly, as  
2 opposed to how the diagnosis actually gets made  
3 and who is involved in it.

4 And then the next slide shows the  
5 other picture of the diagnostic team, and it is  
6 the team members. So you know it is focusing on  
7 the actual main sort of reservoirs of people who  
8 tend to be involved in diagnostic work.

9 The patient-primary care partnership  
10 again was emphasized because that can often be  
11 the starting point or the kind of quarterbacking  
12 or coordinating or facilitating hub. And then  
13 other groups are often quite involved in  
14 diagnosis and play major roles. And those are  
15 kind of bucketed again, radiology, pathology,  
16 specialists, and other healthcare professionals.  
17 Next.

18 Okay so now we get to see it starting  
19 to be put back together. So you see on the left  
20 side the diagnostic process sort of journey. The  
21 patient is entering that lovely circle, getting  
22 the communication, the treatment, the feedback

1       that can happen there within the work system, and  
2       all of that producing the outcomes.

3               So now the outcomes are blown up on  
4       this. So that is the last important conceptual  
5       piece. The conceptual model does not ignore  
6       outcomes at all. And the outcomes are pictured  
7       here as those that would relate to either  
8       accurate timely diagnosis -- so if we are trying  
9       to improve diagnosis, we care about accurate  
10      timely diagnosis and we care about the failures  
11      in that, the diagnostic errors and the near  
12      misses. And those are what then produce the  
13      patient outcomes and systems outcomes and produce  
14      the opportunity for learning and feeding back  
15      into the system.

16             So this is the conceptual framework  
17      that was arrived at. We could have stopped  
18      there, but because measurement was also  
19      prioritized as being very important, that is  
20      where the next picture that we started with comes  
21      from.

22             Now you add this idea of where are

1 failures potentially happening, because we want  
2 to understand the causes for diagnostic failures.  
3 And so to put them on this diagram, across the  
4 diagram, allows sort of the beginnings of  
5 thinking about how to do good measurement work in  
6 this area. And the committee couldn't go very  
7 far on that, which is why it is excellent that we  
8 have this opportunity here.

9 The last thing I just want to point  
10 out and acquaint you with, in terms of that  
11 foundational work, in terms of thinking about  
12 measurement of this area, are just a couple  
13 highlights from the chapter on measurement. And  
14 I will show you excerpts, if you advance.

15 So basically the committee had a dual  
16 focus on improving the diagnostic process. So  
17 that would be the improving diagnosis part, the  
18 diagnostic accuracy, the diagnostic quality part,  
19 and reducing diagnostic error.

20 So diagnostic errors were  
21 characterized in such a way that you would want  
22 to think about which aspects of the diagnostic

1 process are susceptible to failures and what  
2 would be the contributing factors to these  
3 failures. It can be factors within the  
4 diagnostic process. It can be factors within the  
5 team. It can be factors related to the work  
6 system and so forth.

7 So, the committee was using its  
8 conceptual model and input from other frameworks,  
9 which we will get to hear about soon, to give a  
10 context for measurement of both the causes and  
11 the risks of diagnostic error. That was the  
12 focus. Measurement can be the focus. It can  
13 focus on both the diagnostic process steps, the  
14 work system components, or both of them in order  
15 to identify causes and risks of diagnostic error.

16 There are two tables in the report.  
17 And what I have done here -- I would encourage  
18 folks to look at those two tables, but what I  
19 have done here is I have just pulled out the  
20 header, you know the columns -- the column  
21 headers in one example. So, this table, Table 3-  
22 2 provided methods for detecting failures across

1 the diagnostic process and looked at where in the  
2 diagnostic process the failure might occur,  
3 trying to say what you are looking for in terms  
4 of a failure.

5 So for example, a failure to engage in  
6 the healthcare system or in the diagnostic  
7 process. Not having the patient be able to  
8 engage in the healthcare system or the diagnostic  
9 process could be a failure point.

10 Then the nature of the failure. That  
11 could be, say, a delay in patient presenting or a  
12 patient unable to access care.

13 And then the methods for detecting  
14 that type of failure. You could analyze  
15 emergency department, urgent care, or other high-  
16 risk cohorts. You could do surveys to determine  
17 why and what could be done differently. So these  
18 are just ideas.

19 And then the other table was methods  
20 of estimating incidence of diagnostic error. And  
21 this gets at the problem of being able to know  
22 what the estimate of how frequently diagnostic

1 error occurs. And, again, the column headings  
2 break down how you would want to think about  
3 measuring where diagnostic error is occurring and  
4 how frequently. So the data source, the key  
5 features of the data source. Methods for  
6 selecting cases for review would be the  
7 denominator, and methods for determining if the  
8 error occurred would be the numerator with some  
9 examples here.

10 So that is a little less related to  
11 when we think about quality measure, but lots of  
12 the problems that have been encountered in terms  
13 of trying to determine the incidence of  
14 diagnostic error, and the data sources that have  
15 been used, and the limits of some of those data  
16 sources, and the limits of the measure you get  
17 from those data sources, a lot can be learned by  
18 that starting point of looking at that table.

19 So that concludes what I wanted to  
20 share to get you acquainted with a little bit  
21 more background on what the committee was  
22 thinking about as they developed those resources.

1 DR. BURSTIN: That was incredibly  
2 helpful. Thank you. It is actually a great --  
3 that big book into like ten slides. That was  
4 awesome.

5 I have a question for you, though,  
6 because this is broader than diagnostic errors,  
7 per se. From your experience of being on the  
8 panel, how do you reflect on how the diagnostic  
9 errors framework reflects to a framework that  
10 would be more about diagnostic quality? There  
11 may be aspects of this that could be positively  
12 interpreted rather than always the error side.

13 Any thoughts on that?

14 MEMBER MCDONALD: Yes. There was a  
15 lot of discussion about needing to basically have  
16 the sea lift all boats and that a complete focus  
17 on diagnostic error would miss opportunities, and  
18 yet not focusing on diagnostic errors misses a  
19 lot of learning opportunities.

20 Ultimately, I think the framework and  
21 the thinking should support both directions. The  
22 report was, ultimately, titled Improving

1       Diagnosis, which reflected the fact that the  
2       ideas to try to understand where diagnostic error  
3       could happen were coming from a place of trying  
4       to think about how diagnosis really works and  
5       where there could be problems in that. So where  
6       are the opportunities for diagnosis to work well?  
7       It is the same conceptual -- it is hard to come  
8       up with a different way of conceptualizing this  
9       space. So yes, I think the panel was giving us  
10      frameworks and thinking that should be useful on  
11      both sides of that same coin.

12                I would be happy to take other  
13      questions or curiosities.

14                CO-CHAIR GRABER: I would just like to  
15      make a few comments, Kathy, if I could.

16                MEMBER MCDONALD: He was there.

17                CO-CHAIR GRABER: We were so happy to  
18      see this framework developed by the National  
19      Academy because it gives healthcare organizations  
20      a way to approach this. They all know how to  
21      tackle process improvement work. And for the  
22      National Academy to say this is a process, and it



1 has got steps, that is really huge. And it will  
2 serve as the basis for what we are trying to  
3 accomplish as well. We need to think about what  
4 are the measurement gaps and the measurement  
5 concepts that could relate to each one of those  
6 steps in the process.

7           There are three shortcomings in this  
8 framework that I think you should all appreciate.  
9 One is it doesn't incorporate the patients'  
10 perspective at all, and Helen will be talking  
11 more about this. So this is great from a  
12 physician and a healthcare organization  
13 perspective, but it doesn't get to what patients  
14 want. Patients want to feel like they are heard  
15 and that they are valued and that they are well  
16 cared for. And I think those are also things  
17 that, ideally, we should be able to measure and  
18 improve upon.

19           Secondly, diagnosis is both a noun and  
20 a verb. So this framework is wonderful for the  
21 verb, the process of coming up with the  
22 diagnosis. But diagnosis is also a label, and

1       this framework doesn't speak to that quite so  
2       much. So we need to keep in mind that label  
3       failures, and David will be talking more about  
4       that and Hardeep, are also an important concept  
5       that we need to tackle.

6               And a third aspect that has bothered  
7       me for a while, this is a question I was asked by  
8       the guy who runs the Palo Alto Medical Clinic.  
9       And he wondered how he could tell which of his  
10      doctors were good doctors and which were not so  
11      good at diagnosis. And his question was what  
12      observable behaviors are there of a physician  
13      that would allow me to tell that they are going  
14      to be doing a good job with diagnosis or they  
15      aren't. And just keep that thought in mind as we  
16      are kind of percolating through these measurement  
17      things. Because at the end of the day I would  
18      love to be able to answer his question, okay,  
19      here is the three things we should be able to do  
20      to answer that.

21              Thank you.

22              MS. SKIPPER: Okay, next up we will be

1 hearing from Hardeep.

2 MEMBER SINGH: So thank you for this  
3 opportunity to present to you.

4 You know, Mark said we have been doing  
5 this for about 2,000 years or longer, and one of  
6 the questions we have always asked in our  
7 research, why now? Why has there been such  
8 little progress in measurement? And one of the  
9 problems is that diagnosis and diagnostic errors  
10 lies at the intersection of several disciplines,  
11 and all of us know what it takes to get several  
12 disciplines to talk to each other in medicine.  
13 So, if you think about this, it is human factors,  
14 cognitive science, implementation science,  
15 sociology, social work, behavioral science, art  
16 of medicine. I mean you could go on and on. So  
17 it has really been a challenge.

18 We are still debating what diagnosis  
19 is. We have changed definitions of diagnosis of  
20 hypertension, diabetes, sepsis. We keep doing  
21 this. And for diagnostic error, it is even  
22 harder where there is confusion about all of

1 these concepts of what the diagnosis means. Mark  
2 brought out label failures. There is probably  
3 tons of other things as well.

4 There is often also confusion, and I  
5 want to highlight this because it is going to be  
6 important for this panel, with processes of  
7 screening and treatment. There is also confusion  
8 with quality and safety. Where are the  
9 boundaries between quality and safety? So I  
10 might say this is a safety problem, whereas  
11 somebody else might say this is a quality  
12 problem. What does that mean?

13 So in our work, we have taken some of  
14 these things into account about uncertainty and  
15 the fact that this is now black and white. And  
16 in fact, I want to show you these are real  
17 comments by front line doctors when the Institute  
18 of Medicine report came out.

19 And if you look at the comments, and  
20 I am going to read each one of them, it shows you  
21 about how much of uncertainty and sort of  
22 grayness there is in terms of diagnosis. And I

1 especially like the bottom comment, where it says  
2 many of the complications introduced by both  
3 medical, legal, and quality improvement efforts  
4 come from treating diagnosis as a black and white  
5 situation. So this is really important for us to  
6 sort of think about as we go forward in our work.

7 So safety begins with measurement. I  
8 think we all would agree that is why we are here.  
9 We are a believers of things should be measured  
10 and improved. It is hard to improve if you can't  
11 measure. But also it is harder to measure if you  
12 don't define the problem that you are trying to  
13 measure. So, I think some of the work that Kathy  
14 talked about, coming up with a definition by the  
15 IOM was very helpful.

16 What we have done in our work is we've  
17 used a very operational definition of diagnostic  
18 error, which really brings around the concept of  
19 missed opportunities in care. So we do a lot of  
20 retrospective analysis using some of the methods  
21 that Kathy was alluding to.

22 Looking at the case, we look for

1       unequivocal evidence that something different  
2       could have been done. That means that there was  
3       a clear missed opportunity to make a correct and  
4       a timely diagnosis. So we really go into details  
5       of that, and we use several methods that we can  
6       talk about later.

7               We also framed the missed opportunity  
8       within the context of an evolving diagnostic  
9       process. So just because you come in with cold-  
10      like symptoms to your doctor three days after  
11      presentation, and the doc says well this is viral  
12      infection, but ten days later now you have a  
13      sinusitis with facial pain and fever, and you get  
14      an antibiotic. Well, that doesn't mean there was  
15      a diagnostic error the first time you went to the  
16      doctor. So we often take into account evolving  
17      situations like that in our work.

18             And the third concept that we try to  
19      sort of think about is this opportunity could be  
20      missed by any members of the healthcare team,  
21      including the patient. So, this could be a  
22      physician or the nurse, or even the system.

1       There is several things a system can do in order  
2       to miss a diagnosis.

3               So thinking about what is important to  
4       patients: patients don't want to be harmed. So I  
5       think for this committee it is important to  
6       realize that, yes, we are always going to be  
7       looking for everything to be done correct and  
8       timely, but, really, it is the Area B that we  
9       should be focusing on, which is harm from delayed  
10      or wrong treatment and harm from delayed or wrong  
11      test, which our patients do not want that in  
12      terms of what we are talking about here.

13              We like to focus on the green area,  
14      where there are clear missed opportunities.  
15      There are several situations, there are rare  
16      conditions, there are several situations it is  
17      not possible to make diagnosis in a timely or a  
18      correct fashion, and we should not be including  
19      those situations in some of the work that we are  
20      going to be thinking about. It is not possible.

21              Now, in 35-40 years it might be  
22      possible to make diagnosis in every condition. I

1 saw that movie in which they put people on the  
2 scanner, you know Passengers, and the diagnosis  
3 comes right out. And there are so many  
4 conditions. Wonderful. I think, Mark, we'll  
5 get to it but not in our lifetime.

6 So we need to be thinking about what  
7 we can actually practically do today.

8 So what are the foundations for  
9 rigorous measurement? Unfortunately, there is  
10 not a lot of good, valid, and reliable data  
11 sources right now, which really limits us.  
12 Whatever we think about must reflect real-world  
13 practice. We need to think about not just what  
14 is in the doctor's head but what is beyond. So  
15 what Kathy mentioned about the team processes.

16 Mark, to your question, the diagnostic  
17 performance is really just individual and system  
18 performance. So we need to sort of take that both  
19 individual and system-centric views.

20 And we need to be thinking shared  
21 accountability beyond just the clinician. So  
22 whatever we think about, we just can't think



1 about just measures that would be physician-  
2 focused. We need to be thinking about systems.  
3 Systems need to set up and step up to the plate  
4 and be measured as well.

5 So this was sort of our thinking over  
6 the years, which led to the Safer Dx Framework  
7 that I am going to present, give you a little  
8 more details on, essentially was I believe  
9 instrumental. I wasn't there. It was  
10 instrumental to the IOM committee's thinking on  
11 what kind of conceptual framework they should  
12 use. And just a couple of highlights I am just  
13 going to mention, since all of you know what  
14 structured process outcomes are.

15 We have used the socio-technical model  
16 where we have eight dimensions we think about.  
17 David is very familiar with that work because it  
18 is used in the health IT circles a lot, where we  
19 think this a socio-technical system, which is a  
20 complex and adaptive system. So we need to think  
21 about technology as well as non-technological  
22 dimensions.

1                   In terms of processes, we think beyond  
2                   just a single provider visit.

3                   And in terms of outcome, this is the  
4                   hard part because you are not thinking about  
5                   missed, delayed, and wrong diagnosis only, but  
6                   you are also thinking of overdiagnosis, and you  
7                   just can't get away from that situation, even  
8                   though we might try hard and say, well, that is  
9                   not a diagnostic error. It is because we often  
10                  struggle between should I order the test or  
11                  should I not order the test. Will I not order  
12                  the test and miss the diagnosis? And if I order  
13                  the test, I will be overtesting. So we can't  
14                  just take that into -- out of the equation.

15                  So we think about all of that. So  
16                  that is what the Safer Dx Framework looks like.  
17                  We call it a measurement framework, but it is  
18                  really an improvement framework. I talked to you  
19                  a little bit about the socio-technical work  
20                  system, but if you look at the process  
21                  dimensions, there is really five things we really  
22                  focus on in our work. And almost all the

1 diagnostic error work we are doing focuses on one  
2 of those five dimensions or actually its  
3 interactive sort of five dimensions.

4 Well one is when you talk to the  
5 patients. So patient-provider encounter. You  
6 make initial diagnostic assessment. When you  
7 order tests, the tests get integrated, or a  
8 radiologist might read the test, or a laboratory  
9 and a pathologist. And then the tests come back  
10 and need to be followed up. So, there is  
11 abnormal tests that will get lost to follow-ups.  
12 That is the third dimension.

13 The fourth dimension is to have a  
14 referral. So we send referrals to sub-specialist  
15 and often, they get lost in the system. So that  
16 is another dimension.

17 And the fifth dimension, which is the  
18 central dimension, is the patient, which is right  
19 in the middle interacting with the other four  
20 dimensions. So in almost all of our work and  
21 measurement, we consider these five dimensions  
22 very useful in the work we do.

1 All of you would be probably familiar  
2 with this. Measurement has to be reliable,  
3 valid. It could be retrospective as well as  
4 prospective. Right now we are still in the  
5 retrospective phase. We are still learning from  
6 what happened in the past. But the goal of this  
7 measurement, I would highlight two things in the  
8 blue box over there. One is organizational  
9 learning, which we are all familiar with, but the  
10 other goal of measurement is better measurement  
11 tools and definitions.

12 So, I think whatever we do in terms of  
13 measurement is going to stimulate better  
14 measurement tools. Because we are still early,  
15 we still have a long ways to go, which should  
16 lead to safer diagnosis.

17 Now, a couple of other things. This  
18 feedback, which we learned from -- you know  
19 improvement feedback that we learned from  
20 measurement, should lead to changes in policy and  
21 practice but also should be feedback back to the  
22 clinicians as well as the systems for improvement

1 as well. So, that is the highlight of the Safer  
2 Dx Framework.

3 What have we learned after a decade of  
4 doing research in the area? Common conditions  
5 being missed. So we are talking about  
6 infections, cancers, cardiovascular conditions,  
7 and some others. It is the common stuff that  
8 gets missed, despite the presence of useful  
9 information that could have led to the correct  
10 diagnosis. So it could be red flags for cancer,  
11 for instance, or clearly something different  
12 could have been done, and there are plenty of  
13 those situations that we can focus on.

14 We have thought that a lot of the  
15 problems are within the patient-provider  
16 encounter dimension, which is where the history  
17 and the physical and all that initial diagnostic  
18 assessment takes place, but a second very  
19 important dimension that we realized from our  
20 work is follow-up of abnormalities or follow-up  
21 of test results, for instance. So these two  
22 dimensions feature very prominently in our work,

1 including patients.

2 Poor calibration is key. And by  
3 calibration I mean we are always constantly  
4 struggling between under- and overdiagnosis.  
5 This is really a problem for clinicians. Should  
6 I order the test? Should I not order the test?  
7 And we cannot forget that.

8 So I think it is time ripe for correct  
9 retrospective measurements. Signals from  
10 routinely available administrative data is quite  
11 weak for the clinical signals you really need to  
12 make an assessment, whether this is a diagnostic  
13 problem or not. We need to think about stronger  
14 signals. So Kathy mentioned high-risk cohorts.  
15 We have looked at several of these cancer  
16 patients. At average, about a third of cancer  
17 patients, no matter what cancer you look at, have  
18 had missed opportunities in their before they get  
19 diagnosed. So, colon cancer, lung cancer,  
20 hepatocellular cancer, no matter what cancer we  
21 look at, it is about a third that had missed  
22 opportunities. So, that is a high-risk cohort.

1                   Test results get missed. The number  
2                   is anywhere from 10 to 36 percent, depending on  
3                   what study you look at. Plenty of test results  
4                   get missed.

5                   We have looked at some triggers. That  
6                   means these return visits, and Kathy even showed  
7                   you a slide with that as well, where patient  
8                   would come back to the same system after being  
9                   seen, let's say in an emergency room environment  
10                  or a primary care environment, where something  
11                  was missed in the first visit, and then they got  
12                  unexpectedly hospitalized. So that is another  
13                  trigger for us. We call these triggers.

14                  We have built triggers for visits, as  
15                  well as missed results. So after an abnormal  
16                  chest X-ray, you expect to see, for instance, a  
17                  CAT scan ordered or maybe a visit to a pulmonary  
18                  physician. But if you don't see that, we have  
19                  built algorithms that use electronic health  
20                  record data to identify patients who may be  
21                  falling through the cracks of the healthcare  
22                  system.

1                   And of course reports from providers  
2                   or patients. I put that there. Patient  
3                   reporting is very, very early. We can talk about  
4                   that later. Even provider reporting is very  
5                   early. I know Kathy has done work in that area,  
6                   but it is hard to get providers to report  
7                   anything about diagnostic error. So I would say  
8                   it is early.

9                   Well, once you identify a record to  
10                  review, how do you determine what is a diagnostic  
11                  error? When you look at the record for a case,  
12                  how do you determine what is a diagnostic error?  
13                  So we have built an instrument which is  
14                  essentially to think about medical record review  
15                  process and to determine whether this is a  
16                  diagnostic error or not. But the same concept  
17                  could be applied to get more objectivity to  
18                  determine whether this is a diagnostic accuracy  
19                  error, safety problem -- we are still figuring  
20                  out what definitions to use, by the way -- and to  
21                  figure out what is wrong. So that is why I think  
22                  we need a structured approach to think about how



1 to do this.

2 So Helen mentioned why not think of  
3 quality, diagnostic quality versus focusing on  
4 just error. And that is what we have done very  
5 recently. There is a paper that I would highly  
6 recommend that you look at, where we just sort of  
7 framed the problem as a safety problem and then  
8 proposed a structure process and outcome  
9 candidate measures and measure concepts -- not  
10 even measures. I would say they are just  
11 measurement concept for people to look at. And I  
12 am actually glad to see that some of them made it  
13 to the framework that you all sent around. So  
14 thank you.

15 So, this is some of the questions that  
16 we asked in the paper. Here are the six  
17 questions that must be answered for thinking  
18 about measurement related to diagnostic accuracy.  
19 And so Mark mentioned one of them, which was  
20 observable behavior. So, I am not going to  
21 repeat that but appropriate time intervals. Can  
22 we agree upon what is an appropriate time

1 interval to diagnose lung cancer, for instance?  
2 Let's raise your hand if you agree to let's say  
3 30 days or 60 days. We could have this exercise  
4 all day long. So we need to think about what is  
5 a standard for diagnosis of a particular  
6 condition.

7 How do we measure competency of  
8 clinical reasoning in a real-world practice  
9 setting? We talked about team behavior.

10 What about system properties? How do  
11 you know whether VA or Kaiser or any other  
12 healthcare system represented in this room has a  
13 good diagnostic performance? How do you do that?  
14 How do we leverage information technology? We  
15 are all collecting IT like data out to the wazoo.  
16 We are using electronic health records. We are  
17 collecting data how to use information technology  
18 to figure this out.

19 And then how do we leverage patient  
20 experiences to help us improve diagnostic safety?

21 So what I kind of have thought about  
22 this is we use what I would say is actionable

1 measurement. That means we are using measurement  
2 for quality improvement purposes and learning  
3 and, of course, for research. And this  
4 translates into feedback at the system level and  
5 maybe at the individual level. We are not really  
6 ready for public reporting performance  
7 measurement or penalties with diagnostic error  
8 measurement right now or even diagnostic safety  
9 or quality measurement just because I don't think  
10 we have the robustness in the science right now.

11 We really need to engage providers,  
12 organizations, patients. Patients are, of  
13 course, are getting more engaged but  
14 organizations are far from engaged in any process  
15 related to diagnosis. This is not one of the  
16 priorities.

17 Providers are already burned out by  
18 measures of all of the kinds and how do we think  
19 about having some measures that could measure  
20 their diagnostic performance.

21 We need to generate evidence and think  
22 about harm, like I have discussed, and safety but

1 also what is diagnostic reliability? How do we  
2 measure uncertainty in this process? So we need  
3 to think about all that.

4 This is my last slide. Let's only  
5 measure if it is actionable for safety. And I  
6 would emphasize safety and think about sort of  
7 the preventable harm.

8 We can think about sharp-end outcome  
9 measures but really the basic science in that  
10 area is very far behind.

11 I think we are getting ready for  
12 blunt-end measurement concepts related to sort of  
13 system-level performance. In the VA recently we  
14 had a policy change for communication of test  
15 results and when is an appropriate time to make  
16 sure that the patients have received their test  
17 results. We came up with a standard, a national  
18 standard. It was by consensus. We came up with  
19 an actual standard and now we have a measurement  
20 system in place that is looking at the entire VA  
21 to figure out how many people are meeting the  
22 measure for communication of test results to

1 patients. So, we came up with a time line: seven  
2 days for actionable, 14 days for non-actionable.  
3 And so most systems don't have this type of  
4 standard.

5 We need to think about measurement  
6 burden and unintended consequences of measurement  
7 but also I would say I think we need much more of  
8 a measured, cautious approach to inform the  
9 measures we are going to be thinking about in the  
10 next few months.

11 Thank you. And many of the papers I  
12 mentioned are on my research profile, if anybody  
13 wants to look at those. And I want to thank my  
14 funders.

15 I'm happy to take any questions.

16 MR. LYZENGA: Yes, questions or  
17 comments or thoughts?

18 MEMBER CAMPISANO: So I have a couple  
19 of questions. You mentioned that there were a  
20 few valid and reliable data sources. What would  
21 count as a data source or what are your data  
22 sources?

1                   MEMBER SINGH: So we look at let's say  
2                   medical records a lot. And so once you, let's  
3                   say develop, once you get to developing an  
4                   algorithm to figure out what medical records to  
5                   look at, so let's say at any system, Palo Alto  
6                   Medical Foundation -- let's pick on them and not  
7                   the VA this time -- would have let's say 100,000  
8                   visits over a period of a week. Which one do we  
9                   look at?

10                   Now once you select -- let's assume we  
11                   build algorithms to select the hundred that we  
12                   want to look at. Then, we have got to look at  
13                   the case to figure out which. How do you  
14                   determine whether this is a diagnostic accuracy  
15                   problem?

16                   So I think in terms of data, there is  
17                   documentation problems. And as many of us know,  
18                   the chart load and copy and paste is making  
19                   documentation worse than it ever was before.

20                   So I think any source we look at, we  
21                   just don't have the robustness of whether the  
22                   source is valid.

1                   MEMBER CAMPISANO: And is that because  
2 doctors don't want to provide them because of  
3 fear or and then you said also organizations  
4 aren't as engaged as they could be and that  
5 patients are starting to be more engaged. What  
6 types of organizations and what do you see as the  
7 reasoning for not being engaged?

8                   MEMBER SINGH: So I think there is two  
9 different problems. One is the sort of the  
10 engagement problem. Let's measure diagnostic  
11 safety. So I think that is an organizational  
12 engagement problem where you could put together a  
13 system of using algorithms and triggers to  
14 identify some high-risk cohorts or start looking  
15 at all the patients who were diagnosed in your  
16 system to figure out how many were late.

17                   So there are things organizations can  
18 do but I think the problem of data is a separate  
19 one. We sort of have documentation issues. We  
20 sort of just don't document very well.

21                   I was reviewing a discharge summary  
22 the other day and it had seven signatures that

1       were copied and pasted into one discharge  
2       summary. And so it was everybody else's  
3       signature and the person who signed it signature  
4       on the bottom. So, just an example of what we  
5       are doing to our progress notes, which is sort of  
6       the standard of care. That is how the court gets  
7       to know what is wrong in a medical record, what  
8       is wrong in the care of a patient.

9               MEMBER CAMPISANO: Thank you.

10              MEMBER IRONS: I am sitting here sort  
11      of processing and thinking about the word time.  
12      And you know we talk about that lower bar of time  
13      that the process occurs but in your framework  
14      where is -- is time -- how is time that is used  
15      to talk with consultants, where does that fall?

16              Because what I worry about is as  
17      medicine has gone from really a collaborative  
18      process to a more sort of see the patient, get  
19      them out, do this process, we have lost that  
20      interaction. You know you can't find  
21      radiologists anymore to have a radiology  
22      conference because they are too busy reading



1 films. You don't have time to call the lab to  
2 talk about how they interpreted the test.

3 And where is that accounted for in the  
4 framework and how do you even measure that? I  
5 just wanted to know how you think about that.

6 MEMBER SINGH: Yes, so you know the  
7 framework is that of a measurement framework.  
8 Once you identify the problem, you then  
9 understand why we are having the problem. So  
10 what you are talking about is a very strong  
11 contributory factor that means we have looked at  
12 sort of primary care records and there were so  
13 many errors that were so common. And one of the  
14 things was people don't have time to talk to each  
15 other anymore and I think this is a very, very  
16 strong contributory factor and I totally agree we  
17 have time-pressured visits. We don't have time  
18 -- we are basically spending time with the EHR.  
19 So there was a study where you were spending more  
20 time with the EHR than you were with the patient.  
21 But I think that is just one of the problems.

22 Even in vignette studies, when

1 physicians have plenty of time to diagnose  
2 patients correctly, we are still not getting it  
3 right. So now we have examples of several  
4 vignette studies that have shown even when you  
5 give them time, still it is not happening. So I  
6 think time is important in the real-world setting  
7 and we should definitely be thinking about this.  
8 But I would say we are having sort of more  
9 problems than just the time because this is where  
10 the competency, the thinking, the cognitive  
11 process, and the information seeking and sort of  
12 the calibration concepts that I was talking about  
13 earlier are also important. And they are all  
14 contributory factors.

15 MEMBER IRONS: Agreed. I agree. But  
16 just as a follow-up to that, I wonder whether, in  
17 terms of competence, you know as testing becomes  
18 more difficult and we worry about that doctors  
19 don't know what we don't know.

20 MEMBER SINGH: Yes.

21 MEMBER IRONS: And should there be  
22 some sort of a discussion that is automatically

1 part of an interpretation of a result? A  
2 physician just can't go to the computer and look  
3 at the MRI and know whether the radiologist's  
4 interpretation made sense in light of the  
5 clinical context or a genetic testing result may  
6 not be what it seems on paper. Is that -- are we  
7 at that point yet or is there a way to measure  
8 that within your system, within your framework?

9 MEMBER SINGH: No --

10 MEMBER IRONS: How people interpret  
11 the results that they are getting from  
12 laboratories and radiologist --

13 MEMBER SINGH: I mean you can look for  
14 that documentation but we often don't find it. I  
15 mean we routinely miss documentation of even  
16 clearly labeled abnormal results. So, we have,  
17 for instance, looked at imaging studies that  
18 clearly have abnormal imaging labeled next to it  
19 and we are sort of still missing that.

20 I think what you are proposing is one  
21 step even further than that, which is looking at  
22 it, coming and saying well, this doesn't make any

1 sense; let me talk to the radiologist. But we  
2 don't talk to the radiologist anymore. We don't  
3 have radiology rounds. We don't talk to the  
4 radiologists anymore and I think the same is true  
5 for the lab community as well.

6 CO-CHAIR DANFORTH: David and then  
7 Martha.

8 MEMBER SEIDENWURM: So from the  
9 radiologist's perspective, I can't agree with you  
10 more. I mean this has really changed. And I  
11 think an analogy from all of our lives perhaps  
12 for the non-clinicians, remember when we used to  
13 pick up the phone and talk for 15 seconds and  
14 figure out where we were going to meet someone.  
15 Now we spend four days texting and we still can't  
16 figure out where we are meeting and when because  
17 the communication is atomized and lacks the  
18 richness of interpersonal communication.

19 So I think that you really are on to  
20 something. Now how precisely we measure that, I  
21 don't know. How exactly we do it, I don't know.  
22 But we definitely have lost something and there

1 is a subtlety of almost a Bayesian dimension that  
2 we lose because in 30 seconds on the phone, the  
3 referring physician will say no, he doesn't have  
4 a fever, this isn't an infection or oh, you know  
5 they mentioned that they were waking up at night  
6 sweating, maybe it is TB instead of a tumor. And  
7 that is the type of thing that comes out in 15  
8 seconds on the phone that won't come out in 15  
9 months necessarily until some disaster happens  
10 through this atomized process.

11 So, if we can figure out a way of  
12 capturing some of that, it happens, actually, in  
13 our practice best in the disciplines where we  
14 have specific clinical conferences, tumor boards  
15 are a big one, pediatric neuroradiology is  
16 another one. In my practice, we have a spine  
17 radiology one, all the other areas have them.

18 But we do need to capture some of that  
19 richness -- recapture I should say some of that  
20 richness, I agree.

21 MEMBER SINGH: And I think you are  
22 right about the time, bringing it back to time.

1 I think we, a lot of times, are not doing it  
2 because we are so focused on just meeting the  
3 documentation requirements and getting that  
4 patient and going from one to the other.

5 We could pick up the phone and talk to  
6 the radiologist or walk down and look for them,  
7 if we have the time.

8 MEMBER SEIDENWURM: Nobody has the  
9 time.

10 MEMBER SINGH: Yes, nobody has the  
11 time. It does come back to time a lot.

12 MEMBER SEIDENWURM: Nobody has the  
13 time.

14 MEMBER MCDONALD: Quickly, from the  
15 framework perspective before. So some of this  
16 would be kind of that idea of the team work, of  
17 course, and some is the working diagnosis. So  
18 there is not a place in current systems of data  
19 collection to kind of capture that evolving  
20 working diagnosis or the reworking and reworking.  
21 So that would be a piece of this, too. If it  
22 were there, then you could look at it and you

1       could see how we are doing.

2                   CO-CHAIR DANFORTH:   Martha.

3                   MEMBER RADFORD:   Just first a comment  
4       about the last few discussion points.  Well, to  
5       me it is quite obvious why this is the case,  
6       which is cognitive work is not reimbursed as  
7       highly as the other work that the people are  
8       spending their time on.  That is just a comment.

9                   I do have a question for Dr. Singh,  
10       which is could you just highlight for us the  
11       differences between your framework and the NASEM  
12       framework?

13                  MEMBER SINGH:   Kathy, I was hoping you  
14       would do that.  No, just kidding.

15                  MEMBER RADFORD:   Or both of you.  I  
16       don't care.  I mean they seem quite compatible to  
17       me.

18                  MEMBER SINGH:   Yes, they are.

19                  MEMBER RADFORD:   If there are any  
20       glaring incompatibilities, I would appreciate  
21       knowing from you.

22                  MEMBER SINGH:   No, I don't think so.

1 CO-CHAIR GRABER: Hardeep's framework  
2 served as the basis for the NAM framework very  
3 clearly.

4 MEMBER SINGH: But I was just in the  
5 appendix, though, which is okay.

6 But what I wanted to highlight is I  
7 think some of the feedback part, I'm not sure how  
8 much of the feedback part was incorporated  
9 because ours is -- we are going to just present  
10 it back. Can you take it back just a few?

11 So, a couple of the things I want to  
12 highlight is I think Safer Dx is a lot more --  
13 firstly, we came up with these five dimensions,  
14 which you know were instrumental in sort of  
15 guiding our work. The socio-technical  
16 dimensions, on the outside, are very similar. We  
17 use 8-dimensional Socio-Technical Model. You use  
18 the Systems Engineering for Patient Safety  
19 Wisconsin Model, which is where the technical  
20 model originated from. So we think that is quite  
21 compatible. The process dimensions you could  
22 sort of just align quite well I think.



1                   The measurement part and the blue  
2                   circle in the middle is clearly a bit different  
3                   because this is what I call the actionable  
4                   measurement type of framework, where you build on  
5                   reliable valid measures but though that  
6                   measurement has to lead to those four things, it  
7                   is collective mindfulness at the institutional  
8                   level, organizational learning which I think  
9                   everybody sort of knows about. Collective  
10                  mindfulness is basically just comes from aviation  
11                  and other human factors literature.

12                 Calibration is something that we think  
13                 which is really, really key and that is alignment  
14                 between the accuracy of my diagnosis and the  
15                 confidence of my diagnosis. So we have shown  
16                 that physicians are very poorly calibrated in the  
17                 sense that even when the diagnosis is wrong, they  
18                 are very confident that the diagnosis is right.  
19                 So we have shown that in a vignette study. So we  
20                 think calibration is important and the better  
21                 measurement.

22                 So I think the measurement focus is a

1 bit heavier in Safer Dx.

2 MEMBER MCDONALD: Yes and I mean I  
3 concur with that, too. This is definitely  
4 measurement-focused and a little bit more  
5 diagnostic error-focused actually.

6 MEMBER SINGH: Yes, error-focused,  
7 yes.

8 MEMBER MCDONALD: So to Helen's  
9 earlier question, I would say that the framework  
10 from the committee gives you -- it is not just  
11 that one picture. It is those four components.  
12 It is the definition. It is the process. It is  
13 the work system and it is the outcomes. So, they  
14 are complementary and, obviously, that framework  
15 tried to build on this but then this gets into  
16 more of the devil of the details, if you are  
17 trying to think about measurement, which this is  
18 where you have to get pretty detail-oriented for  
19 measurement.

20 MEMBER RADFORD: Right. I think that  
21 part of our call here is to focus on the  
22 measurement aspect. So I thank you very much for

1       those comments.

2                   MEMBER SINGH:   And I would just add  
3       that I think the error focus I think point needs  
4       to be sort of also highlighted.   A lot of what I  
5       told you would be very different in terms of  
6       language from some of the discussions.   And I  
7       looked at what you all sent, which is very  
8       quality-focused and I am going oh, my God because  
9       once you start talking about quality, it is like  
10      this can of worms that just opens up and you can  
11      go on and on about diabetes quality.   Are we  
12      doing the hemoglobin A1cs and the retinopathy  
13      screening and all that.   And we want to stay away  
14      -- in our work, we just stayed from all of that.

15                  CO-CHAIR DANFORTH:   David has had his  
16      card up and then Prashant.

17                  MEMBER NEWMAN-TOKER:   I just want to  
18      take us back one comment to something that Kathy  
19      said and reflect on something that Hardeep said  
20      earlier.

21                  So this issue of the working diagnosis  
22      and the sort of time issue, the sort of evolution

1 of the diagnosis from sort of a tentative I am  
2 not really sure but I think it might be something  
3 in this sphere or a differential diagnosis all  
4 the way eventually sort of combing down through a  
5 working diagnosis that is one that you take  
6 action on from a therapeutic standpoint but you  
7 may still be monitoring and then eventually sort  
8 of closing the book on sort of a final diagnosis,  
9 I think that not only have we not captured that  
10 but we are actually almost deliberately getting  
11 rid of it. And this gets back to Hardeep's point  
12 about data quality and data sources.

13 So one of the key problems that is  
14 actually quite simple in some sense is that we  
15 don't even keep track of what the chief complaint  
16 is. The symptoms the patients come to see  
17 providers with when we are going through the  
18 symptomatic diagnostic process, that first front-  
19 end piece gets replaced with some ICD-9 coded  
20 diagnosis as soon as somebody takes some kind of  
21 first billing action, even if they remain  
22 completely uncertain about that diagnosis. And

1       that loss of information is huge at many levels,  
2       including the fact that, obviously for all the  
3       rest of the providers, it anchors them to a less  
4       than certain diagnosis at a premature stage, as a  
5       practical matter.

6               But from a research standpoint and a  
7       measurement standpoint, it actually makes it  
8       really hard for us to actually go back and figure  
9       out whether whatever diagnostic errors might have  
10      occurred actually related to that original  
11      complaint because it has sort of vanished from  
12      the administrative and billing records. So that  
13      may be something that we want to at least think  
14      about as part of this issue of measurement  
15      framework.

16              CO-CHAIR DANFORTH: Prashant you had  
17      a question for Hardeep?

18              MEMBER MAHAJAN: Actually not a  
19      question but I just wanted to throw out this. At  
20      least the difference that I saw from the  
21      conceptual framework, you know the Safer Dx  
22      framework and IOM was based on the definition

1       because the second component of the definition,  
2       which is the communication of the patient's  
3       health problems. And what I am struggling with,  
4       and I recognize that we are not going to come up  
5       with measures but we are looking at conceptual  
6       framework for measurement, is not only is this  
7       communication a big aspect, which is  
8       contextualized where the healthcare setting is,  
9       but this is also this aspect of health literacy  
10      from the patient's perspective.

11               And somehow it needs to be baked in or  
12      probably a tacit recognition that some of these  
13      may not be ready for measurement, even though we  
14      have a full definition, some aspects are not  
15      possible to be measured at this time.

16               CO-CHAIR DANFORTH: Kerm.

17               DR. HENRIKSEN: Just looking at the  
18      two frameworks that we have seen thus far and  
19      then thinking about the IOM definition, the  
20      second aspect of it, the communication with the  
21      patient aspect, I haven't seen anything in the  
22      existing frameworks presented that are really

1 sensitive to the communication process. And I  
2 know it is sort of embedded in there someplace  
3 but it is not very prominent. And so are there  
4 certain structures and processes and outcomes in  
5 a Donabedian sense that are just relevant to  
6 communication, clear sound communications?

7 And I know there is repeat back and  
8 rubrics and things like that that can be invoked  
9 but for much of the one-half of the definition of  
10 the National Academy's report doesn't really show  
11 up that clearly in these frameworks.

12 MEMBER SINGH: So Kerm, I am just  
13 going to -- so there is a couple of places in the  
14 process dimensions that communication is  
15 measured, if you do, let's say, medical record  
16 reviews to look for sort of diagnostic issues.  
17 One is in the patient-provider interaction. So  
18 the history and the physical and what you do next  
19 is based heavily on communication and listening  
20 to the patient. So I think that is where it is  
21 reflected.

22 The second area I would say it is

1 reflected is follow-up of test results. Clearly,  
2 communication of test results is in the framework  
3 and is measurable and it is, in fact, a very  
4 important area to be measured and that also comes  
5 from the IOM. That is sort of compatible, I  
6 would say, with the IOM.

7 CO-CHAIR DANFORTH: We are going to  
8 take one more question from David and then maybe  
9 we will transition actually to have David Newman-  
10 Toker introduce a third framework. So, we will  
11 have lots of time to talk about and compare all  
12 three.

13 MEMBER SEIDENWURM: So I would like to  
14 go back a little bit to the issue of time, you  
15 know that sort of tiny little font and that sort  
16 of hard to see line at the bottom.

17 You know time is really one of the  
18 crucial things in diagnostic accuracy. And many  
19 of the systematic errors that we see are because  
20 people are hurried and because time is expensive  
21 in the operating room or the emergency room is  
22 what I meant to say. So I wonder if there is a



1 way that we can get at calibrating that and  
2 measuring the appropriateness of the use of time.  
3 And that sounds vague because I think it is but I  
4 wonder if people have any thoughts about how to  
5 incorporate that into our measurement framework  
6 because sometimes we do things too quickly and  
7 sometimes we do things too slowly.

8 MEMBER SINGH: Well I can just quickly  
9 speak. If you are an internist and if you see 50  
10 patients a day, that is probably a measure of  
11 poor safety right there. So I totally hear you  
12 and I think we could think about some of these  
13 measures. I'll stop at that.

14 DR. HUNT: And time is an element in  
15 some quality measures that we are seeing. Look  
16 at colonoscopy. They have actually started to  
17 say how long is it taking you to come out with  
18 the scope. And if it is too quick, then we know  
19 that there is maybe some issue.

20 DR. BURSTIN: And just quickly as  
21 somebody who precepted residents yesterday, some  
22 of their logic of looking at this in the broader

1 context of quality is that you begin to look at  
2 how time is spent overall. So the amount of time  
3 my residents and I spent, for example, on  
4 documentation for billing, if you think about the  
5 broader context, was overwhelmingly  
6 disproportionately the time we spent as opposed  
7 to perhaps thinking this appropriateness of time  
8 concept is difficult to measure but intriguing in  
9 the broader context of which measures and tasks  
10 are not adding value and need to move out to  
11 allow time to do what is considered more  
12 valuable. It is a really interesting question,  
13 David.

14 MEMBER SINGH: And I really like your  
15 point because that is a system-related measure  
16 that we could be proposing as a measure concept  
17 that basically if you are billing and everything  
18 else suggests that you are seeing x-many patients  
19 a day, that is an area of risk that could be  
20 explored.

21 MEMBER NEWMAN-TOKER: And I think in  
22 this sort of in the Donabedian structure process

1 outcome kind of framework that I think we are  
2 headed for, in some sense that is a structure  
3 measure. It is really a measure of capacity. So  
4 institutional capacity, if you have one physician  
5 to see 50 patients in a day, you know 50 patients  
6 for that one physician, but if you have got five,  
7 then you have got ten per physician. So, I think  
8 that may be a very interesting place for us to  
9 explore.

10 CO-CHAIR DANFORTH: I think one thing  
11 to think, though, remembering a couple of  
12 Hardeep's earlier comments, is that time as a  
13 stand-alone measure may actually be inadequate.  
14 I mean you gave a great example of physicians  
15 that had more time and still got the diagnosis  
16 wrong. So there is actually some evidence that  
17 time as a stand-alone measure may be inadequate.  
18 So time potentially combined with other factors  
19 because competence, you know cognitive ability,  
20 bias which we haven't talked about, physician  
21 bias which we haven't talked about today, I mean  
22 there are other things to think about about how

1       that time is being used.

2                   MEMBER SINGH:   And I think, whatever  
3       measure concepts we propose, we are going to need  
4       to think about that these -- it is going to come  
5       as a menu because there is not just going to be a  
6       few things that will satisfy it. This is so  
7       complicated and complex, we are going to have to  
8       propose a menu that measures the entire process  
9       or the structure or whatever else you want to  
10      measure.

11                   MEMBER MCDONALD:   I know you are going  
12      to go but just really quickly from that IOM  
13      perspective, the thoughts around measurement at  
14      the time were that the measurement systems we  
15      have for other types of measurement activity  
16      might not be all we should think about. So I  
17      know you said we are going to move towards  
18      structure process outcome but the thinking was  
19      partly because of that process and partly because  
20      of that time perspective, that there might be  
21      other ways we need to think about measurement  
22      that we haven't thought about measurement so far

1 in this domain. So, I would just like to keep  
2 that out there as the committee sort of  
3 aspirational thought was measurement might need  
4 to be a little different in this area.

5 MEMBER NEWMAN-TOKER: So thanks for  
6 the opportunity to present today. I am not going  
7 to present to you a third sort of competing  
8 model. Can you guys hear me okay?

9 I'm not going to present a third  
10 competing model. This is really, it is  
11 orthogonal to the discussion we were having  
12 before. And I just want to introduce what I am  
13 about to say briefly by explaining where it came  
14 from.

15 So at some point before the National  
16 Academy of Medicine report came out, several of  
17 us were having ongoing internal conversations in  
18 the sort of diagnostic error medicine community  
19 about how to define a diagnostic error and what  
20 terms are we going to use and so on and so forth.  
21 So Mark and I, and Hardeep, and Gordy Schiff, and  
22 Paul Epner started having some phone calls to

1 discuss this issue of what is a diagnostic error  
2 and how are we going to define it and what are we  
3 going to call a diagnostic error, a diagnosis  
4 error, a diagnostic error. And after about four  
5 or five meetings it became abundantly clear that  
6 we could not agree on how we were going to use  
7 these terms.

8 But at the same time, it also was  
9 clear that in concept, the ideas we were talking  
10 about were actually very harmonious. And there  
11 was kind of an underlying structure to that idea  
12 of what we -- how we were thinking about  
13 diagnostic errors. We just wanted to call --  
14 different people were pointing to different  
15 pieces of the Venn diagram and saying no, that is  
16 a diagnostic error. And I want to show you the  
17 Venn diagram sort of in its richness and give you  
18 a little bit of an introduction to that as a  
19 framework for our thinking about what we mean  
20 when we say we are going to measure diagnostic  
21 errors.

22 So my disclosures, as I mentioned

1 earlier, research funding, research support, and  
2 my membership and Board membership in SIDEM.

3 So everybody knows the National  
4 Academy of Medicine definition. The key thing  
5 for this definition from the sort of broader  
6 perspective is that this was framed I think in a  
7 very patient-centric way around the idea of if  
8 you didn't get the right diagnosis in time, it  
9 was a diagnostic error. So that means you have  
10 to have gotten an accurate and timely diagnosis  
11 and that information has to make it to the  
12 patient. And I think that is very sensible. But  
13 one of the important things about this definition  
14 is it doesn't mandate that we be talking about  
15 there was a specific process failure or such and  
16 such was preventable. It just says look, if the  
17 patient didn't end up with the right diagnosis,  
18 that was a diagnostic error. And I think we  
19 should maintain that sort of structure of  
20 thinking as we go forward into measurement  
21 because I think it also helps us a little bit  
22 with this dichotomy between quality and safety or

1       whether we are framing things as error, or  
2       positive or negative. In some sense, because it  
3       doesn't mandate that there have been a process  
4       defect in order to be in this umbrella of  
5       diagnostic error, it allows us the freedom to say  
6       okay, where are we getting -- how are we going to  
7       measure whether we are getting diagnosis right  
8       and not necessarily have to have, in the same  
9       conversation, whether we know exactly where it  
10      went wrong. We can actually just focus on the  
11      piece of the rightness of the diagnosis.

12                So here is the model. And what I did  
13      was I tried to use as inoffensive terms as I  
14      could so that I didn't inflame people's  
15      sentiments as we constructed this model. And  
16      there are two concepts that form the core of what  
17      I am about to tell you. One is the idea of  
18      diagnostic process failures and the other what I  
19      call diagnosis label failures. And I  
20      specifically differentiated between diagnostic  
21      and diagnosis because Gordy was very insistent  
22      that the diagnosis is the label people, the



1 diagnostic is the process part. And it actually  
2 took me about a year to figure out that Gordy was  
3 differentiating between diagnosis error and  
4 diagnostic error when he spoke but I maintain  
5 that differentiation here.

6 And this model is basically the same  
7 as what other people had published before, Gordy  
8 Schiff, Laura Swann, and others that these two  
9 things are sort of separable entities. That is  
10 to say, just to make it concrete, a 50 year old  
11 man comes to the emergency department with chest  
12 pain and they don't get an electrocardiogram and  
13 they are sent home with a diagnosis of reflux and  
14 it turns out it was a heart attack. So two  
15 things happened there. The one case there was a  
16 process failure that the EKG didn't happen. The  
17 second was there was label failure in that it was  
18 called reflux and the patient turned out to have  
19 something else. And the confluence of the two,  
20 in this case, may have come together but they  
21 could also come separately. So the patient could  
22 have been given a correct diagnosis of reflux and

1 still didn't get the electrocardiogram, in which  
2 case there was a process failure without a label  
3 failure. And you might think of that as kind of  
4 a near miss, in some sense. And then there is  
5 the sort of flip side, which is you could have  
6 ordered the EKG and done all the right things,  
7 such as we know, the best that we know, and still  
8 ended up with the wrong diagnosis because it was  
9 a subtle presentation or whatever it was. Mark  
10 had called those before no fault misdiagnoses.

11 And what is in the middle is kind of  
12 this core of this sort of patient safety question  
13 of this sort of preventable diagnostic error,  
14 this idea that we really did something  
15 substandard that didn't meet the known expected  
16 standard of care and, in the process, we had  
17 ended up with the wrong diagnosis label on the  
18 patient.

19 And in some sense, just to kind of  
20 clarify where the National Academy of Medicine  
21 definition fits there, really the National  
22 Academy of Medicine definition is most closely

1 mapped to that blue circle. It is saying I got  
2 the wrong diagnosis and it is not actually  
3 calling for, specifically, with the exception of  
4 kind of saying that it has to be timely, which  
5 sort of allows for the fact that it could be  
6 wrong transiently, if you didn't get the right  
7 diagnosis label, then there was a diagnostic  
8 error.

9           The process failures fall into a  
10 separate category and what I want to try to  
11 convey is that I think that that is a really  
12 appropriate thing for us to do, which is to  
13 disentangle process and outcome because I think  
14 if we try to force measurement on both dimensions  
15 in the same measures, we are going to get  
16 ourselves caught in kind of a messy thicket. I  
17 think we actually have to think about them as  
18 separate types of measurements.

19           Here is what I sort of added to this  
20 model or the first of a couple of pieces I added  
21 to this model that I think are important to  
22 remember as we think forward to measurement,

1       which is that not every process failure is a  
2       substandard care act. Sometimes it's the  
3       standard of care but it is not terribly -- it is  
4       not operating at the highest level that we could  
5       be. So we have seen this a lot where the  
6       literature says that it takes about 17 years for  
7       a new innovation to make it from a scientific  
8       fact, such as it is, to clinical practice. That  
9       evidence-practice gap is huge and it is actually  
10      probably responsible for a big part of the places  
11      where we fall down and don't necessarily get  
12      diagnosis right.

13               That suboptimal, yet still standard  
14      care is kind of a whole other circle. Here I  
15      have drawn it as an oval around the original sort  
16      of process failure dimension and I have called  
17      these sort of reducible diagnostic errors in this  
18      section here where there is an intersection  
19      between the blue circle and this new sort of pink  
20      circle, pink ellipse around the edge.

21               These are not things where we could  
22      point to and say look, you have failed the

1 standard of care but where we could still  
2 envision that well, look, if there is a new  
3 technique or technology that has been developed  
4 at the Houston VA, or here, or there and other  
5 people are operating at this higher level, but  
6 that hasn't disseminated, that is an opportunity  
7 to improve diagnostic quality without necessarily  
8 thinking of it in squarely the standard of care  
9 was breached sort of way of framing it.

10 And finally, there are the sort of  
11 rest of the National Academy of Medicine-defined  
12 diagnostic errors, which are what I called sort  
13 of unavoidable diagnostic errors, meaning we got  
14 the label wrong but we did everything at the  
15 highest imaginable quality for today and the  
16 science just wasn't there to support it. And  
17 obviously, those are opportunities for discovery.  
18 And I think this group needs to at least wrestle  
19 with briefly how that fits into the measurement  
20 framework around the issue of diagnostic quality.  
21 Some people might say well, if it turned out  
22 there was a large public health burden of

1 problems in diagnosis that were unavoidable in  
2 current technology, that might be something that  
3 we had to point our attention to in terms of  
4 greater research funding. So for instance, if  
5 all the screening for breast cancer or something  
6 else is being done perfectly in clinical practice  
7 but it is just our tests aren't good enough to  
8 find the cancers early enough to get the right  
9 treatments, then if we measure how often that is  
10 happening we can get a sense for how much we  
11 should invest as a society in improving the  
12 quality of that piece of the diagnostic process  
13 as well.

14 Obviously, any of these things can be  
15 associated with harm or not harm but I think,  
16 ultimately, from a public health perspective, I  
17 think that the space that we should focus on, and  
18 this is very similar to what Hardeep suggested in  
19 his slide with the harm, is this idea of I think  
20 patients care most about harm. They care less  
21 about process problems and all the things that  
22 sort of they get the wrong diagnosis for ten

1 minutes but it doesn't lead to a problem for  
2 them. I don't think that matters as much to  
3 patients.

4 I think, at the end of the day, this  
5 sort of preventable and reducible misdiagnosis-  
6 related harm space is really the most important  
7 space for us to focus our attention, in terms of  
8 what do we want to measure that is going to help  
9 us solve this problem. And I think secondarily,  
10 the rest of that inferior ellipse there from all  
11 the harms that are associated with overtesting,  
12 overdiagnosis, et cetera, where we are missing on  
13 the false positive side, rather than the false  
14 negative side and we are leading to harm to  
15 patients through the diagnostic process itself.

16 So, what are the measurement  
17 implications? Well, I think it is important that  
18 these are separable entities, that is, the  
19 diagnostic error in the National Academy of  
20 Medicine definition are the blue circle, the  
21 diagnosis label failures, as I called them,  
22 doesn't, per se, require a process failure.

1       Although it is clear that we have to measure  
2       process defects in order to improve our diagnosis  
3       labels, I think we should maintain some mental  
4       separation between those two concepts and really  
5       treat them as different circles.

6               The second is that, obviously, these  
7       process defects alone are sort of near misses,  
8       and that may be important, especially when they  
9       cause harm. And this idea of sort of suboptimal  
10      processes as being sort of one concentric ring  
11      around the idea of a failed process may help us  
12      push more in the direction of quality that it is  
13      not just a problem of we definitely did it wrong  
14      and failed in an absolute sense, but that we  
15      weren't doing it as well as we could have been  
16      and we could do better.

17             Obviously, overdiagnosis and  
18      overtesting may harm patients and harm is a key  
19      parameter to measure. And let me just show you  
20      one concrete example of how I think some of these  
21      principles could be applied in sort of a  
22      measurement concept.



1                   So one of the things that Hardeep  
2 alluded to before that I think is right is that  
3 if you look at administrative data, the signals  
4 are weak. So if you look just at three 72-hour  
5 revisits or whatever, most of them are not  
6 diagnostic errors. But I think actually if you  
7 take a symptom disease framework, which we have  
8 described in the literature before and focused  
9 your attention on specific initial presenting  
10 problems that are potentially related to initial  
11 returning diagnoses, you actually can use  
12 administrative data to find very strong signals  
13 like the ones I am showing you here and you can  
14 do it without necessarily diving deeply into the  
15 process of whether there was a process failure  
16 that led to this outcome.

17                   So let me just explain what I am  
18 showing you here. I am showing you two research  
19 studies from administrative data that look back  
20 and look forward at the same problem, which is  
21 the idea that people come to the emergency  
22 department; they are told they have benign

1 dizziness from ear problems and it turns out they  
2 have a stroke. And then they come back and they  
3 get readmitted to the hospital with a stroke.

4           These are essentially patients who are  
5 being harmed by diagnostic errors. We don't know  
6 whether those errors are preventable. We don't  
7 know whether those errors are associated with  
8 specific process defects from this information,  
9 alone, although we have ample data that indicates  
10 we know exactly what is wrong in this particular  
11 scenario because we have done a lot of work in  
12 this space. But as a measurement, this measure  
13 relies on the analytic piece and it gets us to  
14 this issue of time.

15           So what you can see in these graphs --  
16 and I will just walk you through each of them and  
17 then I will take whatever questions we have -- in  
18 the left-hand graph, we have taken 180,000 stroke  
19 admissions to the hospital and looked back to see  
20 when people were seen and released with a benign  
21 diagnosis from the emergency department in the  
22 days prior to that, in the 30 days prior.

1                   And the red bars that are sort of  
2 highlighted by the red sort of exponential-  
3 looking curve there, are patients with dizziness  
4 and headache. So you can see that there is sort  
5 of an overrepresentation in the week prior to  
6 this stroke admission of these patients who were  
7 told that they just have migraine or they just  
8 have benign positional vertigo, et cetera.

9                   And then we have a comparison  
10 population here of abdominal and back pain  
11 patients beneath that and you can see that they  
12 are mostly flat, sort of randomly distributed.  
13 So there are some people who come to the  
14 emergency room and they have strained their back  
15 and then a month later they get a stroke that  
16 happens, just random occurrence.

17                  But the temporal association is strong  
18 here. And likewise, in the other one looking  
19 forward from discharges for supposedly benign  
20 dizziness, you can see the rate of return in the  
21 top curve for stroke and the rate of return for  
22 heart attack on the bottom. You can see the

1 stroke curve has this peak in the first 60 days  
2 that flattens out to a base rate and the heart  
3 attack is just sort of a flat base rate from the  
4 start. And what that tells us here is that there  
5 is a biologically plausible relationship we know  
6 between transient ischemic attack and minor  
7 stroke and the risk of major stroke afterwards  
8 that is played out over the highest in the first  
9 few days and plays out over the course of 90 days  
10 and it matches exactly this profile event.

11 What this tells us, this sort of red  
12 hatched area here is kind of the space where  
13 misdiagnoses are happening. It is very hard to  
14 imagine that this actually reflects anything  
15 else. And the value of this kind of a  
16 measurement approach is that it is kind of  
17 agnostic to where it is the process defect did or  
18 didn't happen. It just points us to a problem  
19 that patients care about; that is, the outcome of  
20 interest. It is that they didn't want to come  
21 back with a major stroke after a minor stroke.  
22 That was what they actually wanted prevented

1 through prompt treatment at the index event. And  
2 I think that idea of being able to separably  
3 measure outcomes and process is an important one  
4 that we should sort of maintain as we think about  
5 our measurement framework as it is developed.  
6 So, that is all I have to say.

7 CO-CHAIR DANFORTH: We will go David  
8 and then Mira.

9 MEMBER SEIDENWURM: I thought this was  
10 great. Thank you so much.

11 I think a big point that runs through,  
12 in my mind, in the theme of what you are talking  
13 about is the degree of required certainty. And I  
14 think that the example of headache and dizziness  
15 and stroke is -- I am a neuroradiologist. That  
16 is part of where I live my life. And the problem  
17 is, of course, the overwhelming majority of  
18 disease and headaches don't have strokes and the  
19 degree of certainty that is required and it also  
20 goes back to the theme of time because the ER has  
21 to move them along quickly.

22 And so in pursuit of this patched

1 area, we wind up overtesting. We wind up harming  
2 people probably through overtesting. And yet, at  
3 the same time, we don't necessarily have the  
4 tools to find in real time those dizzies that  
5 will become strokes because we don't always have  
6 the tests that would show us that because the  
7 vascular structure that becomes occluded, for  
8 example, might not be readily apparent. The  
9 source of the clot might not be readily apparent  
10 through imaging or whatever. So, there are  
11 metrics and there are guidelines that attempt to  
12 minimize this but, in spite of that, we fail.

13 So, I am concerned if we define this  
14 as diagnostic error we will lose credibility with  
15 the medical community because, conceptually, it  
16 is a diagnostic error. But we have to really be  
17 careful about that if we want to bring our  
18 constituency along with us and have the  
19 credibility to improve the practice if we define  
20 as error a situation in which everything was, and  
21 I will put this in scare quotes, done right.

22 MEMBER NEWMAN-TOKER: So a couple of

1 points there that I would like to unpack. I  
2 think the last point you made is really important  
3 for this group to be thinking about. And I think  
4 this issue of whether we are scaring people away  
5 with the idea of the word error. And this is  
6 really, I want to make sure that we understand  
7 that this is a terminology problem and not a  
8 concept problem. So for better or for worse, the  
9 National Academy of Medicine defined the  
10 diagnosis label failures that I showed you, the  
11 blue circle thing, as a diagnostic error. And  
12 when we say diagnostic error, most physicians  
13 immediately think blame and process problem, like  
14 I did something wrong. And if everything was  
15 done right, then how could it be a diagnostic  
16 error. And that is a terminology fight that we  
17 should not have in designing the measurement  
18 framework, in my opinion. We should acknowledge  
19 that it is important and we should acknowledge  
20 that we may want to focus on the positive side  
21 but I am not sure that we should debate whether  
22 it should or shouldn't be called a diagnostic

1 error because I think the National Academy of  
2 Medicine settled that for better or for worse.  
3 There are arguments on both sides.

4 That is one point that I think is  
5 really important that we have to maintain. I  
6 think the separate question is the one that you  
7 mentioned about well are these things  
8 preventable. And in this particular case, it  
9 turns out that they probably are. We have shown,  
10 for instance, not to get too specific about it  
11 but we have shown that bedside examinations of  
12 eye movements are more accurate than MRIs in  
13 detecting these strokes in advance. And the  
14 problem is, just at the moment, that that  
15 expertise hasn't disseminated and we are working  
16 in a clinical trial that I alluded to before to  
17 disseminate that expertise using devices and so  
18 on and so forth.

19 But the fact that we may or may not  
20 know whether these individual events were  
21 preventable or not is, to me, less the point.  
22 When we think about the diagnostic quality



1 framework, the question is if you use this kind  
2 of an approach to say okay, look, I am going to  
3 look at the top ten diseases and I am going to  
4 have a dashboard that says these are the places  
5 where I see these potential harms that are  
6 potentially reducible there, I am now going to  
7 investigate both why those harms are occurring  
8 and whether there is something I can do to  
9 prevent them and then actually use this kind of  
10 a measurement to, essentially, if you could  
11 imagine putting your finger on top of that hump  
12 and squishing it down to the baseline, that if  
13 you could actually do that in practice, you would  
14 have done something meaningful. That is, you  
15 would have presumably reduced the harms from  
16 missed stroke in this particular case.

17 So I think that that idea of  
18 preventability, we should not be scared away from  
19 measuring outcomes simply because we don't know  
20 in any given case either what the process defect  
21 was or necessarily the exact solution to the  
22 problem, although in this particular case I think

1 we do.

2 CO-CHAIR DANFORTH: We are going to go  
3 Mira, Martha, David, and then Nicholas.

4 MEMBER IRONS: This is just a question  
5 about the graphs there. When you look at the  
6 patients that we are seeing in that prodromal  
7 period, were the signs, symptoms, and historical  
8 information that was presented at the time to  
9 those physicians consistent with evolving stroke  
10 or just consistent with dizziness and headache?

11 I mean I guess what I am trying to get  
12 at is is this a population that we are going to  
13 attribute to misdiagnosis or whatever we are  
14 calling it, delayed diagnosis, a diagnosis that  
15 you can actually subdivide into those people who  
16 really had symptoms and signs of evolving stroke  
17 or did it just not evolve far enough to get to  
18 that point? And that is just a --

19 MEMBER NEWMAN-TOKER: So if I can  
20 paraphrase, you are asking could it have been  
21 prevented, had someone been there who was aware  
22 of what to do.

1                   So, we don't know that from these  
2 particular studies because these studies were in  
3 180,000 patients. They weren't done with chart  
4 reviews and so on and so forth. They were  
5 actually done from datasets where you can't do  
6 chart reviews. But the question you asked has  
7 been answered repeatedly. That is, we have many  
8 other studies. We have done chart reviews on  
9 this specific issue and they all tell us the same  
10 thing. We are doing the wrong examination at the  
11 beside; when we do it at all, we are interpreting  
12 it incorrectly 80 percent of the time; and we are  
13 ordering all the wrong tests on these patients.  
14 So we know exactly what the problem is.

15                   So I can't tell you for these  
16 individuals in these graphs but I can tell you  
17 that we have seen it over and over again in  
18 multiple studies over the course of the last  
19 decade.

20                   MEMBER IRONS: So it is a  
21 heterogeneous population, these people that are  
22 coming in.

1                   MEMBER NEWMAN-TOKER: Well, it is  
2 heterogeneous in the sense that there are  
3 probably different bedside features of patients  
4 who have stroke versus don't. We have actually  
5 shown that you can prospectively differentiate  
6 between the two. But most of these people are  
7 coming in with relatively monosymptomatic  
8 dizziness and being sent home. If they come in  
9 with dizziness and they are paralyzed on one  
10 side, those patients don't get sent home.

11                   So these are the people who are the  
12 subtler ones, what you might call atypical  
13 presentations. And as was mentioned by David  
14 earlier, only three percent of those dizzy  
15 patients have strokes. So this is a small  
16 population but that is 75,000 people a year in  
17 the United States. So, the question of whether  
18 it is a small population is really linked to the  
19 issue of whether we should -- the total number of  
20 patients is how we should be determining whether  
21 something is worth studying in terms of the  
22 public health burden and our ability to do better

1 is what should determine whether we should go  
2 after fixing a process problem, not the exact  
3 prevalence of the incidence of the disease in  
4 this patient population.

5 MEMBER RADFORD: Thank for your those  
6 comments, really all three presentations. And we  
7 are sort of honing in here on measurement as our  
8 focus for this group, which I believe is where we  
9 need to be.

10 And I completely agree with you, this  
11 is a labeling issue. I would label these  
12 measures as possible misdiagnoses because really  
13 what you are doing is you are enriching your case  
14 review population for cases that might show you  
15 an issue. Speaking from a hospital CQO  
16 perspective here, I am always looking for ways to  
17 improve the effectiveness of my very robust case  
18 review process so that I can find more stuff to  
19 fix. And I would love to have these kinds of  
20 measures, essentially, available to me to help  
21 fix things that would delay these kinds of  
22 diagnoses.

1 I think also your focus on defining  
2 cohorts where you can enrich these findings that  
3 are basically enriched for possible problems is  
4 also a productive way for us to spend our time.  
5 Cancer has been mentioned. Stroke is mentioned  
6 here. Chest pain is another one where I sort of  
7 live and breathe. So those kinds of things I  
8 think we probably need to take into consideration  
9 but I agree with you about the labeling and  
10 needing to do a very deliberate due diligence on  
11 that.

12 MEMBER NEWMAN-TOKER: Yes, just on the  
13 last point, I think pretty much if you look at  
14 the literature on this from various diverse types  
15 of measures, if you group things into three big  
16 buckets of missed cancer, missed infection, and  
17 missed vascular events, including stroke, heart  
18 attack, pulmonary embolism kind of stuff, that a  
19 huge, probably about a third of all diagnostic  
20 errors and maybe more than half or two-thirds of  
21 the harms from diagnostic errors fit into those  
22 three big buckets and I do think that there is

1 something to be said for taking a problem-  
2 specific or disease-specific focus for  
3 identifying kind of the big killers sort of areas  
4 and saying that the measurement framework needs  
5 to account for that specificity as well.

6 MEMBER RADFORD: And your techniques  
7 of looking both forward and backward are very  
8 helpful as well. Thank you.

9 CO-CHAIR DANFORTH: David.

10 DR. HUNT: Yes, I think we are going  
11 to, time and time again, mourn the loss of the  
12 use of a differential diagnosis in our  
13 documentation. From a specialty that has a  
14 suitable diagnosis of an acute surgical abdomen,  
15 which is no real diagnosis but it gives you  
16 enough to say that we need to go in.

17 And I think that one of the questions  
18 that we may come across when others look and  
19 critique our work product is that we may be  
20 working at the bleeding edge of Occam's razor, if  
21 you will. That is to say patients can have more  
22 than one condition. Your example, they actually

1 could have had reflux and an MI. So we have to  
2 have -- I think we should have some provision for  
3 -- and I know this is a horrible framing of this  
4 term but I can't think of any better way to do it  
5 -- a p-value for our measures. That is a measure  
6 of the accuracy of our measures, if you would, to  
7 provide the possibility that it was not an error,  
8 that it was -- well, that it was something other  
9 than that.

10 MEMBER NEWMAN-TOKER: Yes, I think  
11 that the beauty of this kind of measurement, at  
12 least on a large scale for a health system or  
13 maybe a hospital is that those gray bars on the  
14 second graph on the right hand side are 95  
15 percent confidence intervals. So those are your  
16 p-values. And you are absolutely right. You can  
17 have both. You can have reflux and an MI and  
18 they can be causally unrelated. But then if that  
19 is true, this pattern shouldn't exist.

20 In other words, this pattern only  
21 exists where there is this initial spike and then  
22 a return to a base rate because we missed



1 something. It doesn't exist if it is just a  
2 random association. If it is a random  
3 association, it should look like the heart attack  
4 one. So, it should basically be I was told that  
5 I was dizzy because I had some ear problem and  
6 then I came back with a heart attack -- random  
7 association. That dashed line of MIs after  
8 dizziness are clearly flat, if you count the 95  
9 percent confidence intervals. And what that  
10 tells us is that we are not missing heart attacks  
11 in dizzy patients but we are missing strokes.  
12 And I do think that having confidence in those  
13 measures, statistically speaking, is actually  
14 really important and one of the nice things you  
15 can do with large data sets.

16 DR. BURSTIN: And maybe just quickly  
17 David could define Occam's razor so we are all  
18 -- not everybody lives in that world and it is a  
19 helpful concept as we talk about diagnosis.

20 DR. HUNT: The idea of parsimony.  
21 That is to say that the explanation for a set of  
22 events or phenomena should go to the least, the

1       smallest set of possible reasons. That there is  
2       parsimony. I'm not sure if I explained it that  
3       way.

4               MEMBER NEWMAN-TOKER: The competing  
5       principle is Hickam's Dictum --

6               DR. BURSTIN: Yes.

7               MEMBER NEWMAN-TOKER: -- which is the  
8       patient can have as many diseases as he darn well  
9       pleases.

10              DR. HUNT: Kerm said it better than I.  
11       It is the simplest explanation for things.

12              CO-CHAIR DANFORTH: We are going to  
13       take the three cards that are up. Then we are  
14       going to take a break so that we can try to get  
15       back on schedule and go to Helen's presentation.

16              So we are going to go Nicholas,  
17       Hardeep, Mike, break, Helen, in that order.

18              MEMBER KUZMA: All right. I had a  
19       thought or question, depending on how this comes  
20       out. So I think Hardeep did a nice job showing  
21       that medical records are really a great source  
22       for identifying when these errors are happening

1 and you showed how administrative data can  
2 possibly identify that. And I am just wondering  
3 are we asking patients when these errors are  
4 happening and is that kind of an untapped area  
5 that we could be using to kind of figure out when  
6 these errors are happening, in addition to the  
7 other things that you presented?

8 MEMBER NEWMAN-TOKER: Yes, I mean Mark  
9 has suggested this a long time ago and I think it  
10 is a very interesting, totally untapped potential  
11 source of data to actually just ask the patient  
12 whether their diagnosis has changed. And I do  
13 think at some level, eventually, that may be a  
14 filter to kind of capture a broad spectrum of  
15 diagnostic errors.

16 The trick is that you have all the  
17 same potential validity concerns and reliability  
18 concerns, depending on the patient's health  
19 literacy or who they did or didn't happen to see.  
20 In other words, if you call somebody in 30 days  
21 and say well have you had a stroke, that answer  
22 may be clear. But if you say was your diagnosis

1 correct of whatever it was that they had, the yes  
2 or noes may not be as accurate as you want them  
3 to be.

4 But I do think it is a totally  
5 untapped source for data.

6 MEMBER KUZMA: And it is not like the  
7 data we have now is perfect anyway.

8 MEMBER SINGH: I'll start with and  
9 just quickly respond to you. So I want to  
10 clarify medical records still are one of the best  
11 sources of truth of what we know but it has to be  
12 often complemented with other sources, such as  
13 talking to physicians and patients or other care  
14 team members.

15 Patients still reported as huge area,  
16 and AHRQ has done work in this area very recently  
17 and has a report -- we actually have -- I have a  
18 mentee who has applied for a K Award in exactly  
19 what you just mentioned, but she has applied to  
20 Agency for Healthcare Research and Quality, which  
21 we hope will be funded.

22 And so you know I think again it begs

1 the question: how are we going to advance the  
2 basic science? So I think this is a very  
3 untapped area. There is clearly concerns about  
4 validity of the information or what patients are  
5 telling them. Do they actually mean what we are  
6 thinking that they mean. And so it needs to be  
7 researched.

8 David, to your question, quickly, on  
9 differential diagnosis. So actually there is  
10 sort of a measurement concept that we have  
11 proposed in the Journal of Patient Safety paper  
12 that I talked about about differential diagnosis.  
13 So definitely that is sort of a shout out for  
14 that paper that you should read. Really  
15 important.

16 But I want to revisit your p-value  
17 concern. I really think we do need to think  
18 about -- I'm not sure whether we are going to  
19 come up with the measure -- what we have done is  
20 we have developed these concepts and then  
21 measured the predictive value. So the positive  
22 predictive value of whatever we are trying to

1       measure.

2               So for instance, if a patient comes in  
3       to the primary care clinic and then got admitted  
4       unexpectedly in ten days, we look at the medical  
5       record at the first visit to see was there a  
6       missed opportunity. So the term that we used in  
7       our work is not error as much but it is missed  
8       opportunities. Was there a missed opportunity in  
9       the first visit? And so the predictive value of  
10      that would be about 21 percent is what we found.

11             We have done some recent work in test  
12      results. So if there is abnormal test results as  
13      flagged by the computer that does not have a  
14      follow-up action, such as FOBT, which is occult  
15      blood in the rectum -- occult blood in the stool  
16      which is not followed up by let's say a  
17      colonoscopy. So we build algorithms to identify  
18      follow-up actions on abnormal tests and make the  
19      algorithms smarter and smarter to figure out  
20      whether the test results were surely missed or  
21      not. And the predictive value of that, after you  
22      look at thousands and thousands of medical

1 records and identify just a small cohort, what we  
2 call sort of picking out the needles in the  
3 haystack, when you look at that cohort, 60  
4 percent predictive value right now we are getting  
5 on medical record review. So we confirmed that  
6 with medical records and 40 percent of the time  
7 when it is not a missed result, it is usually  
8 when the patient has either refused the follow-up  
9 test or they have gone to another system and  
10 gotten a colonoscopy for instance.

11 MEMBER NEWMAN-TOKER: So let me just  
12 respond briefly to the issue of the chart  
13 reviews. I think Hardeep is to be commended for  
14 the tremendous amount of work that he has done in  
15 this space and there is a sense in which the  
16 chart review feels like somehow the gold standard  
17 because it has got such high face validity to  
18 clinicians. What was the story in the chart?

19 We have seen with this particular  
20 problem, with dizziness and stroke, that fewer  
21 than ten percent of the relevant facts are  
22 documented in the charts. And when they are

1       documented, 80 percent of the time they are  
2       wrong, physiologically incompatible physical  
3       findings with the diagnosis rendered by the  
4       clinician.

5               The problem with charts is that it is  
6       highly likely that they are biased towards  
7       underrepresenting the key facts that actually  
8       allow you to determine whether or not a  
9       diagnostic error occurred. It is precisely  
10      because of the failure to record that information  
11      that the diagnostic error was made in the first  
12      place. And as a result, the chart review is  
13      great for identifying what amounts to gross  
14      negligence and I think Hardeep has done that in a  
15      lot of his studies, has shown that there is a lot  
16      of gross negligence out there and missed  
17      opportunities. But it is not a great gold  
18      standard and we shouldn't think of it that way.  
19      We should think of it as the best available means  
20      to get the information we really want, which is  
21      what were the patient's initial presenting  
22      symptoms and signs. And we may think of in the



1 future about ways we can get that information  
2 more reliably than the way that we are getting it  
3 now, which is reviewing documentation that we  
4 know stinks.

5 CO-CHAIR DANFORTH: Mike.

6 MEMBER DUNNE: I think I forgot what  
7 I was going to say.

8 I am naive to this process so bear  
9 with me. And I am not a clinician. I am a  
10 clinical scientist. But having read a few case  
11 studies in the New England Journal, you know that  
12 the initial diagnosis and the final diagnosis are  
13 always the same. No one has missed a diagnosis  
14 in a New England Journal case study.

15 That said, so you have the initial or  
16 differential diagnosis that is created after the  
17 patient interaction. That gets honed down to a  
18 working diagnosis. Then you have whatever  
19 happens to the patient either good or bad and you  
20 have a conclusion or a consensus final diagnosis.

21 The final diagnosis could have been  
22 part of the differential diagnosis but not

1 carried forward. So you get a point.

2 On the other hand, you can reconcile  
3 the final diagnosis with a working diagnosis to  
4 see if there are improvements in the process that  
5 could have been made that would have carried  
6 through from the differential diagnosis all the  
7 way to the end so it looks more like a New  
8 England Journal case study.

9 Not only that but you can measure the  
10 difference between the working and the final  
11 diagnosis, yes/no, almost like in horseshoes.  
12 And I don't know how useful ICD-10 codes are in  
13 helping you to determine what that was but that  
14 is another source of data that you can look at.

15 So that is a relatively simplistic  
16 point of view from a clinical scientist  
17 standpoint but I keep on hearing this throughout  
18 the discourse and it is the only thing that I can  
19 really hang on to.

20 MEMBER NEWMAN-TOKER: So just to  
21 follow-up on that last point, it is absolutely  
22 critical that we try to be able to do that. Like

1 it would be great to be able to measure the  
2 discrepancy between initial diagnosis and final  
3 diagnosis or working diagnosis and final  
4 diagnosis. And there may be things that we  
5 should advocate for in terms of the way the  
6 system records data to actually be able to do  
7 that but right now, those data usually don't  
8 exist. And so those are perfect data that would  
9 be useful for this purpose and, in fact, we have  
10 to kind of back our way into assumptions about  
11 it.

12 So for instance, we say well, if the  
13 person was given an ICD-9 coded diagnosis of an  
14 inner ear problem, then probably the initial  
15 diagnosis -- the initial symptoms were dizziness  
16 and so on and so forth.

17 MEMBER DUNNE: And we always throw  
18 software and solutions like that. But when I was  
19 at Barnes Jewish, there were 27 software  
20 interfaces between laboratory information system  
21 and the various clinician groups within the  
22 hospital -- 27 individual software programs

1       deciphering information from laboratory to give  
2       the results to clinicians and nursing staff.

3               CO-CHAIR DANFORTH: We are going to  
4       have more time over the next two days to talk  
5       about some of the things we are getting into  
6       right now with these questions like measure  
7       concepts, gaps, data sources.

8               For now, we are going to take a quick  
9       break, maybe ten minutes if we can. When we come  
10      back, we are going to get to Helen.

11              I did see that two people had their  
12      cards up. So, if the questions were specific to  
13      David, grab him at the break. If not, when we  
14      move on to measure concepts, make sure you bring  
15      them back up.

16              (Whereupon, the above-entitled matter  
17      went off the record at 11:07 a.m. and resumed at  
18      11:24 a.m.)

19              CO-CHAIR DANFORTH: So Tom, I hear  
20      that you are still hanging in there with us. So  
21      If you have a question, please let us know.

22              MEMBER SEQUIST: Yes.

1 CO-CHAIR DANFORTH: And I am going to  
2 actually turn it over to Helen Haskell now, who  
3 is going to share with us the patient perspective  
4 on diagnostic error.

5 MEMBER HASKELL: Thank you for asking  
6 me to speak. This is going to be a lot less  
7 scholarly, to say the least, than everything that  
8 has preceded me.

9 So I want to talk a little bit first  
10 about why I am here. So I came into patient  
11 safety and diagnostic error through the death of  
12 my young son, Louis, who died in a hospital of a  
13 perforated ulcer caused by NSAID pain medications  
14 following elective surgery. He lingered 30 hours  
15 before he died with no one doing anything for  
16 him.

17 It was considered an egregious  
18 circumstance when it happened and yet I am still  
19 hearing of similar, sometimes nearly identical  
20 cases now nearly 16 years later. And one of the  
21 things that sort of an earlier conversation has  
22 made me think I should add was that I was really

1 the only one who sort of put it together. I was  
2 the only one recognized that he was going into  
3 shock, or at least the only one who said -- I  
4 didn't say it but no one said it to me either. I  
5 don't think anyone else recognized it. And after  
6 the fact, I was the only one who really did a  
7 meaningful root cause analysis.

8 The people who were involved did not  
9 want to see it or did not see it as something  
10 that had an explanation. They saw it as just one  
11 of those things.

12 So I should also add that I work with  
13 patients who have been harmed by their medical  
14 care, not necessarily error. At this point I  
15 have talked to literally hundreds if not  
16 thousands patients and diagnostic error plays a  
17 role in a large proportion of those cases. So  
18 just as diagnosis is central to patient's  
19 experience of the healthcare system, diagnostic  
20 error is central to their experience of harm. So  
21 this has been a real source of frustration to  
22 patients that errors of judgment and other

1 factors leading to diagnostic harm, diagnostic  
2 inaccuracy, have received so little attention  
3 until recent years in the safety and quality  
4 movement.

5 So the most important thing that  
6 patients say overwhelmingly is that they are not  
7 listened to and that their input isn't valued.

8 So even the language of the IOM  
9 report, and I was glad that you sort of  
10 acknowledged that, Mark, that some of that has  
11 also filtered into our diagnostic accuracy  
12 framework, but even the IOM report misses this  
13 point or misses the significance of this point  
14 when it talks about things like communicating the  
15 diagnosis to the patient. You know the whole  
16 concept of a working diagnosis in a conversation  
17 that includes the patient's input every step of  
18 the way is a really critical one. If this isn't  
19 invited, the situation is ripe for  
20 misinterpretation.

21 So in our own case, what happened to  
22 my son, Louis, was called a misdiagnosis but it

1       wasn't really any one person who misdiagnosed it  
2       because they were all listening to each other so  
3       that what apparently happened was that nurse's  
4       station chatter sort of became enshrined as a  
5       diagnosis. So there was never really an  
6       independent assessment. They were not listening  
7       to the patient.

8               So the culprit wasn't an individual;  
9       it was a mindset of superiority and of trying to  
10      save time, which of course they didn't do in the  
11      end. And it speaks to care coordination, which  
12      is probably the biggest problem that patients  
13      face, not just between specialists, although that  
14      is huge, but also within practices. For example,  
15      people not talking to each other, just layers of  
16      people you have to get through before you get to  
17      the person who is actually making a decision.

18             It speaks to culture of safety,  
19      patient-centered care, patient engagement, and  
20      collaboration -- not just a team, but a team with  
21      the patient at the center of it.

22             So we have measures for a lot of these



1 things and I think we need to range further  
2 afield to find more and be sure that we include  
3 more of the ones that we have on our list.

4 So in no particular order, here are  
5 some of the things that I consider important, as  
6 a patient:

7 Encouraging structures and processes  
8 that allow for constant patient input. So you  
9 are talking the medical records. You are talking  
10 about patient reporting but it needs to be  
11 ongoing throughout the process.

12 So there are things like user-friendly  
13 patient portals; bedside rounding in hospitals;  
14 open notes; the ability to annotate your own  
15 records; the use of technique like teach back and  
16 checking back; giving patients a record of their  
17 visit, which McDonald's will give you a free  
18 meal if they don't, but no providers do it unless  
19 you ask. And they are not always happy if you do  
20 ask.

21 And we need, as has been discussed, to  
22 find a way to encourage feedback to doctors about

1 the results of their own diagnoses or diagnostic  
2 errors so they can learn from experience. I'm  
3 not sure how we capture this but we need to.

4 We also need patient involvement. I  
5 think it is critical in the improvement process.  
6 So patient reporting of experiences often  
7 captures things that are not otherwise  
8 documented. As we know, patients report really  
9 different things from their providers and they  
10 usually consider their condition more serious and  
11 it often is actually more in line with their  
12 physiological symptoms.

13 It is an entirely different focus.  
14 Patients value their global well-being more than  
15 disease-specific components. So we need to  
16 capture that focus because that, I think, is what  
17 we need to be aiming for in terms of healing.

18 So patient reporting of symptoms,  
19 patient reporting of their experience within the  
20 medical milieu, which captures problems that  
21 often aren't otherwise documented.

22 I am a huge proponent of patient

1 involvement in root cause analyses and other  
2 quality efforts. Patients, in most places, are  
3 not even interviewed if there is an adverse  
4 event, so that all of the sort of information  
5 that I, for example, had in our son's case was  
6 completely lost to them because people who  
7 realized that they had not done what they should  
8 have done were not going to be forthcoming after  
9 the fact. And while it was going on, they didn't  
10 understand what was going on.

11 So that is pretty much what I have to  
12 say. I would want to add to some of the other  
13 cautions that people have expressed about using  
14 standard quality measures in this context. I do  
15 think this is a new area. Diagnosis has its own  
16 set of issues. The communication, the cognition,  
17 the structure that we have been talking about  
18 this morning, I think it is a new area and it is  
19 a new opportunity to sort of develop new things  
20 and I am concerned that it could lose its impact  
21 if we get bogged down and sort of going back over  
22 the same ground that we have had before.

1                   So that is about all I have to say.

2                   MEMBER CAMPISANO: I just wanted say  
3                   thank you for your comments. And I think that  
4                   you captured something really, really important  
5                   here. Obviously, I am biased as a patient  
6                   advocate and a former cancer patient, but I think  
7                   that the patient perspective is really important  
8                   here, and the communication between provider and  
9                   patient is something that has been touched on a  
10                  little bit today, but I think you emphasized how  
11                  critically important it really is and not just --  
12                  I guess I just wanted to say thank you for  
13                  touching on that. It is something that I don't  
14                  think is talked about quite enough.

15                 MEMBER HASKELL: Thank you. I think  
16                  it is not -- I think the importance of it is  
17                  really not realized at all in the structure of  
18                  medicine, the ways -- patient communication is  
19                  just sort of discounted and really the most vital  
20                  information is there.

21                         And if you filter it through, so if  
22                  you filter it through the provider as a history

1 and physical, which I think are very important  
2 and that was among the things I didn't say that I  
3 think we really need to encourage more of  
4 emphasis on history and physical, more  
5 communication with the patient, at the same time,  
6 even the most skilled provider, just by the act  
7 of communication and relaying to a third party,  
8 the third party being the chart, there is going  
9 to be error. So you have to have the patient  
10 input to say no, this is an error. This is what  
11 I really meant because none of us can communicate  
12 that well. It just doesn't happen.

13 MEMBER CAMPISANO: Yes, and I know  
14 that -- well two things. One, I don't remember  
15 who said it, but in my experience and at a  
16 meeting that I have been at before, a woman said  
17 that patients are oftentimes the most  
18 knowledgeable about their particular disease and  
19 what is going on with them. And I think that  
20 they are often not given the credit because they  
21 might not have the medical background or know all  
22 of the correct terminology, but they are often

1 very knowledgeable about their particular  
2 disease.

3 And the other thing is that -- I lost  
4 my train of thought but I just think that yes,  
5 the communication -- oh, the time factor that we  
6 have touched on. I understand there are time  
7 constraints. As a mom and a cancer patient, I  
8 feel like -- I am a wife and a lawyer. There are  
9 time constraints in everybody's lives. I get  
10 that.

11 But one of the very best meetings I  
12 ever had with a physician was a physician who sat  
13 down with me, an oncologist who sat down with me  
14 and talked to me for 45 minutes about what my  
15 diet looked like. What did my exercise look  
16 like? What my charts had looked like and talked  
17 to me about the results that he saw and how he  
18 thought they were fairly abnormal for what  
19 diagnosis I was being told. And I realize not  
20 every doctor is going to do that with every  
21 patient. It is not possible. But I think just  
22 to feel like I was being heard was invaluable

1 really.

2 CO-CHAIR DANFORTH: David.

3 MEMBER NEWMAN-TOKER: So maybe I could  
4 ask both of you to weigh in on this issue of  
5 engaging patients -- that came up before -- and  
6 engaging patients in measuring diagnostic error.

7 So it has been bandied about that we  
8 could call patients up at 30 days or 90 days or  
9 whatever and say did you get the right diagnosis.  
10 Presumably, if you did that as a cold call, you  
11 would probably get a pretty negative response  
12 from patients in the sense of what do you mean I  
13 might have the wrong diagnosis and wait a minute,  
14 I don't get it.

15 But to what extent do you think we  
16 could legitimately engage patients in that  
17 dialogue from the get-go, expressing the  
18 uncertainty and then actually leveraging them to  
19 either contact us or to respond to our contacts  
20 to them to actually give us the feedback on when  
21 and whether the diagnosis was right or wrong. Do  
22 you see that as an avenue?

1                   MEMBER HASKELL: I think patients  
2 vitally interested in their own healthcare. I  
3 think you can engage them easily from the  
4 beginning. You know I would say you engage them  
5 while they are in the doctor's office or in the  
6 hospital. That is what we have done on some  
7 projects I am associated with, exit interviews.

8                   But patients are very interested. I  
9 mean nobody takes cold calls. I mean you  
10 obviously haven't been trying to do any polling  
11 recently but we can't get people to answer the  
12 phone anyway.

13                  You know but in terms of -- and the  
14 patient portal is also a huge, if you had  
15 something that people could write in, then you  
16 would be able to have an ongoing conversation in  
17 their medical record, which is where it belongs,  
18 I think.

19                  MEMBER CAMPISANO: Yes, I agree and I  
20 think some pharmaceutical companies are  
21 developing patient engagement techniques specific  
22 to certain drugs and I think that doctors'



1 offices could follow that lead to some extent.

2           You know my nurses would text with me  
3 and just say hey, I have got your lab results or  
4 how are you feeling today. And I think I had a  
5 pretty exceptional oncology office in that my  
6 nurses were willing to do that. But I think just  
7 keep in mind that patients are people.

8           MEMBER HASKELL: And what about  
9 enhanced registries? They are also doing that  
10 sort of thing.

11           CO-CHAIR DANFORTH: What I was going  
12 to say, Helen, is I had a conversation recently  
13 with some folks writing in the Pediatric NSQIP  
14 Registry. And they do contact patients after the  
15 visit to ask if they had unexpected return to the  
16 emergency room, an unexpected return to the  
17 operating room.

18           We have been hearing from some  
19 ambulatory surgical centers that they are  
20 contacting patients to ask about unexpected  
21 complications that occurred after discharge and I  
22 think there are opportunities to prepare a

1 patient for a call or to let the patient know  
2 they are going to have the opportunity to provide  
3 additional information about their care.

4 And something that we have learned at  
5 Leapfrog since we started assigning safety grades  
6 to hospitals is that patients are dying to tell  
7 you about their stories sometimes. I mean we  
8 have received so many patient stories, frankly,  
9 we weren't ready to receive. We have had to  
10 partner with ProPublica who has a patient story  
11 project, to help sort of deal with the number of  
12 patient stories that we received.

13 So I think given the opportunity,  
14 patients do want to share their experience, at  
15 least from what we have seen at our organization.

16 And I see Marilyn.

17 MEMBER HRAVNAK: I had a question  
18 about communication. So do you feel that it was  
19 not only communication but the navigation of that  
20 communication? In other words, not only speaking  
21 but speaking to the right set of ears that could  
22 do something with the information? I mean how

1 much of an interplay do you feel there was there?

2 MEMBER HASKELL: I am wondering if  
3 this is a setup question because that was my big  
4 focus at the time. We actually passed  
5 legislation in South Carolina about provider  
6 identification and navigation in hospitals  
7 because we felt really trapped in the hierarchy,  
8 in the teaching hierarchy. We didn't know. No  
9 one tells you how the hospital bureaucracy works  
10 and it is very complicated. So when you get  
11 someone who is not seeing something, you really  
12 have a hard time getting beyond them.

13 So yes, that is very important and I  
14 think provider identification and rapid response  
15 teams, patient access to rapid response teams.

16 And incidentally, I did a close  
17 analysis of rapid response calls to see what was  
18 causing that because one of the things that -- I  
19 think on the one hand when people think diagnosis  
20 they think outpatient, and I know that the  
21 statistics says that most of it occurs outpatient  
22 but when it occurs inpatient, it is much more

1 critical. The patients are helpless. They can't  
2 leave and go to another provider, even if they  
3 are not terribly sick. They are really stuck  
4 there and they have to have some kind of a safety  
5 valve. So, navigation is critical.

6 And we even got, at one point, we were  
7 advising people to call 911 because it at least  
8 gets some attention.

9 MEMBER HRAVNAK: Right and it is that  
10 whole idea of escalating care, too, and how care  
11 is escalated. And I think your point that in the  
12 inpatient setting, it is not frequently a primary  
13 diagnosis that we are making but it is the  
14 diagnosis of a complication --

15 MEMBER HASKELL: Yes.

16 MEMBER HRAVNAK: -- which can be as  
17 important, if not more important sometimes than  
18 the primary diagnosis in that case.

19 Thank you.

20 MEMBER HIGUERA RUEDA: Thank you.  
21 Thank you for those comments and certainly  
22 communication is key in the measurement of

1 quality.

2 I just wanted to bring back the issues  
3 that there are many venues, currently, for  
4 measure patient communication and patient  
5 satisfaction. At least in our hospital, we  
6 measure HCAHPS scores for the inpatient, and we  
7 have similar scores for outpatients. But we have  
8 to be careful of who we establish measurement of  
9 quality because there is plenty of evidence that  
10 shows that there is really no correlation between  
11 good quality and those HCAHPS scores.

12 And you mentioned that there are a lot  
13 of patients that want to bring back their  
14 stories. Actually from a sample of patients that  
15 get these surveys, only 10 to 15 percent sent  
16 back these reports. And there is evidence also  
17 out there that shows that a fair amount of those  
18 reports are more negative than positive. So  
19 patients have more tendency to report when they  
20 have a bad outcome than a good outcome. And I  
21 think that it would be unfair to necessarily make  
22 assumptions that someone is providing poor

1       quality just based on those scores.

2               So at the same time there is a very  
3       relevant important tool, I think that we have to  
4       be savvy enough and cautious to necessarily  
5       establish that that has to be an absolute  
6       measurement of quality.

7               CO-CHAIR DANFORTH:   David.

8               MEMBER HASKELL:   Could I address that?  
9       I mean I think HCAHPS, and I am not as familiar  
10      with the other CAHPS scores but I think HCAHPS is  
11      really specific enough that it might useful in  
12      this context so that you could associate, for  
13      example, did the nurse come when you rang the  
14      call bell? Was your environment sanitary? You  
15      can sort of associate those things with cause and  
16      effect. I don't know, that is just my thought  
17      that those would be a useful tool in the context  
18      of other things.

19              MEMBER SEIDENWURM:   So first off, I  
20      want to thank you so much for sharing your story  
21      and emphasizing the perspective of the patient  
22      experience because sometimes we all get bogged

1 down with some of our technical concerns.

2 But with respect to the point that  
3 Carlos made, which are all true, I regard those  
4 as features of the system rather than bugs  
5 because most of the time, I hope, medical care is  
6 pretty good. You know it does what it is  
7 supposed to do. And what we want are enriched  
8 samples of the times that it doesn't work so well  
9 because if we start out with a low prior  
10 probability, we are going to falsely -- we are  
11 going to have false positive assignments of poor  
12 care.

13 So I think that by starting with some  
14 of the problems that you discussed, I would argue  
15 that instead of being problems they are actually  
16 features of the system that we ought to try to  
17 exploit and that maybe in our measurement  
18 efforts, we can focus on the denominator there as  
19 an enriched source.

20 Now, there will be other false  
21 negatives because some of the bad results don't  
22 get reported in those ways but at least we might

1 start with a higher prior probability and,  
2 therefore, might wind up with a greater  
3 predictive value for identifying correctly the  
4 areas where the system didn't do its job.

5 MEMBER MCDONALD: Thank you, Helen,  
6 very much, as usual, for your insights on this.

7 I wanted to ask you to maybe explore  
8 a little bit more about this side about  
9 explaining to the patient what the health problem  
10 is, so the definition of diagnostic error where  
11 it actually is a diagnostic error if the  
12 explanation wasn't there.

13 How do you think about what would be  
14 sort of the gold standard of explanation and sort  
15 of patient involvement in that piece of the  
16 definition, based on all the patients you have  
17 talked to.

18 MEMBER HASKELL: Well, I think they  
19 would be a discussion with, rather than an  
20 explanation to. So, I don't see that as just  
21 semantics. I mean I think it needs to be sort of  
22 interactive. Does this fit with your symptoms,



1 as you understand it, not a fiat from above, but  
2 a conversation to make sure you have got it  
3 right.

4 You know one of the things we worry so  
5 much about whether the patient understands us,  
6 and I think it is really critical to know if we  
7 are understanding the patient just to make sure  
8 that everybody is singing from the same hymnal,  
9 which is a pretty darn hard thing to do.

10 MEMBER MCDONALD: I would like to say  
11 I was thinking, as you were talking to Jen, that  
12 there is the part that the patient knows  
13 something that may not be picked up and so giving  
14 that opportunity more room to flourish. There is  
15 also the chance that the patient is missing  
16 something about the context that would be  
17 important to the patient's next actions. So, an  
18 emergency room not getting a particular diagnosis  
19 doesn't mean that the diagnosis doesn't exist.  
20 It just means that the emergency room was just  
21 trying to figure out something that was going to  
22 be really urgent like right now and patients may

1 not recognize that if they continue to have  
2 symptoms that it is perfectly fine to continue to  
3 seek care.

4 And so the explanation that says that  
5 is part of that interaction with the patient that  
6 is important in the diagnostic journey for the  
7 patient and for the system to have the patient  
8 get the diagnosis that they need to get. So, it  
9 is all sort of all sides of that.

10 So, I like your adaptation of that.  
11 It was nice.

12 MEMBER HASKELL: This is a tangential  
13 point but something else that I meant to say and  
14 I somehow overlooked it, in the context of my  
15 son's case but in the context of many, many other  
16 cases, the misdiagnosis of drug side effects and  
17 reactions, which is just rampant. And I think  
18 that I don't know exactly how it could be  
19 measured but something that would really  
20 encourage more learning about drug side effects  
21 among both providers and patients and providers  
22 at all levels. I mean everybody misses it when

1       there is a drug reaction.

2                   CO-CHAIR DANFORTH: Thank you so much,  
3       Helen.

4                   I want to turn it over to Tracy now to  
5       talk about something that we started talking  
6       about this morning, which is terminology and  
7       definitions.

8                   DR. LUSTIG: Thank you. And I am just  
9       going to queue this up to get you all talking  
10      about it again, although we have talked a lot  
11      about this already.

12                  And just to reiterate from this  
13      morning, and as a reminder, we are not looking to  
14      recreate what was done in the Academy's report.  
15      We are not looking to redefine or come up with a  
16      new model for the concept of diagnosis. We are  
17      really trying to focus here on the measurement  
18      part of it.

19                  And just as an example, as you all  
20      know, we already have multiple definitions and  
21      there is probably even more than these. Next  
22      slide.

1                   And so I think what our conversation  
2 needs to be, we don't need to necessarily decide  
3 this here and now and today, which is we have the  
4 terms diagnostic error and diagnostic accuracy.  
5 In our last call, there was a sentiment that we  
6 didn't like using diagnostic accuracy for the  
7 purposes of this project. And one of the  
8 questions we raised and want to talk about now,  
9 and we already have started to do this is whether  
10 we really need to focus more on quality.

11                   And just as an example, and these all  
12 came up this morning, we could call it diagnostic  
13 quality, the quality of diagnosis, the quality of  
14 the diagnostic process. And I know those are all  
15 nuances and that is why we wanted to kind of open  
16 it up to discussion.

17                   And then one of the other things that  
18 did come up this morning as well and we have  
19 talked about is whether we need to explicitly  
20 call out safety to call it diagnostic quality and  
21 safety or quality and safety of diagnosis or do  
22 something to reinforce the IOM definition of

1       quality that already does include safety as part  
2       of quality.

3               MEMBER NEWMAN-TOKER:   Could I just ask  
4       that either David, or Helen, or you, Tracy, give  
5       us a capsule summary of what you perceive to be  
6       the major differences between the umbrella of  
7       quality and the specific narrowly-defined issue  
8       of safety just so that we are all on the same  
9       page about kind of the scope and scale of how  
10      they differ?

11             DR. HUNT:   I can start in.   I am a big  
12      fan of a previous IOM report that was authored by  
13      Paul Tang.   Actually, it was commissioned by AHRQ  
14      where he wrote early on that safe care is  
15      indistinguishable from quality care.   And by  
16      saying that, what he said and that whole group  
17      said, is that safety is a subset of quality, that  
18      all things in safety are related to quality but  
19      not all things in quality necessarily have to do  
20      with the specific issue of patient harm.

21             So I am a big believer, and not that  
22      that has to be the guiding voice throughout this,

1 but I am a big believer in that idea that the  
2 safe delivery of care is indistinguishable from  
3 quality care.

4 DR. BURSTIN: I completely agree with  
5 David, and I think that our perspective has been  
6 that safety is very much part of quality but, at  
7 times, I think my personal opinion, like in this  
8 instance, calling it out separately has an  
9 additive effect. That may be something we want  
10 to consider.

11 MEMBER SINGH: And I am just going to  
12 quickly add from our perspective in our work,  
13 safety is sort of the foundation. You have to  
14 get that right.

15 You know United is terrible as an  
16 airline -- terrible. It is like one of the worst  
17 airlines but I haven't crashed yet. So that is  
18 what is important to me, for instance. So that  
19 is sort of the way I would say.

20 MEMBER SEIDENWURM: Sorry. I'm sorry.  
21 I lost my train of thought in your remark. That  
22 was such a great remark.

1                   MEMBER SINGH: I didn't mean to be  
2                   that dramatic but you know.

3                   MEMBER SEIDENWURM: But I guess when  
4                   I think about the safety of the diagnostic  
5                   process, I think about the harms of diagnosis.  
6                   There are harms in achieving diagnostic certainty  
7                   from false positive diagnoses, incidentalomas,  
8                   the harms of the diagnostic process itself, a  
9                   pneumothorax from a lung biopsy, for example.

10                  So I think that when we talk about  
11                  safety here, we want to talk about making sure  
12                  that we calibrate our degree of certainty  
13                  required with the degree of harm. And there are  
14                  numerous example that I see in my practice on a  
15                  daily basis. And we can debate about whether  
16                  dizziness in the ER is one of them, or we can  
17                  talk about something that is more clearly the  
18                  case -- for example, incidental adrenal nodules.  
19                  You know you see we probably caused more cancers  
20                  following these up than we detect net-net-net,  
21                  timing differences and blah, blah, blah but we  
22                  really have to be cognizant of that in the quest

1 for diagnostic certainty. Are we being safe?

2 DR. HENRIKSEN: You know it is a  
3 matter, I think, of -- you know we are at the  
4 National Quality Forum here. It is not called  
5 the National Safety and Quality Forum. It is the  
6 National Quality Forum, and so it is probably  
7 important to recognize the other components of  
8 quality besides safety.

9 And the second IOM report, Crossing  
10 the Quality Chasm, identified five other  
11 components of quality, in addition to safety.  
12 And that was effectiveness, efficiency,  
13 timeliness, patient-centeredness, and  
14 equitability in terms of care.

15 At the same time, just as Hardeep  
16 mentioned, but you know a focus on safety can  
17 serve as a spearhead and create the coattails for  
18 issues of quality to be discussed and measured  
19 and focused on as well.

20 So it is a matter of -- you know the  
21 Joint Commission's Journal is of quality and  
22 safety. Our Center at AHRQ is the Center for



1       Quality and Improvement and Patient Safety. And  
2       so we like patient safety because it is the  
3       spearhead that sort of gets the attention above  
4       the centerfold probably on our national  
5       newspapers and so it can sort of usher in quality  
6       issues with it.

7               And so it has value, and that is why  
8       the two are oftentimes joined together in  
9       different types of organizations.

10              CO-CHAIR DANFORTH: Martha and then I  
11       see Helen and David.

12              MEMBER RADFORD: I am also a huge fan  
13       of the IOM construct of six domains of quality,  
14       of which safety is one. We are asked to focus on  
15       national measurement here and I think it would be  
16       -- this is my own personal bias -- I think we  
17       should focus first on measuring safety. In other  
18       words, diagnostic errors. I think that will get  
19       the ball rolling in measuring diagnosis in all  
20       the other domains as well, in support of your  
21       view as well.

22              So I just think this is where we

1       should start and acknowledge that it is a start  
2       and not an all-encompassing solution to anything  
3       here. That is my bias.

4                   CO-CHAIR DANFORTH: Helen.

5                   MEMBER HASKELL: So my concern is with  
6       these definitions is blurred boundaries. How  
7       unsafe is the delayed diagnosis? I mean  
8       particularly in the case of diagnosis. I think  
9       it is an issue all the way across healthcare and  
10      I am sure it is an argument that you all have had  
11      ad nauseam, but I particularly worry about it in  
12      the case of diagnosis.

13                   I just think that you can call it  
14      whatever you want, I suppose, but you need to  
15      focus on the whole package because it is all  
16      about safety, and it is all about quality.

17                   CO-CHAIR DANFORTH: David.

18                   MEMBER NEWMAN-TOKER: Yes, I just want  
19      to make this point about efficiency and  
20      effectiveness. I do not think it is possible to  
21      have a robust national discussion about  
22      diagnostic error and safety without talking about

1 the flip side that David keeps bringing up of  
2 overtesting and overdiagnosis.

3 I think the concern when you do that  
4 is, of course, that you are just going to spur  
5 people on to do the wrong thing, which is over  
6 test everybody in every situation.

7 So I think you have to make sure that  
8 kind of both are part of that package because  
9 they are two sides to the same coin. We could  
10 call solve the problem of missed diagnosis  
11 tomorrow by simply ordering every test on every  
12 patient in every situation. And it is clear that  
13 that is not good diagnosis. So from a  
14 measurement standpoint, you would not want that  
15 to be your measurement objective was that  
16 everybody got every test in every situation.

17 So, clearly, somewhere there is some  
18 concept of good diagnosis, better diagnosis that  
19 has to factor in. You know most of us think of,  
20 when we think of clinicians as being good  
21 diagnosticians, they are people who kind of get  
22 to the heart of the matter quickly and

1 efficiently with a minimum of testing, and  
2 effort, and time and they get to the right  
3 answer. I mean that efficiency component of  
4 actually getting the right answer without doing  
5 lots of unnecessary tests and without taking  
6 three months to do it is, in fact, core to the  
7 notion of good diagnosis, and I don't think you  
8 can kind of pry those apart by saying well, we  
9 only care about whether we got it wrong or not.  
10 We have to actually talk about whether we are  
11 doing the right thing.

12 CO-CHAIR DANFORTH: Hardeep.

13 MEMBER SINGH: I want to underscore  
14 what Mark was saying about focusing on safety  
15 because that will lead to conversations about  
16 everything else, which is very, very overlapping.

17 And I will give you a very concrete  
18 example. So we started doing work in the VA  
19 where we found a lot of delays in cancer  
20 diagnoses and test results that were abnormal and  
21 were not being followed up. They were all safety  
22 issues. So the conversation started with a real

1 safety problem, where patient harm was occurring.

2 And then that led to discussions about  
3 communication of test results, where we came up  
4 with actual measures on how we are communicating  
5 test results to patients. And in that, the  
6 timeliness came out. So now we say 14 days and  
7 seven days. Efficiency came up where we had this  
8 same discussion. Making it patient-centered came  
9 up.

10 So I think all the conversations were  
11 propelled and stimulated by a concrete foundation  
12 because nobody would argue with us anymore that  
13 this is a problem that we don't want to measure  
14 because we had such a strong foundation for  
15 safety at the core of the issue and it was easier  
16 to pass all those measures.

17 CO-CHAIR DANFORTH: I'll just add --  
18 I am actually going to go back to one of David's  
19 earlier points. I was a little surprised, David,  
20 that you just said what you said because on one  
21 of your earlier slides you said you know we  
22 really need to focus on B, which were those

1 preventable diagnostic errors that we know  
2 results in harm. And I think when you talk about  
3 it in that way to start the conversation with  
4 providers, and hospital leaders, and even  
5 patients, this was a preventable diagnostic error  
6 that resulted in harm, it is something that  
7 everyone agrees shouldn't happen. When we start  
8 to move into defining efficiency of the  
9 diagnostic process, that is harder.

10 So I just wanted to add that point.  
11 I know you have your card back up and I am going  
12 to let you respond and I do see David back there.  
13 So, I am going to go to you after.

14 MEMBER NEWMAN-TOKER: So just to  
15 clarify what I meant by that. So I think we have  
16 to separate our mission and our process in some  
17 sense.

18 So I think the mission here is to  
19 develop a measurement framework that gets us to a  
20 point where patients don't suffer harm from  
21 diagnostic errors. And I think that should  
22 remain at the core of the mission. Like as we

1 start to get around the periphery of every other  
2 imaginable detail in the quality spectrum, that  
3 we need to have that be our touchstone or our  
4 North Star.

5 That having been said, I think we  
6 risk, by being solely safety-focused in a  
7 developing a measurement framework, setting  
8 ourselves up for a degree of failure. And what I  
9 mean by that is let's make it concrete. Let's  
10 pick the dizzy stroke thing where I know  
11 something about it.

12 So, what you heard before is what I  
13 hear all the time. The first question that David  
14 asked today well aren't you going to just over  
15 test lots of people and not just waste resources  
16 but harm people from incidental findings? You  
17 know in the end, you are going to harm more  
18 people than you save, so on and so forth. I  
19 actually think if we don't at least address that  
20 in some way kind of head-on, we risk having  
21 people say these people don't understand what  
22 diagnosis is in the real world. And I think it

1 could happen in one of several ways.

2 I think you could say okay, look, we  
3 are going to actually explicitly say that for x  
4 class of diagnostic error measures, we have some  
5 associated diagnostic quality measures that kind  
6 of counterbalance on this issue of overdiagnosis  
7 or whatever you want to say. Because you could  
8 literally say okay well, look, for the stroke  
9 thing, you should never measure the frequency of  
10 stroke errors without constantly monitoring your  
11 utilization of neuroimaging. You can pair those  
12 two things together conceptually and say the  
13 quality comes out of getting both of them right,  
14 not out of just focusing on the one that patients  
15 care about as such.

16 So I think somewhere in there there is  
17 a hybrid. And I don't know if for every safety  
18 measure there is a quality measure or whether it  
19 is saying this time, for this year, we are going  
20 to focus on safety and the next time it is  
21 explicit it is going to be about the rest of the  
22 quality measurement. Somehow we have to address



1 it at least.

2 MEMBER SINGH: Yes, but I think that  
3 is what Martha was also trying to say that you  
4 start with the safety problem and then you start  
5 thinking about some of the other things that are  
6 in the same equation.

7 MEMBER RADFORD: Right. For this  
8 particular issue, I think once you have the, in a  
9 sense, safety outcome measures, to me it is very  
10 easy to design that family of measures that is  
11 going to give you the quality. Because for  
12 example, just to take the point of overdiagnosis,  
13 you could say okay you have diagnostic errors and  
14 what does it cost. That is very easy for me.  
15 They follow one from another easily. Then there  
16 is the process measures that also can be  
17 developed, et cetera.

18 CO-CHAIR DANFORTH: Why don't we go  
19 David, and then Mark, and Helen.

20 DR. HUNT: Yes, I think what we are  
21 saying, I don't think anything that has been said  
22 would exclude us continuing on the foundation

1       that was laid with the IOM. I mean those six --  
2       when you read the Quality Chasm report and read  
3       the deliberations that they went through to come  
4       up with those six, I think you have a real good  
5       appreciation for the time and the thought that  
6       went into them. And they are not six independent  
7       degrees of freedom. I don't see any way that you  
8       can be equitable without being patient-centered.  
9       You know you can only be as efficient as you are  
10      safe.

11               In today's world, timely treatment is  
12      equivalent with effective treatment. So I think  
13      that --- looking also, I think it is important  
14      that we, as a group, look toward the larger  
15      process that we are a part of, and it is easier  
16      to have policy discussions down the road when the  
17      products from groups like this sit on a  
18      foundation that was already laid. It is easier  
19      to say this is completely consonant with what we  
20      have done before, not that we have to walk  
21      lockstep in. I mean if we find obvious reason  
22      why there should be a difference or that we are

1 somewhat skewed, I think we should go ahead. But  
2 if it is at all possible to stay on that same  
3 foundation, it is a much easier policy discussion  
4 moving forward when we think about how we are  
5 going to go to that next step and that step after  
6 that.

7 CO-CHAIR GRABER: You know I agree  
8 with that. And in terms of next steps, for this  
9 to actually work, we are going to need all the  
10 stakeholders to buy into this and be interested  
11 and maybe excited actually to tackle this  
12 process.

13 So I am a little worried that we will  
14 alienate physicians when we start talking about  
15 errors, the point that David made. It comes up  
16 all the time. And I think where we could go  
17 astray, I think we all like these six dimensions  
18 of quality but it kind of conveys the impression  
19 that we know what these are, that we know what  
20 timeliness is, and we actually know what the real  
21 diagnosis is and we don't. Even the gold  
22 standard is highly fallible and not often even

1 conclusive.

2           So I am a big fan of including all the  
3 six elements but I think in the next sentence we  
4 have to acknowledge what a complicated process  
5 diagnosis is and there is uncertainty at every  
6 step of the way and that it plays out over time.  
7 And it is very hard to judge at one point in time  
8 whether you are really on the right track or not.  
9 You might get a different answer if you waited a  
10 day or a week.

11           So just pointing out that complexity  
12 and the uncertainty of the process I think would  
13 help us get some parties onboard to go with a  
14 comprehensive definition like this.

15           MR. LYZENGA: And just to quickly add  
16 to that, we can sort of -- we can flesh out some  
17 of those sort of nuances as part of our report  
18 and what we put out with this. And in addition  
19 to doing things like emphasizing maybe that  
20 safety is very important and should be focused on  
21 first, in addition to all these other things,  
22 these are kinds of things that we can sort of

1 build around our core recommendations and add  
2 nuance and context, too, as we work through this  
3 project so we are not sort of -- you know we  
4 don't have to end the discussion here. We can  
5 kind of keep working on these things.

6 DR. BURSTIN: Pretty much just to  
7 build on that conversation, I feel like, at  
8 times, these discussions get sort of  
9 unnecessarily complex. I think we know what we  
10 want to focus and safety will largely be the  
11 biggest domain that we are talking about. At  
12 least for me, I don't want to lose the threads we  
13 heard earlier from both Helen and Jen about  
14 patient-centeredness, timeliness, communication.

15 There may, in fact, be new patient-  
16 focused kinds of surveys that may not focus  
17 exclusively on the safety of a diagnostic error  
18 but may give us the kind of information that will  
19 be invaluable to really help transform the health  
20 system. So it may be that those could still be  
21 part of this framework but I don't want us  
22 getting caught up in this.

1           It is a prioritization issue more than  
2   it is an exclusion or inclusion issue, and I  
3   think we probably could just proceed with safety  
4   as the priority but not lose sense of where there  
5   are in fact significant issues in this space  
6   around equity, significant issues about patient  
7   communication, as we just talked about.

8           MEMBER IRONS: I wanted to follow-up  
9   on what Mark said because I think you make a very  
10   important point. And I think that we talk about  
11   things -- when we look at large data sets, we are  
12   looking at things from 35,000 feet and it is hard  
13   not to look at those figures and say, "Oh, my  
14   God, what is going on in those emergency rooms  
15   across those nine states."

16           But I would like us not to forget that  
17   there is a midpoint between underdiagnosis and  
18   overdiagnosis because, clearly, it is easy just  
19   to default to the imaging study because if you  
20   can identify more patients by doing that, it is  
21   timely because if you can identify more patients  
22   by doing that, it is timely.

1 But what is really important is  
2 knowing what questions to ask. You know taking a  
3 good history, actually touching a patient. My  
4 two elderly parents have been in the hospital for  
5 the last month and they are still both  
6 hospitalized and it is amazing how infrequently  
7 someone has laid hands on them. Three emergency  
8 room visits, this doctor never touched them.  
9 Everybody was looking at machines.

10 So, knowing what historical questions  
11 to ask, knowing how to do a physical exam,  
12 actually having the time to think about the  
13 patient in front of you and having the system, I  
14 am a big advocate of making sure that the systems  
15 actually support the physicians. You know  
16 doctors shouldn't be on the phone talking to  
17 insurance companies about preauthorization for  
18 imaging studies. That is where it becomes  
19 unequitable.

20 And so having the systems -- I don't  
21 want that to get lost in this conversation  
22 because otherwise we are going to be talking

1 about sort of the larger issues and forget about  
2 the important pieces of the physician actually  
3 interacting with the patient.

4 MEMBER NEWMAN-TOKER: So just to be  
5 concrete about the question that is on the slide,  
6 I personally would vote for calling it measures  
7 of diagnostic safety and quality, acknowledging  
8 that the group wants to call safety out as  
9 something important but, at the same time, we  
10 want to acknowledge that it can't be the only  
11 thing.

12 And if that meets with the kind of  
13 broader political objectives, if it fits that  
14 framework by having them both there, then maybe  
15 that is a direction that we could all potentially  
16 get behind.

17 I will strongly advocate against using  
18 diagnostic accuracy or error as the main header  
19 title of what we do; error because it is  
20 poisonous, and accuracy because it so laser-  
21 focused on the issues of tests and results that  
22 it misses the big point of the whole process and



1 everything else.

2 CO-CHAIR DANFORTH: Lavinia.

3 MEMBER MIDDLETON: I put my card up  
4 just as you were saying -- I don't want to waste  
5 time and I am in complete agreement with what you  
6 are saying. But I don't think that error is such  
7 a pejorative term. I think in this sphere where  
8 I work, physicians are aware that the system is  
9 broken and I think having as much focus on the  
10 process and the tools that we have available in  
11 order to even make sense of all the tests that  
12 have been ordered or actually be able to capture  
13 them and to create a meaningful differential  
14 diagnosis or treatment is as relevant as making a  
15 diagnosis.

16 So I don't think that pulling out  
17 accuracy and error or taking it away from the  
18 conversation is that bad, but I would include the  
19 focus, as you did in the Venn diagram, and not  
20 just the diagnosis label but also the process  
21 failure and error as well. And I think that is  
22 where you get the buy-in from physicians,

1 especially it is extremely timely as more EMRs  
2 are being rolled out, more groups are being  
3 consolidated and more patients are having an  
4 aggregate of examinations and evaluations from  
5 multiple caregivers.

6 CO-CHAIR DANFORTH: Helen.

7 MEMBER HASKELL: I just wanted to put  
8 in my two cents. As much as I just used it, I  
9 don't like the word error for the opposite  
10 reason. I think it sort of narrows the  
11 definition so people will say well, I met the  
12 standard of care so there is really anything  
13 wrong with this. It wasn't an error.

14 So I think when you talk about safety,  
15 quality, broader words, you remove the  
16 limitation.

17 CO-CHAIR DANFORTH: Martha.

18 MEMBER RADFORD: We are asked here to  
19 develop a measurement framework, really, not to  
20 develop measures, per se. The framework can also  
21 suggest priorities here.

22 I think that reflecting back on 20

1 years in the quality performance measurement  
2 reporting and improvement field, where do the  
3 really good new measures come from? They have  
4 come from various ends of things over the years,  
5 including national initiatives, say the AHRQ  
6 measures, the quality of those you can debate but  
7 anyway, they are there, the CMS measures. But  
8 really right now I think the really innovative  
9 measures are coming from the field. They are  
10 coming from the provider community, doctors --  
11 Dr. Singh and David -- sorry, I can't remember  
12 your last name -- David and Hardeep have given us  
13 a few of those actually really good examples.

14 So if we are asked to develop a  
15 framework, it is really potentially a framework  
16 for everybody. And what I am saying is that I  
17 think at the national level we need to get these  
18 safety measures because then the others can flow,  
19 as I explained before, but it also can inspire  
20 the other parts of the healthcare system to  
21 develop the kinds of measures for the other  
22 domains, the efficiency domain, patient-

1       centeredness, et cetera. There is certainly some  
2       work that needs to be done on new ways to solicit  
3       patient reaction to the diagnostic process or  
4       whatever. There needs to be more work there.  
5       What do you do? The whole movement of patient-  
6       reported outcomes, which is a whole separate  
7       discussion, may not be covered here.

8               And I just think that this -- I am  
9       going to agree with calling it diagnostic quality  
10      and safety and just say that, as far as a tactic,  
11      from the national level, that we do the most  
12      service to the country by defining the kind of  
13      big picture safety items earlier on.

14             CO-CHAIR DANFORTH: Jen.

15             MEMBER CAMPISANO: I just wanted to  
16      agree, one, agree with Helen that I think --  
17      sorry. When we talk about the safety is  
18      important and quality is important, to put on my  
19      lawyer hat for a minute and not my patient hat, I  
20      would just caution against the word error, which  
21      I am sure every physician in the room is aware of  
22      but I think it is incendiary to some degree and

1 it invites blame where maybe blame doesn't need  
2 to exist.

3 DR. LUSTIG: Can I jump in for a  
4 second? Because I think we are getting really  
5 far afield from what we were trying to do here.

6 We weren't ever going to use the term  
7 diagnostic error. The title of this project  
8 currently is Improving Diagnostic Accuracy and a  
9 lot of people said they didn't like that. And so  
10 we were trying to just in general name the  
11 project something different. It sounds like we  
12 are landing on diagnostic quality and safety,  
13 which is fine. We also didn't intend to get here  
14 into what we are prioritizing because that is  
15 going to come up later in the project. And it  
16 does sound like we are already leaning towards  
17 safety being a priority.

18 This was simply meant to be we don't  
19 like the title of the current project. And so I  
20 don't think we necessarily need to keep going, if  
21 people seem to be okay with us calling the  
22 project, in general, Improving Diagnostic Quality

1 and Safety.

2 CO-CHAIR DANFORTH: So let's let  
3 Hardeep and -- I can't see your name tag, I'm  
4 sorry -- and Marilyn their comments and those  
5 will be the last two comments we can take on this  
6 topic. Then I am going to open the line to see  
7 if there is public comment.

8 MEMBER SINGH: So even though we have  
9 had lots of good conversations on quality and we  
10 believe it is important to think about some of  
11 the ways we are going to approach safety and some  
12 measurement issues, I do think that the title of  
13 the project and the report that comes out  
14 ultimately should only have the word diagnostic  
15 safety in it.

16 And there are several reasons, I would  
17 say for that. One is another quality report and  
18 more quality measures is generally going to be,  
19 the physicians say we already have quality  
20 measures in healthcare. We have got diabetes and  
21 all those other ones, hypertension. Why do we  
22 need more?

1                   So the thinking of the front line  
2                   physicians, who we really want to reach out to  
3                   because, unless we engage them, nothing is going  
4                   to change, is not going to be more quality  
5                   measures of diagnosis.

6                   Second, and we have had this issue  
7                   with some of the work that we have done with  
8                   Office of National Coordinator, is we are still  
9                   having integration problems of sort of health IT  
10                  related safety with sort of the patient safety  
11                  because they think our patient -- you know these  
12                  are just two different things. If we are talking  
13                  about patient safety, we are only talking about  
14                  readmissions, and missed diagnosis, and falls,  
15                  and so on and so forth, and infections, but  
16                  health IT-related safety issues are totally  
17                  different. We don't want that; there is a wall.

18                  So let's think who is going to be our  
19                  audience. Who are going to take these  
20                  measurement concepts forward? Who are going to  
21                  be the improvers of what we want to propose?

22                  So the improvers, to me, are people

1       like Martha's crew, who are going to be looking  
2       at sort of risk management, sort of the patient  
3       safety officers, managers. And I don't know if  
4       some of the routine quality measurement concepts  
5       are going to be that appealing to them because  
6       that is not what their areas are focused on, the  
7       foci of.

8                   CO-CHAIR DANFORTH: Marilyn.

9                   MEMBER HRAVNAK: I guess I just wanted  
10       to make the comment that if we are looking at the  
11       next step, then, which is once we decide then to  
12       come up with measures, I think we get into a  
13       little bit of trouble with quality and safety  
14       because I think safety is more a dichotomous  
15       setup. You know you are either safe or not safe  
16       and there is a little bit of gray in there but  
17       there is not much of a spectrum as there is  
18       between low quality and high quality.

19                   And you could argue on a low quality  
20       end that a lot of the unsafe is going to be  
21       there, but I'm not certain that the same measures  
22       are going to translate across both of those.



1 CO-CHAIR DANFORTH: So just so I may  
2 try and understanding, so what you are suggesting  
3 is that we, for the project title we use the  
4 broader title of Quality or Quality and Safety.

5 MEMBER HRAVNAK: I think that the  
6 measures, it depends on where we want to start.  
7 I think that in terms of the measures, I think  
8 that the measures for quality and the measures  
9 for safety may not be overlapping. I think  
10 safety is going to be the subset and it is going  
11 to be much easier to put in a measure for a  
12 practice that is safe and unsafe, versus a  
13 practice that is of the lower quality or a higher  
14 quality, when you get to the measurement tools.

15 DR. LUSTIG: I actually think this  
16 might belabor it more, but maybe this is  
17 something people can look at and give us some  
18 feedback on. So based on sort of our assumption  
19 of starting with a title of Diagnostic Quality,  
20 these were some definitions -- these are  
21 different variations on each other, based on the  
22 academy's report definition that we could be

1 using for our project. And so it was based on  
2 that, one of those three bullets, and then making  
3 it clear that it had the six dimensions of  
4 quality implicit in that definition. But again -  
5 --

6 CO-CHAIR DANFORTH: Maybe we can leave  
7 this up through lunch because I think when Andrew  
8 talks about the framework, a lot of this is going  
9 to come back up. Is it going to be the framework  
10 for diagnostic safety and quality, or the  
11 framework for diagnostic quality?

12 I am always sensitive if folks are  
13 waiting on the phone to give public comment  
14 because I have been one of those folks before.  
15 So I am going to ask the operator to open the  
16 line to see if there is anyone in the room or on  
17 the phone, or Tom.

18 OPERATOR: Okay, at this time if you  
19 would like to make a public comment, please press  
20 \*1.

21 And there are no public comments at  
22 this time.

1 CO-CHAIR DANFORTH: Paul?

2 MEMBER SEQUIST: Hello?

3 CO-CHAIR DANFORTH: Oh, hi, Tom.

4 MEMBER SEQUIST: Hey. So, it sounds  
5 like you are going to break for lunch. I don't  
6 want to hold everyone up. I would just throw my  
7 vote in, I guess. I think it would be sort of  
8 labeling it not as error but something in the  
9 framework of safety and quality, I would favor  
10 more.

11 CO-CHAIR DANFORTH: That's helpful.  
12 Thank you.

13 Paul.

14 MR. EPNER: So as a member of the  
15 public, I have to reflect on the entire morning,  
16 but I will be very brief and have three comments.  
17 Hopefully, I remember what I was going to say.

18 So it is Paul Epner, Society to  
19 Improve Diagnosis in Medicine.

20 In the discussion of process failures  
21 and label failures, and we talk about process  
22 defects, the cognitive issues sometimes manifest

1 themselves as a process defect. I didn't think  
2 to order a test. You can look to see if the test  
3 was ordered and, therefore, it may translate into  
4 a process defect. But there can be cognitive  
5 biases, et cetera, that lead to inappropriate  
6 conclusions for which there may not be anything  
7 measurable in the process. And I would hope the  
8 committee would consider process clinical  
9 reasoning as a part of a process that should not  
10 be ignored and think about that in the total  
11 context.

12 The notion of completing -- this is  
13 the second comment. The notion of completing the  
14 task versus the effective completion of the task  
15 is something I hope you will all reflect on. I  
16 am thinking that Hardeep was talking about the  
17 ability to measure the communication of test  
18 results to patients, but giving the patient the  
19 physician's report with Hs and Ls and asterisks  
20 may not mean anything to the patient. Half the  
21 time, it doesn't mean anything to the physician.

22 So I think we need to always think

1       about when we look in big databases for evidence  
2       that something happened, just because it  
3       happened, didn't mean that it happened  
4       effectively, and that is the difference.

5               And then my final comment is on the  
6       notion of patient engagement and measuring  
7       patient engagement. And the notion of patient  
8       preferences I think may have been mentioned  
9       earlier, but I didn't hear it strongly. So some  
10      patients, for reasons of financial need, for  
11      reasons of being afraid of not being able to  
12      handle the information, knowing they have a  
13      disease that is going to cause or knowing they  
14      may have a disease that may cause them to miss  
15      work and they have got a family depending on  
16      them, so the notion in the process of offering  
17      patients or evaluating patient preferences and  
18      documenting those patient preferences in some way  
19      I think potentially has some value in this whole  
20      issue of the effective communication of  
21      diagnosis.

22               Thank you.

1 CO-CHAIR DANFORTH: We will break for  
2 lunch. We are 15 minute behind schedule. So I  
3 will look to the NQF staff to decide when we  
4 should come back.

5 DR. BERNOT: We can make that time up  
6 between Andrew and my section. So I think if we  
7 come back at 1:15 or even 1:00. Yes, 1:00 would  
8 be fine for us to come back.

9 CO-CHAIR DANFORTH: So Tom, we are  
10 going to drop off. If you want to drop off, we  
11 will email you around 1:00 if you could call back  
12 in.

13 MEMBER SEQUIST: Okay, great.

14 CO-CHAIR DANFORTH: Thank you.

15 (Whereupon, the above-entitled matter  
16 went off the record at 12:32 p.m. and resumed at  
17 1:07 p.m.)

18 CO-CHAIR DANFORTH: Okay, everyone, I  
19 think we are going to get started. So we are  
20 going to start actually by having Andrew review  
21 the proposed framework for measuring diagnostic  
22 quality --

1 MR. LYZENGA: And safety.

2 CO-CHAIR DANFORTH: Don't start,  
3 Andrew. And then we are going to have John and  
4 Andrew review the preliminary results of the  
5 environmental scan that they did. And so let's  
6 start with the framework.

7 And would you like committee members  
8 to hold questions to the end or as they come up?

9 MR. LYZENGA: No, you can ask me  
10 questions, if you like or hold them to the end.  
11 Either way. I think we had actually allocated a  
12 good chunk of time at the end of the day for  
13 discussion of both the framework and the  
14 environmental scan and the measures we found  
15 through that.

16 So if you want, you can hold your  
17 questions until that time or just interrupt me if  
18 you would like to. I am perfectly happy with  
19 that.

20 So as Christy mentioned, one of our  
21 major deliverables for this project is to come up  
22 with a framework for measuring diagnostic

1       quality/diagnostic safety, whatever we end up  
2       wanting to call this.

3               And just to sort of reiterate what the  
4       purpose of this framework is, there is a number  
5       of purposes -- and this isn't actually a  
6       comprehensive list, either -- but among the major  
7       purposes for this framework are to provide an  
8       organizational scheme for us to identify and  
9       categorize diagnosis-related measures, to  
10      facilitate the systematic identification of  
11      measure gaps related to diagnosis and diagnostic  
12      quality, accuracy, safety, and then to facilitate  
13      a systematic approach to prioritizing those  
14      measures or measurement areas and gaps that we  
15      identify, and then finally, to serve as sort of a  
16      conceptual tool or guidance for the development  
17      of diagnosis-related measures in the future.

18              So essentially this is intended to  
19      serve as a tool for us to do our work moving  
20      forward and for others in the field to -- we will  
21      use it to sort of frame our recommendations in  
22      terms of what we think is important to measure,



1       how it should be measured, and what the sort of  
2       key areas of measurement are with respect to  
3       diagnosis and diagnostic quality and safety.

4               What we are proposing here is very  
5       similar to what we saw with the National  
6       Academy's framework and to Dr. Singh's framework.  
7       What I am proposing here is, in some ways, is  
8       sort of a deconstructed version of the Academy's  
9       framework pulled out into -- or embedded within,  
10      rather, Donabedian's structure-process-outcome  
11      model. And I actually got that idea from  
12      Hardeep's Safer Dx framework.

13              The elements of the National Academy's  
14      framework and Dr. Singh's framework seem to fall  
15      actually fairly nicely into these categories. So  
16      it seemed like it made sense, given that this is  
17      the traditional way of looking at measures and  
18      organizing measures.

19              Structure measures address aspects or  
20      attributes of the work system, the sociotechnical  
21      system -- to use Hardeep's terminology -- in  
22      which diagnosis occurs. Process measures

1 addressed those actions or processes or  
2 interventions or things that commissions or  
3 others are doing to support accurate and timely  
4 diagnosis. And then outcomes, obviously, are  
5 what comes out of that process. And I will talk  
6 a little bit more about how we have broken that  
7 category down.

8 So again, the structure domain.

9 Pretty much, if you look at the diagram here, the  
10 Academy's model addresses those -- that circle  
11 there of the work system elements. You can see  
12 there are the diagnostic team members, tasks,  
13 technologies and tools, organization, physical  
14 environment, and external environment.

15 If you go to the next slide, those are  
16 the same elements rephrased slightly. In the  
17 first, these are the subdomains of the structure  
18 domain and we would hope that any structural  
19 measures that -- concepts that we come up with or  
20 measures that we identify, would be able to sort  
21 of be categorized into one of these dimensions or  
22 domains.

1                   And then the process domain  
2 encompasses -- again within that circle of the  
3 Academy's model -- from where the patient engages  
4 with this health system. So including that part  
5 of patient engagement, that will include things  
6 like access to care and other aspects of that,  
7 that cycle of the diagnostic process, and then  
8 communication of the diagnosis. All of those  
9 elements are part of the process domain.

10                   We have sort of tweaked the names of  
11 these a little bit or added on to them with some  
12 feedback from Dr. Graber as we were developing  
13 this. The first is still patient engagement.

14                   The three elements that relate to that  
15 sort of cycle of the diagnostic process we are  
16 calling -- were called information gathering,  
17 information interpretation, and information  
18 integration in the Academy's report. We are sort  
19 of renaming them a little bit or we are adding a  
20 little more detail to sort of reflect the concept  
21 of diagnosis being an iterative and -- cycle, and  
22 something that is ongoing.

1                   But you need to sort of categorize a  
2                   given measure somewhere, so we have the first  
3                   being information gathering, that being those  
4                   steps that you take to conduct a diagnostic  
5                   evaluation, the next step being information  
6                   interpretation, where you take that information  
7                   and generate an initial hypothesis, and then  
8                   information integration, being that hypothesis  
9                   confirmation and revision over time. And that I  
10                  think will -- we intend to incorporate things  
11                  like communication between providers and other  
12                  ongoing activities as part of that diagnostic  
13                  process.

14                   The next element is -- sorry, go back  
15                  -- is communication of the diagnosis to the  
16                  patient. Again, we think that is a really  
17                  important aspect of both the National Academy's  
18                  framework and their definition of error. We want  
19                  to incorporate that into our own definition and  
20                  work.

21                   We also added on another element that  
22                  is acknowledged in the Academy's framework but

1 not, I guess, in some versions of the model. We  
2 added on quality improvement and learning  
3 activities. We wanted to make sure that was  
4 incorporated here, any processes that  
5 organizations or clinicians are taking to learn  
6 from what is happening and improve the quality as  
7 its own dimension that could be measured through  
8 process measures.

9 The outcome domain, again, at the very  
10 end there, if you want to skip to the next slide.

11 How we've broken this -- what we are  
12 including here in outcomes is both what are  
13 typically sort of construed as outcomes with that  
14 being patient outcomes, clinical outcomes. But  
15 also we are including intermediate outcomes  
16 which, in this case, is what we are labeling  
17 diagnostic errors, for example, a missed  
18 diagnosis or a late diagnosis. Those sorts of  
19 diagnostic outcomes, I guess you might call them,  
20 we are bucketing them into the -- or calling  
21 them, for our purposes, intermediate outcomes.  
22 And we can discuss whether that is appropriate.

1                   Another next dimension is those  
2           patient -- actual patient and clinical outcomes.  
3           This is kind of, I imagine, maybe a tough area to  
4           address, but we would like to make some progress  
5           toward identifying some clinical outcomes, actual  
6           patient outcomes that could be associated with  
7           diagnostic performance and the quality of  
8           diagnostic care.

9                   Patient experience being the next,  
10          obviously, really important aspect of this as  
11          well.

12                   And then system outcomes being things  
13          like cost, resource use, efficiency, and -- as  
14          acknowledged again in the Academy's report --  
15          things like the patient and consumer confidence  
16          in the system which is, again, maybe a hard thing  
17          to reflect in measurement, but is something that  
18          we wanted to account for here.

19                   So that is the basic outlines of that.  
20          We will get more into this as we -- we sent a  
21          document to you that laid out those domains and  
22          also had some measure concepts associated with it

1 to sort of illustrate how measures might be  
2 associated with each of those domains. Those  
3 were taken from Hardeep's paper and some concepts  
4 that we were suggested by our co-chair, Mark  
5 Graber. And as we get into our environmental  
6 scan results -- we actually didn't include those  
7 concepts in our analysis there but we will -- as  
8 we move forward -- incorporate both those  
9 concepts and any concepts that we come up with as  
10 a group in our exercises in terms of identifying  
11 measures and potential measures and where we can  
12 identify gaps.

13 So maybe I will just take questions  
14 here. Yes.

15 CO-CHAIR DANFORTH: Martha.

16 MEMBER RADFORD: Could you go back to  
17 the thing where you had a circle around a bunch  
18 of it?

19 Yes. So I was a little concerned  
20 because you are leaving off treatment there.  
21 Because response to treatment is a very key  
22 diagnostic tool and I just would incorporate that

1 in there. And perhaps there is monitoring --

2 MR. LYZENGA: Do you think that should

3 --

4 MEMBER RADFORD: -- the diagnosis on an  
5 ongoing basis, refining it, et cetera. That is  
6 an important piece.

7 MR. LYZENGA: Sure. I think we  
8 intended that to be included in the information  
9 integration step. If you go to the next slide,  
10 it includes, again, sort of hypothesis  
11 confirmation and revision, that being sort of  
12 that continuous process of learning from your  
13 treatment approaches.

14 But if you and others think that it  
15 may need to be called out as a separate domain,  
16 we could consider that.

17 MEMBER RADFORD: I'm not sure it is  
18 a separate domain but it's just to mention  
19 somewhere that response to treatment is part of  
20 the diagnostic process.

21 MR. LYZENGA: Okay.

22 CO-CHAIR DANFORTH: Mike.



1                   MEMBER DUNNE: Maybe I had better wait  
2                   for Act 2. This is just general right now, right?  
3                   This isn't a plan for what you want to do, what  
4                   you want to measure, how you are --

5                   MR. LYZENGA: It is supposed to, I  
6                   guess, serve as, again, sort of a framework for  
7                   filling in that detail in the future. We would  
8                   hope that this would sort of identify the major  
9                   categories in which measurement might occur. And  
10                  there could be all kinds of measures that would  
11                  fit into this but we would hope that any measure  
12                  that comes up could be, in some way, categorized  
13                  into one of these domains just for the purpose of  
14                  sort of organizing our thinking and identifying  
15                  again where there are gaps in measurement or  
16                  where we want to prioritize some particular area.

17                  MEMBER DUNNE: Because I keep on  
18                  coming to the conclusion that all of this is  
19                  going to be very, very different for each  
20                  clinical entity.

21                  MR. LYZENGA: Oh, absolutely.  
22                  Absolutely.

1                   MEMBER DUNNE: I mean you are almost  
2 going to have to define separate parameters for  
3 each -- you know, for sepsis, for stroke, for  
4 this, for that.

5                   MR. LYZENGA: Yes, and so there will  
6 be -- yes, there may be many measures that fit  
7 into this. And that is -- yes, you wouldn't -- I  
8 expect, at least, you would have a measure that  
9 is information gathering or diagnostic  
10 evaluation. It would be something much more  
11 specific, specified out, likely for a particular  
12 condition or set of conditions that would then  
13 reflect the quality of the information gathering  
14 process or the diagnostic evaluation, as an  
15 example. So these are, yes, just very broad  
16 categories that are intended to serve as an  
17 organizing framework for much more specific  
18 measures that would kind of fit into that.

19                   MEMBER DUNNE: So do you see, in the  
20 long-term, that these will be used to develop  
21 diagnostic pathways for all of these clinical  
22 entities?

1                   MR. LYZENGA: I don't think so. I  
2 mean -- what do you mean by pathways?

3                   MEMBER DUNNE: Well, let's take  
4 sepsis, for example.

5                   MR. LYZENGA: So like the process  
6 measure around sepsis that you have to sort of  
7 take certain steps and things?

8                   MEMBER DUNNE: Yes, what is the  
9 differential diagnosis? Once you learn the  
10 diagnosis, what is the appropriate treatment?  
11 You know, what type of testing is involved? How  
12 is a septic patient engaged?

13                   MR. LYZENGA: Yes, so I imagine -- I  
14 mean, you could, potentially -- I don't think  
15 this is what we intended it necessarily to be but  
16 we -- that is an interesting idea that you could  
17 sort of apply this entire framework to, say, a  
18 clinical area or condition like sepsis and,  
19 across each of these domains, come up with  
20 structure elements that reflect the quality of  
21 diagnosis for sepsis or the sort of conditions  
22 for correct and appropriate diagnosis of sepsis

1 and then process steps in each of these domains.

2 MEMBER DUNNE: Right, because you can  
3 measure that.

4 MR. LYZENGA: Right. Well, we hope  
5 so, and that's what we --

6 CO-CHAIR DANFORTH: David, David,  
7 Hardeep, and then Helen.

8 MEMBER NEWMAN-TOKER: So, just to  
9 follow up on Mike Dunne's point before I get to  
10 my other question. I think this is an important  
11 issue, is that a lot of the measurement in this  
12 space is likely going to be problem-specific  
13 because we know that the problem with diagnosis  
14 is highly problem-specific. And there are some  
15 generalizable elements of it, but we have to be  
16 mindful of that as we construct the framework.

17 And in particular, I think we have to  
18 be mindful of the fact that when we are talking  
19 about measuring outcomes or diagnosis label  
20 failures and correct diagnoses, you are focused  
21 on diseases. But when you actually start talking  
22 about correct process and the diagnostic process

1 being high quality or low quality, or associated  
2 with error or not, you actually have to focus on  
3 clinical-presenting problems or symptoms.

4 So it is not what did you do in sepsis  
5 patients. It is what did you do in people in  
6 whom sepsis might be suspected who had a fever or  
7 low blood pressure or this or that or the next  
8 thing, not -- because you don't know the  
9 diagnosis up front. So you have to look at  
10 diagnostic process performance in the context of  
11 a high-risk situation or clinical-presenting  
12 complaint or problem, not the reverse. It is  
13 only when you are talking about the outcomes that  
14 you can sort of take that disease frame.

15 Can we go back to the outcomes one?  
16 My question here, when you started talking about  
17 -- sorry, go up one more, the subdomains. So you  
18 said that diagnostic measures sort of mostly fall  
19 into the intermediate outcomes. I would like to  
20 just maybe hear a little bit more discussion  
21 about that and get some reflections of folks --  
22 including Helen and our patient representatives -

1 - to have a sense for where that shakes out.

2           So, like you can think of an  
3 intermediate outcome measure that says like was  
4 this an assay for whether you had this gene  
5 defect in a colon cancer right or wrong. Was it  
6 a false positive/false negative? I think  
7 everybody would kind of agree that that might be  
8 thought of as kind of an intermediate outcome.  
9 But is it an intermediate outcome when we get to  
10 the point where you are given a diagnosis and  
11 then it affects your treatment? Maybe you want  
12 to reflect on your experience there?

13           MEMBER CAMPISANO: Sure. Where do you  
14 want me to start?

15           MEMBER NEWMAN-TOKER: Well so, to you,  
16 was that an intermediate outcome or was that a  
17 patient clinical outcome? In other words, when  
18 does a diagnostic failure of some kind fall out  
19 from being an intermediate to being a patient  
20 outcome? Is it when the patient is harmed? Does  
21 that harm include the psychological harm of being  
22 given the wrong diagnosis? Where is that

1 transition point from intermediate to patient-  
2 centered meaningful outcome happen?

3 MEMBER CAMPISANO: I can sort of go  
4 over the discussion that we were having in the  
5 break a little bit to review my background.

6 In August of 2011, I was diagnosed  
7 with what we thought was metastatic breast  
8 cancer. And I had a five-month-old son at the  
9 time. Discounting the fact that my OB/GYN had  
10 thought it was mastitis and dismissed me several  
11 times, by the time I was diagnosed and then  
12 treated for four and a half years for metastatic  
13 cancer, I thought my oncologist knew what he was  
14 doing.

15 And I still think that he is an  
16 excellent doctor, but earlier this year it came  
17 out that I probably had stage II breast cancer  
18 and, at the same time, sarcoidosis, which can  
19 mimic cancer on scans, apparently. And that came  
20 out because I had a lung biopsy this spring,  
21 finally. And so I don't know where I would  
22 consider that error to have occurred or, you know

1 -- and obviously my outcome is better than I  
2 thought it was going to be. So I don't know  
3 where I would fall into the framework.

4 MEMBER NEWMAN-TOKER: So but Jen, I  
5 guess what I was trying to ask was -- obviously,  
6 it is a horrible story. At what point did it  
7 cease -- so, an intermediate outcome is sort of  
8 some kind of accounting tabulation or along the  
9 way that we didn't get it right but it may or may  
10 not have had any downstream impact on a patient  
11 outcome.

12 And I guess what I am trying to figure  
13 out is how soon in the process of that problem  
14 did you experience the real-world harm of your  
15 situation?

16 Was it at the point where you started  
17 getting side effects from chemo for a disease  
18 that you didn't have, or was it the moment they  
19 dropped the bombshell of the C diagnosis and said  
20 that you were going to die? Or when was the --  
21 when did we cross over into meaningful harm that  
22 we want to be preventing?



1                   MEMBER CAMPISANO: I would say that  
2                   the majority of the harm that I experienced was  
3                   probably psychological. And that came within the  
4                   first week, when they went from saying yes, it is  
5                   breast cancer to we did a PET scan we see spots  
6                   in your spleen and your lungs and your chest wall  
7                   and your abdomen, and you are probably going to  
8                   die in the next couple of years.

9                   MEMBER NEWMAN-TOKER: So I think the  
10                  issue there that this brings up is whether  
11                  getting that diagnostic label, in and of itself,  
12                  may be a patient or clinical outcome, never mind  
13                  what happens to their medical condition. And I  
14                  think we have to be careful about how we define  
15                  what is an intermediate outcome versus a real  
16                  outcome for patients.

17                 MR. LYZENGA: And I should say that we  
18                 -- I think Mark brought this up in one of our  
19                 recent conversations, that we should be  
20                 considering those psychological effects and I  
21                 think we had intended those to be in the patient  
22                 and clinical outcome area, not in intermediate

1 outcomes. That would -- I think the intent was  
2 for that to apply to those, I guess, label  
3 failures and that any effect of that label  
4 failure on the patient -- whether that is mental  
5 or psychological, physical -- would be considered  
6 a patient outcome or clinical outcome. And I  
7 don't know if that makes sense to everybody else.  
8 This is exactly what we want to talk about.

9 MEMBER HASKELL: Would a better  
10 distinction be near miss?

11 MR. LYZENGA: Yes, you could consider  
12 those near misses, the intermediate outcomes  
13 where there was a label failure.

14 I mean, well, it would -- even if it  
15 did result in harm, I think then you would want  
16 to account for it I guess twice, in some sense.  
17 You had the label failure -- the diagnostic  
18 error, if you want to call it that, or the missed  
19 diagnosis -- and then the patient harm that  
20 occurred if it was not a near miss.

21 MEMBER MCDONALD: Actually I think  
22 what you are saying is you could have a near miss

1 -- whether we count that as an intermediate  
2 outcome or not could be debated -- but that there  
3 still could be a patient outcome from a near  
4 miss.

5 MR. LYZENGA: Right.

6 MEMBER MCDONALD: I mean somebody  
7 doesn't actually have to -- if they knew that  
8 there was a near miss.

9 MR. LYZENGA: Right. If that caused  
10 some -- yeah.

11 MEMBER MCDONALD: That could have an  
12 effect, yes.

13 CO-CHAIR DANFORTH: David.

14 MEMBER SEIDENWURM: Two points. One  
15 is that I would like to add a little bit to what  
16 Martha said. And I think not just treatment as a  
17 diagnostic tool but also just observation, just  
18 doing nothing and waiting as a diagnostic tool.  
19 And I think it would be very important to include  
20 that explicitly in our thinking.

21 The other thing is --

22 CO-CHAIR GRABER: Can you say that

1       again, David, a little louder?

2                   MEMBER SEIDENWURM:   Sure.   I'm sorry.

3                   So what I was wanting to say was that  
4       I wanted to add a little bit to what Martha said  
5       about counting treatment explicitly in our  
6       evaluative process.   And sometimes doing nothing  
7       is the best diagnostic test and just watching  
8       because many processes are self-limited, many  
9       symptoms are self-limited or many disorders are  
10      self-resolving.   So they don't all need to be  
11      investigated.

12                  And then the other point I wanted to  
13      ask about is how do we conceptualize the idea of  
14      a negative diagnostic test when, in fact, the  
15      patient doesn't have anything but we have given  
16      them the idea or they have, themselves, gotten  
17      the idea that they might.   And so we see this all  
18      the time in headache, back pain -- perfect,  
19      another one.   I mean there are a hundred great  
20      examples.

21                  And so I feel sometimes like we are  
22      the arsonists who set the fire and then get the

1 medal from the mayor because we heroically put it  
2 out.

3 And so I don't know exactly how to  
4 think of this in our taxonomy here.

5 MR. LYZENGA: We could consider it a  
6 -- well, intermediate -- I don't know, an  
7 intermediate outcome, in some sense, a system  
8 outcome maybe.

9 MEMBER NEWMAN-TOKER: Well I think  
10 we're straying into the territory of  
11 overdiagnosis and overtreatment and so -- with  
12 overdiagnosis being defined as sort of a  
13 condition that it actually is but you don't --  
14 the patient shouldn't care about because it is  
15 not really going to make a difference.

16 The issue here -- in terms of the harm  
17 to the patient -- you know, the same way we just  
18 said, if an overdiagnosis -- like you say that  
19 somebody has thyroid cancer and it was something  
20 that was immaterial -- you may have gotten the  
21 correct diagnosis label in some sense but you  
22 have made a diagnostic process failure in another

1 sense because you found something -- if you  
2 pursued it in an overly aggressive way -- that  
3 you weren't supposed to find.

4 I think it is when it becomes  
5 psychologically harmful or harmful to the patient  
6 in terms of overtreatment that it then sort of  
7 falls off into this clinical outcome bin. So I  
8 do think that there is a way to kind of make that  
9 transition from diagnostic error or overdiagnosis  
10 or whatever to harm from that.

11 CO-CHAIR DANFORTH: Hardeep.

12 MEMBER SINGH: So I want to pick up  
13 from what Mike said and make another related  
14 point.

15 So you asked for disease-specific  
16 measures. Is this framework going to inform  
17 every -- you know, measures for every single  
18 disease? I don't know if that necessarily needs  
19 to be the case right now. Maybe another 50 years  
20 or 100 maybe that would be more relevant because  
21 I think the problem is there is too many things  
22 going wrong at the same time.

1                   So in one of our studies, in 190  
2     diagnostic errors in the primary care setting,  
3     there were 67 different conditions involved.  
4     None of them was more than six percent of the  
5     entire subset and then some were just like two,  
6     one and two -- you know, like right at the end.  
7     So, there are so many things to fix.

8                   So, you could take a disease-specific  
9     approach if there is a really high-risk condition  
10    like sepsis and use this type of a conceptual  
11    framework to make sure you are covering ground  
12    and then maybe focus on that as an outcome  
13    measure.

14                  But as far as the process measures and  
15    the system structure measures that we are sort of  
16    thinking about, I think they will be fairly  
17    generic, that you don't need a disease-specific  
18    approach for every single structural, every  
19    single process measure. I think disease-specific  
20    approach, for instance, in one of our papers that  
21    you took was for cancer. So for colorectal  
22    cancer, high-risk condition, have a measure as an

1 outcome.

2 So does that sort of help you sort of

3 --

4 MEMBER DUNNE: Sure but when I think  
5 about things like timeliness, you take sepsis and  
6 then you take chronic lymphocytic leukemia and  
7 the timeliness of diagnoses is a world apart or  
8 even --

9 MEMBER SINGH: Oh, yes, absolutely.

10 MEMBER DUNNE: -- tuberculosis.

11 MEMBER SINGH: Yes, well, lung cancer  
12 and colorectal.

13 MEMBER DUNNE: It has got to be within  
14 the framework of when therapy is going to provide  
15 a benefit and when you have lost that.

16 MEMBER SINGH: Very true. And that is  
17 why I think outcome measure. So an outcome  
18 measure for like maybe 60 or 90 days for  
19 colorectal cancer diagnosis but shorter time for  
20 lung cancer diagnosis would be more relevant. So  
21 that was sort of my reflection.

22 The other thing I was just going to



1 mention quickly is there is a very important  
2 measure that is on the previous -- the one about  
3 the quality improvement and learning activities  
4 that we shouldn't sort of lose sight of. I'm not  
5 sure which slide it was on -- but that is really  
6 important because I am going to ask this question  
7 to you, Jen, is what did your system -- your  
8 health system and your providers -- learn from  
9 your experience and what did they change?

10 MEMBER CAMPISANO: I hope that they  
11 have changed how they approach new patients who  
12 present with seemingly metastases that they  
13 investigate further. You know, I think it is not  
14 100 percent accurate, but there is a blood test  
15 for sarcoidosis, for example. You don't have to  
16 necessarily biopsy every lesion.

17 But I am not entirely sure. That is  
18 a good question. I haven't asked.

19 MEMBER SINGH: And I would say most  
20 missed diagnoses we learn nothing and we move on,  
21 in most cases like this we move on.

22 So I think really that quality

1 improvement in learning activities needs to be a  
2 very strong component of trying to sort of think  
3 about measurement in that area to make sure that  
4 physicians, nurses, the healthcare system, are  
5 making progress to what I think is actionable  
6 measurement.

7 MR. LYZENGA: And just --

8 DR. BURSTIN: Just one quick thought  
9 on the process outcome question.

10 MR. LYZENGA: Yes, go ahead.

11 DR. BURSTIN: It is a very interesting  
12 question, Hardeep. Just going along with the  
13 comment about sepsis, there are, in fact, three-  
14 hour bundles for sepsis so you don't miss  
15 anything, that you don't, in fact, miss the early  
16 identification and treatment.

17 So I'm not sure there are always going  
18 to be outcomes but I understand where you are  
19 going. But I don't think we want to be so  
20 exclusive to say you would then not have, for  
21 example, appropriate bundles around diagnosis to  
22 make sure you don't miss anything for some of

1 those three very high-risk areas you mentioned  
2 earlier.

3 MEMBER DUNNE: But getting back to  
4 what David said -- and most of the time you don't  
5 know what you have to start with, but there is  
6 going to come a time where you are going to want  
7 to work backward, when you have the final  
8 diagnosis and you want to retrospectively  
9 evaluate whether it was done appropriately from  
10 the start. And in that case, now you have got  
11 disease-specific guidelines.

12 MR. LYZENGA: And in fact in our  
13 environmental scan -- you will see this in a  
14 moment -- is mostly that type of measure to the  
15 extent that we found things like intermediate  
16 outcomes. And most of the process ones as well  
17 are focused around specific conditions or  
18 diseases.

19 One of the measures we found was  
20 persistent indicators of dementia without a  
21 diagnosis that -- over a period of time in a  
22 nursing home a patient has been exhibiting

1 behaviors and characteristics that would suggest  
2 -- and even undergone assessments that should  
3 have prompted a diagnosis of dementia, but that  
4 diagnosis was never made is the sort of measures  
5 that we are finding and that we, I think, would  
6 expect.

7 I think you are unlikely to get -- and  
8 something I kind of wanted to say about the sort  
9 of the definition of diagnostic error, too, in  
10 some ways is -- you know, I think maybe we can  
11 make some recommendations around what we think  
12 the most important way to think about diagnostic  
13 error is. But in terms of specific measures, you  
14 are unlikely to have like a measure of diagnostic  
15 error. It is more likely to be some particular  
16 condition or set of circumstances that reflects a  
17 diagnostic error in one of those ways that is  
18 very sort of detailed and specified.

19 So in some ways, the sort of question  
20 of how you define diagnostic error is kind of  
21 moot for those considerations, although I do  
22 think as part of our recommendations broadly, we

1       probably want to have some thoughts around how we  
2       think diagnostic errors should be conceptualized.  
3       Even though once you get to the specific measure  
4       level, it kind of becomes irrelevant in some  
5       ways.

6                   MEMBER NEWMAN-TOKER:   Can I just  
7       follow up on that?   I know Helen has been  
8       waiting, but just on that point, that issue of  
9       how disease-specific we need to get, I do think  
10      that there is a middle ground there. Which -- for  
11      instance, the example you gave about carrying an  
12      undiagnosed condition for x number of visits,  
13      encounters or whatever, is kind of a  
14      generalizable idea.   The same way that what I  
15      showed you about the stroke stuff is a  
16      generalizable idea.   You can do that symptom-  
17      disease para-framework with chest pain and heart  
18      attack.   And you can do it with dyspnea and  
19      pulmonary embolus, and fever, and sepsis, so on  
20      and so forth.

21                   So when we think about developing a  
22      measurement framework -- rather than individual

1 measures -- maybe what we want to do is get  
2 granular enough that maybe it doesn't apply to  
3 everything, but that it applies to sort of a  
4 class of problems, where people can start to plug  
5 in -- fill in the individual things. Maybe for  
6 dementia it is a slightly different set of  
7 criteria than it is for missed cancer or  
8 something else. But like the undiagnosed  
9 condition for three or more times is, in and of  
10 itself, maybe kind of the framework level that we  
11 want to get to.

12 CO-CHAIR DANFORTH: Helen.

13 MEMBER HASKELL: No, I just wanted to  
14 sort of put my stake in the ground again about  
15 making this patient-centered. So instead of  
16 explaining to the patient, you have discussions  
17 with the patient. And the primacy really of the  
18 patient and experience outcomes, you seemed a  
19 little dubious about that. I think that is  
20 really central.

21 And then the quality improvement  
22 learning activities, again, patient involvement

1 really changes those and makes them much better  
2 and they also are areas that are of critical  
3 importance to patients to know that there has  
4 been improvement.

5 CO-CHAIR DANFORTH: Prashant.

6 MEMBER MAHAJAN: So I have to confess  
7 I am getting more confused. And you know you can  
8 all just put it down to my ER background but the  
9 way I look at it is we are coming up with a  
10 conceptual framework that provides the best way  
11 to explain the patient's condition. So that is  
12 the definition that we are going by. It is to  
13 explain the health problem in a timely and  
14 accurate manner and communicate that to the  
15 patient.

16 So I am with Hardeep, in that sense,  
17 that if we go down the path of having individual  
18 measures from the provider perspective, I think  
19 it just adds to a layer of confusion.

20 For instance, in the sepsis issue,  
21 there a bunch of measures already out there. So  
22 is accuracy and diagnosis of sepsis and added

1       measure in how we are going to respond to that  
2       and how people are going to take this on. It has  
3       become a little bit difficult to operationalize.

4               So the way I was thinking about it is  
5       we could consider measures what can be done in  
6       the three domains of structure, process, and  
7       outcome that will enhance the ability to provide  
8       that accurate explanation. So, rather than going  
9       towards individual conditions -- I am just  
10      throwing this out -- if it could just involve x  
11      number of providers trained for x number of years  
12      in certain conditions, something like that,  
13      versus timely access to patients to clinics. In  
14      that sense, it sort of takes away -- because  
15      whatever that will allow the diagnosis to be made  
16      in a timely manner, rather than going down  
17      individual path.

18              Because in sepsis, my only argument  
19      toward sepsis is there are a bunch of bundles out  
20      there but it is a very heterogeneous condition  
21      and most of the bundles have not been shown to be  
22      effective because it does not necessarily treat



1 the original condition.

2 So what now has happened is certain  
3 states have now institutionalized those bundles  
4 but yet there is no clinical acceptance and you  
5 have this dichotomy of some measure of quality  
6 but not being accepted.

7 I was just throwing that out. Maybe  
8 it is just my confusion, but I am --

9 MR. LYZENGA: Yes, and I think the --  
10 I wasn't saying necessarily that we ought to be  
11 focusing on specific conditions. That was what  
12 we found in the environmental scan so far. I  
13 think we should certainly try to push towards  
14 sort of broader measures if we can make those  
15 sorts of recommendations of things that capture  
16 more cross-cutting issues around diagnosis and  
17 diagnostic quality.

18 I think in particular you mentioned a  
19 couple of ideas and those seemed like structural  
20 measures to me, and my inclination would be to  
21 say most of the structural measures are going to  
22 be much more cross-cutting and about sort of

1 creating the conditions in which diagnosis can be  
2 made successfully and that is very unlikely to be  
3 conditioned or disease-specific, at least in most  
4 cases.

5 And you know in terms of the  
6 processes, those may get more specific or not.  
7 These are exactly the types of things I think we  
8 want to discuss over the course of this project.  
9 And right now we are kind of creating this broad  
10 framework for conceptualizing diagnosis and what  
11 elements we might be able to measure. But as we  
12 move on, I think we ought to get more granular as  
13 we can and make recommendations around what we  
14 think measurement should look like. And I think  
15 this is exactly the sorts of conversations we  
16 want to be having moving forward.

17 CO-CHAIR DANFORTH: David.

18 DR. HUNT: Just to -- this is probably  
19 a reiteration of how this product will be  
20 consumed as we identify and create the cubbies,  
21 if you will, that the individual measures will  
22 fit in.

1                   From a policy framework,  
2           organizations, groups at HHS may then look and  
3           say: well, you know we have a whole bunch of  
4           measures in this domain, but it seems as though  
5           we need to have someone develop measures in say  
6           patient engagement or hypothesis confirmation  
7           because it seems as though we are missing a lot  
8           when people do studies of root cause analysis.  
9           And that will help us understand what areas we  
10          may want to improve our measure portfolio, if you  
11          would.

12                   In which areas do we have enough  
13          measures? And if we have a somewhat balanced set  
14          of measures in a particular domain, that might  
15          lend you to say well this might work. These  
16          group of six might work well for a composite  
17          measure.

18                   So this is, in large part, filling out  
19          the little cubbyhole places where then we can  
20          work on areas of improvement.

21                   CO-CHAIR DANFORTH: I am going to do  
22          two more comments from the Davids and then I am

1 actually going to turn it over to John to review  
2 the environmental scan because I think that will  
3 actually help some of us better wrap our head  
4 around the concept of the framework when you see  
5 some of the example of measures currently exist  
6 and where they would fit in the framework. You  
7 will see that it actually ranges through a bunch  
8 of settings in clinical areas and conditions.

9 So, the last two, then John. So,  
10 David Newman-Toker and then --

11 MEMBER NEWMAN-TOKER: Just quickly, in  
12 terms of Prashant's comment. I think it brings  
13 up a really important issue, which is that we  
14 should be careful not to stray into the notion  
15 that says we know which process defects that are  
16 out there are kind of causally linked to the  
17 specific diagnostic errors, and we should focus  
18 our attention on all of these specific process  
19 defects that are clearly responsible and, if we  
20 fix them, they would reduce the outcome of  
21 interest.

22 I think it is tempting to do that but

1 I actually think we have no idea pretty much for  
2 anything because, to my knowledge, there has not  
3 been a single intervention that has shown that  
4 you could actually decrease patient harms --  
5 which is sort of ultimately where we are getting  
6 to -- from an intervention focused on some  
7 specific aspect of the diagnostic process to get  
8 to the point of decreased patient harm.

9 And Hardeep can correct me if I am  
10 wrong, but I am not aware of any such studies.  
11 And so even if there are one or two out there,  
12 they are not across any meaningful set of domains  
13 and we know that the process defects that are  
14 responsible are going to differ across problems.

15 So I think we need to measure process  
16 and we know that that is the place that we can  
17 change in order to influence outcomes, but we  
18 should be a little agnostic about which process  
19 problems are the causal ones. We should be very  
20 careful about drawing too many inferences about  
21 which ones matter the most.

22 MEMBER SEIDENWURM: Thank you. And

1       this is not to be considered the last word in any  
2       way. I just wanted to make sure that we  
3       considered the problems caused by the EHR  
4       technology itself in the diagnostic process and  
5       how some of the human factors, perhaps -- or lack  
6       of human factors and their design -- contribute  
7       because I think that a big problem that we see is  
8       that there is a lot of information that is hiding  
9       in plain sight and there is a lot of debris in  
10      the medical record that obscures the ore that you  
11      are trying to mine.

12               And the famous example of the Ebola  
13      case in Dallas was quite likely exacerbated or  
14      even caused by inadequate either design or  
15      implementation of the EHR.

16               MEMBER SINGH: I actually wrote a  
17      whole series on this case. So it is actually not  
18      just was the EHR. The physician had clear access  
19      to the nurse's note and could actually read -- if  
20      he had gone on a different screen -- that the  
21      patient had travel history to West Africa. So, I  
22      just wanted to --

1                   MEMBER SEIDENWURM: This is the last  
2 word. I rest my case.

3                   CO-CHAIR DANFORTH: No but I mean just  
4 to go back to David's point, there are I think  
5 some sort of discrete measures that aren't  
6 perfect or ideal measures that do sort of get at  
7 what you said. I mean I think CMS tried to  
8 implement or maybe even for a limited time  
9 implemented a DVT measure that looked patients  
10 that were at risk for DVTs didn't received the  
11 prophylaxis and then got a DVT.

12                   So I think within the diagnostic  
13 process, where the risk is identified and the  
14 treatment clear and then not given, and then the  
15 bad outcome happens, there are some small  
16 discrete examples, potentially, to learn from.

17                   MEMBER NEWMAN-TOKER: So an  
18 intervention was introduced that increased that  
19 quality measure and then it decreased the harms  
20 from DVT like PE in patients?

21                   CO-CHAIR DANFORTH: Yes.

22                   MEMBER NEWMAN-TOKER: Can you send me

1       that?

2                   CO-CHAIR DANFORTH: I will. And  
3       again, so we looked at this measure carefully at  
4       Leapfrog because it was a great example of you  
5       have this defined population that is at risk and  
6       you have a defined care protocol for prophylaxis,  
7       and then you just didn't give it them and they  
8       got the DVT.

9                   You know what I mean? It sort of --

10                  MEMBER NEWMAN-TOKER: But that is a  
11       treatment thing. I mean is that a diagnostic  
12       thing?

13                  CO-CHAIR DANFORTH: But they were  
14       identified. So they were diagnosed as at-risk  
15       for a DVT, and then they didn't get the correct  
16       treatment for that risk that they were diagnosed  
17       with, and then they got the DVT.

18                  MEMBER NEWMAN-TOKER: Well that is  
19       actually its own little interesting can of worms  
20       that we should discuss. I mean is that what we  
21       mean by diagnosis? I mean --

22                  MEMBER MCDONALD: Diagnosing the risk



1 and following up with a treatment for that risk,  
2 as a pair, right? Because that is what you are  
3 saying.

4 CO-CHAIR DANFORTH: Right.

5 MEMBER MCDONALD: And it is the pair.  
6 The pair didn't happen.

7 CO-CHAIR DANFORTH: Right and it is a  
8 paired measure. I mean that was what in the  
9 measure.

10 MR. LYZENGA: More, I think you are  
11 asking if just the assessment of risk, are we  
12 considering that diagnosis.

13 MEMBER NEWMAN-TOKER: So there is a  
14 whole domain of a prognosis and risk  
15 stratification. There is like an entire  
16 scientific field around this sort of idea. And  
17 this is a murky area because it is somewhere in-  
18 between screening and symptomatic diagnosis.

19 And I think we can all agree that when  
20 a patient comes in complaining of a headache or  
21 back pain or whatever and we don't get the  
22 diagnosis right, that that is diagnosis, but it

1 is murkier and murkier the more you get into the  
2 issue of asymptomatic screening and asymptomatic  
3 risk assessment and so on and so forth. That is  
4 potentially scope creep that could be huge for  
5 the framework, and we should at least know where  
6 we stand on that.

7 CO-CHAIR DANFORTH: So I guess the  
8 reason I brought it up is because of the  
9 conversations we have throughout the day about  
10 sepsis. I mean some of that is early  
11 identification of the sepsis patient, not  
12 responding appropriately when the patient  
13 presents with those symptoms of sepsis.

14 MEMBER NEWMAN-TOKER: Well it is  
15 slightly different. So there you are talking  
16 about recognition of sepsis signs. That is  
17 really symptomatic diagnosis.

18 What you were saying is this is a  
19 patient who has no symptoms of DVT but has the  
20 following high-risk setting or behavior. They  
21 are in the setting of the hospital. They are  
22 post-operative from an orthopedic or

1       neurosurgical procedure. They are such and such,  
2       and such. And if that is part of diagnosis, then  
3       I am not saying that it shouldn't be, but I am  
4       saying that if it is, this is an even bigger and  
5       more thorny complicated problem than it already  
6       was.

7                 DR. HUNT: I think it is as big and  
8       thorny as you might suggest because in the case  
9       of the DVT, if I do a low pelvic surgery, I am  
10      automatically putting that patient at risk for  
11      DVT. I know that. So part and parcel of doing  
12      that procedure is that I should take the steps to  
13      confirm or at least make a diagnosis or exclude  
14      it because I know that I put that patient at  
15      risk.

16                MEMBER NEWMAN-TOKER: But it is  
17      precisely the fact that you know, by having done  
18      the lower pelvic surgery, that to my mind makes  
19      that a treatment error issue, at treatment safety  
20      issue, rather than a diagnostic one.

21                The main thing that makes diagnostic  
22      errors different from treatment, so those that

1 actually consider them different because are some  
2 people who think it is all just sort of one big  
3 thing, but to the extent that people  
4 compartmentalize between the two, the diagnostic  
5 piece involves that uncertainty in not knowing,  
6 as opposed to --

7 DR. HUNT: Right. Not all my patients  
8 get a DVT.

9 MEMBER NEWMAN-TOKER: No, no, but that  
10 the procedures that you put in place after a  
11 procedure that are based on whatever risk  
12 factors, they are based on age, or they are based  
13 on the type of surgery, or they are based on the  
14 immobility, or this or that, those are all  
15 entirely predictable events that are -- there is  
16 just a probabilistic association with whether or  
17 not your patient will get a DVT. But your path,  
18 as a clinician, is actually quite clear.

19 The diagnostic trouble is that your  
20 path is not clear. And I do think that this is a  
21 murky and important issue for us to settle before  
22 we do this for a year and then realize that we

1 weren't clear on whether risk stratification was  
2 part or not part of the mission.

3 CO-CHAIR DANFORTH: So let's do the  
4 environmental scan and see if other examples of  
5 measures that address this question come up.

6 DR. BERNOT: Okay well really I don't  
7 want to cut off -- the discussion is really good.

8 I do want to start. I think maybe it  
9 would be helpful to take just a half a step back  
10 and get to what David said because David and I  
11 are right on the same page except cubbyhole is  
12 way better than what I came up with.

13 And when we are looking at this from  
14 the NQF and how do we take this huge topic and  
15 really try to get it down into something at the  
16 end of a couple of meetings is valuable. There  
17 was a few things we were thinking of. One of  
18 them is just we are going to have all of this  
19 data or these processes and these frameworks  
20 presented so we have some sort of data dump. And  
21 I think we tried to do that this morning. And  
22 then come up with what these cubbyholes might

1 look like. And that was what Andrew was going  
2 over. So those may be cubbyholes.

3 And I think one of the things that is  
4 important is do those make sense. Are you able  
5 to put your measures into those cubbyholes or  
6 not, regardless of whatever measure it is you  
7 come up with? So that is one thing.

8 The second thing is: what do measures  
9 or concepts look like in those cubbyholes? And  
10 what I am going to do here is go over and say:  
11 when we look at what is out there, where do they  
12 fit in the cubbyholes, to get to what David's  
13 point was? We might be overloaded. If we are  
14 overloaded in places, I am sure we could all  
15 guess where we are overloaded.

16 And then the last thing, whether it is  
17 tomorrow or throughout the course of this process  
18 is starting to get some priorities. So now we  
19 have the cubbyholes. We know what could fit in  
20 the cubbyholes and then we can prioritize them  
21 and hopefully, that is a framework or foundation  
22 for future measure development. And so it is not

1 to say all this discussion is not great because  
2 this discussion is fantastic. We are already  
3 getting to the priority point, I think, to make  
4 sure we are focusing on the patient and make sure  
5 we are having a method that connects diseases.

6 So that is what I just wanted to take  
7 that half step back so that when I am going  
8 through the environmental scan I can show you how  
9 some of the measures that are out there already  
10 hang on this and then we can say is this a  
11 sufficient framework for measure development.

12 So I hope that makes sense.

13 DR. BURSTIN: Just one thing to add.  
14 Just keep in mind also a really important piece  
15 of this that David mentioned. There is a lot of  
16 Davids here.

17 MEMBER NEWMAN-TOKER: This is like the  
18 David committee here.

19 DR. BURSTIN: I am just going to call  
20 him Hunt. David Hunt said earlier was we also  
21 the reason to have a framework like this is to be  
22 able to say this is a new area of measurement.

1 We don't have a lot of measures. We are going to  
2 try to fit some into some of the cubbies as  
3 appropriate. But really importantly, where are  
4 the empty cubbies? Where are the areas you guys  
5 are prioritizing as being some of the most  
6 important areas, like let's say, for example, the  
7 discussions with patients that we have just  
8 talked a lot about so far today. That is likely  
9 going to be a pretty empty cubby and maybe one  
10 that then rises to the top, in terms of saying if  
11 you are going to develop measures in this space,  
12 make sure you focus on those.

13 DR. BERNOT: Empty cubbyholes.

14 All right. So what I will do is just  
15 go over the environmental scan. There is two  
16 parts we did on this. The first one was a  
17 literature search and we did ask research  
18 questions to try to look at what all literature  
19 is out there. The second part is looking at the  
20 actual measures that existed that we thought.  
21 And I am sure we can go around and say you missed  
22 a measure or if you have this. I don't know if



1       you categorized this exactly but I do think,  
2       though, the order of magnitude will be the same  
3       and we certainly want to get it accurate so I am  
4       not trying to say we want to be imprecise but I  
5       don't think it is going to change the order of  
6       magnitude.

7               So when we look at the overview, what  
8       were we really trying to do? Again, these still  
9       use the diagnostic accuracy wording, because that  
10      is what we had in the original proposal but say  
11      diagnostic quality and safety, just for the sake  
12      of this presentation. But what metrics exist?  
13      So what measures are out there? What are the  
14      approaches? What has been written in this space?  
15      What already exists? So that is really what we  
16      tried to do here. Can you go to the next slide?

17             So the literature review I think is an  
18      important end component to this. And it was very  
19      important to us, at least internally, to be  
20      reviewing this to make sure we were identifying  
21      the areas. Not surprisingly, some of the most  
22      important literature is from people in this room

1 and we have heard about this literature already  
2 this morning. So I think it is an important part  
3 of the end product but it is not something just  
4 in terms of keeping the scope reasonable for this  
5 two-day meeting, we are not going to focus as  
6 much on the literature, although I think  
7 experience with literature should influence how  
8 we go forward. And we really tried to do that.

9 But just to let you know, these are  
10 the sources we looked at. We tried to be  
11 comprehensive and we went through the PubMed, the  
12 Grey Literature, measure inventories, again. Can  
13 you go to the next slide?

14 So I think this is probably, since we  
15 are really trying to get to a measure development  
16 framework, where we wanted to spend our time, at  
17 least, and so we went through all of these  
18 explicitly and looked at some key words. There  
19 is other places we looked at measures or found or  
20 they were referred to us but these are the ones  
21 that we looked at very explicitly and very  
22 systematically, I should say. Can you go to the

1 next slide?

2 And these are the key words. We  
3 talked about this at the web call, too. So I  
4 don't want to belabor it. Some great feedback  
5 came back from committee members after the web  
6 call and said hey, these ones in blue, can you  
7 add some other terms and go back and take a look  
8 and see what that does to the inventory that you  
9 can find. So, we did that. We added all those  
10 key words.

11 And this is a living list. As we come  
12 up with more things, we are happy to continue to  
13 refine the overview.

14 A couple caveats on this. Just as we  
15 looked at things, and when I get the sheet in  
16 front of you and we go over what we hung in these  
17 cubbyholes, there was a couple assumptions we  
18 made that I do think should be brought up for  
19 discussion after we are done with this. One of  
20 them is we did not include asymptomatic  
21 screening. We had to make a cut at some point.  
22 Is that a diagnosis of colon cancer for a person

1 who just came in for their -- they are 50 years  
2 old. So, I am just putting that out there that  
3 we did not include these. These can be up for  
4 discussion.

5 A couple of other caveats of things we  
6 did not include were strict overuse or  
7 appropriate use measures, where it is simply  
8 looking at a utilization, not necessarily the end  
9 diagnostic tool. So, we made those decisions,  
10 and they can be reversed.

11 What we did include were comorbid  
12 conditions. So, you have a diabetic patient and  
13 did you diagnose their peripheral neuropathy or  
14 did you screen for their peripheral? We did  
15 include that. We didn't believe that was as much  
16 of an asymptomatic screening as a disease  
17 progression. And we are trying to get to that  
18 best diagnosis of the disease. So, we did  
19 include those.

20 And then any staging of a disease. So  
21 different staging of cancers, especially that  
22 might have had a different treatment, we tried to

1 include those measures. Go to the next slide.

2 So with that said, there is not a lot  
3 of measures out here anyhow. And what you see  
4 here is the summary data for the form that you  
5 have, the colored sheet you have in front of you.

6 So just looking, that is actually --  
7 I'm sorry there is a typo on there. It is  
8 structure 1, process 45. We will fix that.  
9 Sorry about that. And outcome -- yes, very  
10 impressive. We are forward thinking.

11 So process 45 and outcome is 8 and  
12 that is of the 54 measures that we found and felt  
13 that they fit into the key word search that we  
14 did.

15 Any questions about that part, so far,  
16 like just how we got to this part?

17 CO-CHAIR GRABER: Would this have  
18 included Joint Commission measures?

19 DR. BERNOT: Yes, any measure that we  
20 could, yes, that we could come across.

21 And again, I am certain that there are  
22 still other measures out there that we did not

1 include. And there is a couple other little tiny  
2 things we didn't include.

3 For example, one place might have a  
4 COPD measure that looks at spirometry diagnosis  
5 over 40. One of them has it over 18. We  
6 included that only once in there because I think  
7 from a conceptual point of view it is not two  
8 different measures. I know it is from the actual  
9 measurement science but the concept was somebody  
10 who was looking at spirometry and COPD for the  
11 point of this.

12 MEMBER MAHAJAN: So can I ask this  
13 question? Were these measures that you found  
14 largely disease-specific or rather condition-  
15 specific, or were they more cross-cutting?

16 DR. BERNOT: They were largely  
17 disease-specific. And actually I am going to  
18 hand it off to -- well, after I finish these, I  
19 am going to hand it off to Andrew, who actually  
20 put together just some qualitative analysis on  
21 the measures, these 54 measures -- again, just as  
22 a way of looking at the measures and getting a

1       feel for what is out there right now.

2                   And we could cut it a million  
3       different ways and probably still be correct, but  
4       we are just trying to come up with something that  
5       makes sense.

6                   Go ahead and go to the next slide. So  
7       now I am going to relate the measures back to  
8       what Andrew went over. So, if you thought about  
9       he had the three -- he had structure, process,  
10      and outcomes. And then with the structure, he  
11      listed some subdomains, which are the ones across  
12      the top of the first page and what you see out  
13      there. Structure is a little bit strange, since  
14      there was a total of one measure that we came  
15      across and you can see which of the buckets that  
16      it fell into. So we are short on structure in  
17      general and there is only one of the categories.  
18      So, that is not necessarily even needing a graph.

19                   But go to the next slide. I think it  
20      will make a little more sense when we get into  
21      the process measures.

22                   So no surprise. Where is our patient

1 engagement? We are already seeing may be a hole  
2 in what is out there. Patient engagement has one  
3 but when we get into the information stuff, the  
4 stuff that we, as at least presently as  
5 clinicians, know what to do. We know how to take  
6 stuff. And did we run it? Did we not run it?  
7 Did a process occur or not occur? That is where  
8 you are starting to see the measures.

9 Now this does not equal 54 because we  
10 believe that some things can fit into multiple  
11 categories, just to let you know that.

12 And again, so we thought for structure  
13 there were certain aspects, certain cubbyholes  
14 that might make sense that are different when it  
15 comes to process. Again, all these tried to come  
16 from Hardeep's framework, at the time IOM  
17 framework. So that is where we came up with  
18 these.

19 But all of this is up for debate. You  
20 may say there is a seventh category or a fifth  
21 and there should only be five. That is the  
22 discussion I think we want to make sure we have



1 the right buckets to put these measures into.

2 Go ahead to the next slide. And for  
3 the outcomes you can see, again, our label of  
4 intermediate outcome, you make a good point.  
5 Maybe we don't need an intermediate outcome.  
6 Maybe that is a patient outcome and we say we  
7 want to get this down to three buckets and that  
8 better visualizes the data as to where we  
9 actually have measures. So that is our hope in  
10 this.

11 And I want to stop because I know I  
12 went over a lot of stuff, and I want to make sure  
13 that I was clear because I think a lot of the  
14 future discussions are going to drive off of what  
15 we are hoping to get. So I will stop here and  
16 see if there are any questions.

17 CO-CHAIR DANFORTH: Hardeep, do you  
18 have a question?

19 MEMBER SINGH: I don't know. Maybe I  
20 will wait for the last one.

21 CO-CHAIR DANFORTH: Okay. David.

22 MEMBER NEWMAN-TOKER: Can you go back

1 one slide for the process measures list? So  
2 could you tell us a little bit more? You talked  
3 about there being overlap between categories.  
4 Did you find a lot of overlap between those three  
5 ones that are talking about information  
6 gathering, interpretation, and integration?

7 DR. BERNOT: What we found was, again,  
8 based on our use of the words, we found that the  
9 most was over the information gathering and the  
10 information interpretation that a lot of times  
11 they were one in the same. This was run and it  
12 was determined to be blank.

13 MEMBER NEWMAN-TOKER: Right. So I  
14 mean I guess I think one of the questions here --  
15 you know this process of developing the framework  
16 is all about deciding what level of granularity  
17 you want and how much lumping and splitting to do  
18 but I do think that it is not surprising that  
19 there was a lot of overlap in those spaces  
20 because they are kind of inextricably linked. So  
21 one might consider condensing and then  
22 consolidating them into clinical reasoning skills

1 or something else that can kind of weave all that  
2 together. I don't know exactly what, but rather  
3 than splitting things that are almost impossible  
4 to differentiate from one another.

5 MEMBER MCDONALD: I might argue the  
6 other direction though because there is like a  
7 lot of work that has been done sort of in the  
8 laboratory context that is really about the  
9 information gathering, getting that as good as it  
10 can get. Of course there is interpretation  
11 within the lab but that is still constrained to  
12 that piece. So it might be helpful to keep  
13 things in their separate buckets if there are  
14 actions that would be taken in separate buckets.

15 MEMBER NEWMAN-TOKER: Well, I don't  
16 feel strongly about it.

17 DR. BERNOT: And if you look, just as  
18 you glance through, hopefully this is pretty easy  
19 to read. But if you look at maybe pages 2, 3, 4,  
20 and 5, you will be able to see how some of the  
21 measures hit one, some hit both of those  
22 categories. There are a number that do fall in

1 independently but I thought that was the most  
2 overlap. But these are good points. We want to  
3 make the most -- the simplest amount of buckets  
4 or cubbyholes that we can put these measures in  
5 and actually have some value as to say this one  
6 is empty and this one is full and know where our  
7 priorities should be.

8 MEMBER NEWMAN-TOKER: And maybe to  
9 Kathy's point what we need to do is actually not  
10 just ask whether these things are theoretically  
11 different but whether they can be measured  
12 separately.

13 So in the sense of if information  
14 gathering can be measured by looking at charted  
15 documentation as a discrete entity and saying if  
16 it wasn't written down, it wasn't gathered, then  
17 maybe that is its own thing that is discrete and  
18 separate from interpretation.

19 CO-CHAIR DANFORTH: I think, too,  
20 there are some examples of those measures that  
21 have the check boxes in both. So we might even  
22 after want to look at some of the examples where

1 the NQF team has said we think it falls into both  
2 buckets and see if that is -- you know based on  
3 these descriptions, is that what we would think?

4 I'm going to go to Mark and then  
5 David.

6 CO-CHAIR GRABER: We had this  
7 discussion internally, whether these are the  
8 right buckets. An alternative way to do it would  
9 be to say that there are things that happen early  
10 in the diagnostic process versus things that play  
11 out over time. Would that be a more helpful way  
12 to classify?

13 MEMBER NEWMAN-TOKER: Maybe or things  
14 that happen at the bedside versus things that  
15 happen in the interactive process with the rest  
16 of the healthcare team. I don't know.

17 MEMBER SEIDENWURM: Just to understand  
18 a little bit more about how the categories were  
19 separated, would something like interoperability  
20 be considered information gathering? In other  
21 words, you could look in somebody else's -- when  
22 I say somebody else's, the same patient's but

1 some other hospital's or whatever information  
2 system, or would that be in the information  
3 integration, or would that be part of  
4 communication? How would we think about that?  
5 Because I think that we do need to get -- that  
6 would be back a notch under structure.

7 And there is a couple of those out  
8 there and I am not sure they were captured in the  
9 document.

10 CO-CHAIR DANFORTH: Hardeep and then  
11 Martha.

12 MEMBER SINGH: So I am going to just  
13 quickly reflect on the categorization and I am  
14 going to revisit some of the earlier discussion  
15 probably at the same time.

16 So I would think this is where those  
17 five dimensions that I walked people through this  
18 morning are really useful because even though  
19 they have overlap, they are sort of patient-  
20 centric. So you have got the patient engagement.

21 But there is doctor-patient  
22 interaction. So, this is where all the cognitive

1 stuff happens, the information gathering, the  
2 refinement, and you order some tests, you talk to  
3 the patient.

4 Then you get the test done, which is  
5 the lab or the radiologist. So if David, the  
6 neuroradiologist reads the MRI wrong, that is  
7 that dimension, which is the information  
8 interpretation.

9 The third one is follow-up of test  
10 results. So, he reads the MRI and I miss it. So  
11 I never followed up or I didn't communicate to  
12 the patient the third dimension.

13 The fourth is you can add subspecialty  
14 referrals and all that.

15 So I think that categorization avoids  
16 a little bit of this artificial distinction  
17 between some of the other integration and  
18 hypothesis generalizations because you just have  
19 one doctor-patient interaction as one dimension  
20 and then you put everything related to that  
21 within that dimension. So in this diagram, it is  
22 the brown one for instance. So that would be the

1       only way you could refine, if you wanted to, the  
2       categorization.

3               The second comment was sort of more  
4       revisiting the earlier discussions on are we  
5       trying to improve the 10,000 diagnoses or  
6       diseases, the diagnosis of those 10,000 diseases  
7       that WHO has or are we actually trying to focus  
8       on some narrow high-risk areas that we want to  
9       fix? And again, the point being patients care  
10      about delayed and wrong treatment, delayed and  
11      wrong tests.

12             So with that in mind, I was thinking  
13      a lot about the DVT example. And then when you  
14      said that 50-year-old with the CRC, with the  
15      colorectal cancer, I had actually written down  
16      earlier, just to given an example. So if your 50  
17      year old man presents to the primary care doc and  
18      does not get offered a colonoscopy and a year  
19      later they have colorectal cancer diagnosed, what  
20      are we going to call that and why? Anybody have  
21      any strong preferences here?

22             How many would call it a diagnostic



1 error? A 50-year-old came -- okay, how many of  
2 you would call it not a diagnostic error?

3 Okay, how many of you want to know  
4 whether the physician asked whether there was a  
5 family history or not? What if I tell you that  
6 that patient had a brother who was diagnosed at  
7 the age of 35? They needed a screening  
8 colonoscopy but did they need a diagnostic  
9 colonoscopy or not?

10 So if I missed a screening opportunity  
11 because they had no family history of colorectal  
12 cancer, that is a screening opportunity. But if  
13 they had family history of colorectal cancer,  
14 that was a diagnostic opportunity. So I am kind  
15 of reflecting on David's point earlier that I  
16 think we are going to need to sort of think  
17 through some of these intricacies.

18 And then to point out there is lots of  
19 screening type measures here. So, are we done?  
20 I mean this is 56. Why do we need more?

21 Why do we need more? Why can't we  
22 just stop there and pick the four or five or

1 seven that we --

2 MR. LYZENGA: We could but they may  
3 not be the right --

4 MEMBER SINGH: Exactly! That is the  
5 point I am trying to make. They are not the  
6 right measures because they do not talk about the  
7 things that we all are interested in, which is  
8 missed and delayed diagnoses, which is, again,  
9 the framing point that I was sort of trying to  
10 make earlier.

11 We are going to have to come up with  
12 some priorities in what are the types of measures  
13 we are going to focus on.

14 So was there a missed opportunity to  
15 diagnose a DVT in your patient, for instance?  
16 That is the question. And if there was an  
17 asymptomatic patient, there was no opportunity to  
18 diagnose that patient with a DVT at that  
19 particular point of time. I would say you could  
20 call it a screening failure, or a surveillance  
21 failure, or a preventive failure but I'm not sure  
22 we can plug everything into a diagnostic category

1 and we are going to have to be really careful;  
2 otherwise, everything is diagnostic, which is the  
3 reason why we have not made any progress in this  
4 for the last several decades.

5 CO-CHAIR DANFORTH: Martha and then  
6 Kerm.

7 MEMBER RADFORD: Just a quick comment  
8 about the one structure measure. It probably is  
9 the same as David's but I just want to say it my  
10 way, I guess.

11 So it is helpful to sort of bucket the  
12 structure measures in the way that you have done  
13 but I also think it is helpful to somehow  
14 reference where in the diagnostic process this --  
15 if this is an actor.

16 And again, on this one, the one that  
17 you have here, it is information gathering and  
18 then communication is where that acts in the  
19 diagnostic process. So I just would ask that if  
20 we find anymore structure measures, we at least  
21 reference that option.

22 And then I would also suggest that

1 maybe suggesting new structure measurement areas  
2 or measurement concepts might be a real service  
3 as well.

4 MR. LYZENGA: Sorry just to clarify,  
5 did you say that the structure measure we have  
6 here could also be -- it would be --

7 MEMBER RADFORD: Right, you have  
8 binned it in technologies and tools, which is  
9 absolutely correct. But it also could be binned  
10 in where in the diagnostic process. They are not  
11 mutually exclusive, that's all.

12 CO-CHAIR DANFORTH: Kerm.

13 DR. HENRIKSEN: Yes, one thing that  
14 the discussion has sort of made me think of is  
15 something that we really haven't talked about and  
16 that is measure usability. And these three areas  
17 of information gathering, interpretation, and  
18 integration. If the researcher and if the  
19 thought leaders that are on top of this subject  
20 matter can't really easily separate this  
21 cognitive process in these three stages that are  
22 very intricately linked and interactive, if you

1 can't come up with a useable measure that doesn't  
2 take two days to figure out and we actually agree  
3 on this, then it is a measure usability issue.

4 And so one thing that the framers of  
5 this could possibly do is see what the user and  
6 our reliability is in being able to categorize  
7 things in these areas. And if there is a lot of  
8 confusion and core interrelated reliability, then  
9 you need to collapse the category and create a  
10 higher order category, or hybrid, or a  
11 combination, or a composite.

12 MR. LYZENGA: You might have just  
13 created some homework for the committee. If you  
14 guys are open to that, we could try something  
15 like that and see how others assign these  
16 measures into the various buckets and see what  
17 kind of integrated --

18 MEMBER NEWMAN-TOKER: I would vote  
19 that when you do that exercise you try to also  
20 use Hardeep's four categories and see which one  
21 ends up being more accurately, reliably  
22 classified.

1                   MEMBER IRONS: So I would just like to  
2                   add my voice to some prior calls for  
3                   consideration of a category for what to do with  
4                   patients who are at risk for conditions that then  
5                   require screening afterwards. You know if next-  
6                   generation sequencing becomes more and more  
7                   pervasive, as it is not targeted, we are going to  
8                   have children that are currently being screened  
9                   for a targeted reason and they are going to be  
10                  identified with BRCA1 mutations, other adult  
11                  onset conditions, and how that is followed. And  
12                  if it is not, what we call that missed diagnosis,  
13                  10, 20, 30 years later is going to create a whole  
14                  other category of concerns.

15                 I mean it is probably going to be the  
16                 biggest tsunami that is coming our way, in terms  
17                 of presymptomatic screening.

18                 MEMBER SINGH: Hang on. So you mean  
19                 to say after they have had the next-generation  
20                 sequencing?

21                 MEMBER IRONS: Right.

22                 MEMBER SINGH: Okay.

1                   MEMBER IRONS: Yes, so you know for  
2                   example, a child may have intellectual disability  
3                   and anomalies and if it not targeted to the  
4                   symptoms, there is actually a panel of adult-  
5                   onset diseases that they are also screened for  
6                   and not only them, but their families.

7                   CO-CHAIR DANFORTH: Kathy and then  
8                   Mike Dunne.

9                   MEMBER MCDONALD: That makes me think  
10                  it something with the comment. So I was just  
11                  going to extend what we were hearing about the  
12                  structure and the tie-in to the process.

13                  I know we don't have a lot of  
14                  structure measures but they said that this will  
15                  be a whole. Some of the slides before and just  
16                  the discussion makes me think that we need to be  
17                  clear about these structures tying to kind of  
18                  what the vulnerability is diagnostically, so it  
19                  is not, obviously, just any structure. And I  
20                  know you guys are thinking about that. It just  
21                  wasn't in the text. You know they get a process  
22                  tied to the diagnostic problem or diagnostic

1       quality structure tied to that. And I think with  
2       structure, particularly, it is going to be  
3       important to be a little more explicit about what  
4       that tie is, whether it then gets binned into  
5       some process piece or not, just tie it in.

6               The reason I was thinking it related  
7       to your comment, you know you can imagine that  
8       there would be a structure that would be some  
9       sort of registry that would allow some sort of  
10      population monitoring of a group of patients who  
11      are now known to be a higher risk and that that  
12      would be a system approach, not just the one  
13      clinician at a time approach to that potential  
14      need to sort of engage more proactively in using  
15      the diagnostic information that is available. So  
16      that could be a structure as well as then there  
17      could be gaps in terms of using that information  
18      at the clinical level.

19             MEMBER IRONS: But then just to  
20      follow-up on that, it will also require us to  
21      shift our definition of whose patient is really  
22      the doctor's patient. Because if the sequencing



1 is done on the child and the child has a BRCA1  
2 mutation, then it either came from the mom or the  
3 dad. So is the child -- whose responsibility is  
4 it to follow the parent, when the child is  
5 somebody's patient? So it is a whole other can  
6 of worms.

7 MEMBER RADFORD: Just to focus also on  
8 your very good comment about the structure  
9 measures, very few structure measures have a  
10 structure outcome link and that is what I like to  
11 see as well on structure measure, even this one.

12 CO-CHAIR DANFORTH: Mike.

13 MEMBER DUNNE: I was just going to  
14 mention a possible additional source of  
15 information. I was just fooling around here and  
16 went to the LTRC, which is the full free text  
17 online legal review journal search system, and I  
18 typed in diagnostic errors and got some really  
19 interesting results back, one of which had to do  
20 with patient interaction.

21 So it might be another source to look  
22 for additional materials for your environmental

1 screen. That's it. Thanks.

2 DR. BERNOT: All right. Do you want  
3 me to turn it over to Andrew?

4 Just to wrap this up, and just to let  
5 you know, this is the -- the things we are going  
6 over is pretty much the last of what I consider  
7 the data dump to the group. And really, from  
8 here on out, it is trying to take all of these  
9 things we talked about and really come up -- do  
10 we have the right buckets, the right cubbyholes?  
11 And we can actually make those changes or get  
12 those suggestions today. And then how do those  
13 work with measure concepts?

14 So Andrew is going to talk a little  
15 bit about the measure concepts, as well as just a  
16 little bit of qualitative analysis he did, just  
17 to give a little more flavor to some of these  
18 measures.

19 MR. LYZENGA: We didn't actually  
20 include the concepts in here.

21 DR. BERNOT: Oh, sorry about that.

22 MR. LYZENGA: These are still just

1 environmental scan.

2 This is just very briefly just  
3 another, again, as John said, sort of another way  
4 to slice it, just trying to look at themes that  
5 emerged from the measures we identified.

6 And there is a range of different sort  
7 of topic areas. A couple of the major ones, as  
8 you might expect, we called a type of measure  
9 appropriate use of diagnostic criteria or  
10 diagnostic tools. And you might expect that to  
11 be the largest area of measurement currently  
12 because that is sort of the low hanging fruit  
13 when you have something very discrete you can  
14 measure. There is a test or a process you are  
15 supposed to follow for this particular condition.  
16 Did you do it? Again, kind of low-hanging fruit.  
17 Not necessarily where we want to be in really  
18 getting at the quality of diagnosis, at this  
19 point.

20 A number of measures that we have  
21 called sort of care coordination, communication  
22 between providers and appropriate documentation,

1 and that sort of thing.

2 Sorry, David did you have a question?

3 DR. HUNT: Is the category of  
4 availability and/or deployment of diagnostic  
5 resources part of appropriate use of diagnostic  
6 criteria and tools?

7 MR. LYZENGA: No, sorry. So there is  
8 a zero there.

9 DR. HUNT: Okay.

10 MR. LYZENGA: This is a little bit  
11 confusing.

12 DR. HUNT: So those two aren't  
13 combined?

14 MR. LYZENGA: No.

15 DR. HUNT: Okay.

16 MR. LYZENGA: And this is a little  
17 confusing. These categories were done with the  
18 concept, so there is a number of the measure  
19 concepts that did fall into these categories but  
20 they are a zero for the actual measures that we  
21 found through the environmental scan.

22 Completeness of diagnostic assessment

1 was another sort of the larger. And basically,  
2 trying to determine whether -- and that had a lot  
3 to do -- and maybe that is the wrong name for it  
4 but whether, again, things were appropriately and  
5 fully documented, whether, in some cases, the  
6 diagnosis was granular enough to be useful or  
7 whether it was recorded in an appropriate way and  
8 communicated. Next slide.

9 I just wanted to go through that very  
10 quickly.

11 And then to what we were talking about  
12 before, we tried to break it down a little bit  
13 into which sorts of clinical conditions the  
14 measures applied to.

15 And to Prashant's question I think  
16 there is not a lot, four I think here, that you  
17 could consider cross-cutting, that didn't have a  
18 particular clinical condition associated with  
19 them. Lots in the area of oncology. Again, as  
20 you might expect, it seems to be a prominent  
21 area.

22 There are some of these like dementia

1 and stroke that could probably be considered all  
2 under neurology. That was another sort of large  
3 category.

4 And I should note that many of the  
5 ones that we considered, oncology, and a number  
6 of the others, as well, were maybe also more --  
7 you might more preferably consider them lab-  
8 related measures. There is quite a lot of those  
9 of whether you did the appropriate laboratory  
10 tests and then reported those laboratory results  
11 in the appropriate way. They just happen to be  
12 focused on cancer conditions.

13 So, that is it. I just wanted to give  
14 you sort of another slice at the data and way of  
15 looking at it.

16 But again, to your question before,  
17 most of them were condition -- were procedure-  
18 specific, not a lot of cross-cutting measures, at  
19 this point, although the concepts that we  
20 received and that we pulled from Hardeep's paper  
21 and that Mark suggested, there were a lot more  
22 cross-cutting ones that we may want to propose

1 for future development.

2 CO-CHAIR DANFORTH: Prashant.

3 MEMBER MAHAJAN: I just wanted to  
4 mention, at this point, that as we think more  
5 about this, we could consider that condition-  
6 specific, which would be certain high-risk  
7 conditions, specialty-specific, which could be by  
8 different age range, but I would also want to  
9 control by healthcare setting-specific because  
10 certain conditions may be diagnosed specifically  
11 only in that situation versus not.

12 CO-CHAIR DANFORTH: David, and then  
13 Hardeep, and then back to Mike.

14 MEMBER NEWMAN-TOKER: So just in terms  
15 of the last slide of how they were aggregated  
16 with a lot of sort of discipline-specific stuff,  
17 I would discourage us from doing that too much  
18 because I think it bespeaks of the  
19 compartmentalization and siloing of the care and  
20 we really are trying to kind of -- that the  
21 diagnosis is the outcome of the team process.  
22 And I think when you say well, this is your

1 piece, and this is your piece, and that is your  
2 piece, I think it takes in a bad direction  
3 overall.

4 I am really surprised -- I'm not  
5 surprised but I am noticing that more than half  
6 of your process measures are not what I would  
7 call diagnostic. I would call them either  
8 screening, risk assessment or staging.

9 Now, I think, at some point, we have  
10 to come to either an agreement or you guys have  
11 to just say that those things are in or out but  
12 we have to know that when we are arguing about  
13 what the framework should look like and how many  
14 things fit into a cubby and so on and so forth  
15 because I would not have pulled these out and  
16 said these are measures of diagnostic performance  
17 in the traditional sense.

18 I realize diagnostic testing is  
19 involved but there are a host of these things,  
20 including monitoring for treatment complications  
21 and other things that involve diagnostic tests  
22 but don't fit the sort of what comes to mind when



1 most people talk about missing or not getting a  
2 diagnostic error, or not getting a diagnosis  
3 right in a patient.

4 MR. LYZENGA: Yes and we had this same  
5 debate as a team as we were looking through the  
6 measures and we made some decisions but we said  
7 should we or should we not include these types of  
8 measures and wanted to bring it to the committee  
9 to let us know whether we ought to include those  
10 kinds of measures.

11 Those were some of the major questions  
12 measures where you have a diagnosis, diabetes  
13 say, and you are screening for likely  
14 comorbidities or common comorbidities. We  
15 initially included those, said that those were  
16 diagnostic-related. But if the committee thinks  
17 that those should not be included, we don't feel  
18 strongly about it.

19 Again, we did not include the  
20 asymptomatic screening measures that we found.  
21 We figured that was too sort of far afield.

22 Some of the other ones, again, like

1       you said, the staging of disease, we did include  
2       those but we don't have to.

3               I can't remember what some of the  
4       other sort of categories were but we would  
5       welcome any thoughts from this group on anything  
6       you see in that inventory, at this point, if you  
7       think it is appropriate or inappropriate to  
8       include and why or why not.

9               CO-CHAIR DANFORTH: Hardeep and then  
10       David.

11              MEMBER SINGH: So I was just thinking  
12       I think this is coming together very nicely.

13              So I am just going to sort of reframe  
14       some of what you said and then maybe propose some  
15       actionable next steps. So, I am just thinking.

16              So everybody is agreeing that the  
17       structure process outcome is, in general, a good  
18       way to approach. I think this is good. So that  
19       is like the Step 1 of what we are going.

20              The Step 2 is I think we are coming up  
21       with subdomains that we want to try to include  
22       within structure process outcomes. So I say

1 within structure, we have got the IOM, lots of  
2 tools, technology, work environment kinds of  
3 things. We can add the 8-dimensional Socio-  
4 Technical Model just to complete that.

5 But I think more of this is this is an  
6 approach to make sure that we are not missing  
7 anything, rather than having every one of these  
8 be accounted for for a measure.

9 So in the same way, in the process  
10 one, you have got the IOM processes but we can  
11 include say for these five processes, we are  
12 getting to the point of reminding ourselves that  
13 this is just sort of a thinking, to inform our  
14 thinking of measures.

15 And for outcomes, it is generally  
16 patient, providers, and systems; patient,  
17 providers, and care teams, and then systems. So  
18 that would be sort of the organizing framework.

19 And then is the important one. I  
20 think that is sort of Step 3, which is sort of  
21 what we are struggling with. And I just quickly  
22 wrote down, especially after what Prashant said,

1       you know I think we are thinking about this is  
2       where we are going to need to have discussions.  
3       What are the high-risk conditions we should put  
4       forward for proposed areas of measurement?

5               So they could be high-risk because  
6       they are certain conditions or diseases, so  
7       infections, cancers, and cardiovascular  
8       conditions came up, or they could be high-risk  
9       populations. And the high-risk populations could  
10      be children or it could be other vulnerable  
11      populations that we have talked about, other sort  
12      of patient disparities.

13             There could be high-risk settings. So  
14      we know emergency rooms are high risk. We know  
15      primary care is high risk. And so we come up  
16      with a list of the third layer, if you will.

17             And then I am wondering we had a  
18      prioritization exercise at the committee, HIT  
19      Safety Committee, and we recently had one at the  
20      Diagnostic Error meeting in Los Angeles, where  
21      the 20 measures, 19 or 20 measures or measure  
22      concepts that we had in the Journal of Patient

1 Safety paper that came up this morning, we just  
2 asked people, I mean asked basically rate them A  
3 through F and the ones we discussed would be  
4 where people mostly ranked Fs or As just to get  
5 the other's perspective. There was some  
6 diversion.

7 So like half the room said A and the  
8 other half said F. And then we would say okay,  
9 let's understand why. And I think that  
10 prioritization exercise really helped. I haven't  
11 looked at the data but I have the data. Of the  
12 19 I think the committee or the group, rather,  
13 agreed to about six or eight of them being really  
14 superstar measures that they thought should go  
15 forward for further development. And some they  
16 just ruled it out out of the list of 19.

17 So I think that is sort of the way I  
18 am thinking that we are bringing together some of  
19 the concepts.

20 And some of the screening stuff we  
21 will just weed out because people won't agree.

22 MR. LYZENGA: Right. And sort of a

1       sneak preview, tomorrow we are intending to try  
2       to get you guys to brainstorm sort of just any  
3       concepts that you can come up with for measures  
4       of diagnostic quality or whatever you want to  
5       call it, just to come up with as many things as  
6       we can. We will then sort of map those against  
7       our current framework as sort of a test case.

8               Again, I think it would be useful to  
9       see if when we come up with a large number of  
10      concepts or measures, are these fitting in well  
11      to the framework. Do we need other categories?  
12      Is this not adequate or appropriate?

13             But then as we get -- we will have  
14      those concepts and we will, moving forward,  
15      probably in the next meeting or after that, do a  
16      prioritization exercise and say which of these  
17      concepts or measures do we think are really  
18      important. Which are less important? And try to  
19      sort of things out that way, very similarly to  
20      what we did in HIT Safety.

21             CO-CHAIR DANFORTH: David, Mark, and  
22      then Martha.

1 DR. HUNT: I don't want to get stuck  
2 on this. And I definitely don't want my voice to  
3 be the loudest but I just want to point out that  
4 the discussion of risk in screening, they are  
5 really the same thing. Screening is what we have  
6 identified as high-risk areas.

7 And to break the tie, and I don't know  
8 which way we should fall, but to break the tie,  
9 would it be at least reasonable to consider, from  
10 the patient perspective, what would a patient  
11 say? A 58 year old man who has never had a  
12 colonoscopy, should my doctor have done some  
13 screening to diagnose that colorectal cancer? So  
14 from the patient perspective, would they consider  
15 that a misdiagnosis and could that be a  
16 reasonable way to sort of break the tie? Just  
17 offering up there.

18 MEMBER NEWMAN-TOKER: We should hear  
19 from our patients but I think -- I should think  
20 so. I mean I think, again, patients care about  
21 getting harmed. They don't really care about  
22 what we call things or which buckets they are in,

1 I think is my general sense.

2 And I think, for instance, if we ask  
3 Jen whether staging was part of the diagnostic  
4 process, I think we would get a very clear  
5 answer, that the diagnostic error she suffered  
6 was part of the staging process.

7 CO-CHAIR GRABER: Yes, we know one of  
8 the biggest buckets for diagnostic error is  
9 delayed diagnosis of cancer and the biggest  
10 bucket within that is failure to screen or  
11 failure to follow-up on screening. So I would  
12 feel very bad if we left screening off the table.

13 I would like to get some sense of the  
14 group. Is it okay to leave screening inside our  
15 bucket? We are going to include screening.

16 MEMBER SINGH: We have screening  
17 measures on cancer, don't we?

18 CO-CHAIR GRABER: Yes. There seemed  
19 to be some sense that we wanted to exclude  
20 screening. I didn't quite follow that argument.

21 Is everybody comfortable with  
22 including screening within our domain?



1                   MEMBER SINGH: I mean in VA our rates  
2 of colorectal screening are so sky high, we are  
3 not investing as much. It is like plus 90.

4                   So I don't know.

5                   MR. LYZENGA: Again, we made the  
6 distinction between asymptomatic screening and  
7 screening for, again, likely or common  
8 comorbidities. And we kept the latter but did  
9 not keep the former. And I don't know if others  
10 have thoughts on that.

11                   Should we be keeping asymptomatic  
12 screening?

13                   MEMBER NEWMAN-TOKER: I actually think  
14 asymptomatic screening is more important to keep  
15 than what you have called symptomatic which, in  
16 my mind, isn't exactly the right way to refer to  
17 it. It is standard disease-specific asymptomatic  
18 screening.

19                   You are saying if someone knows that  
20 they have diabetes, there are some known  
21 complications that they should be monitored for,  
22 which is slightly different than sort of general

1 population screening of people of a certain  
2 demographic group. So it is symptomatic in the  
3 sense that they know that they have diabetes. It  
4 is asymptomatic in the sense that they may not  
5 know that they have numbness of their feet. They  
6 may not know the actual symptoms of the  
7 complications.

8 I am fine keeping screening in. I do  
9 think there is an even bigger rung of clinical  
10 decision-making around risk stratification that  
11 we got into earlier, which was the run around the  
12 DVT, which that is neither are you screening an  
13 asymptomatic population with a diagnostic test to  
14 look for a specific disease, nor are you  
15 investigating a symptomatic complaint. You are  
16 actually just applying treatment based on a risk  
17 stratification.

18 Now you could argue that if you don't  
19 do that, if you don't ask them the questions  
20 about the risk factors, that that somehow is a  
21 diagnostic screening process that you should go  
22 through to get the point of treatment but I do

1 worry that if you actually draw the confines  
2 around what that includes, I think you will find  
3 that almost every clinical reasoning decision  
4 will fall into that bucket in any treatment  
5 scenario. Like you are in the middle of a code  
6 and you don't accurately risk stratify which  
7 pathway you are in in the code. Is that a  
8 diagnostic error? In some sense it is. It is a  
9 clinical reasoning error, whatever. But I don't  
10 know whether we want to go there.

11 MEMBER SINGH: I mean here is an NQF  
12 measure. Colorectal cancer screening, percentage  
13 of patients 50 to 75 who are appropriately  
14 screened for colorectal cancer. So why are we  
15 going to pursue something that is going to  
16 reinvent the wheel?

17 MR. LYZENGA: Well we are not  
18 proposing new ones, just whether that should be  
19 included in our inventory and then included in  
20 our prioritization exercise. Or should we put  
21 those measures off to the side and say they are  
22 not diagnosis related, we are not even talking

1 about them?

2 DR. LUSTIG: I think what we were  
3 thinking, and again, this is just our initial  
4 decision, was there were so many screening  
5 measures that we were thinking about conceptually  
6 as, to use the words of the Academy Report, a  
7 patient comes to the office with a health problem  
8 of some kind and what you do from that point  
9 forward. And so we were trying to eliminate all  
10 the general screening recommendations, not just  
11 you have a 58-year-old male in your office and  
12 you should be recommending screening to get to a  
13 diagnosis. But this is what we wanted to present  
14 to you and you could say no, we do want to  
15 include all this.

16 But we were starting from the point  
17 that someone has come to you with a problem and  
18 what you do with that. I don't know if that  
19 helps clarify.

20 MEMBER MCDONALD: I think in the text  
21 somewhere, we would have to check, but I think  
22 the text actually suggests that coming with the

1       problem can include coming with the need for sort  
2       of asymptomatic screening because you are a  
3       certain age. So I don't think it was off the  
4       table from the conceptual perceptive at that  
5       point.

6                   DR. LUSTIG: I thought heard the term  
7       health problem.

8                   MEMBER MCDONALD: I know but the  
9       health problem in the text I think is described  
10      as potentially including this.

11                  MEMBER NEWMAN-TOKER: Well I do think  
12      there is an intermediate possible solution, which  
13      is to include it but explicitly put it off to the  
14      side and say look, screening is part of the big  
15      diagnostic process but there is a whole set of  
16      U.S. Preventative Services Task Force  
17      recommendations and so on and so forth and we  
18      were addressing a different piece of the  
19      measurement, probably where there aren't robust  
20      measures and so on and so forth.

21                  CO-CHAIR DANFORTH: Okay, we are going  
22      to go in this order, on the left side of the

1 room, my left, Martha, Helen, Prashant, we are  
2 going to come back to Mira, and then Kathy, based  
3 on how I saw cards go up.

4 MEMBER RADFORD: I am going to agree  
5 with the last comment and just say we were asked  
6 to develop a measurement framework. And I think  
7 we can certainly call out screening as part of  
8 that and acknowledge that there is a fair number  
9 of screening measures already. And if other ones  
10 need to be developed, it is pretty clear how to  
11 do it because it has been done so many times.

12 I really think that the biggest  
13 contribution we can make is in the empty cubbies  
14 and to point out where we need new measure  
15 development work, where we need research into the  
16 structure and process outcome links that support  
17 measures, and where you think -- where we think,  
18 really, that the measurement, that the new  
19 measurement low-hanging fruit might be.

20 CO-CHAIR DANFORTH: Helen.

21 MEMBER HASKELL: Well, I agree with  
22 that. I don't support the inclusion of

1 screening. I think we can say there are  
2 screening measures -- the U.S. Preventative Task  
3 Force Services. My other concern about screening  
4 is overdiagnosis. So, I agree, really, with  
5 everything that Martha and David have said.

6 I am not at all uncomfortable with  
7 this small measure set and identifying gaps and  
8 ambitions.

9 CO-CHAIR DANFORTH: Okay, some cards  
10 went down. He is thinking about putting it back  
11 up. He is not.

12 So, Mira and then Lavinia.

13 MEMBER MIDDLETON: So I am going to  
14 suggest that one way of bringing this altogether  
15 may be to focus on risk. And patients are either  
16 at risk for a condition because they come with  
17 symptoms, they have physical findings or symptoms  
18 and they are ill, or they are at risk because  
19 they have a family history of a condition that  
20 gives them increased risk, or they are at risk  
21 because they have a condition diagnosed in  
22 childhood that has late onset problems, or

1 because they have some screening test that is  
2 either a genetic screening test. And maybe that  
3 is one way of prioritizing it, keeping the  
4 screening in there.

5 Because I think as we go on, more and  
6 more patients are going to be at-risk for  
7 symptoms that lead to misdiagnoses based on  
8 conditions that are diagnosed early in childhood,  
9 rather than those presenting with symptoms. We  
10 may be able to presymptomatically diagnose that.

11 So focusing on risk and why you are at  
12 risk may be one way of bringing it all together.

13 CO-CHAIR DANFORTH: Lavinia.

14 MEMBER MIDDLETON: So I think that  
15 many of the process risks related to pathology  
16 and diagnosis have been well-established, to the  
17 point where if you look at the delta of the  
18 hospitals and physicians who report out these  
19 measures that is very small. So like last year,  
20 greater than 99.6 percent of all reporting  
21 hospitals reported that their Barrett's esophagus  
22 reports had a statement on dysplasia.



1           I think the real opportunity is with  
2           the communication of the diagnosis. So for each  
3           one of these that you have for the measure, I  
4           would focus more on communicating, making sure  
5           that there is processes in place and documenting  
6           how this information is communicated to the  
7           patient.

8           MR. LYZENGA: We will keep that in  
9           mind for tomorrow when we are coming up with  
10          concepts.

11          CO-CHAIR DANFORTH: I was so  
12          preoccupied with left side I didn't see on the  
13          right side who put their name card up first. So  
14          I am going to trust that one of you will let me  
15          know.

16          MEMBER HRAVNAK: I just wanted to  
17          speak in favor of including risk assessment and  
18          screening. And I think my reason for that is  
19          that I think we need to think sometimes about  
20          what it is that we are diagnosing. Are we  
21          differentiating between a primary diagnosis of a  
22          disease process versus catching a diagnosis of a

1 complication? And again, I just worry that if we  
2 leave out the risk assessment and screening that  
3 we are going to lose that kind of -- do we wait  
4 for somebody to develop symptoms before we start  
5 jumping on the bandwagon or do we try to prevent  
6 those?

7           There are many screening tools for  
8 that long list of 15 complications leading to  
9 failure to rescue, you know infection, DVT, GI  
10 bleeds, skin ulcers. So I just feel like we are  
11 really losing that end of the diagnostic spectrum  
12 if we don't include that.

13           CO-CHAIR DANFORTH: David.

14           MEMBER SEIDENWURM: So I agree that we  
15 should include screening with sort of a sidebar  
16 that there is enough done on it. The one area in  
17 screening, and I think we should maybe suggest  
18 this as a population health type of metric, is in  
19 the area of overdiagnosis which I believe is  
20 principally noted in large groups of people. And  
21 I think that we would be remiss, perhaps, if we  
22 didn't include some kind of community or some

1 unit overdiagnosis metrics with respect to  
2 perhaps thyroid, breast, and prostate cancer,  
3 which I think are the most suspicious for that in  
4 our society right now.

5 So maybe we could propose that as one  
6 gap but, otherwise, I think the focus should not  
7 be on screening.

8 CO-CHAIR DANFORTH: Helen.

9 DR. BURSTIN: Yes, just this has been  
10 a great discussion. It raises a lot of good  
11 questions for us.

12 I think one of the other ways, besides  
13 cubbies, I tend to think of frameworks as trees.  
14 And in some ways, it may be very illustrative to  
15 show the volume of measures that fit only into  
16 this one branch, only this one cubby to the  
17 exclusion of everything else. So by actually  
18 showing how many are really just about diagnostic  
19 testing, et cetera, with no then connection to  
20 communication, with no connection to how it is  
21 used, may actually be very illustrative to make  
22 the case of why the other branches shouldn't be

1       there.

2                   And so actually loading this one up  
3       may not be a problem but it might be really  
4       important for us -- I forgot who said it. I  
5       think it was actually you, Missy, who made the  
6       point of who often in fact some of these measures  
7       cross some of those domains and how often they  
8       are just lone wolves out there and did you just  
9       collect that data, information gathering phase,  
10      where we have got plenty. But to Hardeep's  
11      earlier point, I don't think this is what many of  
12      us think of when we think of looking at the  
13      safety and quality of diagnoses.

14                  MR. LYZENGA: Just one more sort of  
15      nuance that I just remembered. We also did not  
16      include measures that were focused on overuse of  
17      diagnostic tools like MRIs for back pain. We,  
18      again, excluded those and I just wanted to throw  
19      that out there and see if others wanted to  
20      include them on that sort of overdiagnosis theme.

21                  MEMBER NEWMAN-TOKER: I think what you  
22      want to do is not include all of them. I think

1       you want to marry those to underuse in those  
2       domains. I think you want to make an explicit  
3       pairing for people so that they understand that  
4       they have to monitor both sides of this argument,  
5       both false positive, false negatives kind of side  
6       of things.

7                   CO-CHAIR DANFORTH: Okay, actually --

8                   MEMBER MAHAJAN: Can I? Sorry. Can  
9       I just --

10                  CO-CHAIR DANFORTH: Yes, one second.  
11       David Grenache has been so patient, actually.  
12       So, we are going go David on this side of the  
13       room, then Kerm, and then Prashant.

14                  MEMBER GRENACHE: Right. Thanks. I  
15       don't to belabor the risk versus diagnosis issue.  
16       I agree with David Seidenwurm.

17                  I'm not a physician. I am a Ph.D.  
18       clinical chemist. I do a lot of screening tests  
19       in my laboratory. I am not convinced that  
20       assessing someone for risk is the same thing as a  
21       diagnosis. You can be at risk for a disease but  
22       never develop the disease. That's obvious.

1                   And there is a slippery slope here  
2                   because, as you screen people, you are going to  
3                   end up with lots of false positives, this whole  
4                   premise of screening, and you are going to end up  
5                   with overdiagnosis and potential harms. And  
6                   there are very well-known harms from screening.

7                   CO-CHAIR DANFORTH: I almost wish we  
8                   could develop, I think it is Hardeep's term, a  
9                   calibration measure, a structural measure focused  
10                  on calibration. What are you doing at a facility  
11                  to balance overutilization with underutilization  
12                  related to diagnoses? I mean I think everything  
13                  I am hearing sort of gets that issue that Hardeep  
14                  brought up very early this morning around  
15                  calibration.

16                  Herm.

17                  DR. HENRIKSEN: Just going back to  
18                  Helen's comment, whatever we do I think screening  
19                  and staging and those types of processes have to  
20                  be acknowledged and the rationale.

21                  The screening issue is unresolved but  
22                  it, indeed, has to be acknowledged. And whether

1       it is in a sidebar or an appendix, or some other  
2       way of treating it, it has to be certainly  
3       acknowledged because it would be deficient not to  
4       acknowledge it.

5               And so the way you treat it in any  
6       final report or any final classification system,  
7       as long as you justify it and explain it clearly,  
8       will be serving a valuable purpose I think.

9               CO-CHAIR DANFORTH: Prashant, and then  
10       Helen, and then Hardeep.

11              MEMBER MAHAJAN: Yes, I just wanted to  
12       make a nuance to what David -- DNT said, is if we  
13       are going down the path of overdiagnosis and  
14       overtesting, the real-world situation is patients  
15       who are seen in the emergency departments and  
16       some other places frequently get overtested  
17       because of the environment that they practice in.  
18       So we have to nuance that factor. If we are  
19       going to do certain disease-specific high risk,  
20       high reward type of a condition, then that  
21       approaches better but if you are just going to go  
22       into this wholly of overdiagnosis and

1       overtesting, we have to be a little careful.

2                   CO-CHAIR DANFORTH:   Helen.

3                   MEMBER HASKELL:   So my concern with  
4       this, aside from the overdiagnosis, is with all  
5       these little measures on these very specific  
6       topics that it really detracts from the  
7       overarching themes we are trying to emphasize.

8                   I am just concerned that it is  
9       confusing.   Am I saying something that has  
10      already been said?

11                  MR. LYZENGA:   No, I was just saying we  
12      will try to fix that tomorrow.

13                  CO-CHAIR DANFORTH:   Hardeep.

14                  MEMBER SINGH:   So I was just going to  
15      add, sort of building on what Helen just said, I  
16      think it is probably okay to sort of just say  
17      yes, we have thought about screening but one  
18      thing that sets us apart, we should all agree  
19      that we are focusing on a specific or defining  
20      the problem that we are trying to solve.

21                  And I thought, putting in the context  
22      of risk, I think what we are trying to do is



1 looking for high risk situations for either  
2 missed, delayed, or wrong diagnosis. So whether  
3 you look at it from any perspective, if our  
4 rationale for doing some kind of prioritization  
5 exercise tomorrow or whenever is around is this  
6 situation or measurement concept really relevant  
7 for conversations around how you reduce the high  
8 risk situations for missed and delayed and wrong  
9 diagnosis. I mean if you got a shared  
10 understanding, that is useful.

11 I am not sure why we should spend too  
12 much time on screening when we can't even do  
13 basic history and basic physical exam anymore.  
14 We just had a study that is going to come out  
15 hopefully in a few months that about half of  
16 patients who have spinal epidural abscess were  
17 seen by multiple physicians with red flag  
18 symptoms, including fever, neck pain, and I could  
19 go on and on, neurological symptoms. I mean no  
20 matter which conditions we look at, we are  
21 finding we can't even fix the very obvious stuff  
22 and we can't even recognize red flags anymore.

1                   So I am not sure how much emphasis on  
2 screening will help.

3                   CO-CHAIR DANFORTH: I guess I think  
4 maybe I would like verification on one point. So  
5 I understand the concept and the uses of the  
6 framework. I am wondering if this is the right  
7 time to ask the question that based on the  
8 comments that people have had and the discussions  
9 we have had about additional work we might do to  
10 the framework is are we saying that potentially  
11 if we develop a framework like this for improving  
12 diagnostic safety and quality that the framework  
13 would be appropriate for diagnosing diseases --  
14 so they come to the emergency room with dizziness  
15 and it is a stroke but would it be appropriate  
16 for diagnosing for complications? So back to  
17 Marilyn's point.

18                   And if we are not saying that, then  
19 can we leave the framework open for both kinds of  
20 measures or are we saying that framework is  
21 appropriate for one and not the other? I think I  
22 would like clarification on that.

1                   MEMBER RADFORD: I would say that,  
2                   again, this is a document that we are producing  
3                   and it is a lot of recommendations. And part of  
4                   the recommendations can be basically the NQF full  
5                   employment act, where we have subsequent groups  
6                   that are going to look at aspects of this that we  
7                   are not focusing on because we are prioritizing  
8                   what we are going to focus on, which will happen,  
9                   I guess, over time.

10                  So I don't have a problem with the  
11                  document setting a framework for not just this  
12                  group, if you will.

13                  MR. LYZENGA: Yes and I think that is  
14                  the intent is both to serve as sort of an, again,  
15                  organizing tool for us but then as a framework  
16                  for others moving forward to identify what the  
17                  gaps in priorities for measurement are? I mean  
18                  as a tool in both of those senses.

19                  I mean I suppose we should have some  
20                  specificity about we are including and not  
21                  including. But in terms of the specific measures  
22                  I get a sense that these screening measures are

1       going to be a fairly low priority anyway. And to  
2       Martha's earlier point, I think the real  
3       important work that we are going to be doing is  
4       seeing those gaps and trying to come up with  
5       ideas to fill them. But I don't know.

6               Any more thoughts to help us clarify  
7       what we should or should not include would be  
8       welcome. But again, I think the more important  
9       part will be coming up with new ideas.

10              CO-CHAIR DANFORTH: Okay, Nicholas.

11              MEMBER KUZMA: I was just going to say  
12       that for the complications of the diagnosis, in  
13       some ways I think that is a communication error.  
14       Because you have made the diagnosis. You also  
15       need to be communicating what are the downstream  
16       effects of that diagnosis. So, if you are  
17       looking where in the framework to fit that, I  
18       think that is kind of where I would think about  
19       putting that.

20              CO-CHAIR DANFORTH: Kathy.

21              MEMBER MCDONALD: I think some of  
22       these discussions are showing us that there are

1       some places where it gets a little squishier.  
2       You know and if we are thinking sort of patient-  
3       centeredness, this idea of what the consequences  
4       of a miss is, whether it is from a screening  
5       perspective or a risk assessment perspective, or  
6       a straight out more clear area of diagnosis. So  
7       this idea of kind of the write-up and the  
8       framework, I think we are still going to be  
9       challenged. But even writing up or framework-  
10      wise, as long as there is the desire to have  
11      cubbies and split, it is tougher where there is  
12      these tensions and where it is squishier. So,  
13      that will be something to have -- you guys will  
14      get to figure that out but it exists in this  
15      area. It definitely exists in this area.

16                   CO-CHAIR DANFORTH: David Hunt.

17                   DR. HUNT: I just want to repeat what  
18      Hardeep said also that I think it is more  
19      important if we come up with a system that  
20      somehow or another down the road doesn't find a  
21      place for something that is regularly understood  
22      to be a diagnostic error. I think that is the

1 better -- that is the worst error we can make.  
2 If something fits into multiple places, or we  
3 have a little bit more, having a cubby too small,  
4 I think is the biggest problem.

5 And I guess we are honing in on the  
6 idea that this won't be among the very long list  
7 of perfect frameworks that NQF has developed  
8 before.

9 CO-CHAIR DANFORTH: Carlos.

10 MEMBER HIGUERA RUEDA: I keep  
11 listening around the room and I think we are all  
12 saying the same thing all over and over again.  
13 And I don't think that we can pretend to resolve  
14 all the issues in medicine in this where it is  
15 creating -- because at the end of the day the  
16 only thing that we do is diagnosis and treatment.  
17 Well, you can mention maybe some prevention as  
18 well. It should be very important.

19 But regardless of that, I think that  
20 we are losing a little sight. I mean we have  
21 very good feedback from patients here. And what  
22 I am hearing is that communication is a big issue

1 and I feel, at least in my clinical practice when  
2 I see with my colleagues that that is certainly  
3 true. I think that we see a huge area of  
4 measurements that come out every day that make  
5 the practice of medicine miserable. I mean like  
6 a lot of physicians here, you won't disagree that  
7 is very cumbersome to practice nowadays because  
8 are doing all this -- we have a list of I don't  
9 know how many measurements here that we have to  
10 fill in the computer and paperwork and so forth  
11 and we are losing the sight of practicing  
12 medicine. And I really would like to see in this  
13 group to be very pragmatic about the measurements  
14 that we are going to come out with to -- I like  
15 some of these examples here, where a structure  
16 and process are really important around the  
17 patient and to give their providers some  
18 measurements that are really going to give  
19 support to enhance that communication. I think  
20 that that is really where we are failing because  
21 everything else, if we go to the minutia of data,  
22 a lot of these things we don't have enough data

1 to make recommendations. Maybe we can make  
2 recommendations of research questions that need  
3 to be answered on a lot of these things. That is  
4 for sure. But other than that, I really would  
5 like to see that those measurements rely more on  
6 the communication, the process, and, again, give  
7 the providers what they need to practice good  
8 medicine.

9 CO-CHAIR DANFORTH: David.

10 MEMBER NEWMAN-TOKER: So several  
11 people have said things that allude to this issue  
12 of how granular our task should be. So when we  
13 talk about this issue of lumping and splitting,  
14 if we said our measure framework is structure,  
15 process, and outcomes, and our measurement  
16 concepts within that framework are the things  
17 written on this page, you know these subdomains,  
18 as you call them, we could probably be done and  
19 we could all agree within a few minutes that that  
20 is a good conceptual framework.

21 But if we want to go one rung deeper  
22 than that, which I think we do, to say within



1 each of these subdomains, what are the sorts of  
2 measures that could be built or developed. We  
3 have to find that kind of middle level between  
4 the subdomain you have listed and the concrete  
5 measures you have listed that doesn't get us  
6 stuck in the weeds around well is this diabetes  
7 retinopathy thing an important thing or not an  
8 important thing because we are going to be in  
9 deep trouble if we are there.

10 But saying okay, this is a class of  
11 measures about asymptomatic screening in patients  
12 with known conditions that have disease  
13 complications. The measurement concept is about  
14 monitoring for disease complications. And there  
15 is a different one for measuring for treatment  
16 complications, when you give someone a drug or  
17 you do this, or treatment complications after  
18 surgery, you know the DVT in post-op, or  
19 whatever. I think that is the level that we want  
20 to hit and I don't think we have got the words on  
21 the page yet. Hopefully, we will do that  
22 tomorrow. But I think we have to be careful

1 about not getting all the way to the level of  
2 granularity of what these individual measures are  
3 and that we dial it back a little bit to get  
4 something that is both informative but not  
5 unmanageable.

6 CO-CHAIR DANFORTH: Prashant.

7 MEMBER SINGH: Would Andrew mind  
8 showing the committee just maybe like an example  
9 from the HIT Safety Report? Because I think that  
10 is what sort of David is also suggesting that  
11 giving examples and showing high priority areas  
12 and then maybe just a concrete example. We have  
13 been calling them measures. We call them  
14 measurement concepts. Examples may be worth it.  
15 I don't know.

16 MR. LYZENGA: We'll see if we can pull  
17 that up. But David, I think you put it really  
18 well. I think that is exactly what we are trying  
19 to do. We are trying to get a level below these  
20 subdomains and try to flesh out a little bit what  
21 are the types of things, sort of measure  
22 concepts. Again, conceptually, what do we want

1 to be measuring within these domains? What is  
2 important to be getting diagnosis right and  
3 avoiding errors?

4 To the extent that we do come up with  
5 anything that can be a little bit further  
6 specified, not to the point of a fully  
7 implementable measure but if we come up with here  
8 is a potential numerator and denominator for this  
9 measure, that would be helpful, I am sure, for  
10 the field and measure developers moving forward  
11 but I don't think we need to get to that level.  
12 But we want to get to the level you were talking  
13 about, at least.

14 MEMBER NEWMAN-TOKER: But I think if  
15 you wanted to do that, you might want to do it  
16 for the specific domains that are known to be  
17 high risk.

18 Like you might want to say okay, look,  
19 for cancer, infection, and vascular events, we  
20 want to do two rungs deeper than where we are  
21 with the subdomains, rather than just one but we  
22 want one for sort of the big picture.

1  
2 MR. LYZENGA: Or even identifying,  
3 again, what those key conditions are and saying  
4 these are some conditions or areas where we think  
5 it might be fruitful to pursue specific measures  
6 within.

7 CO-CHAIR DANFORTH: While the NQF  
8 staff look for the NQF staff look for the HIT  
9 example, we are going to take about a 10- or 15-  
10 minute break and then come back.

11 So Tom, if you are still with us on  
12 the phone hanging in there, we will be back in 10  
13 or 15 minutes.

14 MEMBER SEQUIST: Okay, thank you.

15 (Whereupon, the above-entitled matter  
16 went off the record at 3:08 p.m. and resumed at  
17 3:38 p.m.)

18 MR. LYZENGA: All right, so for the  
19 next 20 minutes or so, or however long it takes,  
20 we are just going to very quickly run through the  
21 concepts that we received from Mark and that we  
22 pulled from Hardeep's paper, just to give a sense

1 of what we are looking for tomorrow, as we are  
2 trying to brainstorm concepts. I just thought it  
3 might be useful to quickly run over this so you  
4 can see what we are looking for and what you  
5 might want to be thinking about tonight and then  
6 looking toward tomorrow.

7 So, let's see. Can you blow it up at  
8 all? Can you scoot over at all? There, just to  
9 those, yes.

10 So again, just to give you a sense,  
11 these are the sorts of concepts that we were  
12 hoping to have you come up with tomorrow. These  
13 are not fully specified measures, like we have in  
14 sort of this other preliminary inventory. They  
15 are generally a bit more vague, sort of  
16 conceptual. This first one, for example, staff  
17 involved in diagnosing patients have appropriate  
18 competency to do so.

19 If you were to create an actual  
20 measure out of this, you would have to define a  
21 whole lot of terms in what competency means, in  
22 this case, who the appropriate staff are to be

1 measured, who is involved in diagnosing patients,  
2 lots of details that you would have to flesh out  
3 and define and specify for that. But for our  
4 purposes, we just kind of want to get some ideas  
5 of what a good thing to measure -- if you were to  
6 pursue a measure like that, we would like to see  
7 a measure assessing that the staff involved in  
8 diagnosing patients are competent to do so.

9 The same with the next. The provider  
10 mix is appropriate for the complexity of the  
11 case.

12 So just a fairly high level, not at  
13 the high level of our framework domains like  
14 information gathering. That is a little bit too  
15 broad but not quite so specific that you can  
16 actually go into a hospital or a clinician office  
17 and implement the measure but an idea of what a  
18 measure might look like, if we were to pursue it.

19 If you would scroll down to the  
20 process one so we can see some examples of those.

21 I think we were talking about it a  
22 little bit on the break and we are not going to

1 try to have you assign these to our framework  
2 subdomains. We are just going to stick with the  
3 broader overall topics of structure, process, and  
4 outcome. We are going to break you into some  
5 smaller groups and have you just come up with as  
6 many of these types of concepts as you can. So  
7 just think about what is important to get  
8 diagnosis right. What are some things that might  
9 be measurable in that area? And then to think  
10 about -- you know you can use the subdomains that  
11 we have as sort of a mental framing. Try to  
12 spread your concepts across those different  
13 subdomains to the extent that you can so we don't  
14 have a lot bunched under tools and technology,  
15 although if we do, then that's okay if it is a  
16 really important area but sort of use that to  
17 guide your thinking a little bit. But you don't  
18 have to say this measure is going to be in the  
19 information gathering stage. We won't make you  
20 do that at this point. But just think of  
21 structure, process, and outcome measures that  
22 would be important to evaluating the quality and

1 safety of diagnosis.

2 And again, I think you have these  
3 documents in front of you, if you want to take a  
4 little bit of a closer look.

5 So this is just to give you an idea of  
6 what we are looking for tomorrow.

7 I don't know if we have anything much  
8 else to cover right now. We could --

9 CO-CHAIR GRABER: Andrew, could I ask  
10 a question? This is all new to me, writing  
11 measures. And it seems to me that certain things  
12 can be stated as either a structure or a process  
13 measure. And I don't know how you decide which  
14 is better.

15 Like here it says second opinions are  
16 available. So as a structure thing, if you could  
17 rephrase it and say 50 percent of cancer patients  
18 get a second opinion. So, is there a preference  
19 for how you would like us to do those?

20 MR. LYZENGA: No, and in fact you  
21 could do both, if you like.

22 CO-CHAIR GRABER: We could do both.



1                   MR. LYZENGA: Yes, I think we -- and  
2 then we can -- the idea right now I think and  
3 tomorrow is just to get as many ideas as we can  
4 on the table, basically, as many ideas for  
5 measuring and measure concepts as you can.

6                   We have some subsequent meetings,  
7 where we will go through and we will kind of  
8 refine those ideas. If we have things that are  
9 kind of competing like that, maybe we can decide  
10 we would prefer a structure measure over an  
11 outcome measure or, rather, a process measure in  
12 this area where we think we can combine these two  
13 or we can rephrase these a little bit and then we  
14 will prioritize. We will have an exercise where  
15 we try to decide which are the most important and  
16 which are the least important but we will do that  
17 in a subsequent meeting. Right now, again, just  
18 trying to get everything we can out on the table  
19 so we have some material to work with,  
20 essentially.

21                  Do you have a comment, David?

22                  DR. HUNT: Yes, basically to that end,

1 we don't necessarily have to identify, even if it  
2 is structure.

3 MR. LYZENGA: Fair enough.

4 DR. HUNT: If you have a great concept  
5 you know fits into this domain, that could be  
6 work for others later down the road.

7 MR. LYZENGA: Absolutely.

8 DR. HUNT: Because that fine splitting  
9 of hairs is sometimes very difficult.

10 MR. LYZENGA: Yes, I think that is a  
11 fair point. So we don't even have to think about  
12 it at that level. Just anything you can think of  
13 that might be worth measuring, some idea of a  
14 thing that might be measurable or something that  
15 is important in a diagnostic process or as a  
16 diagnostic outcome that we should consider.

17 MR. LYZENGA: Any other comments from  
18 our co-chairs or anybody? I think we can  
19 probably end a little bit early, then.

20 Will you pull up the dinner slide  
21 again? So just to remind everybody, 6:00 p.m.  
22 dinner at P.J. Clarke's. There is the address.

1 I hope you all can attend.

2 Otherwise, we will see you tomorrow.

3 MR. EPNER: Do we have any public  
4 comment?

5 MR. LYZENGA: Oh, Paul, you are right.  
6 Public comment, absolutely. You are doing my job  
7 for me.

8 So yes, we will get comments in the  
9 room and then maybe we can turn to the phone  
10 after that.

11 MR. EPNER: So I have to say two  
12 things, even if the train has left the station.

13 So on the issue of how broadly to go  
14 and whether to include screening, et cetera, I  
15 would encourage the committee to go very broad in  
16 its description of the framework, even if it says  
17 in this body of work we can only focus on  
18 complaint-specific.

19 I think of all screening as, building  
20 on Mira's comment, is risk-based, whether the  
21 risk is because of age or gender or because I am  
22 having surgery tomorrow or because I am having a

1 certain kind of treatment. It all influences  
2 pretest probability or pretreatment probability  
3 of success.

4 So, again, I would just go very broad  
5 at the high level so everything has a place, even  
6 if you can't do that, focus on it now.

7 And the only other comment is on the  
8 term overdiagnosis. Some people have heard me  
9 talk about this before. I think it is a term  
10 that gets lots of use and it is an inappropriate  
11 term in most cases. In most cases, it tends to  
12 be a bad treatment decision. You are acting on  
13 something that you didn't need to act on. Or it  
14 is a misdiagnosis. You are calling it something  
15 when it is really something else.

16 The case where you are diagnosing  
17 accurately and has nothing to do with the  
18 treatment as some kind of syndrome x and it is an  
19 overmedicalization, from what I have read, that  
20 seems to be a pretty small percentage of what is  
21 going on when people talk about overdiagnosis.

22 I think we know words matter. And I

1 would hope and encourage the committee to be  
2 careful in joining the bandwagon of this  
3 overdiagnosis to bring focus to an area of  
4 overtesting, where people do things with it they  
5 shouldn't be doing, which is an overtreatment  
6 problem.

7 So, I would just ask us to think or  
8 ask you all to think about that. Thank you.

9 MR. LYZENGA: Thank you. Yes, great  
10 point.

11 Operator, do we have any comments on  
12 the phone?

13 OPERATOR: Okay at this time, if you  
14 would like to make a comment, please press \* and  
15 then number 1.

16 And there are no comments at this  
17 time.

18 MR. LYZENGA: Okay, thank you.

19 Yes, Tom, do you have anything to add?

20 MEMBER SEQUIST: No, I'm all set.

21 Thanks.

22 MR. LYZENGA: Okay, great. Thank you.

1 All right, well we are adjourned then,  
2 unless there are any other remarks.

3 See you at the dinner, if you go, and  
4 if not, see you tomorrow.

5 (Whereupon, the above-entitled matter  
6 went off the record at 3:48 p.m.)

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Before: NQF

Date: 01-10-17

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