

Clinical Quality Public Hearing Transcript June 7, 2012

Presentation

MacKenzie Robertson – Office of the National Coordinator

Thank you. Good morning everyone, my name is MacKenzie Robertson with the Office of the National Coordinator. This is the Clinical Quality Hearing held by the HIT Policy Committee's Quality Measures Workgroup and the HIT Standards Committee's Clinical Quality Workgroup. This is a public hearing and there will be time for public comment at the end. The meeting is also being transcribed so please be sure you identify yourselves before making any comments. Instead of a formal roll I think it would be better just to go around the table and have everyone introduce themselves and mention which working group or committee you're on. So, I'll start with Kevin.

Kevin Larsen – Medical Director for Meaningful Use - Office of the National Coordinator

I'm Kevin Larsen, I'm the Medical Director for Meaningful Use at the Office of the National Coordinator for Health IT and I help support the Meaningful Use Quality Measures Workgroup.

Jacob Reider, MD – Senior Policy Advisor – The Office of the National Coordinator for Health Information Technology

Jacob Reider, I'm the Acting Chief Medical Officer of the Office of the National Coordinator for Health IT.

George Hripcsak – Columbia University NYC

George Hripcsak, Columbia University, on the Meaningful Use Committee.

John Derr – Golden Living, LLC

John Derr, Golden Living, I'm on the Standards Committee and on the Quality Workgroup for Standards Committee.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Larry Wolf for Rick Chapman on the Policy Committee also on the Certification Adoption Workgroup and the Care Coordination Workgroup for Meaningful Use.

Arthur Davidson – Denver Public Health Department

Art Davidson, Denver Public Health on the HIT Policy Committee.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Paul Tang, Palo Alto Medical Foundation on the Policy Committee and Meaningful Use Workgroup.

Floyd Eisenberg – Senior Vice President of Health Information Technology – National Quality Forum

Floyd Eisenberg with NQS HIT area on the Standards Committee and the Clinical Quality Workgroup.

Marjorie Rallins – Director of Measures, Standards and Informatics for the Performance Improvement Division – American Medical Association

Marjorie Rallins, Director of Measures, Standards and Informatics for the Performance Improvement Division of the AMA and I'm on the Vocabulary Taskforce of the HIT Standards Committee, and also serving in Karen Kmetik's place today.

David Lansky – Pacific Business Group on Health – President & CEO

David Lansky, I'm on the Policy Committee and I Chair the Quality Measure Workgroup for the Policy Committee.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

Ahmed Calvo, Senior Medical Officer, Office of Health IT and Quality at HRSA, HHS and on the Quality Workgroup.

Norma Lang, RN – University of Wisconsin

Hi, good morning, I'm Norma Lang, I'm at the University of Wisconsin, Milwaukee and I'm on the Quality Measures Workgroup, also serve on the Care Continuity Assessment Record and Evaluation.

Eva Powell – National Partnership for Women & Families

I'm Eva Powell with the National Partnership for Women & Families and I serve on both the Quality Measures Workgroup under the Policy Committee and the Quality Workgroup under the Standards Committee, as well as the Care Coordination Workgroup on the Policy Committee.

Helen Burstin – National Quality Forum

I'm Helen Burstin, I lead Performance Measures at the National Quality Forum and I'm on the Quality Measures Workgroup.

Blackford Middleton – Harvard

Good Morning, I'm Blackford Middleton; I'm a guest of the ONC presenting today on CDS.

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)

I'm Becky Kush with CDISC for Research Standards and I'm on the HIT Standards Committee.

Tripp Bradd – Skyline Family Practice, VA

I'm Tripp Bradd and the Quality Measures Workgroup.

Jason Colquitt - Greenway Medical Technologies

Jason Colquitt, Greenway Medical Technologies on the Standards Committee Clinical Quality.

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

Leslie Kelly Hall from Healthwise, I'm on the Standards Committee, on the Meaningful Use Subcommittee, the Care Coordination Subcommittee of Policy, the Patient Engagement Subcommittee of Policy and I Co-Chaired the Patient Engagement Power Team for the Standards Committee.

MacKenzie Robertson – Office of the National Coordinator

Thanks is there anyone on the phone as well, any Workgroup members or Committee members on the phone?

Keith Boone – GE Healthcare

This is Keith Boone with GE Healthcare; I'm on the Clinical Quality Workgroup of the Standards Committee.

Sharon Terry – President and CEO - Genetic Alliance

This is Sharon Terry; I'm on the HIT Standards Committee and the Privacy and Security Workgroup and the Patient Engagement Workgroup Power Team.

Robert McClure – Chief Medical Officer - Apelon, Inc.

This is Rob McClure; I'm on the Quality Workgroup.

MacKenzie Robertson – Office of the National Coordinator

Okay, is there anyone else on the line?

Aneel Advani – Indian Health Services – Health & Human Services

Yes, this is Aneel Advani from Indian Health Service; I'm on the Quality Standards Workgroup.

MacKenzie Robertson – Office of the National Coordinator

Great, thank you everyone, before I turn it over to David and Marjorie to open the meeting I'm going to let Jacob give some opening remarks.

Jacob Reider, MD – Acting Chief Medical Officer – The Office of the National Coordinator for Health Information Technology

Thanks, MacKenzie and thanks everybody here and on the phone for joining us today. On behalf of ONC I welcome everyone and thank you for your hard work in putting your testimony together, those of you who are testifying today, and of course members of the two committees. We are really excited about this combined meeting of the Workgroup of the HIT Policy Committee and the HIT Standards Committee. I think we started talking about having this meeting about five or six months ago with the chairs of both groups with the idea that we really need to work together as the folks who are thinking about the standards and how these things fit together technically and also the policies and how the policies will guide those technical puzzle pieces fitting together.

We've got some great testimony today from some folks who may actually be looking at this a little bit differently from how we've been doing it before. I think some of the feedback that we have gotten about quality measures from Stage 1 and I think both Workgroups have been thinking about in terms of Stage 2 and Stage 3 is how do we do this differently? How do we think about this in a different way? And so I think we'll hear some great testimony today from some folks who might give us some fantastic insight into how they are doing things, how are they making perhaps optimal use of Meaningful Use and how that might inform us for how we're going to think about this in the future. So, thanks very much, MacKenzie, and I'll turn it over to David for some opening remarks.

David Lansky – Pacific Business Group on Health – President & CEO

Thanks, Jacob. First, thank you all to the presenters who came from far distances and on short notice to come and join us today. As Jacob said, we really need your help. We are at an early stage of a long journey, even though we think we've been at it for a long time we know we haven't and this is a juncture as we now are coming to the end of the development of the Stage 2 requirements and we're all beginning to work on Stage 3, I think we have a very sober understanding that the journey we're on has a lot of lessons to teach us and we're counting on you all to inform our thinking so that as the different committees begin to contemplate what the Stage 3 requirements might look like, we do that based on much better understanding of what the early experience has been both within the Meaningful Use Program and outside of it with all the experience you all bring us to. So, we really appreciate your taking the time to inform our thinking that way.

I especially want to thank Marjorie for coming in on behalf of the Standards Committee so that we have a parallel discussion going on with both the standards and policy issues that are surfacing. The only thing I'd say about context, what I think the Policy Committee folks are looking for out of this discussion is some guidance as to what we can do, what policy tools do we have available to us to help you be more successful in what you want to do?

We have a pretty limited portfolio of tools and while there are a lot of issues I know from your written testimony that you'll surface for us today that we need to understand as the context for our work, at the end of the day we have a limited set of tools we can use to try to be helpful. And, so to the extent you can point us in the right directions of what we can do in the standards work and in the policy work, the Meaningful Use criteria, the quality measures criteria that will help us greatly in shaping the recommendations we make in turn to ONC and CMS. So please be as pointed and forthright as you can be in telling us how we can do our jobs better.

With that, again I just want to thank you all and thank Kevin in particular for helping put this meeting together on relatively short notice and MacKenzie for your help in getting us all orchestrated. And let me turn it over to Marjorie for any opening comments.

Marjorie Rallins – Director of Measures, Standards and Informatics for the Performance Improvement Division – American Medical Association

No additional comments other than I support your initial ones. I think I'm going to reserve my comments for midway through the discussion to kind of level set. I think that would be a better place for those. So, with that I think we should turn it over to Ahmed for panel one.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

Well, thank you very much for the invitation today and for your interest in speaking with us today. I want to thank you upfront for your impressive testimony in the written material. And what I'm hoping to do is to blend this into a dialogue both internal to the group that's presenting in an interface with the committee as a whole. So that's my personal approach.

I should disclose I have a bias in that I believe HIT and quality are in fact built for each other, a marriage made in heaven, and HRSA has actually in fact, taken the steps to...you know, I sit in the Office of Health IT and Quality so we've merged that set of dialogs in the past being parallel. So, we're looking forward to your sophisticated insights. This is complex stuff.

For the sake of time I'm going to basically suggest that we not spend a lot of time giving your bios individually. I recommend that people in the audience read those and that we go straight to welcoming Cathie, Greg, Joe, Michael, David and Janice, and we'll go in that order. I'd like that request that each of you give an opening presentation and that we probably would be wiser if we reserve the bulk of the time for the conversation in the whole room rather than have any one of you go on for a long period of time.

So, that's my initial set of rules that I would suggest. And would turn it over to Cathie and welcome your opening statements. I'm going to be keeping track of our time here with this neat little App that does time clock tracking and so we have a certain window of time. Cathie?

Cathie Furman, RN – Senior Vice President of Quality and Compliance, Virginia Mason Medical Center

Well, you're a man after my own heart, it sounds like you've been trained in the Virginia Mason production system and cycle times. So, good morning, it's an honor to be asked to testify today. I am the Senior Vice President of Quality and Compliance and I have been a Registered Nurse for more time than I'd like to admit and have a Degree in Health Administration. My responsibilities for the last 20 years at Virginia Mason has been leading the strategic quality work and therefore part and parcel to that is trying to understand how well are we doing.

I also sit on several boards that have been able to give me an external perspective of what some of these organizations are trying to do, such as the Puget Sound Health Alliance and the Executive Committee of the Washington Patient Safety Coalition. I'll just say upfront my passion is patient safety and my concern with Meaningful Use and how we're proceeding is the impact on patient safety and I'm going to share a couple of examples of that as I go through.

So, I do have experience in both inpatient and ambulatory nursing and I just have to say coming from Virginia Mason we do believe that health care is a team sport. I don't think it is only the physicians who need to have this information at their fingertips. It needs to be the entire team whether it's the pharmacist, whether it's the nurse, whether it's the respiratory therapist and I'm not sure that that has been as clearly understood with the work so far.

In terms of factors limiting the IT ability, I think a good example of that is Virginia Mason has lauded by Leapfrog and others to be one of the safest hospitals in the country. Our hospital is used not only by our own employed physician group but by two other large medical groups, Group Health Cooperative and Pacific Medical Center and the interoperability between the different EHRs that those three groups have isn't there. So, we don't have access in the hospital as an inpatient nurse to the ambulatory records of those other two medical groups.

From a clinical decision support perspective that means that the folks who are doing the abstracting for things like SCIP and CMS hospital compare have to resort to paper. Why? There isn't a standardized nomenclature, so we're getting better. CBC for all three means the same thing, but we might call weeds and grasses, an allergy to weeds and grasses, very different in those systems and therefore we can't pull that information.

There is a lot of unnecessary variability in the delivery of health care. We own that, one person wants to call something one thing and another provider wants to call it something else. We don't have any encoded representation of clinical care that everyone agrees is the same thing. Before we begin to even leverage the potential of Health IT we must eliminate the unnecessary variation in the delivery of care and that means as a nurse I used to think that I had the very best way of doing something and I have to agree that everybody's going to do it the same way. So, at Virginia Mason we use what we call standard work to standardize that. We need to do that more. Too much customization leads to safety issues.

How we can support this is the standard approach, as I mentioned, to documentation. One that builds reliability into our patient information and electronic medical records. The SCIP metrics is a good example. We don't have standard ways to code that information. What we have often is text blobs that don't relate, we can't pull out and from a resource perspective, burdensome resource perspective, the clinical decision support has to look in many different places trying to find that spot because we as health care providers haven't agreed that this is going to be the one spot that we're going to put this into the electronic medical record. And because there has been so much...and quite frankly, I think from a free market perspective we've been sold the customization of these different vendors such that I can make my front page look the way I want it to look, Greg can make it look his way and therefore, we don't have the visual cues when we need to identify something.

Unfortunately, no IT system can provide meaningful...that I'm aware of, can provide population data. So, we cannot understand once they leave our system what's gone on with them and therefore, it makes it very difficult to improve the health of a community, and a whole population. We don't understand even when they've been readmitted to a different hospital, we don't know that. Representing a provider organization, I can tell you providers want information. They are yelling, not yelling, but.

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Yelling.

Cathie Furman, RN – Senior Vice President of Quality and Compliance, Virginia Mason Medical Center

Yelling for information about how they are doing because they want to do better and yet we cannot give them the information because all we have is administrative billing coding data which doesn't tell them how their population of patients is doing and how they could do better in order to create better care for their patients.

Creating a role for vendors in quality improvement means changing the vendor focus from meeting the requirements, which is currently what we see happening. They're all focused on Meaningful Use requirements, but they're not understanding...they're not producing things that are usable in the flow of care. And so what happens is that there's lots of work arounds and that, to my mind, impacts safety. We're really focusing on the lowest bar, which is the reporting versus evidence-based clinical care that helps our patients.

I also want to make a point that I believe from my understanding it's a common practice for software companies, regardless of the industry, to produce new versions with known defects. In health care software deficiencies can lead to really serious consequences and we at Virginia Mason experienced that when our vendor upgraded their lab software that led to inaccurate results reporting. The potential...thank goodness we caught it before there was a significant impact on a patient, but that's what the potential risk is and I don't think it's the same with other software industries when lives are involved.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

Can I step in for a second and just clarify?

Cathie Furman, RN – Senior Vice President of Quality and Compliance, Virginia Mason Medical Center

Sure.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

That there is a little clock that we've just put up and so everybody's going to get about 5 minutes for this opening salvo.

Cathie Furman, RN – Senior Vice President of Quality and Compliance, Virginia Mason Medical Center

Okay.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

And that way we'll get to the group discussion further. So, if you could make your...

Cathie Furman, RN – Senior Vice President of Quality and Compliance, Virginia Mason Medical Center

I'm going to wrap up.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

Thank you.

Cathie Furman, RN – Senior Vice President of Quality and Compliance, Virginia Mason Medical Center

Great. So, because we at Virginia Mason have the fortunate ability to produce...to put some resources into fill in the gaps of the current situation with health care technology right now. One example is what we call the health maintenance module to make it more visual for patients we have a checklist similar to aviation where, quite frankly, I cannot get by with skipping my colonoscopy, you know, they know, but that was something that we had to design ourselves within the organization so that we're ensuring that in ambulatory care, evidence based prevention interventions are occurring.

And right now what we're working on from a team perspective is looking at the evidence-based clinical practice and putting it up on what we call a clinical Andon board, which is a large LED, obviously patient information is blinded, but so that everybody whether it's the nurse, the doctor or whatever can see when something has not been taken care of yet and that will help us improve care. And we need to do more of those kinds of things.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

Thank you. So, I'm going to ask that the clock be reset, which actually he is ahead of me already and then shift straight into Greg and we'll sequence through, thank you.

Gregory A. Maynard, MD, MSc., SFHM – Clinical Professor of Medicine – Director – UC San Diego Center for Innovation & Improvement Science

Thank you very much and thank you for having me here to testify today. Again, my name is Greg Maynard. I work as a Clinical Professor of Medicine at University of California San Diego as a working hospitalist but also as a quality improvement person trying to move care forward at our institution and

also have a center for innovation and improvement science that works with lots of other hospitals. I also act with the Society of Hospital Medicine as their Director of the Center for Hospital Innovation and

Improvement and in that capacity, and in the other center I run I am fortunate to work with literally hundreds of centers going into their hospitals seeing what their problems are and seeing how much in parallel they have with our own local problems at UC San Diego.

I think this first question about what factors limit Health IT's ability to support quality measurement improvement needs more than 5 minutes, but I will echo some of what's been said. I think it's very frustrating to know that the data are there and that we cannot get it. It's very frustrating to know that faulty software and user interfaces there are endangering patients sometimes and that we can't change it because it's a training issue and that will be up maybe in the next upgrade.

It's frustrating that we are told that we can't share the dangerous parts of the software because we're under legal threat. It's frustrating that we sometimes have difficulty sharing best practices even for people with the same vendor because they're on different versions or because we've had to modify the electronic medical record or the information systems to the degree locally with local talent that we can't transfer that to another center very easily.

So I work with many great centers. The best ones like Virginia Mason have extra resource, a real drive for quality improvement. They are modifying their systems so that they can not only tell what the score

is, that is where they have been and how they're doing on something, they can also tell if they've got momentum, they're putting things in graphic displays. And they can tell basically, you know, where the ball is going to be sometimes when you're really doing well, that means that basically not only do you know how you did on DVT prevention last month because you've got a count of hospital associated BTE, you know what your prophylaxis rates, not through the Meaningful Use numbers, which in this case I'm sorry to say are fairly meaningless use, they don't move the improvement ball forward very much.

They know how they're doing on prophylaxis because they've gone to the trouble of crafting their own display. They've had to put their own programmer to work at it to find out who is on what and then they identify who is at risk for DVT or whatever the condition is, and who do I need to focus on out of these 500 patients at my hospital today. Where are the 30 that I need to focus on? So that, unfortunately, is the exception where you've got the outcomes, you've got attention to the process so that you know, you get guidance about where you need to be and then you know what's going to happen, you know who is really at risk and who can I go after. I think, again, there is myriad of problems, but people are finding ways.

I think Health IT and quality measurement and the quality life cycle can be accelerated if you get the right information to the right provider in the right format that they can use it. And we are pretty low on those things right now. We want tiered security, user friendly interface, reports that look different for different end-users depending on what their capacity is, and we want real-time data and we want that real-time data to roll up automatically and be able to present to our board to show us what the performance is over the long-term. Currently, we don't have that and everybody's striving for those sorts of things. But it's a tough row to hoe right now. And the only places that can do this are putting lots and lots, and lots of their own customization work around the products that we have to work with.

I think I'll pretty much leave it there. The testimony that we'll hear I think parallels a lot of what I've written in my written testimony. Thank you for the opportunity.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

Thank you. Joe?

Joe Kimura, MD, MPH – Medical Director – Analytics and Reporting Systems – Atrius Health

I will wait for the clock to start. I'm in the penalty box, all right. I want to thank Dr. Larsen and the committee for the opportunity to engage. I think going after Greg, so my medical group is a purely ambulatory practice group. We do not have hospitals. We're based in Eastern Massachusetts and we

leverage lots of different hospitals in our community for the care of our patients and in that context when we're thinking about how Health IT and data can help us improve the quality and safety of ambulatory care provided to our patients and communities there is a lot of stuff we could talk about, but I think the bulk of the work that we're doing today really is about the hard work of operations improvement in health care. The reliability, the efficiency and the effectiveness of what we're doing to be able to get patient centeredness, quality, cost, actually optimized the best that we can.

In order to do that, I really think about that as the blocking and tackling of health care. But it drives...it is such a large source of medical errors. I mean, we've talked about the inefficiencies and variations from provider to provider, that if we don't do that all the fancy plays we draw up for the other neater things we could be doing actually have a very low probability of being implemented and effective across our practice. So, we need to be able to do that really well regardless of whatever IT tool comes forward. And I think that's where we say...or operations improvement for us is a core competency if we're striving to be a data driven adaptive learning organization.

And in that sense in my role as a medical director of analytics in sort of the business intelligence systems we strive to make our systems be able to support that, right? That's what my delivery system really needs and to be able to do that we're thinking about how data is used in the change processes, what's

expected, what types of data are actually needed at the front lines of care to do change, the usability of the interfaces that needs to change based on the user, and those users, again aren't necessarily all the power users at the top who love the exploratory capability of getting through everything, it's actually very simplistic, right?

And, so we think about customer markets in terms of our own users for analytics in IT. We have to figure out ways to make it easier. All of our doctors are overworked and they're trying their hardest and, you know, to have the tool make it harder to do the work that we're asking them to do and that they want to do becomes very frustrating and that's a tough conversation that we have to have a lot going forward.

And then finally of course when we're thinking about the usability we also think about the broader spectrum of metrics and the type of metrics that are sort of more linked in with those operations improvement, be it clinical, financial or operational.

I think there is one other area that, at least as an ambulatory practice and we lump it together with quality, is potentially a new domain that I'm not seeing a lot in at the moment and that actually is the role of the patient actually in really striving to improve quality so the patient and communities are integral as we really try to partner with them to improve quality and a lot of the outcome measures and process measures we think about have a lot of involvement that require us to be really good partners with the patients.

So, in that sense developing new ways and innovative ways to engage those patients in wellness and self-management of chronic conditions becomes critical. And for us that's something we think a lot about. So, we think about from the analytics and BI perspective patient directed analytics and decision support for them in order to be able to improve patient engagement.

So, in closing, actually I like the term, I may actually give you some time, you know, I think for us as an adaptive learning organization, you know, our goal is to continually strive to improve our delivery system. I wrote down here basically for us it's to provide the right care, the right way, to the right patient, at the right time, and in the right setting every time. Thank you very much.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

Thank you. Then gentleman just yielded a minute extra to you.

Joe Kimura, MD, MPH – Medical Director – Analytics and Reporting Systems – Atrius Health

That's collaboration in health care right there.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

We'll nevertheless, go ahead reset the clock for you and say go.

Michael H. Barbouche – Founder/CEO – Forward Health Group, Inc.

Good morning, thank you for inviting me and thank you to Kevin and MacKenzie. My name is Michael Barbouche; I work for a healthcare measurement company called Forward Health Group in Madison, Wisconsin. I'm a math person and I trained in health services research. I've worked in health care my entire life and I have only ever worked with data and so that's given me this great perspective. But I think more directly I'm married to an internist and she's out there. She manages about 1300 patients in her panel and when I was on the Staff at the University of Wisconsin it was very strange to me that I had such unbelievably rich access to this data and she had none. She had absolutely none and that seemed strange.

I'm basically a guy that goes out and gets the data. So you can dispatch us into any setting and in about six to eight weeks we'll get rich beautiful data flowing, the stuff that is the end-goal for all the work you're doing. So, the data is there. It has always been there. But somehow we have to figure out better, more efficient ways to get at that information.

I've built something that solves a very important riddle and that's probably what helped get me at the table here today. I built a public reporting venture that many of you may have heard of called the Wisconsin Collaborative for Health Care Quality. So, that was at the behest of employers and payers and we had one very simple goal, apples-to-apples measurement at patient level outcomes for as many physicians in the state, as many systems. And we were able to do that in 2004 and we didn't have standards from you, we didn't have structure, we didn't have measures, we didn't have anything, and the majority of the practices didn't have EMRs, they had paper. But yet, we were able to build that out to do that.

And the way we were able to do that in part was because we were able to get, first and foremost I think the buy-in and the support from the administrative and clinical leadership within the systems that, hey, this measurement stuff's important, they really embraced that. But, also then there is a real challenge and there was a question yesterday at the data palooza, you know, the hard part here now for Health IT and what's limiting its role is that the systems that are embracing the technologies and going forward, they missed some important building blocks. They don't know who their doctors are. They don't know what a PCP means. They have fractured definitions.

If we look at the newspaper like this morning, there is a big merger in New York happening apparently. Those are two huge organizational cultures that are going to have to come together. They don't have defined standards within even one organization now it's going to be much larger. So, these are some of the challenges where it isn't necessarily a technology problem. I think we have an organizational culture shift. I know it's not possible for this hearing to produce this, but the greatest tools that we need to create are a set of tools to help, you know, physician leaders figure out how to change compensation

because they have no idea of how to get off the RVU.

There are a few, Virginia Mason and others that have...but everybody else out there, they're still eat what you kill. These are some of these strange simple things that stand in the way, yet the data that we all seek is the data I think that will help, really help us move in the direction we all need to go, which is dramatic improvements in population health. We have rate limiting steps that are important.

There are not enough data analysts out there and they're not going to be, and if anybody is good at slinging data in a health system they immediately get hired away by the chair of transplant or cardiology to control the data within the system, to win battles internal, not to figure out how to get more data to move across the system. These are just odd, strange phenomenon, but yet I must tell you that the data, all of the very rich data, all of the outcomes data is there.

What we need to do...we do some great work and I would love to chat with you in HIV and have measures, those are very important and fundamental, but when trying to look at collecting measures

across multiple HIV providers across an entire state, in this case in Minnesota, they're going to the lowest, lowest, lowest possible common denominator. They're not looking at things that would matter, not the clinical results. They're saying did you have two or more offices in a year because that's the simplest thing they can measure. Yet, there are CD4 results and other things sitting there ready to be really harvested and more importantly really there to help benefit the outcomes.

So, we need to think about not just how this technology fits but also who we're helping with the technology and where they are because the systems that we want to improve, they don't know how to do it yet and that's where we really need to help them. Thank you.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

Thank you very much. Please reset the clock again and then we'll let David start. Thank you.

David A. Burton, MD – Health Care Quality Catalyst

Thanks very much. Ahmed alluded to the fact that what we're dealing with is a complex matter and I think rather than dive into what you can read that we've written I'd like to offer what I hope is a simplifying construct, a way to think about what we're all interested in and about.

Our health care system I think consists of excellent building blocks. They're based on solid science, sophisticated technology, but we use them in a highly wasteful manner. And I think what we need to do is to develop, and we're all here and I'm preaching to the choir, a much more data driven system that focuses on three things, more clinical effectiveness, more cost effectiveness, which I would submit we're not even close to being able to measure and a safer system. If we're going to achieve those objectives, then I think our quest really is to ring waste out of three generic categories.

The first category is care process waste, utilization. There are lots of forms of this but if we take the simplest and the initial in the medical model, it is not ordering things that are neither diagnostic nor contributory. So, if I have heart failure what I really want to know is what the ejection fraction is. I also would like to know the BNP because if it's low and I think I have heart failure I'm treating somebody that probably doesn't have heart failure. There are some contributory tests that I may do if they are indicated like a chest x-ray to see if there is a pleural effusion, to see if there Kerley B-lines, you know, are there indications, but that chest x-ray is not going to be as specific because the findings that are consistent with heart failure can be consistent with other conditions as well.

If I take those two categories and think of those as circles, the diagnostic circle is important and in fact, if I'm not doing the things that are in the diagnostic circle, I'm not really taking good care of the patient, I'm not clinically effective. If I'm doing too many of the contributory on every patient, if every patient gets the same workup, I'm not being as efficient as I should and if I'm jumping to a ventriculogram in order to get the information that I could get out of an echo, I'm pretty wasteful, you know, I'm 10 times the cost of what I could have gotten which would have been adequate to initiate the treatment for the heart failure patient.

The second category of waste which Cathie spoke some about, that's work flow waste. So, the first is what did I order? The second is how efficiently did I deliver what I ordered? And here the methodology to get at that is, in fact, traditional lean TPS kind of methodology, value stream maps, A3s, etcetera. The problem is that we've done those in a vacuum historically. We haven't been able to measure even simple things like time stamps and say how much time did I spend at that particular stage. We need also to be able to integrate not just time stamps because the steps in a value stream map are not of equal cost and so we need to be able to bring in and integrate financial data, particularly costing data in order to focus our energies where we have the greatest opportunity for improvement.

Third area of waste is patient safety waste. It has both clinical content and standard work or value stream mapping, lean types of implications. There is standard work to identify and process failures in medication administration or blood transfusions, but there is also science behind who should be getting a protocol to prevent patient injury.

The other dimension of this is that we need three legs of a stool in order to make this effective. We need knowledge assets and I would submit to you we badly need a standard way to load knowledge assets into EMRs. There is no standard API. There is no way that I can make seamless my commercial grade content and getting it into the EMR.

The second thing we need is to use those knowledge assets, that standard of clinical content to inform the analytic system so that we're not loading something here and measuring something different on the back end. We introduce a lot of noise to widen out the control limits.

The third thing and most difficult thing is in fact to take the visualizations of that analytic system and the knowledge assets as starter sets and get buy-in from clinicians who are going to lead implementation and let them fingerprint, and beat up on, and modify until they own what they're going to implement, then we have a shot, but that implementation is the most difficult step.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

You hit it right at zero, I'm impressed. Janice?

Janice Nicholson – CEO i2i Systems

Good morning. My name is Janice Nicholson, I'm the co-founder and CEO of i2i Systems and for 12 years I've been focused and dedicated to helping the health sector make the best use of their data through smart technology. What do I mean by that? It's really technology that supports easier and greater access to data and improves efficiency of the care team staff. Our 200 plus clients deliver care to over 1,000 sites in 29 states and include community health centers, health center controlled networks, physician group practices, hospitals, medical colleges and public health departments. We have learned from them. Really struggled with them. And have done our best to understand really the health care processes so that our solutions can best support their clinical and quality improvement work.

Our mission statement, creating healthier populations, has consistently guided our product and service development and we've never wavered from that commitment. We're honored to be here today to share our thoughts and suggestions really on behalf of our clients most notably, the hundreds of health centers and small primary care practices that we serve.

First, let's just go right to the heart of the matter. What factors limit Health IT ability to support quality improvement and quality measurement? My response is really based on field experience in supporting hundreds of clinics and practices who are using more than 30 different PM/EHRs systems. Honestly, I would like to tell you that we have figured out why Health IT investment has not resulted in more dramatic improvements to outcomes of care and that we have the solution, the silver bullet, we do not. What I can share with you are three of the top challenges we have experienced in helping organizations realize benefit of HIT adoption.

The first challenge is that of standards and interoperability. Obviously, you have heard a lot about this already. EHRs say they operate but at what level they don't say. Much of the data in EHRs about patients is customized unstructured data even within the same EHR templates allow a patient's medical data, that is smoking status, to be stored in different locations of the database using different representations. This means that while the definition is the same, the information available is not. This lack of EHR vendor standardization and inability, unwillingness to share customized, unstructured data cripples efforts to address Meaningful Use and severely limits analytic capability of EHR data.

The second challenge is that EHRs do not fully support Meaningful Use requirements. Health IT analytic capabilities are currently not evolved enough to support tactical operational and strategic population health management for continuous improvement, this hampers organizational leadership, management and even care teams in proactively monitoring and improving performance. To meet Meaningful Use Stage 3 organizations need tools that will support long term sustainable change. A simple example of this is HbA1c testing for diabetics. Evidence-based guidelines suggest A1c screenings for a diabetic patient should occur at least twice during a year-long period. This simple adherence tracking for one

patient becomes very complex and quickly accelerates when managing thousands of diabetics and many of my customers do.

The third challenge is lack of incentive to achieve higher levels of performance. We often see organizations drawn to our solutions mainly for required reporting to payers. We encourage organizations to leverage our tools to their fullest, but sadly many are satisfied with threshold performance since there are not enough incentives to drive up performance, this really does speak to the lack of data-driven culture incented to measurably improve health outcomes.

In closing I'd like to summarize three opportunities that arise out of the challenges just presented. First, Health IT vendors must provide clinics open access to data and remove barriers to standardization and interoperability. Performance can then be measured in a reliable way and shared across the health system.

Second, we need to face the reality of what EHRs currently deliver. There is no single comprehensive, all inclusive HIT solution that will meet everyone's needs today and in the future. We have to help providers understand the intelligence tools that they need so they can plan and budget for what will be required to monitor, improve, and sustain health outcomes.

Third, we need to increase the percentage of revenue directly related to pay for performance. Organizations need to be incentivized for behavior that drives change; this will naturally catalyze the quality of lifestyle that results in high performance. We can be optimistic if we address these opportunities, successes within our grasp and it can come at a price that you, me, and the nation can afford. Thank you.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

Thank you very much and just for clarity, I saw that as just the first stage in our discussion today of the opening salvos. I'm going to move now to stimulate cross testimony dialogue as the next group by taking a moderator prerogative and asking a couple of questions and then I'll open it up to the whole conversation of the committee. And I would request that when you speak if you could please say your name upfront. This will greatly help with the transcript process later. That's true for the committee as well. Thank you very much.

So, the context is right now for me the national quality strategy, and that has a whole lot of implications to the notion of person-centered dialogue around measures and HIT and systems, and it also has this broader construct of health as opposed to just health care. And so from this point of view, especially I want to thank Kevin and whoever lined you guys up because I saw a sequence of hospital and ambulatory care, and sort of the systems thinking, and the specialist, and consultation of partnerships out to population health.

My question to start for all of you is what data do you need to collect to improve performance that you don't currently have? It's a wide open question because I heard initially from Michael that the data is already there and I guess I'm trying to puzzle that through. Please say your name when you speak to this. Thank you.

Cathie Furman, RN – Senior Vice President of Quality and Compliance, Virginia Mason Medical Center

So, this is Cathie Furman. I'm not sure that I can answer that and the reason for that is we have lots of data, most of which is in text blogs rather than discrete data because of the adaptive change issues with...and lack of understanding that if I want to dictate, that it's going to actually be able to get pulled back out. But even with that, just our experience at Virginia Mason, we've recently gone through trying to get...we've got 15 years of clinical data that we wanted to put into a system to match it with our financial and our demographic registration information similar to what David was talking about in order to have a...we purchased a product called Amalga to really have at the fingertips of the provider information to pull out.

Well, we worked with a vendor, not a small vendor by the name of Microsoft, and they couldn't do it because we had so many data elements and variables over 15 years. I think it's...I know it's at least more than one terabyte. I'm thinking it was closer to two terabytes, that they had to actually go to a third-party vendor and it took what we thought was going to be three months, it took over 18 months. And so we're just now starting to pull information. But that's the complexity of the data that we've been collecting.

Gregory A. Maynard, MD, MSc., SFHM – Clinical Professor of Medicine – Director – UC San Diego Center for Innovation & Improvement Science

Greg Maynard. Well, I would be...the structured problems alone, that is the text-based data that we can't get at alone, let's leave that in Nirvana land for a while. We can't get the very basic data. We have

hospitals that have...they know that insulin, anticoagulants and narcotics are the most dangerous meds in the hospital with the most adverse drug events. Most hospitals don't know their hypoglycemia rates. Most centers don't have the glucose displayed in a manner that tells you when they are getting low. Most people can't find how many bleeding episodes they have had from anti-coagulation in the last year, and that's because this data is in different places, in different silos. And the user interface to get at that data is complex. And like you said there are not enough sequel programmers and techies and people who can get at that data with the current interface even if they had all the data in one place.

What I ended up doing for a lot of my career is going to one data owner to the next data owner, to the third data owner, to the fourth data owner to pull things together in one report so that I could get at least some glimpse at what's going on in my hospital. And they all act like librarians with precious books who think like a good librarian protects the books instead of gives out information. So, it's not a matter of what...I mean, the data are there most of the time it's just that we can't get at it very easily.

We need better user-friendly interfaces so we can get at this data, this wealth of data that's out there. And going through a central vendor or having one set of Meaningful Use measures will never get you there. You need to be able to have the user interface of the improvement teams doing the work to go get the data.

Joe Kimura, MD, MPH – Medical Director – Analytics and Reporting Systems – Atrius Health

So, this is Joe from Atrius Health. I guess for us...so we've been fortunate to have sort of an integrated claims data warehouse with an EMR warehouse structure that is linked and so we do feel like we're in a place where we have a lot of capability in terms of sort of longitudinally looking at information. That being said we're an ambulatory group and so a lot of our ECF, SNF care, home care, etcetera and obviously hospitalizations, we don't get that kind of internal data. We have interfaces that we try to build to get that information. But, obviously, like we said, we admit to many different hospitals and not all those hospitals can send us the information.

So, one of the big gaps for us is we rely on claims data to try to get that kind of information back to us, but only in the relationships where we have risk for those particular insurers do we get that information. So, in our particular market where half of our business is risk and half isn't, we're blind actually to things outside of our system for about half of our patients. We have rich EMR data but we're sort of not

seeing that outside. That being said, claims have lagged.

So, the other problem is timing. So it may still be there, but it's not available to us when we need to act on it and so that to me is also an inaccessibility issue. And when we think about getting real-time information, getting real-time information from our system is one thing, getting it from outside systems is actually, you know, adds yet another layer of complexity on the fact that you're only getting claims data. So, we think about can we tap into things like the ADT feeds from hospitals to get more real-time information to help us do a little bit more around the case management and care management.

And then the last thing actually is operational data. I still think sort of our ability to change work flow requires a significant amount of detail about being able to measure that work flow and when I look through our care improvement teams fanning out across organizations it saddens me the number of times I see them saying, you know, I'm just going to pick up the clip board and do this, right? And do that again

and again and you sit there and say that's horrible, you know? And you know you watch that again and again, and again, and you're saying this is stuff we should be able to capture. We should be able to systemize it because you see them do it in derm, you see them do it in neurology, you see them do it in orthopedics. And you're like, my gosh we should be able to do this better. My department should be able to pull this information and provide this for you in a way that actually is accessible to the care teams actually doing the work.

So, in that sense, yes, there is data that's there. There is other data that we're not getting available to and the whole...I too will leave the unstructured data elements because I think that's another large area of things where if we want to make truly meaningful measurements that clinicians understand and feel compelled to actually manage even without financial incentives or other sort of motivations, you need that clinical context and a lot of that comes from that contextual information in unstructured data. So, without that capability I can give them this narrow look of what they're trying to improve but without that context it's really hard for them to buy-in.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

Thank you.

Michael H. Barbouche – Founder/CEO – Forward Health Group, Inc.

Michael Barbouche. I'll address your question directly but with a bit of a twist. So, people show up in Las Vegas with a little cheat card for blackjack when they should hit on something and I've not seen it for all of our integrated health systems but I imagine their card says buy an EMR, oops that was expensive, well we're going to get the Meaningful Use funds, that's good. Wait we can't do anything, so now we need to buy a data warehouse. Okay, so we did that. Wait, we still can't get anything so then we have to put something else in place that still isn't there and so we have this quest, I don't know where it comes from, for big data. And my argument to you would be we need really small data, very, very small data, like data that's actually right to what Dr. Maynard said.

We don't know in any functioning system, even leading systems really who the patients are and how they're doing. I'll give you a great story. We were meeting with the Chair of Cardiology. The kind of guy that, you know, if you were on the table or loved one this is the guy you'd want working on you and he grabs his wine glass and he slams it down, he actually slams the glass down and he breaks the stem, and he says when I see my patient in the ER the ejection fraction is captured as a discrete variable. And when I see them in my clinic it's lost I can't get it. And he said, my EMR vendor has a moral obligation to fix that. I said, you know, it's not a moral thing it's probably a 25-year-old kid who could catch a flight home earlier and he doesn't know what an ejection fraction is and nobody there told him what an ejection fraction is or why he'd want to keep that, it can be fixed, it's not a hard fix. Of course, those resources after the install are very hard to get at.

And so, it's about teaching these systems how to fish and the fishing is really about the journey they're going to have to go on in improvement. So, the data that is missing, to answer your question directly, begins with very basic questions like, you know, who are your primary care physicians, it's not an easy question to answer. There is no good answer for that and there is no definition that NQF or anybody can create because is it the endocrinologist, the PCP? I don't know, you guys have to decide as an integrated system or as a physician group whether or not you're going to call the endocrine a PCP.

Getting to places like, you know, which patients belong to which doctors, that's the magic key here, but there's no algorithm as well for that that this committee or anyone is going to create. Instead, the clinicians who know their patients well are going to have to become vested and owners of the data, use the data, and it's through their use of the information that we'll begin to get it better aligned and better established to begin to drive the improvement that we need.

David A. Burton, MD – Health Care Quality Catalyst

David Burton. I just would echo what Michael has said. I don't think the answer is in big data. And I think of the things that we could get if we really had superb NLP and it wouldn't help us a whole lot. I think one thing we neglect is the Pareto principle and if we use the Pareto principle we can actually reverse

engineer this and figure out what data we need because Brent and I had a term at Intermountain that we called recreational data collection and most times when you get a group of physicians together, and it's even worse if you get a national group of physicians together, and say we're going to create a database and you pick STS...VO, whatever, the thing that comes up is, well, what might we ever want to know? And, you know, you end up with 300 data elements. And when you actually get practical about it and start using those data elements, maybe you use 75 of them if you're really sophisticated.

And, so what we've done over the years is we've said let's invoke the Pareto principle. Let's group our clinical activities together as work processes and then let's take the variable costs as the best surrogate for resource consumption and risk to the patient, and let's sort those by two things size based on the variable cost and variability from provider to provider and what you end up with is a four-box matrix. In the upper outer quadrant you've got large processes that are highly variable, you know, the Lord made common things most common and so if you take big processes that are highly variable, you are most likely to make a difference in terms of the health of the population.

Then if you take those processes and again if you take a group of physicians and say have at it, tell us how this works, what you end up with is a 22 page algorithm that's based on clinical decision support and you've got a thousand metrics that you could report on. What you need to do is limit the physicians to 5 slides and say I want you to do me a high-level conceptual flow diagram. How does this work? How do we take care of patients that are pregnant? Out of that will come at a maximum 6 or 7 things that you ought to measure.

Okay, if you do that Pareto analysis and let's just take the inpatient data, which are more available than Joe's ambulatory data, what you find consistently across mobile systems is that there are about 20 to 25 care process families like heart failure, pregnancy, ischemic vascular disease and so on that make up 80% of what you do. Within each of those if you say I want 5 to 7, let's just start with the 5 to 7 most important indicators, what are the things that you really need to measure and therefore manage? And by the way, there is a reason that telephone numbers are seven digits, that's as many as we can remember. So, if you start getting above 6 or 7 metrics you will soon overload the physicians.

But, if you took those 25 care process families, you took the 5 to 7 key indicators and said those really are the data elements that we need can we define the cohort? Can we define the metric specifications around those key indicators? Can we figure out a consistent calculation methodology? Can we figure out what the target ranges are consistently and you know what we're really into a little bit of data governance. And in all of the people we've worked with that's the sorest need that's almost always absent. And that's where your data quality assurance comes in.

We went through an interesting exercise a few months ago and said, well, why don't we automate the CMS measures? We can, the problem is when you go out and start looking for those there is so many data quality assurance problems that what you're going to do is have an army come through larger than the army that's abstracting the charts now in order to automate those and what we've decided is, well when you get to pregnancy and you develop your care process model be sure you include the...requirements, etcetera, in that care process model because when you go out and say to clinicians we want you to fix these data quality problems and the reason we want you to is so we can report to CMS so that we don't look bad on the scorecard, it's not very motivating.

If on the other hand, you say we're going to improve care for pregnant patients. We're going to reduce the elective inductions less than 39 weeks and, oh by the way, while we're at it fixing the things we need to fix in order to improve the care, we're going to fix the...stuff too, we'll just grab that on our way through. That's a lot easier sell than trying to fix CMS measures or any other arbitrary measure.

So, I think as has been said by several, the data are there. We don't have the ability in most cases to integrate them. So I have one source of truth with regard to clinical data that I get out of the EMR.

A different source of truth that I get out of PeopleSoft or...on the financial data. We need to be able to link those. And to Michael's point, we need a common linkable identifier. So, if I bring a claim system in to the data warehouse and I bring a financial system in, and I bring a clinical system in, I have common linkable identifiers around those in terms of providers, in terms of patient ID, etcetera, so that I can

integrate those into a single source of truth. Those are the kinds of things we need. I don't think the answer is going to be in big data, I think it's going to be in using the data that we have more intelligently and in an integrated fashion.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

Thank you. Jan?

Janice Nicholson – CEO i2i Systems

Janice Nicholson. You know, I would say my perspective is going to come much more from the primary care setting, which is a big area that I work in and I would say data is needed in two ways. First of all, if we're going to meet Meaningful Use Stage 3, which is ultimately you want to...you want these organizations to change outcomes; they have to have real-time data at the point of care to do that. Planning, morning huddle, the ability to ask any questions. How many diabetics do I have that are coming in tomorrow? What's due for them? How many women are coming in next week that need to

be papped? These are things that they have to answer first. That's part of what is going to get them there. In the primary care setting they're trying desperately to say how do I truly create healthier patients? The data must be there for them to do that.

So we have to have real-time data and that data has to be leveraged. It's there and it can be leveraged. I agree with Michael. I think, second, we have to have data for strategy at the organizational level for the tactical stuff. We've made a decision to improve the number of paps that we're going to do. Are we doing it? What doctor is doing the best? What doctor is not doing the best? Why are we not doing it? Those types of statistical reports have to be available at the organizational level to answer those types of questions, to measure their performance so that they can improve.

I do think that we need big data but it's not the first thing we need. We have to have the tactical data first. On a national level if we really want to improve the health of patients, we have to identify where the best practices are happening. We have to identify where the worst practices are happening. And, you know, that is an important step. The problem that I sort of see is so many are jumping to that step. Let me go to the big data warehouse that becomes completely inactionable for me with real-time data, it's not going to solve the problem at the setting where I'm seeing the patient. I need to start planning. I need to start doing morning huddles. We have to get smarter about the way we're delivering care. We have to move away from reactive and move into proactive. The data has to be there for it.

And I would say the data that's needed is any of the data about the patient that gives the team the ability to offer the best care, whether it's smoking status, whether its behavioral health issues, whether it is, you know, self-improvement issues around BMI levels. The data has to be there to actually deal with it before they ever get to the hospital. Thank you.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

Thank you. Well, you know, you actually anticipated my next question and so what I'm going to suggest is to ask you to add what you may think you would need to add using the previous discussion as a foundation. The question is, what are your perspectives on how we should grow IT support for quality improvement? In other words, not for billing purposes or for, you know, all of the other aspects that we've addressed. And in particular priorities and sequencing that you would suggest. Again, I hear this a bit from David in terms of the algorithm analysis, etcetera. But I want to just open it up as...and you don't have to go in order, by the way, if you need to. Go ahead. Michael.

Michael H. Barbouche – Founder/CEO – Forward Health Group, Inc.

Michael Barbouche. I'll go first and I'll be brief and I'll support Dr. Burton here. To his example of perinatal quality improvement. The most important thing that Health IT can do right now is create a very simple tool, a very intuitive tool for this specific example that allows people on the care team to say these are the people who are pregnant right now. Who are the moms you're taking care of, because we can't use analytics to do that very well? We can't go into the data and figure that out accurately. But if we

could figure out a way to talk to some of the nurses and say, hey by the way, you know, we just check a box or we can begin to then build out a denominator of who the pregnant moms are. And then to the 5 or the 7 measures, we could begin to track those. And that's not a measure, that's not a standard, that's an adoption of Health IT in a manner that allows the users to become the better owners of the data.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

What I just heard, just to translate it into some of the history in the collaborative, was we need a good sense of what that active patient population is for the practice and for the individual, and the population or focus around any particular condition that you're really going to be doing something actionable at the local level. Is that a fair translation of what you just said?

Michael H. Barbouche – Founder/CEO – Forward Health Group, Inc.

It is. We simply need the users to engage and own their data. And right now they're creating the data, but it's a one-way path. They're entering it, but they don't get it back and so we want them to now enter, but in a manner that they know will help them.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

By the way, if you need to signal to me, you can just put your sign up and I'll know how quickly which one went up. Go ahead, Cathie.

Cathie Furman, RN – Senior Vice President of Quality and Compliance, Virginia Mason Medical Center

Thank you, Cathie Furman, Virginia Mason. I just wanted to add to what Michael was saying, you know, to put it clearly, what we need IT support for are rules-based tools in the moment of time of care. So if this, then what...rather than having to go back to some huge database and ask, we need it when the patient is in front of...and I would expand it beyond the physician...to whether it's the nurse, whether it's the pharmacist, right then if the patient is telling me this, we need to have those rules-based tools right there to bring that information in so better decision-making can happen.

Gregory A. Maynard, MD, MSc., SFHM – Clinical Professor of Medicine – Director – UC San Diego Center for Innovation & Improvement Science

I'll take a shot, Greg Maynard. I fully endorse what David was talking about, about identifying the most important problems, figuring out what measurements are actually going to move the improvement process forward and building the systems around those measures, that's not what's been happening, but that is the way to go.

The other part I'd say is that we need better interfaces to get at this data, both the archived data that shows up in our databases or data warehouses once a day at midnight in a hospital system, but also the

stuff that's going on right now. As everyone has been saying, we need to raise the situational awareness for these high priority patients. You know how we find patients with CHF in our hospital? We look for who is on IV Lasix. Is that stupid? Yes. But it's the best we can do right now because there is no identifiable tag for, hey here's a CHF patient. Please start using the CHF protocol, we've put all this time into it, Mr. Protocol, meet Mr. Patient, you know?

So we need things that raise the situational awareness about here is the opportunity. Here are the tools we already have in place, engage, you know, go for it. I don't think we're going to get there if we rely on a few EMR and informatics vendors to do this. So, our current architecture is that once you have a vendor, you've got a vendor and you can't change them and you're waiting for their next upgrade or analytics engine to come out. And so everybody's trying to build this themselves.

In the meantime, there is a wealth of innovative, very smart, very tech-savvy outside vendors who could hook into those same databases and provide you with real-time web-based programming that's very flexible, very user friendly, but our IT people don't want them to come in because there's too much problem with that right now or it's again the librarian guarding the books. And if we had a more App-like

architecture, I put this in my written testimony as well, but if we had a more App-like architecture where you have a basic structure, you have outside vendors who could hook into your system using HL7 standards, etcetera, etcetera and switch out those components if one of them is not working in an interchangeable way, then you'd really drive some competition, some innovation and have much more rapid acceleration of getting good data.

David A. Burton, MD – Health Care Quality Catalyst

David Burton. I just want to underscore what Greg just said. One of the challenges that we will end up dealing with potentially in Stage 3 is inflexible architecture in data warehousing. And if you have an inflexible architecture that you've got to know, again, everything you might ever want to know when you build the data model, you're in trouble because there is no way you're going to know all of the things that you need to know. So, you have to have a flexible data architecture. And the amount of transformation that you do with your ETLs when you're bringing your source systems in needs to be minimal so that you're not mired down every time an upgrade comes with rewriting all of those transformation routines.

Where you want your transformation is from source data mart to subject area data mart and I think that's one of the fallacies out will right now, is that there is too much enterprise or the opposite problem is you're at too high a level. It's a summary data mart approach and you get your data for that specific thing. But when you say, gosh, I'd really like to know the financial aspect of this, not just the clinical, you're starting over. So that's one point, is that the data architecture or the EDW architecture needs to be flexible. You need to be able to change it in a few hours not a few months.

The second point is I think there is a sequence at a macro level to what we're trying to do and it starts with knowledge assets. You really start with what is the diagnostic algorithm? And right now if it fits in

CPOE, it's pretty compatible. You can make it almost seamless, if it doesn't, for example, if you're looking at indications for referral, I've taken care of this patient, I've taken him down through the treatment cascade, I'm not getting to the targets that I want to get to and so now I need to send this patient off, what are the indications? If I try to load that in it's pretty difficult. It's even harder to load in indications for intervention.

I got this patient referred as a cardiologist. I see the patient now what do I need to be sure is in place before I do the Cath and potentially do an intervention which may, you know, not improve the health of the patient but add a lot of expense? Those things we don't have a good standard way to load those knowledge assets into the EMR and until we do, we'll still have very wide control limits, a lot of noise in there because of the various ways that it's loaded.

Second point is that those clinical effectiveness guidelines, and I frankly, personally don't like the evidence-based medicine approach because only about 15% of what we do is evidence-based. But there is a lot of other good consensus and guidelines and so on out there that are useful, it isn't all or none. It doesn't have to be an RCT in order to be useful. A lot of quasi experimental design evidence is very helpful and is much better than craft of medicine apprenticeship.

So, we need to upgrade what we're loading in as far as commercial content is concerned and we need to get away from everybody reinventing that wheel, every organization, every new care process starting from scratch trying to develop a knowledge base. We need to upgrade and encourage the development of commercial grade clinical content. Then we need an interoperability between and therefore some standards as to how you load that in. Well, once you load it in, then it should inform the analytics aspect of this. It ought to be driving what the cohort definition is, what the specifications are.

Then the third element, if we're ever going to change the outcomes is you've got to have a deployment system. You've got to have teams and tools that help the clinicians want to lead the implementation. Otherwise what you end up with is a lot of science projects and not really any change in the outcomes and the patient health.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

Thank you. Let's shift to opening the questions from the panel and the committee as a whole. Go ahead. And I again remind you to say your name before you start speaking so we can get the transcription correct. Paul?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Great, thank you. Paul Tang. One, I want to thank the panel for such an elegant presentation of what the problems are. And the reason we put together this hearing is because I think we do have a moment of opportunity. We haven't had that in the decade in the past of influencing things in a much more dramatic way than sort of one person talking to one vendor at a time and I think you've all said that.

So our objective is can we get your advice on what Meaningful Use objective or quality measure would stimulate the vendor's and the healthcare organizations to go on the journey that you've all described? So, we looked for a measure for usability and haven't really found one, as you can imagine. One that might be closest, the click meter, because every upgrade...we will know exactly how many clicks more it is, which is actually a reflection of work flow, which you all described as well. Similarly, as being work flow we've looked for a measure for work flow effectiveness and haven't found one. And a measure for data stewardship, which was raised. In a sense, stewardship is not just having data. Is it the right data? Is it clean? Is it the data integrity? It's all that and in some sense there is a mind shift that we need to make about that.

So, in going back...so one of the things we did talk about in the Policy Committee was sort of like a quality measure platform. It's a bit like the architecture that David talked about. Can we as healthcare organization users have more control over what data, where it's stored, and what can we learn from it versus having these things come to us hardcoded? And talked about a quality measure plug-in that would fit in there that would be changeable over time as the science matures, but also be responsive to our local initiatives.

So a comment on that kind of concept, but really what Meaningful Use objective or measure could stimulate some of the changes that you all are seeking? Because that is the lever that we have with

This particular program and it has been, as you point out, a rather influential and powerful one. Let's take advantage of it to achieve or overcome some of the problems that you enumerated. So thoughts?

M

Yeah. I guess my first thought on that one is the comment that both Greg and David made around sort of this aspect. I think we are in different spots of maturity as we're thinking about our data systems and our capabilities, but the common theme around, you know, to get locked into a particular tool and, you know, be completely wedded to that, hoping that the next upgrade handles some of these things, that's challenging. And as we get more sophisticated in our systems, I mean, we think about value, right? Not just quality now. So, everything is patient experience, cost and quality, you can't just look at quality alone now. So, that involves integrating those systems and the different tools that people have focused on, sort of financial type analytics versus clinical analytics, versus experience analytics, you need to plug and play and find the combination that works, that our organization buys into, understands, our physicians feel compelled this is good information. That plug and play capability is something that I'm hoping we can sort of set some directionality that, you know, helps...I don't want to say helps or forces, you know, that capability to always be open, right? So that we could begin to be able to swap out some of that stuff in a little bit more of a less arduous way.

And, I'm not talking like global EMR systems, but literally pockets of analytics capabilities, ability to get the particular types of information. If our clinicians say we need to go after this and someone over there does that really well, love to be able to bring that in and plop that down and not have to say, you know, can we borrow the sequel code to get that kind of stuff, but literally willing to use that as a vendor and plug and play along those lines. That to me feels like something that we could use regardless of where we are earlier on the maturation of business intelligence, you know, center of excellence models to advance

business intelligence center of excellence models. I think it could be universally used across there. So, that's the thought that first popped into my mind.

Cathie Furman, RN – Senior Vice President of Quality and Compliance, Virginia Mason Medical Center

And I think I understand your question correctly. I guess from a policy perspective what would be really helpful is to create a policy that requires all of us to come up with standard documentation of clinical care practices that are standard nomenclature so that all vendors, all organizations are talking the same language. So, regardless of whether you're inpatient, skilled nursing, ambulatory, that when we say this is what I think...this patient has CHF, that we're using the exact same language so that that data transfer across the patient's life is transferable.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

Again, I want to congratulate for a second because you anticipated my third and fourth questions. So I'm going to say them, which was the question of supporting the movement of quality from an organizational perspective in the person-centered view including not just the hospitals but home care, long-term care and really from my view the other community services that are out there because they're not just getting health care, they're really interfacing with all kinds of things in the community.

And then the context, as I said earlier, of evolving the quality agenda from a broader sense of health not just health care. So, if you could incorporate that into your answers as you go forward. And we'll go to Eva next, but finish the answers to Paul's question. Thank you.

Michael H. Barbouche – Founder/CEO – Forward Health Group, Inc.

Michael Barbouche. Measure one, does this doctor still work here? Measure two, primary care or specialist? Measure three, do they take care of a population of patients or not? MPI, tax ID, you have all those answered. The only context we don't have is from the system itself saying whether or not that's how this works. They don't know within the system. You don't know as the measurement body. And absent those very basic descriptors it's going to be very hard for these measures to apply in a meaningful manner. So, I would really say that the data stewardship falls not to the committee to figure out a way to create this, but back to the systems to own their data and to own these processes and say, yeah, this is what we mean when we say this person is a primary care doc and yeah, that's what we mean when this person is active and current with us because we can't see it in the data.

Cathie Furman, RN – Senior Vice President of Quality and Compliance, Virginia Mason Medical Center

I'd like to just, this is Cathie again, I'd like to just add to Michael's list, which I think is great. We also need to identify the patients because patients don't necessarily always go to the same doctor, to the same system. So, we really have got to unique patient identifiers.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality - Human Resources and Services Administration – Health and Human Services

Thank you. Eva? Then I'll circle back to David and Larry, and take them in that order.

Eva Powell – National Partnership for Women & Families

Thanks. I just want to address the elephant in the room and I think it's an elephant in every room where interoperability is discussed, and that's the fact that data equals money and power. And I don't see Meaningful Use changing that. So, in my darkest days I then kind of spiral into how are we ever going

to fix this because it seems to me that inherent in every single comment you've made is this issue of it's not the technology. It can be done. We can hook these pieces of data together but the incentives...and this goes way beyond Meaningful Use incentives. The incentives are strong to keep this data apart. And so...and to me that is anathema to patient centered care.

So, how are we ever going to provide patient centered care and care that is right for every patient at the right time, as you've all said, when really it's only the individual people in the system who are working to try to do that? That every other piece of our system is working actively to keep that from happening because it's their business model.

And so, again, I don't want to spiral into a sea of negativity here, but it seems to me, like when we're thinking about the Policy Committee and what we can do in Stage 3 to try to address this issue, it seems like we've taken a step toward part of the answer in giving patients access to their own data because when you start talking about having flexible data architecture and a data source mart and summary data mart, the ultimate flexible data architecture is the patient themselves if they have access to all of their information. And I don't want to pin all data collection on the patient, obviously. But, I'm really curious as to what opportunities you all see in this notion of transparency, which is radical in our health care system, and how the patients and their families might play a role there.

M

I could start. No, I think we strongly believe that, obviously, the patient is a major driver of health care in the future, right? So in our model and understanding, workforce issues going into the future, we're not going to have enough doctors, nurses, care teams, you name it and, you know, the body of stuff that we're going to do and, you know, this auspicious body, the numbers of measurements we're going to have to do going forward, there's no possible way the care team itself or the delivery system itself can do that alone.

So, absolutely we think about how do we get that patient better involved, more engaged in that process and I think as part of that transparency is very important. The first thing we talk about is transparency within our own organization about all the things that we talk about in value. I mean we talked yesterday about the fact that physicians don't know how much things cost, right? So, you know, as doing shared decision making with the patient, if you don't know what it costs, it's hard to have a cogent discussion with your patient about some of that stuff.

So, again, internally there's a tremendous amount of transparency that can be there that again the care team can't communicate with the patient. I think as you go forward it is interesting...I mean we've...the idea of like the personal health record and sort of data being transportable with the patient and then this starts to open up the big data concept of there's lots of other information sources coming from communities, right? So city data, environmental data, etcetera, that definitely can impact asthma rates, ED rates, all those kind of stuff that we talk about and how do we integrate all that together?

In some sense it's great, I know that we think about that in the big picture as stuff that we'd like to do. But, I would say that in our minds that's still again, I don't know what next step, but that's still a next step portion for us as opposed to we need to be sure that we do the things that we know really work well, reliably, effectively, every single time and that's probably our primary focus now. But, absolutely acknowledge the fact we need to head to that next place.

Gregory A. Maynard, MD, MSc., SFHM – Clinical Professor of Medicine – Director – UC San Diego Center for Innovation & Improvement Science

Greg Maynard. I'm kind of going backwards. I've been thinking about what Paul was asking about the Meaningful Use and how are you going to, you know, what measures would help and I think it goes back again to saying that, you know, instead of having measures of number of clicks, you can get there by putting these things in case-based formats.

So, if we do identify these top things that we need to know from an electronic health record based on what our high volume, high implementation gap problems are where we know that, you know, things should be here but they're down here. If we do that and define those data elements, then the way to

test the vendors is to say show me today, you know, in your record right now who's on what prophylaxis for DVT for example. Tell me who in your hospital cannot get out of bed, because we know that that's a marker of poor outcome.

I'm telling you right now that most places can't tell you who cannot get out of bed, the ambulation documentation is text-based and it's highly variable. So, what we've been doing is we've been constructing measures over what everyone can measure, what we need to do is define what the measure should be based on what we need to know.

David A. Burton, MD – Health Care Quality Catalyst

Yeah, I just had a comment to Greg's comment. I would argue strongly in the same direction that you focus, when we do Pareto analyses, what we find is that the top 10 equal the top 50%. And from system to system, number one, number two and number three may change places but usually not beyond that. And so if you were to take the big ones, the heart failures, the pregnancies, the ischemic vascular disease and so on and say rather than create a list of 39 quality measures, maybe we limit it to a smaller number because you begin to get some meaningful information by having everybody who has a big process anyway, that they ought to be working on, working on one of those top 5 or top 10 at the most trying to get at these issues.

The second point to Paul's question. There are two issues that we would like to incent. One is the data quality assurance that we've talked about. The other is the EMR optimization around that. So, if we figure out what we're going to capture that's part of the issue and we reverse engineer that like we've been talking about, here are the key indicators, that's what we need to capture. Now how do we optimize the EMR? When we did pregnancy at one particular client we found 14 different ways of recording gestational age. Well, if you're going to say we would not like you to induce before 39 weeks you have to know what the gestational age was before you can do that and so is it 39.1, is it 39W1D, you know, what are all the permutations you can have of that so that the vocabulary that people have talked about is really a beginning place in terms of data governance, but after you do that then you have to have a process to optimize the EMR. And unfortunately, often the clinical folks that knows the most about how to optimize the data aspect of it are in a separate silo from the IT folks who are basically responding to the loudest physician voice about what needs to be fixed in the EMR as opposed to really strategically saying, here's our big process, here are the indicators that we want to capture, here's the optimization and it's an integrated team that's doing that so that there is some ownership where we're headed.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality - Human Resources and Services Administration – Health and Human Services

Thank you. Before Cathie answers, I'm going to suggest we're going to shift to our rapid cycle quick question kind of piece, but David, Larry, and Leslie have their card's up I've got you in that order and please proceed.

Cathie Furman, RN – Senior Vice President of Quality and Compliance, Virginia Mason Medical Center

Real quick, back to Eva's question, one of the things that we've been experiencing in the last six months really partnering with patients and families is through the implementation of our patient portal and it's quite frankly a little embarrassing to realize how the medication list and the allergies that we thought per patient were accurate aren't really and that's a safety issue, right? Clinical care has been complaining for years about the patient compliance problem, but, we really need to understand what are you taking and what aren't you taking in order to make good decision-making. So, I think that is one way that we can really partner with patients and families to help us help them.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

David?

David Lansky – Pacific Business Group on Health – President & CEO

Thanks, Ahmed. Our role here is working on a national level with some tools of federal policy obviously and I know you don't want the federal government to be dictating to you the processes of care that you implement in your organizations either directly or indirectly and quality measures have the risk of becoming an indirect means of the government prescribing a set of processes for care by counting them and reporting them and paying you for them and so on.

So, the other extreme, to the extent we pushed the measurement agenda toward outcome measures which measure across the longitudinality of care, you all identified the reasons why that's very hard to do for any individual providers subject to the EHR incentive program. What would you advise us for Stage 3 of quality measurement to put forward as a set of reportable quality measures that presumably align with other federal programs like PQRS and physician compare and so on, presuming that's the case, what would be the set of measures for national recommendation that would help you drive local measures that you use without necessarily public reporting and oversight, and standardization?

So, the balance between the public reporting framework of national standards for measurement and your ability to innovate and adapt, and customize to drive local improvement, how should we think about that balance and what would you advise us to do?

Joe Kimura, MD, MPH – Medical Director – Analytics and Reporting Systems – Atrius Health

Well my first thought, this is Joe Kimura, my first thought is actually again merging what Greg and David had said. So, the exercise I think many of us do is we have a public, the national measure and then we have a discussion internally, well what was the concept behind that and what's truly the clinical intent of that and can we capture that adequately in order to help drive quality of care in our practice? And there are sometimes when you look at it and say, hmm we don't think we want to do that one, you know, because we either have discord or we have disagreement about that and we will have to change that.

So, the challenge is if the challenge is to create a metric based on the available data that you have, then, I think you're limited in the sense of creating meaningful metrics that will be able to translate and just pass through directly with the standards and all of those things. Because, I think every measure that's come through we sort of change, at least in my organization, we change and adjust for internal reporting to help drive QI in our organization. So, in that sense, I'm not sure how much more specific the policy can be without acknowledging this fact that there is sort of non-standardization about how these concepts are and that, you know, even if it's truly based on administrative data or EHR data, a lot of the data is locked away and it's hard to get those concepts.

If you pitched far forward and said, okay let's start with that clinically most meaningful concept, and that's what you want to try to incent going forward and you will let each one of us determine and figure out how we're going to measure that concept and be able to demonstrate that, tremendous heterogeneity, tremendous amount of effort that each individual organization then has to do to create that, but I feel like that's...I'm loath to think that if you're limited to the types of data that you're thinking about when you're getting...constructing a quality measurement, we're always going to see those measures and say I've got to change this, you know, it's not going to be what our people want at this point. So, we have to rewrite it and rewrite those specs and adjust the specs for what our physicians want to look at.

David A. Burton, MD – Health Care Quality Catalyst

I think, Dave Burton, I think the largest chasm right now is between payer and provider, and I think that the number of truly integrated delivery systems that have a payer organization that is economically integrated with them is going to be too small to demonstrate what we need to demonstrate. So, I'm not sure I know how to do it, but I think the right thing to do is to figure out...I know how to do it technically, to figure out how to bring in as a source system a participating payer that is not economically integrated with the owner of the EDW in the delivery system or vice versa. If the payer has the EDW, can you bring that in as a source system? Now there are some data stewardship issues and you probably need a third-party that's independent that says here's who has access and does the security testing and is the guarantor that people aren't going to see the data that it shouldn't be seeing from either side.

The reason that's important, in my long-ago prior life I was a founding CEO of Intermountain's managed care plans and one of the things that we learned was that we had an incredibly rich episode-based view of care from that perspective and we really could see what the population, what the community was seeing and that was the most accurate perspective of the value to the community. The problem was that if I used an episode treatment group or in all of them had symmetry as the Intel chip inside these days, what I get is I go out and I grab the admission as a blob and I have no ability to drill down inside that admission and it only represents about 40% of my premium dollar. So, it is pretty important to know where the variability is in that.

If I have the right architecture in my EDW and I bring the payer data in and I have my case mix data and as I said earlier if we have common linkable identifiers that allow us to pull in the subject area margin the data from those two systems, now I have an episode view of care so that I can manage populations, I can do true disease management, but when I get to the point of highest variability, I have the ability to drill down inside that case mix system and begin to establish a variation. Now, I just took a quantum leap as far as my ability to measure and manage outcomes.

Michael H. Barbouche – Founder/CEO – Forward Health Group, Inc.

Real briefly, Michael Barbouche, to answer your question, obviously, we can't get anybody to agree on what the right measures should be, certainly not the surgeons ever, that's very difficult. So, I would say that Meaningful Use Stage 3 would be, you know, the first Tuesday in April there are no outpatient clinics that day and we are looking at data perhaps for the first time prospectively, not retrospectively like, hey we submitted, here's your check and here was your report, but, hey here's your population and here's how you're doing and how we're going to be able to improve that going forward.

The sea of measures when we meet with clinicians, we say to them well the only certainty is that the measures are going to change, don't worry about that and whatever the standards are, they'll move around, don't worry about that, you need to pick one, just one and figure out if you can improve and start that improvement journey. I think that's the part that's missing because we are using measurement in the way you describe, is the way to kind of way, well okay here it is and it's retrospective. And we just need Stage 3 to be the real pivot to prospective.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Great discussion and I think a pretty good lead into where I want to go with this. You're all in organizations that have been successful in actually using data to take action and to overwork our librarian analogy that keeps coming up, there are librarians who are archivists who think their goal is to protect the unique items and there are librarians who are access people who think their goal is to get you to the information you need. So, there is a culture shift there, it's not just a role and a title, there's a culture shift there. So, what is the one thing in your organizations that was the tipping point for shifting the culture? What are the things you think we should be looking at?

M

I can start. We moved our entire analytics department into the Chief Medical Officer's area. So, we divorced that data warehouse architecture. They remain IT, but I'm an internist, I lead our analytics department and so I am fully linked in with the discussions about where we are going clinically, operationally and financially and bring that back to help lead the agenda and the strategy for analytics.

So, it was a structural move for us that helped then decide, you know, we're the customer for the warehouse team so we set their agenda by saying this is what we need and it has helped and I think we are again fortunate we have our systems that David actually talks about with a unique identifier across our warehouse and, you know, we have to buy products that sort of allow us to do these CMI adjustments internally so we don't have to depend on what the payers tell us and all that. But we were able to do that because we said, look we can stop doing some of the other, I need to say I love our IT folks, IT oriented things and say the business needs this so that's why we're going to prioritize our action and how we're going to focus on developing the warehouse resources.

Gregory A. Maynard, MD, MSc., SFHM – Clinical Professor of Medicine – Director – UC San Diego Center for Innovation & Improvement Science

Greg Maynard, I'd say that for us the culture came when we had hospitalist and other clinicians become the IT leaders and also, when we were able to demonstrate with some, you know, 2 or 3 demonstration breakthrough projects that, gee you really can make a huge breakthrough improvement if you have the right real-time data delivered to the right person who can act on it that sort of was the proof of concept of

what we call measurement, you're measuring something and you put it in the hands of the right person and they can intervene and do an intervention to improve the care before the patient leaves the hospital not finding out that you did a bad job six months ago, finding out instead that there was an opportunity to improve right here today that you take care of today.

So, when we did that demonstration very convincingly in 2 or 3 topics then the enterprise said, gee we've got to change our way of thinking, we've got to make this easier because it took a long time to get those first demonstration projects done.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

Cathie and then straight to Leslie, because we're going to be out of time. Janice?

Janice Nicholson – CEO i2i Systems

Janice Nicholson, I'm a vendor so what I can share with you really is my client's experience. When I saw the culture change for them, it was when the data was available and they became knowledgeable about where they were and it was no longer behind an iron curtain, they could say where they were progressing, they could see where they were not progressing, they could make data informed decisions and I've been doing this for a very, very long time. We just had our most recent user conference and from the very first year that we had a user conference, the number of providers that attended in our last user conference was a difference in 75%. So, what I see the cultural change is, is they are engaged because they're now informed, that's what I see.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

Cathie, you will get the last word, because we're out of time.

Cathie Furman, RN – Senior Vice President of Quality and Compliance, Virginia Mason Medical Center

Well, thank you. I would say that the cultural change for us happened when we began down the path of Virginia Mason production system, one of the key components of that is actually going and watching clinicians trying to provide clinical care to their patients and I'll tell you, it brought tears to my eyes to see people having to run all over the place to get the information that they needed. Nurses who were using paper, scissors and highlighters getting data off the information system, infection prevention, but didn't have the data in a way that was useable. So, they were taking scissors and scotch tape, and highlighting to try and create a report that was usable that they could then take care of their patients. So, really opened up everyone's eyes and because all executives, and all leaders use that method it developed a sense of urgency that we really have to do something different.

Ahmed Calvo – Senior Medical Officer – Office of Health IT and Quality – Health Resources and Services Administration – U.S. Department of Health and Human Services

Well, thank you very much. I want to thank the panel for your very thoughtful testimony and we look forward to circling back in further conversation. Thank you very much.

David Lansky – Pacific Business Group on Health – President & CEO

I would ask everyone to take their seats so we can keep moving. Can I ask you all to take your seats and we'll keep moving through the program. They don't get that many breaks. They don't get a break after an hour and a half. I know how these go. Can I ask people involved in the second panel to come up and take their seats? Can I ask you all to take your seats so we can get started? And the committee members can you all come back around the table, too, please?

We're going to turn the gavel over to Norma Lang who is going to take us through our second panel this morning. Just let me add my thanks to all of you for coming and joining us today. Norma?

Norma Lang, RN – University of Wisconsin

Okay, as soon as I have a panel we'll start. Here's another person and it looks like we have another person, anybody see...

W

She's here...

Norma Lang, RN – University of Wisconsin

She's coming, okay. Well, okay, since we have such a task master here who won't even let people get out for a natural break, oh, somebody has a Port-A-Cath, yeah, some people have better capacity than others and depending on your age too I think goes along with it. So, here we are with our second panel and the first one was so interesting it was hard for some of us to not want to enter right in. So, we have another wonderful group coming up.

I'm Norma Lang and I've been on the Quality Measure Group and I volunteered to chair this and I just would like to make a few introductory comments in that I've been in this business for a long time. I'm probably one of the longest in this room, starting way back when we had the regional medical programs and we had all these goals of trying to have the best system and then we went through an era of PSROs and, PROs, and retrospective audits, and then we moved to having informatics, and quality measures, and terminology. It's been a long journey I would say, multiple decades. And there are some days I wonder if we've made a whole lot of progress and then I look and I think well maybe we've made some progress.

My most recent experience that makes me want to always jump in is for the last 7 years I've been working in Wisconsin with Aurora Healthcare System, which is one of the biggest integrated systems in Wisconsin that have 15 hospitals, home care, the 4th largest in the country, something like 4000 physicians, 8000 nurses who deliver a full range of care in an integrated system and some of the goals that you were just talking about I keep thinking we get so close, we get so close and yet it's so complex. So, that's given me a real-time view of how things, you know, might and could work and we did also have one major vendor and then in the best vision of the administration they decided to change to a second major vendor, that was also a very interesting experience and I won't be totally sharing that, if anyone wants to talk about that over break time we can.

I also have considerable involvement with the aligning forces in the Wisconsin Healthcare Collaborative and I'm also on the WISHIN, which is our Wisconsin HIE, trying to figure out whether those data elements and the minimum data set that we will be sharing in an exchange and in the past I've also been on the board of the National Quality Forum. So, that gives me a lot of experience in what we're talking about and my kind of impression is that we're doing quality developments on steroids. I don't know if you feel that way, but every day if you're on any kind of lists the stuff is coming out and if you try to keep up you're lucky if you can keep up in your own narrow area much less on everything that's going on. So, that's the good news and I think the bad news.

If I had just a couple of things that I would dream about, if I could, everyone can have a dream, number one would be that we would understand what one click means in the system, one click and that every click that we could ever think about would produce data that was valid, reliable and useful because there's so much in our system, I think with just one more click we could get all of this other stuff and we are almost inundated. We deal with, the last time I was talking with Aurora's data warehouse, 7 terabytes of data sitting there. So, I kind of like to see Michael and others tell us a little bit more about how not to get buried in that. So, one click and I'll tell you there are a group of nurses out there that would be extremely grateful if that would happen because they get left with holding the responsibility for a whole lot of systems just like the days they did when they were having the paper charts.

I would also like to think that, number two, we would really start with patient centered rather than provider centered or disease centered, or whatever and that's almost said because I'm a mother, wife, grandmother whose had intensive experience in the last even couple of years with the system and you wonder sometimes could we just start with us and then build a system accordingly and we're much more than congestive heart failure, valve replacement, taking blood thinners, all of those things everybody's got

a great idea for that piece, but we come together as a family and we have a whole host of things from, like literally from birth to death and it would be really good if we could think about that.

Also, there is a lot of words right now on coordinated longitudinal care and I think we need to give some visibility to how we're going to do that so that I don't just get my piece that I'm interested in, but the whole one. Also, somebody brought it up before, but trying to deal with the costs that are associated with this. I understand that most people don't know and we expect patients to behave, we expect providers to behave, but none of us really know until you get that bill and in the last year I've been saving my bills from intensive work and insurance in trying to say, I'm pretty intelligent, but wow, is that something to try to figure out and then you're supposed to have choices as a consumer. So, I just wonder about that.

I also wonder about, we we're talking today about clinical decision support. Who is that support really for? Is it for physicians, is it for pharmacists, is it for nurses, is it for patients, families? And if so, how does that really work? I think we have a model of clinical decision support that's around a disease with a particular intervention that usually is aimed at a physician or physician group, that's a very limited view of decision support.

My other concern is with that, patients and families are very complex. We focus so much on that chief complaint or that chief thing and most people now, and especially at my age, very rarely come in anymore with one thing and one set of medications. It's very hard to even pull that out because it's so interactive.

And, my other two points that I'd like to plead for, is we are full of alphabet and acronyms and we're creating every day as I get in the e-mail, it seems that we should really pay attention to a very old principle, you have to spell it out the first time you use it and do not assume that anyone else in the group has an understanding of that, we just rattle along and in some of the Workgroups I'm in and especially the one that's dealing with the care coordination and the continuity assessment, it's just full of acronyms. I finally said one day, let's put a whole list of these acronyms out there and let's be sure we understand and we started to ask the group do you really know what that means? And people didn't want to admit that they didn't quite know what that acronym meant. So, if we could do that, if we expect our patients and our policymakers to understand we should do that.

And my final comment before I get the panel engaged is that yesterday, talking about new terminology and I won't ask somebody to do it now, but through the e-mail came a call for participation. We're not going to call it clinical decision-making anymore we're going to call it Health E Decisions Initiative, so who did that? Anyway there's a whole new panel starting yesterday at 4:00 that was inducted and asked for volunteers from ONS, ONC I'm sorry saying why don't you join us, we're going to have a whole new S&I Framework initiative called Health E Decisions and so that we're going to be able to talk about this.

So, I worry a lot that we just get going and you go on down the line and you pick up clinical decision support or decision-making and you pull that out of even doing a search but now, we're going to call it something different. So, maybe we don't have to address that now, but I'd like for somebody to address it because it was the title for this particular topic area. So, with that in mind, I'm going to let Blackford, Mary, am I saying it right if I say Fauzia, Julie and Patrick or Pat?

Patrick Yoder – Hennepin Country Medical Center

Patrick.

Norma Lang, RN – University of Wisconsin

Patrick begin and in the first slide, since Blackford has slides he raises the first four questions for this group. So, we will just take a little time to go through those. I won't go through those, but those are the ones we will pick up again later. So, if you would go ahead, Blackford and do that, thank you very much.

Blackford Middleton, MD, MPH, MSc – Partners HealthCare System – Harvard Medical School

Good morning, thank you, Norma, it's a pleasure to be here. My name is Blackford Middleton; I'm from Partners HealthCare System and Brigham and Women's Hospital and Harvard Medical School. I trained as an internist and as a clinical epidemiologist and then finally in health services research and realized

that doing health services research was going to be stymied by the lack of high-quality data from clinical environments. So, I've spent the rest of my career trying to build those clinical tools, EMRs and the like.

I think it is a unique opportunity at the moment, as Paul said, to think about where we are in this progression of HIT adoption. We need to be at an inflection point in some ways. My concern I have for the policymakers and I've said this before, is that in many ways we have a definition of the destination with Meaningful Use metrics and those kinds of assessments; however, the journey to reach the destination is really up to the individual implementer or each system pursuing that destination.

In some ways I think we're like in a car on a journey to San Francisco without a map and the map in my opinion is really these shareable knowledge-based artifacts that Dr. Burton actually mentioned in the prior panel and has been the focus of my work since approximately 1997 when we created the knowledge bank system for on-line sharing in medical logic. I think it is the source of our problems, however, this lack of shareable knowledge because each of us, even with the measure of specification has to implement it in a way that could be potentially unique and variable. Similarly, on CDS it's the core problem that each of us has to take the knowledge-base, the evidence-base or again aptly put by Dr. Burton the experience without clinical guidelines and implement that as rules and it's highly variable.

So, the thesis I'd like to leave you with today, the conclusion right up front is while we think often about data liquidity, I'd like to suggest we think equally well about knowledge liquidity that data and knowledge have to be shared freely to optimize the care of our patients and that will be the focus of these few comments.

So, the questions we're asked to address are what is the role of the clinical decision support; by the way this doesn't count against my time I assume?

Norma Lang, RN – University of Wisconsin

And he can't have the timer on there with doing these slides. So, I've got the timer. Okay, I'll start it at the end of these questions.

Blackford Middleton, MD, MPH, MSc – Partners HealthCare System – Harvard Medical School

Terrific, perfect.

Norma Lang, RN – University of Wisconsin

Is that a deal?

Blackford Middleton, MD, MPH, MSc – Partners HealthCare System – Harvard Medical School

Thank you, kindly. So, what's the role of clinical decision support in the quality lifecycle? How does

CDS relate to quality measurement? How might aggregate measurements of the usefulness and outcomes of CDS interventions be used to foster improved techniques for CDS delivery? And how can the alignment between quality improvement initiatives and clinical decision support be improved? What additional things need to happen to blend these communities? And how can Health IT better support quality measurement or improvement?

And this was just a perfect setup for me to draw upon a paper from 1993 where Sue Henry and Les Lenert and I tried to put together this circle, the quality integration cycle which shows very explicitly I hope the connection between the technology, our standards for representation and measurement, and data, and then finally decision support, and analysis. Over the years any number of different buzzwords can go into each one of these buckets but it's really this virtuous cycle, if you will, that has to address representation issues, measurement and reliability of measurement or clinimetrics, as Alvin or Feinstein would call it, data representation and controlled medical terminology, and models. And then finally, what are the analytics that make sense to use and provide feedback to the user at the point of care?

In many ways, CDS and quality I think are two ends of a spectrum, you know, an afferent and an efferent limb, obviously, in many ways CDS is the afferent limb, it's the "if" does this population or this knowledge apply to this patient? It suggests and action, hopefully and makes it actionable. It of course defines a

cohort to which this applies and the inclusion or it is inclusive in its approach, CDS we deem clinically not to miss anything that should be done and yet it is subject to inclusions and exclusions and is really focused on process most of the time.

Quality is the efferent limb I would hope, resulting from clinical care processes including decision support, it's the "then" we have to perform a measurement, we have to define a cohort to subject the measurement to, it may be more exclusive though in character depending upon what the quality measures being used for, also has to deal with inclusions and exclusions and is possibly process oriented but typically is much more outcomes oriented in the sort of Donabedian framework.

I thought the first panel though did sort of allude to one of the core problems that I see in the whole CDS and quality measurement connection that is arriving at a value proposition that makes sense for the end-user, the clinician. Why should the clinician actually care to enter structured data for clinical decision support or outcomes analysis? What does it mean for the clinician as opposed to being simply the data entry clerk entering data into a transactional system that's supporting billing? Bill Stead and others have commented on this in the NCR Report.

So, we did a bunch of experiments on what we called Smart forms, which compiled for the user what he or she should do and I'll show you a couple of quick pictures. And in this technology we aim to provide decision support assessing risk and stratifying the patient and predicting therapeutic response, providing alerts and reminders, giving therapeutic guidance but connecting all of that to an outcomes picture for the end-user that actually makes sense to the doctor. What's happening to my patients? I think it's fundamentally connecting these dots, the outcomes data to the clinical process of care and the decision support so that the user sees and appreciates value. Absent that the physician just feels like he's being a data entry clerk and no measure, no CDS may work well.

The CAD diabetes smart form summarized clinical data for the physician to review, the documentation environment but most importantly on the right-hand side made very actionable recommendations for the end-user to do things in the clinical workflow. Interestingly, in our randomized control trial of the technology, it had a two and threefold effect on the baseline CDS performance rates of the EMR at Partners, this when used resulted in 2 to 3 time's better compliance with decision support. The quality dashboard that was shown to clinicians gave them an insight into their performance so that they understood how their clinical documentation and using the CDS related outcomes.

The question arose too about measurement, however and I think the measurement of CDS is going to be exceedingly important for us to differentiate that which works well from that which doesn't work well in CDS. Right now in some environments, the estimate of overridden alerts is as high as 95%. We see it all the way from very low to very high in our own environment at Partners and we've created a metric, a number needed to remind it's a traditional 2 x 2 approach to performance and reminders that allows us to differentiate reminders from those which work and those which don't and we're going to use this metric to try to improve the overall CDS performance for the end-user.

So, now to the question at hand, how do we relate CDS and quality measurement frameworks? I think the NQF effort that Floyd Eisenberg led and I was pleased to participate in, in the quality data measurement, the quality data foundation and quality data model shows the connection between quality measures and CDS and we really have to find a way to reuse the fundamental building blocks in measures and in CDS, they're not always exactly the same, but here we show how we used the NQF value sets for diagnosis classes, lab data classes and medication classes in constructing both e-Measures and CDS logic for expression in the EMR.

So, in closing, I apologize I've had to go quickly, but we recommend, and others I think are thinking along the same lines that we leverage and standard the value set definitions for both CDS and e-Measure implementations. We suggest there be a standard e-Measure specification and that's not of course a specification of one e-Measure, it's a knowledge representation formalism for e-Measures that can build off or relate to the HQMF and the QRDA for example, sorry for the acronym soup, but really has to address the implementation issues that we know well from implementing CDS in measures and practice.

Provide corollary standard e-CDS specification to help the decisions effort I think will help in this regard, coordinate, align and standardize the CMT to support the above and then share. Most importantly, share these e-Measure and e-CDS specifications as implementable specifications that can be simply downloaded and used in an EMR or subscribed to as a cloud service as recommended in the next bullet. And we have submitted to the committee a proposal that would pursue some of this work for your consideration. Thank you.

Norma Lang, RN – University of Wisconsin

Thank you for those initial comments. You may want to, in our discussion section pick up what else you...then the other points in there. Thank you very much. Mary, we'll move to you and you do get the timer on.

Mary K. Goldstein – VA Palo Alto Health Care System and Stanford University

The timer will come on, okay, great. So, good morning everybody, I'm Mary Goldstein, I'm from VA Palo Alto Health Care System and Stanford University. I'm going to talk today from my perspective as a primary care physician in geriatrician and an investigator whose been working on CDS for quality improvement for more than a decade in work funded by VA HSR&D, by NIH, NLM and some work concluding by ONC through the SHARP Project.

We have extensively implemented and evaluated CDS and have worked with stakeholders including front line health professionals and clinical leadership and the work has taken me on a journey in many directions to do good CDS. We have to consider workflows, human computer interface, unintended consequences, what makes guidelines actionable, the relationship of performance measurement to

decision support, and most recently natural language processing to extract important structured information from free text in the electronic health records.

Although I am with the VA I do want to note that my views expressed today are my own and do not necessarily represent those of the Department of Veterans Affairs. So, as with all our speakers there are many things I'd like to talk about here, but in this five-minute opening statement I'm going to focus on the one thing I think is the most important for next steps in CDS and that, I believe, is that we need to address patient complexity and to arrive at standards that will allow for addressing patient complexity.

As Blackford mentioned, many reminders are overridden and it's often with good reason because of what they don't address. Much CDS to date that's integrated with workflow and embedded in the EHR is based on very simple reminders which provide decision support to achieve very simple performance measures. When an office practice or a healthcare system is early in its stage of becoming a learning organization that does self-monitoring and evaluation, and is not yet performing well on the basic measures, these can be quite powerful and give a lot of room for improvement. However, many patients do not have just one condition. Patient complexity is increasing.

In December of 2010, Department of Health and Human Services published a strategic framework for multiple chronic conditions in which they noted that 1 in 4 Americans have multiple conditions. Application of overly simple rules can actually lead to patient harm in some cases, clinicians know this and that's in some cases why they are overriding a large number of measures. And physicians/clinicians are eager for guidance. So, CDS systems can address this by providing systems to allow for patient complexity.

Complex clinical knowledge can be encoded into knowledge bases and linked to patient data from the EHR. The systems currently available can allow for really complex knowledge to be encoded so you can take account of as much of the clinical data as is available to account for multiple diseases, histories of adverse reactions and interactions of how one disease affects another, and one treatment affects another.

Another related point is that we don't know right now what we will need in CDS in a few years. Medical knowledge is evolving all the time. So, we need methods to have systems that will allow external CDS systems to be connected to diverse electronic health record systems rather than to have everything built

directly into the EHR which becomes rather rigid and inflexible. Allowing for external CDS linkages calls for having CDS standards, some of which have been developed and are underway but we need further support for CDS standards and we could talk more later about what that might involve.

We also need systems that will interact multiple guidelines and other tools as they apply to the same patient and there is work going on in that. For example, my colleague Mark Musen is leading a project with which I'm involved called GLINDA that's a GuideLine INteraction Detection Architecture for interacting multiple guidelines.

Inherent in shared decision-making with patients with chronic conditions is availability of information about prognosis and we need data systems that include functional status and other prognostic information for patient centered care and my time is up. So, the rest will come up in the Q&A I'm sure.

Norma Lang, RN – University of Wisconsin

Okay, thank you. Fauzia?

Fauzia Khan, MD – Chief Medical Officer - DiagnosisOne

Thank you. My name is Fauzia Khan, I'm co-founder of DiagnosisOne which is a knowledge technology company and has developed CDS analytics applications over the last 7 years. Before joining DiagnosisOne I have a decade of hospital experience. My role today is to oversee algorithm design, knowledge acquisition and in generating of evidence-based and consensus-based clinical content as well as to ensure semantic interoperability of our tools using national standards such as SNOMED, LOINC, RxNorm, etcetera.

Our clients include several EMRs ranging from larger EMR vendors such as Allscripts to mid range such as Athena, to smaller EMRs such as...In addition, we work with state public health departments and HIEs

providing CDS and analytic capabilities. DiagnosisOne is committed to improve outcomes and patient safety by providing these tools and we are thankful and honored to be invited to provide testimony today.

We see interventional CDS as being an integral part of any effective quality management program. In our judgment, care providers will be required to deal with multiple quality programs which will involve hundreds of quality measures simultaneously and many of these measures will be similar with only subtle differences. This is simply not possible without CDS tools.

A properly designed CDS system will form the heart of continuous quality improvement processes that can be implemented by both large and smaller provider organizations. I agree with Blackford that CDS plays a critical role in improving quality of an organization.

If we define quality measures as being developed both by standards organizations and locally by the providers, then CDS can be used to guide providers in real-time to implement those guidelines. Additionally, the same CDS capabilities can deliver the analytics which are needed to manage the quality program and implement provider and patient incentives that then drive the desired behavior. This point was also mentioned by the first panel. The care providers need to have one source of truth, they do not want one program which provides intervention and another program which provides analytics. We believe it's important to have both of these on a single platform.

In our experience with both retrospective and prospective studies we have found that when presented with evidence-based interventions in areas that care providers have some influence in selecting providers are much more receptive. Providers want to be involved in this process of selecting which CDS interventions they are going to receive. They also want to know what is the logic behind those interventions. So, they are not happy with just a black box with issues of certain recommendations. Physicians really want to be involved in this process and want to take ownership of that process and when they do they are much more receptive to appreciate these interventions. So I'm not surprised by 95% override if there was no buy-in from the clinicians that might be the result.

For instance, if we provide an intervention to do a mammogram after 1 or 2 years, whatever they agreed to, the physicians really appreciate that but it needs to be intelligent enough not to issue that recommendation in patients who have double mastectomies. If the alerts are not intelligent physicians will override them.

The single biggest thing that we can do is to require EHRs to incorporate a meaningful number, the greater than 100 rules of real-time interventional CDS capabilities which are flexible enough to allow physicians to choose what they wish to subscribe to.

Progressive EHR vendor's such as Allscripts and Athena are already doing that, they are gathering feedback from their clinicians whether in user groups or electronically and they take that feedback and they incorporate that in building these rules and catalogs for these providers. Thank you.

Norma Lang, RN – University of Wisconsin

Thank you very much. Julie?

Julie Scherer - NewMentor

Thank you, Ms. Lang. Thank you, Kevin Larsen and the members of the HIT Policy Committee and Standards Committee for inviting me to give testimony today. My name is Julie Scherer and I'm the Chief Operating Officer of NewMentor. NewMentor is a technology-based information services company with over 15 years of experience developing high-quality evidence and practice-based clinical knowledge solutions for the healthcare industry. We develop a variety of clinical information solutions including order sets, CDS interventions, analytic applications, and patient care surveillance solutions. Our solutions incorporate evidence and practice-based guidelines, quality measures, and requirements from federal and state quality initiatives.

In our experience, clinical decision support connects quality measurement with performance improvement. Without CDS, quality measurement becomes an artifact of a quality improvement process that may not improve performance. It can be useful to think of quality improvement as the why, quality measurement as the what and CDS as the how to achieve the what. CDS should be part of every aspect of the quality lifecycle, planning, design, implementation, analysis and evaluation, and reporting.

When integrated into the clinical workflow CDS becomes the mode of force that drives clinical process change and results in quality improvement. The CDS content relevant to each quality measure should be identified during measure development and it should be integrated into all phases of the quality lifecycle.

When CDS is integrated with the entire quality lifecycle it serves as a central role in the clinical process and realizes its potential to drive improved performance. Without this integration CDS remains ancillary and ineffective. CDS suffers from a weakened state of system improvements that characterizes the healthcare industry today. While initiatives of the ONC, the AHRQ and others are beginning to effect change, the task of operationalizing the reporting, monitoring and measurement of CDS programs such as would be standard operating procedure in other industries remains at an early stage of development.

Historically, the focus of CDS evaluation has been the quality and evidence-base of the content rather than the effectiveness of the CDS presentation and the relevance, and timing of its delivery. We feel this must change for CDS to have a role in quality improvement.

The understanding and interpretation of aggregate measurement is not the challenge. The challenge is fostering among all stakeholders, hospitals, vendors, healthcare systems a commitment to the creation of metrics that can be used in tandem with the creation and implementation of CDS solutions along with a concomitant commitment to sharing the results of their measurement with each other. Without such commitments the value of CDS outcomes reporting may go unrealized.

There is a significant disconnect between the conceptual framework of the quality improvement initiative and the operational environment that we found in which these initiatives should be implemented. We see several opportunities for improving the alignment between quality improvement and CDS implementation and these are as follows.

CDS should be a part of every phase of the quality lifecycle including and especially quality planning. The CDS community should communicate the workflow and clinical process requirements of each quality measurement initiative to the quality community.

The quality improvement in CDS communities should collaborate in the development of systems for implementing CDS as part of quality improvement and the quality improvement in CDS communities should collaborate in the design and development of the systems and processes for evaluating and measuring CDS effectiveness and outcomes as a part of quality improvement. The potential for Health IT to support quality measurement and quality improvement could be realized if the CDS and quality improvement communities were able to harmonize their efforts as follows.

ONC should continue to lead the clarification and standardization of vocabulary by which clinical knowledge is structured and rendered computable and it should continue to drive the creation of an intervention standard that is both consumable by systems and interoperable among them. Together, ONC and the quality improvement community should take the lead in defining CDS and quality measurement as an integrated single solution. Meaningful Use should be used as a program for defining the operational requirements of achieving CDS informed quality improvement goals. Thank you.

Norma Lang, RN – University of Wisconsin

Thank you, that's right on the button. Patrick?

Patrick Yoder – Hennepin Country Medical Center

My name is Patrick Yoder; I currently manage our Clinical Decision Support Program at Hennepin County Medical Center in Minneapolis. I think I'm probably going to bring a little bit different perspective from the trenches on how decision support is really built and used inside an organization. Prior to being at Hennepin County I actually worked in industry on clinical decision support as well. So, I have spent about 10 years actually focused on clinical decision support. I'm actually a pharmacist by training and I am at the core, really a systems guy. So, I like to develop systems. So, I would just like to provide a little perspective from the organizational stance.

So, implementation, as most people know in this room, implementation of electronic health records is difficult and time consuming. However, it's really just the beginning of our marathon. The optimization of the tool is really far more work than actually selecting it and implementing it and rolling it out and the support for this work meaning the optimization of the EHR is relatively nonexistent in Health IT today.

So, when you first implement an electronic health record you obviously begin to accumulate large sums of data. So, if you look at our infrastructure at Hennepin County Medical Center, we have about 7 years of data, millions and millions, and millions of rows of patient data. And that data really begins to provide transparency inside the organization and that transparency is pretty uncomfortable at times for many, many stakeholders. And often times is very overwhelming because the need for improvement is broad and overwhelming and it's really hard to decide, you know, which things do you work on first.

And what you really begin to figure out is that the lack of systematization is very prevalent and inside our organization that really takes care and takes very good care of a diverse population, we have tremendous systematization problems in our system.

So, in the optimization phase, health systems such as HCMC begin to use the initial data collected during the implementation phase to improve care. However, the EHR alone nor the data alone can really drive that significant quality improvement. So, quality improvement, after you spend a little bit of time in the data and trying to use the tools to impact care, it really comes down to care process transformation. So, the EHR...you have to use the EHR along with that and specifically decision support inside the EHR and the data, the outcomes of that decision support and those care process standardization work.

So, at the core of the work is standardization of clinical work across the enterprise meaning you take care of the same disease in the same way every place that it's done. In addition, you would use systematization of fragmented clinical processes throughout and then you align the supporting technology, meaning the decision support tools inside the electronic health record that are used both to

deliver care and document care and the data use all of those different pieces together and what we find at HCMC is that really decision support development or the request for decision support development actually drives the standardization, because there is this myth that the EHR is a magic bullet and it's going to solve all your problems and the reality is, is it cannot do that unless you standardize your clinical processes.

So, the current quality measurement model is directed at process and outcome measurement and although this is great for us to get a good sense of how well an organization delivers care, and the quality of that care, it doesn't really represent commitment to the spirit of the measures. In fact, the immense pressure to deliver numbers at times actually makes you work toward delivering the numbers versus delivering the spirit of the measure. So, to begin to address this stuff we need to internally align and shift process and outcome measurements from a retrospective model to a prospective model focusing on the data elements that we actually have available in the EHR today and then building on top of that, of course.

In addition, we need to add measurement in reporting which provides transparency of the core work of quality improvement in the organization, which is really the organization's ability to achieve clinical transformation inside its walls and begin to standardize clinical practices. So, this for example, could be quality measures for aggregate or individual reporting of CDS intervention usage and effectiveness and in fact at HCMC we have found that this is a really good surrogate marker for how well you've transformed the clinical processes. Because if the CDS isn't used you haven't really changed the processes. If the CDS is used and highly used and very effective you've done a good job actually reaching the constituents and changing the clinical process. Additionally, and I'll kind of echo some of Blackford's comments as well, additionally, we need to...

Norma Lang, RN – University of Wisconsin

...

Patrick Yoder – Hennepin Country Medical Center

Oh, sorry, two comments. We also need to build an environment that really in a sense is scalable crowd source model for knowledge and this basically can be driven by standardized and open knowledge sharing and also an open and standardized process for clinical process representation, and modeling.

Norma Lang, RN – University of Wisconsin

Thank you, maybe that's a good place to go back and go through again is the recommendations for specific steps for the standardization structure, interoperability and also, I heard the complexity going through there. So, we could go along the way or you could just...anybody who would like to respond to next steps, steps that we should hear that this group might with and I see you shaking your head, Mary, maybe you want to start?

Mary K. Goldstein – VA Palo Alto Health Care System and Stanford University

There are a few things, so we have already mentioned we need to have CDS standards and by that I mean standards that will allow for interoperability such as some things like Ken Kawamoto's open CDS which provides a layer to connect different EHRs to different external CDS, because we don't know what's coming and we don't know how things need to be changed all the time. But we also need to be patient centered in the care and one step toward being patient centered is looking at all of the patient's problems at one time in a coordinated way, which is something we should work toward having CDS do.

But another way of being patient centered is to have available the information the patient needs about prognosis to understand what the implications are of different treatments that might be offered and the prognosis not only in terms of life expectancy, but also in terms of other well-being things that matter to patients such as functional status and that means we need data elements, and some standardization of how to encode data elements that will allow these very important concepts to be included in prognostic information, and we need to be able to link to things like risk scores or other computation tools to help with these sometimes complex computations about what is the likelihood of various outcomes.

And finally, we need some ways to standardizing incorporation of patient preference into decision-making and I think it's funny that Health e-Decisions has come up as the name because actually Amar Das, my colleague, published a paper on which I'm one of the authors several years back that was a prototype which he called Health e-Decisions of a system that included...

Norma Lang, RN – University of Wisconsin

It takes a while to get implemented doesn't it?

Mary K. Goldstein – VA Palo Alto Health Care System and Stanford University

And it was designed with the idea it would be put on a patient portal for a healthcare system with electronic health records, Paul and that would include both elicitation of the patient's preferences in a structured way that could then be put into a decision analytic model to run it and say, given the preferences you've expressed, here's the choice here that gives you the best likelihood of the outcome you want.

So, there are many different methods of doing patient preference and I believe the state of the art is not such that we are ready to just say this will be it, because there's not agreement. There are several different very good methods. But, I believe we should have agreement that there should be some sort of range of ways of encoding patient preference and there needs to be some attention to this issue of the controversy over to what extent you will allow patient preference to be a factor in measuring quality, because you want to be sure it's really the patient's preference and wasn't just a simple opt out of, oh, I'm going to say the patient didn't want this and so this measure doesn't apply, but having a formal way of encoding patient preferences in the electronic health record and letting them change over time just like any lab value does. So, I think those are some of the things that we really can put on our plate for consideration.

Norma Lang, RN – University of Wisconsin

Blackford and then Julie.

Blackford Middleton, MD, MPH, MSc – Partners HealthCare System – Harvard Medical School

Thank you, I'll follow on Mary's comment because the open CDS standard and evolution has been described. We work closely with Ken Kawamoto and it might be useful for the committee to hear about the CDS Consortium experience. We've been funded by AHRQ and the ONC in both the CDS Consortium and advancing CDS project to try to wrestle this very problem of knowledge representation and sharing and implementation as a sharable object or a web service down and, you know, I think the services spec is 1/3 of the problem actually.

You need to think also about the knowledge representation formalism of course, which will be then expressed by the service, but also then how it hooks up to the App, so the receiving App, the sort of the App Store idea or substitutable Apps came up in the first panel. We need to see the EMR community recognize perhaps increasingly that their customers aren't always going to be able to do all this knowledge engineering. There will be useful resources outside of the application itself and that there is going to need to be a standard way to hook up to it.

And what the CDS Consortium has elaborated are 2 prototype standards we suggest. We've contributed the patient information model to the VMR effort and we've established a knowledge representation standard, a prototype standard, we'd be happy to share with the HL7 body as well. But what the representation formalism addresses is not only the knowledge component, the logic if you will, but also how it has to be bound to the appropriate controlled data, the controlled medical terminology.

In the old days the curly braces problem stymied knowledge sharing in many ways because even with an acceptable logic representation that I might agree I still had to bring in that HL7 medical logic module or medical logic rule and then bind it to my local data types in the curly braces problem. We can obviate, you can obviate the curly braces problem in one fell swoop if you standardize what data has to come out of an EMR to be used in externalized quality reporting or decision support services, you know, then, we can say it's your problem Mr. EMR to have an externalizable representation no matter what is the internal representation that can then be acted upon by any number of externalized services.

So, it's critical interaction direction between the knowledge representation, the service specification and the application integration that has to be addressed simultaneously for these kinds of ideas to work. This is not just pie in the sky theory by the way, we have implemented now these web-based services for Partners LMR for NextGen EMR and for the Regenstrief implementation of care-web at Wishard, and we have 11 different rules firing with many more in the pipeline.

And the last point I'll just throw out is I think, you know, this knowledge...we talk often about the data tsunami and big data and all the rest of it. But the knowledge tsunami is going to be equally bad, right? Now we've implemented the immunization guidelines from CDC and just the adult and pediatric immunization guidelines resulted in over 300 rules. We look at the pharmacogenomic knowledge base that's being built at the Harvard Partner's Center for Genetics and Genomics and the lowly primary care end-user practitioner is going to be overwhelmed with the tsunami of, you know, advanced forms of decision-support that are coming down the pike. So, I think it's not just an ONC and HIT stimulation problem this is actually core to the future of medicine.

Norma Lang, RN – University of Wisconsin

Julie, and then we'll go to Fauzia.

Julie Scherer - NewMentor

Thank you. So, I agree with much of what Dr. Goldstein and Dr. Blackford have said. NewMentor has had a lot of experience in developing CDS interventions both inside of EMRs and in systems or services outside of EMRs. I would say there's a couple of things that we found that we would encourage you to think about in terms of policies and standards to make it more effective. One is that, and I think we've already said this and we all agree with this, CDS has to be tightly integrated into the workflow. It has to be prospective.

Now, to do this, we actually need not just the ability to get the patient data out of the system and have it be as clinically complete and in contextual as possible, we also need to have the ability to get the interventions back into the system and in front of the user at the right time. We have to know who the user is. We have to know what information or action they need to take and we need to be able to provide that to them in an actionable form. This requires another mechanism or channel back into and through the EMR, because I think one thing we can all agree to, at least for the foreseeable future, clinicians will use the EMRs as their primary clinical workflow tool.

So, if we're actually going to do CDS and have it be applicable and effective, and usable, these interventions for CDS have to go back into that process and I would say that in the solutions we've developed for hospitals and health systems, this has been one of our biggest challenges.

The other thing that we spend much of our time delivering services for to our clients, our hospitals and health system clients is in thinking about their own clinical decision support and clinical knowledge assets and how are they going to manage them, and maintain them, and update them over time? We're asking many of these organizations to become content publishers. They have to now manage these assets once they become part of their own EMRs and many of them are not really capable or haven't even started thinking about what it's going to take to do that. And, so I think that's another place where we need to think about where CDS needs to live, how do we sort of provide it to be the most up-to-date, most accurate, most relevant at the right points in time and make that as transparent as possible into the clinical workflow.

Norma Lang, RN – University of Wisconsin

Fauzia?

Fauzia Khan, MD – Chief Medical Officer - DiagnosisOne

I agree, couldn't agree more with Julie that we need to take in the patient information and we have to provide back actionable information for the clinicians which can be ordered in a one click manner which we were just talking about, which means different things in different EMRs. What we have utilized is HL7 version 3 CDA document. So, we take the information from the patient summary, the CDA or CCD document and provide back orderable interventions which are already coded in the different standards

such as SNOMED CT, LOINC, whichever, they are extensible across different standards so each EMR can pick the standard that they are comfortable with, so for us this was useful, we have done it for thousands of decision support interventions for various EMRs over the last 4 or 5 years and I would encourage ONC to look into HL7 version 3 CCD, CDA document as a vehicle to provide decision-support.

I also want to comment about the patient centric versus physician centric. I agree that we really need to be patient centric. What we have done, we have built rules and guidelines or information which goes back to the patient. We were part of the Google Health PHR for as long as it is around. So, we have mirror image guidelines which are written in Grade 8 standards and they provide information to the patient about that particular specific intervention which we are recommending to their provider and also it links out to many of these very comprehensive websites such as diabetes.org by ADA which can be a resource to these patients because we agree and believe that patients really have to take an active role in the management of their problems.

Norma Lang, RN – University of Wisconsin

Okay, I have one question and then we have two other that our group up here want to ask. I would guess I would be remiss to say we talked about patients being complex, the caregivers or the providers of the health professions are complex and so we hear so often of the data and knowledge being organized around what the physician needs. There are multiple other people who also have a body of knowledge. How are you thinking about dealing with that? And of course, you know, I represent 3.1 million nurses who provide most of the care in this country who are really feeling quite marginalized in all of these discussions and so... but it's physical therapists, it's social workers and especially when you move out of this acute episode and you want to move to a longitudinal care there's nothing more frustrating than a home care nurse going in and not even knowing, almost zero except if a physician maybe ordered something that has no relevance to really what's going on with this family at home. So, how do you do that complexity of patients and complexity of professionals? And you were smiling so...

Mary K. Goldstein – VA Palo Alto Health Care System and Stanford University

Well, you know, I'm a geriatrician obviously team care is essential although I would think that all efficient office practices even in caring for single disease patients have set up systems where they know how they communicate well with different people in the office of who does what. What does the nurse do, how does the physician effect quickly communicate with the nurse about what will happen and the nurse back to the physician, etcetera and HIT systems can definitely support this by parsing out tasks to

different people and this has to be done in a customizable way because each setting has different roles present.

So, we've begun working with a VA group who has for one of the VA networks, a VISN, has a clinical dashboard that's designed for multiple views both for managers and also for panel management and a view of who has an appointment today. And they show the measures and however everyone's doing, which is really helpful and they already have a way for communication by team members of who is doing what. We're working with them to add in decision support that's specific to the person who you parse out a task too.

So, there are certain things...and it's one of the PCMH patient centered medical home principles is to have everybody work to the max of their professional judgment capability licensing, etcetera and that you can break apart the tasks that need to be done in order to achieve that patient care staff or patient outcome into roles of different individuals by different disciplines and then provide them specific advice about what to do, but in a way that everybody can see it. So, everyone on the team can see what's in their inbox of tasks to do, what's the support of how to do it and can also see what's the status of the task that other people are working on.

Norma Lang, RN – University of Wisconsin

So, is there a source of truth for other disciplines in what goes into the electronic record?

Mary K. Goldstein – VA Palo Alto Health Care System and Stanford University

A source of truth? I'm not sure I understand what you mean?

Norma Lang, RN – University of Wisconsin

What I put in as a nurse saying here's my diagnosis of a pressure ulcer, is that a source of truth and I think we have to deal with a lot of this right now and I mean are kind of just...kind of superficially going over that, but there is functional status, there are pressures ulcers, there are falls, there's a whole lot of data that is now going in and it's saying, well a physician needs to put that in, but who has the knowledge and the knowledge representation to do that are other disciplines. So, I just...

Mary K. Goldstein – VA Palo Alto Health Care System and Stanford University

My personal view is that they definitely do not want to limit this to physicians putting that information.

Norma Lang, RN – University of Wisconsin

If you're going to a record to compare sometimes what the physician puts in, what the nurses puts in and there isn't and interrelated reliability there for some of these things.

Mary K. Goldstein – VA Palo Alto Health Care System and Stanford University

Yes, and of course HIT can help that by surfacing, identifying and surfacing those issues for resolution.

Norma Lang, RN – University of Wisconsin

Right, but that's not real comfortable, anyway I just thank you for taking and Fauzia wanted to say something. Blackford and then we need to go to the other people.

Fauzia Khan, MD – Chief Medical Officer - DiagnosisOne

Thank you, I just want to add we talked about so many types of CDS interventions but if we are going to limit ourselves to one intervention in Stage 1 and 5 in Stage 5 we are not going to go anywhere, this puts a very low ceiling rather than setting a floor and people just put CDS on the back burner.

Norma Lang, RN – University of Wisconsin

Thank you.

Blackford Middleton, MD, MPH, MSc – Partners HealthCare System – Harvard Medical School

I just want to comment to underscore Mary's observations and approach. In the CDS Consortium knowledge-based transaction we receive a conforming CCD, one is it's conforming because the C38 standard actually isn't strong enough to specify what are the control terms you need to have in the message so we've defined a conforming CCD as we call it and we think moving upstream in the CDA probably is a good idea, but we're also going to analyze with ONC's help, you know, what is the VMR data package and how applicable might it be.

The second part of this analysis has to think about not only snap shot decision-support but also stateful decision-support that is what data objects are maintained over time for decision-support. The second piece I'll agree in terms of how do you target CDS. We've in the CDS Consortium; a return message is the assessment, the recommendation, the target actor and the explanation. And the actor can be patient, provider, nurse or physician, or case manager as the case may be depending upon the inference.

In other experiments, we've found actually that patient directed CDS can be equally good or augmenting to provider directed CDS. We found, for example, patients receiving diabetic reminders, diabetes care reminders were not only activated themselves, but further activated their providers, every physician knows what this feels like, the patient comes in but he comes in more or less tuned to the problem at hand with a disease diary and questions, and then recommendations that they want to talk about.

Lastly, the context issue I think is something that has to be addressed in the data model or the representation issue because it's not going to be just the actor, it's going to be what type of doctor is it, is it a geriatrician, the cardiologist, the primary care, who is responsible for what? And what is the, you know, location of care? Is it actually, you know, the primary care suite or is it the endoscopy suite where different decision support has to apply so we can whittle down some of the overriding problem.

Norma Lang, RN – University of Wisconsin

Okay, wow, that relates. I've got, this is my order Floyd, Eva, Gayle, Larry, Leslie and David Lansky. So, go for it.

MacKenzie Robertson – Office of the National Coordinator

I'm sorry, there are people on the line as well and John White who is also on the phone also has a question to add to your line-up.

Norma Lang, RN – University of Wisconsin

Okay, so when did he get in the queue?

MacKenzie Robertson – Office of the National Coordinator

I was just notified. I think he is speaking. John is that you?

Norma Lang, RN – University of Wisconsin

Okay, John why don't go ahead then, is that all right, Floyd?

Floyd Eisenberg – Senior Vice President of Health Information Technology – National Quality Forum

Yes.

P. Jonathan White – Agency for Healthcare Research & Quality (AHRQ)

Thank you, Floyd, I appreciate it. So, hello everybody I thank you for your excellent presentations. I just heard something during the presentation that I wanted to quickly address, Julie, I think said that historically the focus of CDS evaluations has been the quality of the evidence-based content rather than the effectiveness of the CDS presentation, relevance and timing of its delivery. Certainly, we've got good evidence about the quality of content, but we actually do have a reasonable amount of evaluation about the effectiveness of the presentation and the relevance of its timing and delivery. I've got several projects that I have funded in the recent past and are still ongoing that would take issue with that. We actually have a good evidence report also that we put out in April talking about the broader...the across systems impact of decision support on process measures. We don't have good evidence about outcome measures, but I just didn't want to leave you with this impression otherwise.

Norma Lang, RN – University of Wisconsin

Okay, thanks, Julie? Okay, thank you. All right, Floyd?

Floyd Eisenberg – Senior Vice President of Health Information Technology – National Quality Forum

Yes, thank you. So, I actually have a couple of questions. I'll try to merge them into two. So, I heard...first of all this is a terrific panel and I really appreciate how you were able to get a concise definition of what was being done. What I think I heard was CDS manages the workflow, data workflow and clinician, and maybe the patient workflow to enable outcomes, and enable the measurement of outcomes. And, so what I did here was that there are ways to look at effectiveness and Blackford presented some slides showing whether they're effective or not, but I'm looking for how would you suggest or do you suggest that individual systems should be able to evaluate every EHR? The effectiveness of CDS and how would they do that? Is there some model they could use? And how could they evaluate effectiveness in the context of the role of the person performing it which may also be the patient or the patient's caregiver not necessarily a clinician?

The other question around that is how do you deal with elements that have been problematic in implementing quality measures exclusions where if it's something that somebody has to enter because it's a preference it's extra work. If it's passive because it's already there it's a little bit easier. But, how do you reconcile on the CDS side where perhaps you need to know more about exclusions even measures?

Norma Lang, RN – University of Wisconsin

Julie, did you want to start?

Julie Scherer - NewMentor

Thank you and Dr. White thank you for your comment. Our comments were sort of based on the fact that when we've looked at literature and we've looked at the effectiveness and the impact rate of CDS, if you look at the literature today it's actually still relatively low, it's in the single digits in terms of...if you look at the CDS that's reported and the actions that are taken on it most of the time clinicians ignore it, right? So, this is a question of specificity which I think in some ways, Dr. Eisenberg you're getting to.

In terms of the specificity problem in the measurement, what we've done is we've actually provided capabilities to our hospitals to start to categorize the impact of those CDS alerts or the CDS reminders or the smart forms. So, basically, follow the chain of impact, right? And when you have them follow the chain, they get very smart very quickly about what the alert is doing, which ones are working, which ones aren't working, whose ignoring the alerts, why are they ignoring the alerts? And what's been very interesting is it's become a very collaborative process of both quality and clinical team. Because the clinical team wants to make sure that they are making the right decision.

And our systems that we've designed and implemented are quiet enough that more than 75% of the time the clinician, whether it be a doctor, a nurse, a physical therapist takes the action and actually it can be twofold, one it can actually be ordering the medication or the lab, or taking an action. The second can be documentation. And what we've found is that documentation is critically important to the overall success and impact of the CDS because that enables the quality team, as you were talking about, Dr. Eisenberg, to understand if this patient is excluded and if it's excluded for sort of a qualified exclusion purpose like the patient is being transferred to hospice or whether it's actually for a clinical reasons, right? There is a clinical reason why I'm not going to prescribe this stat and at discharge, right?

So now we actually are finding that this enables the clinical team and the quality team to communicate proactively at the point of care not retrospectively after the patient has left the hospital. So, quality issues are sort of surfaced, potential quality issues are surfaced and addressed more quickly and the whole team is now thinking about the impact of those alerts. That's what's really driven sort of the adoption that we've seen and we've also found there are certain solutions or sort of reminders or certain kinds of interventions in certain environments that aren't as effective. And it also helps them understand what's effective and what's not.

Fauzia Khan, MD – Chief Medical Officer - DiagnosisOne

I just want to make a brief point to this discussion that we have worked extensively with EMR vendors and in my opinion or in our experience they form a great team and great partners, but they don't seem to have the capabilities to do that on their own, to dwell at the metrics, to build the clinical models and to follow the outcomes and the CDS intervention effectiveness.

Norma Lang, RN – University of Wisconsin

Thank you.

Blackford Middleton, MD, MPH, MSc – Partners HealthCare System – Harvard Medical School

I just wanted to add a couple of thoughts to the great comments already on the table, you know, one, I wanted to tease out Floyd the distinction between evaluating CDS and EMR that might occur in a certification process versus the evaluation of CDS which occurs in EMR as implemented, because they are extremely different. You know, in the certification process, we have to assess the quality of the knowledge base, its implementation in the product, its functional expression in feature functions and whatnot that can be evaluated pre-implementation.

But, then upon implementation it's sort of the usual method set for evaluating CDS, did it affect, did it affect outcome, did it affect cost? We think that this number needed to remind idea though is going to be useful, it uses the standard 2 x 2 method set that will allow us to differentiate how many reminders it takes me to order the hemoglobin A1c and if it takes too many something is wrong with that rule or the context or it's expression, etcetera. The number needed to remind idea can be broken down to fine tunely

evaluate whether the user is acknowledging the reminder, ignoring the reminder or acknowledging and acting upon the reminder. So, you can really get a very sensitive assessment of the decision support expression at the screen.

I think the other comment though Julie alluded to also was to your other point or question, was that the knowledge expression for CDS...because of subtleties and what you're trying to capture or exclude in the different cohorts of CDS versus outcomes is different. So we may have common building blocks like value sets and expressions and whatnot but you have to be careful that it's not be exactly the same thing.

Norma Lang, RN – University of Wisconsin

Thank you.

Mary K. Goldstein – VA Palo Alto Health Care System and Stanford University

One comment about the question on exclusions and I think the whole concept of well we have measures and then there are exclusions, when the measures are overly simple, the exclusions are many and you don't have anything to say then about all those excluded patients. And of course, no matter how complex the measure and no matter how much data, there will always be some patients whose situation can't be accommodated so there will always be some exclusions. But, I think we need to move toward having more complex measures that are actually taking account within the measure of what would be best for patients with that complexity so that there then are fewer exclusions. We don't think of it just in terms of, oh this one is out and that we have something to say about all those patients who are increasingly becoming that's who our patients are, those complex patients.

Norma Lang, RN – University of Wisconsin

Thank you. Okay, is that still...?

Patrick Yoder – Hennepin Country Medical Center

Yes, just a couple of comments. So, in terms of specificity, when you're really building this stuff inside you basically build the workflow, the process that you're capturing enough information to figure out the different details and then if you can't, you basically ask the question in the workflow, you know, does the patient have this exclusion criteria? And then, in terms of how to actually implement real-world measurement of this stuff, the data is there, I mean in the EHR, you know, it tracks pretty much everything that any user does. However, the drive to actually use it is pretty low in the organization and so if you really...what we found is that as you can begin to push the use of that data and really how effective your decision support is working you actually do two things, you find where your processes are breaking down, but you also begin to drive higher quality data for analysis in the data mart downstream.

Norma Lang, RN – University of Wisconsin

Thank you. All right, Eva is next.

Eva Powell – National Partnership for Women & Families

Thanks and thanks to all of you and I'm particularly pleased that the topic of shared decision-making came up pretty early in the conversation. And that's where I'd like to focus my questions, which are two of them and I really liked the notion and I think it's a really helpful thing to direct us that the request for CDS drives standardization. And, so I'm curious as I think about shared decision-making in the patient focused CDS rule in that process, are there patient specific variables and some small starter set, if you will, of goals and outcomes that patients are particularly interested in that could be quantified now based on your experience? Or is that just, you know, the world is open. My guess is that there may be a starter set that we could begin to work with.

And the second thing that I'd like to know, given this ability to provide patients with information that's truly meaningful to them in making their decisions is going to be critical to addressing the broader cultural issue that more is better. And this will be a tool not just for patients but for providers who are put in the really difficult place of knowing that an antibiotic is not going to help, but you've got a patient in front of you demanding it and you've got 8 patients for the same time slot that started five minutes ago. So how

operationally do we get CDS and quality measurement to work together? In other words, what operationally does the intersection of this CDS and quality measurement look like?

Norma Lang, RN – University of Wisconsin

And who would like to start with that? Okay, Fauzia?

Fauzia Khan, MD – Chief Medical Officer - DiagnosisOne

We looked at the patient focus rules in quite depth over the last 4 or 5 years, as I said we aligned with Google Health and we provided a rule set. I don't think there's a standardized set which is available, but we got a lot of consumer feedback from Google Health, the people were really interactive and they gave us feedback. We didn't do any formal studies yet. We have all that information. We found that patient's information if it's richer it leads to much more meaningful decision support interventions. And if we have information on their race, ethnicity, their preferences, then the intervention which are going back mostly...it is usually just a text guideline to them, there are no orders as you know. The recommendation becomes more and more meaningful to them. That's one comment.

On the other one, CDS and quality measures, I think they should be 100% aligned. All quality measures should have a CDS component otherwise it's not possible to either benchmark these quality measures or to really improve on them because you can't send any interventions at point of care which is where the action happens.

I just want to give one more comment about the complexity of rules that have come up several times and we believe in what we call graceful degradation, which is that we give precedence to those rules which are very complex, very rich. So, if we have all those 10 data points we can issue that rule, but if we only have 2 data points that the patient is a diabetic and has this age, we can give them a much simpler rule and we use precedence to organize these rules and they degrade, as you say, the complex ones live at the very top and the simple rules at the bottom of that quality CDS.

Norma Lang, RN – University of Wisconsin

Anyone else? Okay, Blackford.

Blackford Middleton, MD, MPH, MSc – Partners HealthCare System – Harvard Medical School

I'll chime in, you know, it's a great question, Eva, and, you know, just harkening back to the experience we have in our CT on patient directed CDS, this idea of shared decision making I think is still evolving. Of course we can alert the patient and they can take their own actions and that may prompt a discussion which didn't otherwise occur. But, I might hazard a little bit of caution that we don't get requirements from policy makers ahead of the state of the art and the science in shared decision making and patient preference assessment. It is a very challenging thing to do and to do it well and reproducibly at scale; I might suggest we're not quite there. There are preferences which of course we gather now in routine clinical practice and are used every day, but that's not the same shared decision making, you know, full utility patient preference assessment that I think sometimes people are talking about.

I think the preference sensitive approach to decision support would be the right way to go. What kind of CDS can support preference sensitive decisions that the physician might...clinician might otherwise not be considering? Are there a starter set of patients prefs that are used in practice? You know, I'm not so sure, you know, maybe the SF1, how you doing today? You know, what would you like to do now? What can we focus on clinically right now? What's the goal?

And the intersection of CDS and quality measurement, you know this is I think the point of this panel. We believe, and I think I speak for the group, you know, there are some common building blocks that we really need to standardize upon to allow us to then elaborate both quality measures and CDS interventions in a way that really accelerates, you know, their development. And then we need to open up products to allow insertion either, you know, import and interpret or service-sized quality measure insertion and CDS insertion.

Norma Lang, RN – University of Wisconsin

Okay, Julie, one quick point?

Julie Scherer - NewMentor

Yes, I have quick point. So, one of the solutions that we've worked on and that we've really seen evolving is the opportunity to provide, as you said, sort of parallel clinical decision support to clinicians and patients about a certain problem or a treatment or sort of a context. And we found that that's effective when you have a clinical team who sort of represents multiple disciplines and you have someone who really is in charge of coordinating that care.

So I think care coordination is a big part of this in making sure that the discussion, the patient/clinician discussion happens. But when that is in place within organizations, what we are finding is that informing the patient and informing the clinician sort of from a similar body of clinical knowledge, obviously not the same recommendations but from a common body, you do have a more informed, more engaged discussion. And I think you have a better...we've documented that there is a better and a more comfortable shared decision making process that occurs.

Many times we talk with physicians about this and they are uncomfortable with the concept of shared decision making because they do not want to deal with the knowledge gap on the patient's side. And so sort of by providing parallel and letting the clinician know what you've sort of provided to the patient as well as sort of having someone who is involved in that care coordination we found has really facilitated the process.

Eva Powell – National Partnership for Women & Families

Just a clarification question. The common body of information, are you talking about the common source or what exactly do you mean by that?

Julie Scherer - NewMentor

So, I mean, yes. I mean by common body I mean common set of guidelines, common set of quality measures, sort of thinking about sort of the evidence source and the practice source that underlies the clinical decision support intervention and recommendation and making sure that those are in parallel, and those are consistent. Now, one of the challenges you have with maintenance is that you need maintain those, right over time? And we do know that practice changes, in many fields it changes quite rapidly. So, that's actually part of the design questions that we deal with.

Norma Lang, RN – University of Wisconsin

We're going to move on to the next question. I do want to state with patient preference...speaking as a patient, it's very hard if you don't know the cost implications of this. I've just been dealing with this with some eye medications that are up to several thousand. I think cancer patients are dealing with this. It's a brand-new kind of time for us in terms, yeah, you could do that but it's going to...and then with the insurance company I don't see how you can avoid that and expectations to be making decisions. Okay, Gayle?

Gayle Harrell – Consumer Representative/Florida – Florida State Legislator

Thank you. Thank you so very much I do want...I was a little late coming in. I want to introduce myself. I'm Gayle Harrell, I'm a member of the Policy Committee and a State Representative from Florida and also a practice manager of a large practice and mammogram center.

In our Policy Committee over the last month, last month we had a major discussion on where decision support really should take place and I'm sure Paul remembers the discussion, as does Larry, on who is ultimately responsible for really seeing and understanding, and acting on what you're doing in the moment of ordering CPOE. And how we, in the use of scribes, in the use of that team approach to health care, and I would really like your insights on does...do you need to have all members of the team be part of that decision support mechanism? Is it only the physician who must order after that decision support has to take place at the ordering point? Where is this...what is the role of the scribe in a situation like this? And what's the team approach to decision support?

Mary K. Goldstein – VA Palo Alto Health Care System and Stanford University

I'd like this address just the part of it about when the decision support happens just on that issue of should it be at the time of ordering. Even setting aside who else on the team it's for, if it were just for the physician because we know from neuropsychology cognitive studies that people have automated decision making most of the time and then smaller portions of time when they are doing deliberative and experts are, just like everybody else, physicians are usually in their flow where they're doing their automated work from automated processes and there is a period of time in the encounter in which they are in a deliberative decision making mode and then they're thinking what will I choose to order? But by the time they get to the EHR to put in the order they're usually in that automated mode. And when in the automated mode people are not receptive to interruptions and interruptions can derail them, make them forget something important that they were doing and they get taken off in a different direction. They can actually be harmful and also slow people down and annoy them.

So, you only want to put your most important interruptions like big red flag, this is a terrible adverse reaction or something at that point and you want to get to them with things that are intended to support the decision at the time when they're in that deliberative mode of thinking in decision making. So, it is not necessarily the case that the optimal time for decision support about ordering is at the moment of order entry.

Now, about the team care, I think, I'm not sure if you were here at the time we talked about all that before and I've said various things about that, so I'll kind cede this time to others who may have additional things they want to say about that because I think we do need support for all members of the team but different support for different members, you know, the scribe may need support about things a scribe needs to know of what to capture, what to hear, what to write down, what language is important that might be quite different from the decision about what action to take and you would want to tailor the support to the role of person receiving the support.

Norma Lang, RN – University of Wisconsin

I suppose we could ask why there was a need for a scribe when the electronic records were supposed to make this much easier and it seems what it did is create the need for a scribe, which we used to have way back when, anyway, Blackford would you speak?

Blackford Middleton, MD, MPH, MSc – Partners HealthCare System – Harvard Medical School

I just want to underscore Mary's comment, I can't resist because it's so important. This teachable moment idea has to be really clearly identified and, you know, Daniel Kahneman's thinking fast, thinking slow, great discussion on how the decision-making process changes depending upon the context and where you are with your biases and whatnot.

The second point though is about accountability, you know, right now we treat decision support as if its shotgun, everyone gets the same decision support. There is no fractionation or differentiation of that decision support going to cardiology versus case manager, versus primary care, whatever, we've got to do that, it's really incumbent upon us to do so because otherwise...it will improve your data, too because you get more response from the right alert for yourself.

Norma Lang, RN – University of Wisconsin

Thank you, all right, I think, okay, all right moving on then to Larry.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So, you've touched on this a little bit, but the sort of two related parts to one question. Meaningful Use 1 had an initial piece of decision support being required. Meaningful Use 2 looks like it's going to have more. But, I'm hearing one of the problems that we seem to have consistently, which is those levels are being seen as a ceiling and it's really not our intent. Our intent is that they should be a floor. So, in your answer to the second part, think about this first part of how do we get people out of the mindset that the requirement is a minimum standard, not a maximum standard?

So I'm hearing this shift from we used to worry about the quality of the knowledge in the decision support, and now we're shifting to focusing on the use and its ability to actually affect change in behavior and change hopefully in outcomes. So, as we look at Stage 2 is there anything we should look at measuring that we should build into the reporting requirements that would either help us as a nation or help individual providers actually see where their CDS is helping them?

Patrick Yoder – Hennepin Country Medical Center

So, I'll take a first shot. So the...so your first point is, you know, how should we measure this stuff? I think in addition to actually placing the requirements for so many rules or so many interventions into the measurement, it's also saying some representation of how effective that is really inside the EHR or inside their clinical process. I mean, that is what really it comes down to at the end of the day. We have tons and tons, and tons of decision support and we actually haven't been limited by the number inside there at all. It's really just kind of driven from the wrong spot, right? So, it's all driven from the measures and toward the measures and not the process standardization that you really need to build as the basis to do continuous quality improvement on top of. So that...adding that level of reporting around the effectiveness of the decision support would really require you to not only target the measure itself, but also target the standardization of the process as your baseline to begin improving on top of.

Norma Lang, RN – University of Wisconsin

Anyone else?

Blackford Middleton, MD, MPH, MSc – Partners HealthCare System – Harvard Medical School

I'll just echo Patrick to a degree and add the other response to the other question about ceiling. You

know, I think you do have to measure whether or not the physician or the ordering clinician acknowledged or acted upon the decision support. I recently had to see a consultant in my own clinical care and the scribe was being used and if we have a scribe in place, decision support is not going to the person who might learn from it and avoid the same alert the next time. So, I think if you measure acknowledgment and the appropriate action, those are process measures that you can get out of the EMR and of course you can measure the traditional outcome, is the hemoglobin A1c controlled?

On the ceiling point, you know, I think it's reflecting where we are, you know, in the course of this HIT stimulus. For most people who are adopting HIT and never had anything before, you know, five rules is a big deal and they haven't had anything before. So, that's kind of...they're viewing this from, you know, kind of below, if you will, the criterion. Everybody else, large environments and those who did adopt previously, you know, the thresholds are meaningless to us because we're way over.

Julie Scherer - NewMentor

I think one of the things that we've missed in Meaningful Use, sorry this is Julie, one of the things we've missed in Meaningful Use is the linkage between CDS and quality measures. And I think as this panel talks about, this is the improvement part of quality improvement and measurement is the measurement part of the process, right? So we need to look at the improvement process and we need to sort of incent people to connect those parts and to think about the whole process both the performance side,

which is what CDS is aiming to improve, as well as the measurement side which hopefully shows the outcomes.

In the hospitals we've worked with they are so I'd say, caught up and hyper-focused on putting in place the infrastructure of the systems and the processes and the data they need to do measurement that you can't even start the conversation with them about the performance part of the loop. And they don't see it as a loop. So, I think one of the opportunities that the Policy Group in particular has here is to really sort of enable and encourage the market, and the implementers of these solutions, the hospitals, the health care organizations to think about this as a performance process, as a performance cycle. And the combination of CDS and measurement to enable them to improve that process.

And I think as you move, sort of think about Meaningful Use 2 and Meaningful Use 3 tighter linkage between the actions that are being taken and the measurements of that and encouraging people not just

to report the results, report the results over time and incenting them for improvement, I think you will find we'll achieve that greater linkage within the adopters.

Norma Lang, RN – University of Wisconsin

Okay, thank you. Leslie?

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

Hi, this is Leslie Kelly Hall. Thank you for your great presentations. I'm struck by the conversations earlier in the first panel and now about alert fatigue, about the whole idea of the gradation of preferences or direction either something is nice to have, to something is going to cause pain. And as we look to the future and add patients into this mix of shared decision making that becomes even more cloudy. And I wondered if Dr. Goldstein or Dr. Middleton you could speak to either the open CDS work that you're doing or other standards that have started to develop this sort of grade of alert, because without that it seems that any sort of direction a system provides can be easily ignored because it's all just noise. That seems to be fundamental whether we're talking about clinical measure, quality measures or integrating patients into shared decision making.

Mary K. Goldstein – VA Palo Alto Health Care System and Stanford University

I'll kind of take a start at that. So, this is Mary Goldstein, yeah, thanks. So, I completely agree that there is a need to have some prioritization of the recommendations sort of based on importance and strength of recommendations, something like open CDS provides standards for how to have interoperability of systems, but I would say its agnostic about what the knowledge content of the system is.

And I believe it's very important that we identify who is the source of authority for the knowledge in each system, which should be, you know, the health care system should have...or the office practice, somewhere should have some groups embodied that's the governance body that say's they are responsible for which guidelines will they adopt if they take on someone else's system to not have to do it themselves that they decide which ones they will take on or they decide to do it themselves. They decide what's the source of authority they'll use.

And that within that process there should be a process of prioritization of recommendations and that one of the things we're building into the groups of encoded knowledge bases in different clinical domains that we do is a way to flag recommendations on the strength of recommendation and then to subgroup them into clusters. And then that means you have that encoded with it and then someone can make a choice about, well, how far down your list do you want to go?

And there are choices that can be made like we think within our health care system people can handle three reminders per visit and we're going to cycle them or we're always going to always pick the top three. These are important governance choices that a clinical source of authority has to make about for this health care system or this office practice.

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

What if the source, this is Leslie again, what if the source of authority is the patient who simply states I will not accept blood by-products, I do not want intubation, I do not want nutrition. These are not options and so as we add the role of the patient into these things regardless of what our clinical care guidelines might state, a patient does have an absolute say. So, I would really like to hear comments on the role of authority varies and is not always clinical, and how do we build that structure in design as we go forward?

Mary K. Goldstein – VA Palo Alto Health Care System and Stanford University

Well, I think that's a great question and a great expression of a principle and of course the ultimate source of authority for what will be done is the patient and that it might be a rule incorporated that if the patient is given an absolute refusal of something, that that rule trumps all the other rules and that that would be encoded.

But again the people who are putting the system into place for that practice need to know how do we...they need to have a set of principles of how will we incorporate all of the rules, including the patient information, to set the priority levels for them.

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

Thank you.

Blackford Middleton, MD, MPH, MSc – Partners HealthCare System – Harvard Medical School

I would just add very quickly, you know, this idea of respecting patient preference of course is a first principle in medicine, it's not, it doesn't have to do with CDS or outcomes or whatever. If the patient says no blood products, of course clinically you should have a conversation about the merits of that and then respect the patient's decision. So, there is good science which suggests that alert tiering, differentiating the alerts from those which you must pay attention to, from those which are interesting versus those which you can safely ignore is extremely important.

Most of the commercial knowledge bases for medication drug-drug interactions come with data that clinicians never want to see because it's just not really that helpful to me clinically. One experiment we've done with ONC's support is to differentiate the high value drug-drug interactions that must be full stop alerts versus low value drug-drug interactions which should not ever be shown. So that paper has been published and we can use that kind of idea again, tiering to fractionate, if you will, those decision support.

Mary K. Goldstein – VA Palo Alto Health Care System and Stanford University

And just one other quick thing about one of these SHARP projects that ONC funds is developing methods for setting specific factors, which is another aspect of this. And so there might be a general rule about for diabetics you should do such and such and one office might say we never want to miss it, so alert us at 5 months if it's due at 6 months and another office might say we don't want to bother our people with alerts unless they fail it so don't trigger it until they pass the 6-month point. And there are a host of setting specific factors at that point even if there is agreed upon general principle of what it should will be and have ways to incorporate those into standard CDS will be useful.

Norma Lang, RN – University of Wisconsin

Thank you, and David, do you want the final word?

David Lansky – Pacific Business Group on Health – President & CEO

I think Marjorie does.

Marjorie Rallins – Director of Measures, Standards and Informatics for the Performance Improvement Division – American Medical Association

So, I want to thank the panel again for your very thoughtful comments and I think we've learned a lot today and we have some direction. It is now time for lunch. And we're scheduled to be back at 12:45, but I will look to MacKenzie to tell us if we need to adjust that time because we've gone over a bit.

MacKenzie Robertson – Office of the National Coordinator

I might turn it back you, I mean, do you guys think a half hour is enough time? We have some people that ordered lunch that will be delivered into the room, but I don't believe everyone has done that.

Marjorie Rallins – Director of Measures, Standards and Informatics for the Performance Improvement Division – American Medical Association

Okay, so we should make it 12:55?

MacKenzie Robertson – Office of the National Coordinator

Then 12:55, yes, okay.

Norma Lang, RN – University of Wisconsin

I want to thank this panel.

Marjorie Rallins – Director of Measures, Standards and Informatics for the Performance Improvement Division – American Medical Association

Time to come to order again. Calling all panel members. Time to come to order again. The next panel is panel 3, and the focus is on e-Measures and the moderator is Eva Powell and I will turn it over to Eva to start the discussion.

Eva Powell – National Partnership for Women & Families

Great, thank you and I'm going to forego reading of bios because we all can read and they're in your packets. Instead I'll do just a brief level setting and then turn the time over to our distinguished panelists.

One of my greatest concerns in this whole process of Meaningful Use has been the issue of quality measurement and how can we leverage the capacity of Health IT to ensure that the measurement of the future actually meets our measurement needs, because one thing that I think folks all agree on is that the current measure set really is very ill equipped to meet the needs of the future in terms of quality measurement. And yet without the measures there how do we ensure that the Health IT capacity is actually put in place and used?

So we seem, to me, to be in this kind of chasing our tails mode. So, I'm hoping that this panel will help shed some light there to help us know how in the process of establishing criteria for Stage 3 can we get out of this chasing of our tails and really move forward in advancing the field of quality measurement not just the submission of random measures that may or may not have meaning or even be accurate and reliable, and valid. So I'll turn the panel over to Floyd. And we'll go in line from Floyd

to Ferdinand, to Phyllis and to Keith who is on the phone, and to Rich, and to John, and I think I saw Rich, but anyway, hopefully he'll be here by the time we get to him. So, go ahead, Floyd.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

So, thank you to the committee for the opportunity to present. This is Floyd Eisenberg from National Quality Forum. Since NQF is a measure developer we can only provide a high-level assessment of the process from the vantage point of neutral evaluator and endorsers of measures and developer of tools and infrastructure that should support development of e-Measures. And we can help as a coordinating body to facilitate both neutral convening roles and innovations in the endorsement process to move forward for a de novo development of e-Measures and strengthen new and valuable relationships between measure developers and EHR vendors and also users of measures.

The shift from retooling of existing quality measures to de novo measurement from electronic data sources presents an important opportunity to foster innovation but also challenges. The measure development process needs to evolve to better use data that are available at the point of care through EHRs, current measure development process has been focused primarily on available data often from claims or perhaps from abstraction, which is very cumbersome for data collection and effort. Previously measurement has been limited by inability to get some data that are present directly within EHRs.

So, the new paradigm would be for measure development to develop new relationships and coordinate between measure developers, EHR developers and users of measures. The proposed shift to a two-stage NQF endorsement process is intended to provide an endorsement process that better aligns with measure development. The two-stage process outlined in the diagram in your testimony would allow an early focus on importance of the measure, including evidence of the underlying measure focus, potential impact and gap in care or variation across providers. The assessment can be done before a measure is specified and ready for testing. It can also allow collaboration among measure developers and EHR vendors and users systems to identify feasibility, and requirements as the measure is developed from the start.

Recreating existing measures has been shown not to be as valuable in this vein and up-to-date problem lists in the EHR can remove some of the requirements that happened because claims didn't have enough information and more information had to be identified in order to properly determine the right list of patients. But EHRs can provide more information to help us in that vein.

It's also critical that the measures be tested and endorsed in order to make sure they are valuable and feasible, and reliable, and valid. The NQF measure testing taskforce report looked into this and I recommend review of that report to identify requirements for testing and reliability, and validity. We also welcome the opportunity to work with measure developers, EHR vendors and others to identify standards for feasibility testing.

Data and information needed to create e-Measures was question 3, and while EHRs have great promise there is still a lot of work to be done to leverage capability of EHRs. In order to identify new areas of measurement, delta measures, that can change over time such as a blood pressure improvement for the same patient at 6 to 12 months, incorporation of patient risk, identifying how patient reported information can be used to come up with the same results that were intended.

The quality data model provides a common technological framework for defining clinical data needed to perform measurements and it suggested that measure developers should create measures for EHRs de novo, thinking first about data that can be reasonably expected from EHRs but also to identify data requirements that extend beyond current EHRs and determine high priority areas that need to be addressed within EHR certification, and through new methodologies to capture those data. Some of the examples we heard this morning were related to ejection fraction and gestational age, but there are certainly others in that area. So, we look forward to participating in this process through neutral convening and thank you very much.

Eva Powell – National Partnership for Women & Families

Thank you and Ferdinand?

Ferdinand Velasco – Vice President and Chief Medical Officer of Texas Health Resources – Chair HIMSS Quality, Cost and Safety Committee

Thank you and good afternoon and thanks, Dr. Larsen, for the invitation to participate. I'm Ferdinand Velasco, or Ferdie Velasco, the Chair of the HIMSS Quality, Cost and Safety Committee. I also wear another hat, I'm the CMIO for Texas Health Resources which is a not for profit health system in North

Texas. All of our hospitals achieved Stage 1 of Meaningful Use last year. And previously I've also worked with NQF on a number of panels related to measure development, but it's in the role of a representative of HIMSS that I am on the panel today.

The Quality, Cost, Safety Committee last August convened a Workgroup consisting of the various stakeholders, providers, EHR vendors, measure developers and other experts to come up with a set of recommendations for enhancing the life cycle of the development of measures for the EHR incentive program and other federal programs and the output of that activity was a letter, a set of recommendations which HIMSS vetted and ultimately transmitted to the Secretary of HSS in January and that was attached to the written testimony that I'll be sharing with you. I'm going to be speaking largely to those nine recommendations right now.

I guess to boil it down, there are nine recommendations, but if I had to use three words to describe or to highlight the themes here I would say standardization, transparency, and validation. So, you'll hear those themes embedded throughout.

So, recommendation one, the development of a library of standardized and endorsed value sets to be used by measure developers when creating or retooling measures that value set library would then be referenced by measure authoring tool to be used by the measure developers.

Recommendation two is to create a central location for the maintenance, publication and updating of e-Measure specifications. This is consistent with other HIMSS policies and recommendations related to having a place for sub regulatory guidance and information. We specifically in our letter recommend a time frame, an 18-month lead time between the availability of these measure specifications and when these measure specifications go into effect at the beginning of a reporting period for each stage of Meaningful Use.

Recommendation 3 relates to the development of a measure development enterprise, which looks at the entire life cycle from development, endorsement and implementation, and the role of the NQF, and you can refer to the specifics of that recommendation.

The next two recommendations speak to that issue of validation. Number 4 is the testing, the rigorous and comprehensive testing of measures that is needed in sort of laboratory types of environments.

Recommendation 5 is the concept of pilot or field testing of these measures in the field, in actual health care settings.

Recommendation 6 is essentially the modification of existing testing and certification procedures that reflect our earlier recommendation with respect to the e-Measure development and testing process.

Recommendation 7 is the need for implementation guidance, this is something we heard very loud and clear from our providers, you know, there are e-Measure specifications that are out there, they speak at a very technical level, they don't really provide providers or for that matter even EHR vendors with a clear picture of how those measures need to be leveraged.

Recommendation 8 is the recommendation to harmonize clinical and financial code sets.

And, finally, recommendation 9 is the recommendation to establish a multi-stakeholder and long-term private/public partnership as an advisory group to help shepherd the various recommendations that have been outlined above.

I would note that these recommendations were transmitted, as I mentioned, to the Secretary back in January and we're encouraged that there have already been some developments and evolutions and discussions that have been taking place along the lines of some of these recommendations. So, it's encouraging to see that you don't have to wait for the Stage 3 rulemaking process for some of these recommendations to be acted upon. So, with that I thank the group for the opportunity to share our recommendations. Phyllis?

Eva Powell – National Partnership for Women & Families

Phyllis, go right ahead. Well, just go right in and I'll nod to Keith verbally since he's on the phone.

Phyllis Torda – Vice President for Strategy and Quality Solutions Group - National Committee for Quality Assurance

So, I'm Phyllis Torda. I'm Vice President for Strategy and Quality Solutions Group at NCQA. There are many familiar faces in the room, but just for the record, NCQA is a non-profit committed to improving health care through measurement, transparency and accountability. I hope I can pick up on many of the themes raised by Floyd and?

Eva Powell – National Partnership for Women & Families

Ferdie.

Phyllis Torda – Vice President for Strategy and Quality Solutions Group - National Committee for Quality Assurance

Ferdie, thank you, and build on them. And the experience on which I'm going to be basing most of my comments today is that we respecified, NCQA respecified 24 measures for Stage 1 of Meaningful Use in collaboration with our partners Mathematica Policy Research and Booz Allen & Hamilton, and the AMA, PCPI I would note, we have respecified or developed 65 measures that were included in the Notice of Proposed Rulemaking for Stage 2 and we anticipate developing approximately 20 new measures for Stage 3.

So I'm very pleased to have the opportunity to talk with you about what we've learned through that process because I think we're at a point where we can really look back on what we've learned and leverage it for Stage 3 and we can do that right now, we don't need to wait to do that.

NCQA is a measurement organization, over the past 20 years is very appreciative of the opportunities that are created by electronic health records. I mean, we've lived with the straight jacket of claims data and paper charts for years, and we recognize that EHRs provide a number of opportunities that we haven't had. They provide opportunities to access clinical data elements that are needed for evolved measurement that includes new data elements, particularly perhaps relevant to specialty care. We

often hear why don't we have more measurements of specialty care? Specialty care often requires access to very detailed clinical data. So we have an opportunity for that.

We also have the opportunity for new uses of data elements and an example of that would be some of the delta measures recommended by this committee that we're now in a position to be able to look at change over time or at least in theory we are. I'll get back to that in a minute.

EHRs offer us the opportunity to combine data across settings and sources. Across settings it's very important to get at some of those coordination of care issues. And I can tell you that when we look at new measures that have been...new measure ideas that have been proposed, probably the single biggest barrier has do with the lack of flow of information from one setting to another and that still exists. But we also have the opportunity to incorporate patient reported data.

And EHRs provide the opportunity to use data to support improvement as you've recognized. I heard the very tail end of the last panel and I think I am going to pick up on some of their themes. We need to take that data and turn it into information, take the granular data, turn it into information so that it's understandable and usable by the providers, and incorporate it into clinical decision support.

Clinical decision support if done right can actually make some measurements ultimately obsolete. You can use the measurement to identify weaknesses in performance, put in decision support to address those weaknesses and as compliance gets high, may not need to continue to report the actual performance measures because performance will be very high. Anyway, that's the hope.

I want to talk a little bit about the challenges that we faced in realizing the opportunities created by EHRs and then I will get to solutions. It's easy to be overwhelmed by data and we've seen that everybody is overwhelmed by data. We're like kids in candy shop and we can create lots of new measures that require lots of new data elements, and that creates implementation issues, and workflow issues.

Our current standardized measure specification processes for e-Measures do not support complex calculations. I think Floyd alluded to this; the blood pressure delta measure is an example of one that's not currently supported. Change in functional status another one; I could go on with examples. We need better validation measures for both the accuracy of calculations and completeness and interoperability I've already talked about.

Some sort of positive suggestions, whenever possible I think we need to be grouping measures to provide...

Eva Powell – National Partnership for Women & Families

Continue, but I just want to remind you...

Phyllis Torda – Vice President for Strategy and Quality Solutions Group - National Committee for Quality Assurance

Okay, yes, yes. Whenever possible we need to group measures to provide or use the data to group measures to provide a more complete picture. We've heard this from many stakeholder groups that we have convened. I would suggest that we consider certifications and reporting requirements that are specialty specific. Not every specialty needs the same data elements or the same measures and we can reduce the burden on EHRs by thinking that way.

We need to test measures for feasibility in advance settings. Our current testing methodologies test for what exists today and we need to think about how to test for what can exist in the future, especially if supported by certification. We have some ideas about methodologies to do this and we would be

interested in thinking more about how to work with vendors on what I would call a wholesale approach to testing. What can we test at the vendor level and then what can we test at the site or installation level?

And then finally always keep in mind that as we impose requirements on EHRs we also need to be mindful that we can't impose so many clicks, collection of so many data elements that the EHRs are not usable. Thank you.

Eva Powell – National Partnership for Women & Families

Thanks, Keith, you're on the phone?

Keith E. Campbell, MD, PhD – Director of Clinical Decision Support - Veterans Administration Office of Informatics and Analytics

Yes. Good afternoon or good morning from the West Coast. Can you all hear me okay?

Eva Powell – National Partnership for Women & Families

Yes.

Keith E. Campbell, MD, PhD – Director of Clinical Decision Support - Veterans Administration Office of Informatics and Analytics

Very good. Well, thank you for the opportunity to speak to you today. My understanding is that if I were there I would see many familiar faces in the room. Since people are familiar with me and some you may know that I wear several hats at different times. I just want to comment that today I'm here in an official capacity as the Director of Clinical Decision Support for the Veterans Health Administration Office of Informatics and Analytics and I'll just limit my comments to that specific role.

In my testimony today I'd like to discuss how to ensure and leverage measures in a clinical context in ways that improve the patient's experience of care and the health of populations that may also lead to a reduction in per capita costs of health care. The Department of Veterans Affairs strongly believes that improving the U.S. health care system requires simultaneous pursuit of these three aims. In our experience it is clear that in order to achieve these goals measured development can and must be improved.

Measurement infrastructure and data capture that is coordinated with clinical decision support and particularly of analytics within the Health IT System will help to ensure a comprehensive approach to such improvement. This should lead to the highest quality of health care both as delivery system as well as with patient outcomes.

VA views the measurement development process as one that must first identify the desired data elements which are encoded for a particular measure and then isolate the sources of that data within the electronic health record. The current process requires advanced knowledge of what desired data elements should be included in the health information technology system, which results in decreased measure flexibility with regards to new data sets. And so if I were to go back to the previous discussions, the things that I want to build on is the need for detailed granular data at the point of care, as well as standardization of that data in order to achieve the interoperability between the Health IT Systems and the electronic measures that we want to develop.

Historically, the data element identification process has been significantly hampered by a lack of encoding standardization across health care delivery sites, health care delivery organizations and health care systems. As a result, implementers struggle with multiple encoding and messaging systems overlapping semantics, inconsistent data representations and uncoordinated content, and release cycles.

Furthermore, the data elements typically used include billing diagnosis, labs and medications, fine grained clinical observations from the point of care are largely unavailable for measurement and improvement activities. The VA believes that these measures can better leverage capabilities through extending standards and making them easier to implement.

Our office currently has a pilot project which focuses on a collection of fine grained encoded clinical data from the point of care such as symptoms presented in an outpatient visit that use data for real-time

clinical decision support, as well as secondary uses including performance measures for all aspects of clinical care. This project takes advantage of electronic record capabilities including discrete data field and the ability to monitor that clinical data over time to the EHR.

With the challenges of scale and complexity in mind our project is focusing on how best to harmonize legacy in future health information systems while also simplifying the overall system architecture so that problems are more approachable. Our current activities seek to address these challenges in the development of a simple integrated model, or SIM for short, for representing encoded data and on lightweight expressions of granulated objects or LEGOs to transform the data collected at the point of care as well as legacy data into the SIM representations which can then be used for electronic measures or other secondary uses as well as decision support at the point of care.

The SIM model uses the SNOMED terminology model as its foundation including description logic that SNOMED uses, other terminology such as LOINC, NDF-RT and RxNorm are integrated into the SIM representations by transforming them into the same logical representations that SNOMED uses and handling them as SNOMED extensions. This representation together with the SNOMED model or style guide provides a foundation for post coordination of terminology content; this coordination is an important capability that helps maximize coded content coverage.

We use a simple representation for the LEGOs to transform this legacy data by taking each data and defining four fields. Those four fields include first a discernible an encoded expression of the thing that you're trying to assert, the timing for which that belief is accurate, a qualifier that's used to represent the status of collection of that value, such as whether it's null to be consistent with the HL7 null flavors, as well as positive assertions such as patient entered or parent reported and then finally a value statement that represents whether it's true or false or a numeric measure.

Toward that end I have a short statement as part, sorry, a short example that's part of the testimony that I have provided in written form that gives an example of what this looks like. And to date we have built approximately 1500 of these to support data capture and reuse them focusing primarily on pressure ulcers and venous thromboembolisms which are related to important quality of care measures that we're using within the VA.

Eva Powell – National Partnership for Women & Families

Keith, I just wanted to remind you that you are out of time. So, if you could wrap up in the next couple of minutes, thanks.

Keith E. Campbell, MD, PhD – Director of Clinical Decision Support - Veterans Administration Office of Informatics and Analytics

Yes, I'm on my last paragraph.

Eva Powell – National Partnership for Women & Families

Great, thanks.

Keith E. Campbell, MD, PhD – Director of Clinical Decision Support - Veterans Administration Office of Informatics and Analytics

We have found that...and currently we're constructing the back end data systems to store and query these granular observations. Thank you.

Eva Powell – National Partnership for Women & Families

Very good. Thanks. Okay, great, Rich, go ahead.

Richard Elmore – Office of the National Coordinator – Query Health

Hi, thank you. My name is Rich Elmore and I'm the Vice President of Business Development at Allscripts. I recently took a leave of absence from Allscripts to serve as ONCs Coordinator for Query Health establishing standards to send questions to the data while keeping patient level information safe at the data source and their established distributed query networks are using these standards and pilots for

insight on diabetes and hypertension, national and regional situation awareness, post market surveillance and dynamic querying for quality measures.

The Policy and Standards Committees have the opportunity to introduce strategic changes here that can result in agile responsive and clinically relevant measures for Stage 3. Right now the clinical quality measure development process is slow. It's unresponsive to the rapidly evolving state of medicine in the country. Measures may take 1-2 years to define and once defined measures then take several more years to move through a regulatory cycle, get incorporated in EHR systems, deployed to providers and then finally implemented for recording.

Quality measures even in their latest most formal expression using the Health Quality Measure Format or HQMF are impossible for a system to digest automatically as HQMF is verbose and not fully computable with aspects of measure even described in text. Ambiguity in measure specification leads to multiple interpretations by providers and thus variability which then requires rework during the implementation and measure in the field.

EHR developers who work with quality measures have described the need for greater clarity and specificity on supporting data requirements upfront and validation that required data elements can effectively be collected in the provider workflow. Measure development can also be improved by focusing on a common set of building blocks which could be used to create simple computable queries which could in turn serve as a foundation for more complex queries. This will also help us to mature the queries without having to reimplement and redefine each concept as part of each individual complex query.

So, how can measures better leverage electronic health record capability? Collaboration with HL7 NQF and CMS Query Health Standards will enable Health IT vendors to dynamically respond to queries, including queries that align with quality measures. So assuming the data is being captured the quality measure cycle time could go from years to truly a matter of days. The ability to generate measures nationally in a short cycle time has powerful benefits for patients and patient populations while enabling researchers and health care organizations to substantially reduce costs and increase fees.

Blackford talked about the importance of having an externalized set of target data that could deal with the curly braces problem. Query Health Standards do just that in a manner that is aligned with the quality data model and consolidated CDA. Query Health Standards provide a road map to better leverage EHR capabilities for dynamic querying of EHR for quality measures. The standards include the questions, a new more parsimonious HQMF, the target data, ONC's clinical element data dictionary or CEDD, the results QRDA categories 2 and 3 in a query envelope. Query Health pilot is being conducted by Allscripts who evaluate Query Health Standards and target data to deliver sample quality measures.

And so how can the measurement infrastructure and data be leveraged for other types of improvement? Quality measures are an important class of aggregate measures that can be immensely valuable clinical quality measure queries where the query health standards apply with alignment of Stage 3 goals for improved outcomes in establishing a learning health system to rapid feedback mechanisms.

Cool big data in healthcare has its benefits, but also has several drawbacks. Big data is typically managed in large pool data sets combining data from many settings of care. While there are terrific applications for pooled data including registries and other successful use of large research and commercial databases, there are also critical issues to policy and strategy that must be resolved. Query Health Standards can serve as a safe on ramp to big data.

Ultimately we're at a defining moment for standards that will enable quality measures, big data analytics, clinical decision support all in a distributed environment. Researchers will be able to leverage these standards to send questions to the data. Questions can be sent to numerous data sources including EHRs health information exchanges, PHRs, payer's clinical records or other clinical records. Aggregate responses leave patient level information secure behind the data sources firewall and those responses can support questions related to disease outbreak, quality, research, post-market surveillance, performance, utilization, public health, prevention, resource optimization and many

others. The opportunities are truly endless. Thank you very much.

Eva Powell – National Partnership for Women & Families

Thanks, Rich, and now John.

John Schrom - Epidemiologist - Rock Health

Thank you for the opportunity to be here today. My name is John Schrom, I'm an Epidemiologist from Minneapolis. I've spent over a decade working in various aspects of healthcare from providing direct patient care to serving in a policy role for a municipal county in state government, to providing epidemiologic and analytical support for hospitals, and clinics. However, about a year ago I traded in my khakis and polo shirts for hoodies and jeans and I made the leap from a hospital cubicle to Silicon Valley startup. I'm currently a Fellow at Rock Health, which is a health technology incubator in San Francisco where I'm working on developing a medical informatics startup called Epi.md. The work that you're doing is incredibly important. Defining the standards and methods for storing, exchanging and utilizing health information is critical for improving quality and lowering costs. However, without the appropriate use of technology these goals are simply not possible.

I'm in a unique position. I've seen the dark corners where data live in a hospital and I've also tried to work from the outside and the inside to shed light on those data and it's really hard, and perhaps surprisingly it's not made any easier by the epically large health companies that exist today.

From my experiences, there are three key areas to improving how we handle data, the processes that we use to translate that into clinical action and how we leverage our electronic health records along the way. First, focus on developing, documenting, and opening standards. While I feel and understand the attachment to HL7, particularly because I was born in the same decade as it, it costs over \$1,000 to simply have access to it. That may not seem like a lot to companies with revenue in the hundreds of millions or billions of dollars but, at Rock Health, I get a \$20,000 grant to start a company and I have to use that money to pay for staff, technology, and business expenses. So, while we're working on issues that could benefit from the use of such a standard, I simply don't have the resources to both start the company and pay for access.

Additionally, documentation of available standards and ontologies is often difficult to understand. I was at a happy hour with some other Rock Health Fellows recently. We were talking about...one of my friends was complaining about some of the problems that she was running into, she was working diligently on building tables relating different clinical concepts that type 1 diabetes is a type of diabetes, which is a type of endocrine disorder, so when I explained what SNOMED-CT was, she was quite frustrated. That was exactly what she was looking for, but she just didn't know that it existed.

By contrast, there's a telephony company in San Francisco called Twilio. They provide text messaging and phone services for developers via a really simple web interface, but part of their success has been a result of their crystal clear documentation, their code examples and libraries (often submitted by fellow users), and "developer evangelists" who are simply paid to answer questions and promote the platform. So, healthcare needs to have a similar focus on improving documentation. We all want to speak the same language, but there are varying levels of technical and clinical understanding that impedes our achievement of this goal. Any work that can be done to help developers understand and utilize existing standards and ontologies will help to ensure that efforts in the young Silicon Valley health technology community are not wasted.

Second, require all EHRs to have a standard API (Application Programming Interface) that is accessible to both patients and clinicians. In the current system, data are locked in proprietary and often nebulous data structures that force hospitals to do one of three things, they can use the EHR's limited analytic functionality, they can look for limited third-party solutions, or they can just give up.

Further, there's an inherent problem with quality measures and clinical decision support systems, they create more work for already overworked clinicians. By making data easily accessible in a language that is commonly understood by developers, which is typically RESTful APIs, the health care industry can begin to leverage the bright and innovative Silicon Valley minds to solve these problems. There exists an incredible opportunity to create technology solutions that leverage EHRs to help scale primary care but that can only begin to happen when data are easily accessible.

Finally, be ready to start accepting data directly from patients. The average 24 year old will spend more time on Facebook in the next week than with a physician in the next 20 years. So, as you can imagine, there is a digital data trail of where patients are going, how they're feeling, who they're interacting with, what they're eating, and pretty much anything else you can imagine. There's a significant clinical signal that can be derived from that data but only if it's accessible and if it's linked to the patient.

So, what if you could develop quality measures that target children who live or visit homes older than 1950 for lead screening or cardiovascular patients who live near highways for increased follow-up, or frequent bar patrons for alcohol assessments and STD screenings. All of those ideas are supported by public health studies, but have only recently become possible, thanks to the increased adoption of EHRs, Todd Park's open data initiatives, and the maturation of social media.

So, we're at an exciting point in the development of our health care system. Measures are an integral part of that development. However, with the right planning and forethought we can use this as an opportunity to develop and implement the standards that will drive health technology for decades to come. Thank you again for the opportunity to be here today. I look forward to the continued discussion.

Eva Powell – National Partnership for Women & Families

Great, thanks to everyone. I think we're going to have a really interesting conversation and I see Leslie's card up and as the other moderators have done I'll take the opportunity to ask the first question. I heard a lot about testing and the importance of that obviously is critical to a main element of NQF endorsement, and yet I also heard a lot about the need for transparency and sharing of knowledge, and resources, and per my comment in the previous panel the majority of incentives are to withhold data, and to keep it as a part of what we compete on, and compete for.

And so, I'm just, what I struggle with in this process of trying to direct our nation in this quality measurement process is how we can use Meaningful Use to overcome some of these huge issues that are not going to be solved by one program? So, I'll throw the question to the panel. How can Meaningful Use play a role in ensuring that we are collecting and sharing the information about what we know is already going on? We know that people are tweaking existing measures or making their own measures in order to provide useful information. We know technology is not a problem. Technology can do whatever we tell it to do.

So, how do we use Meaningful Use as a lever for advancing the major development process? Because, it seems to me like we have a federal program that is an incentive, it's not an entitlement so we're not going to be imposing anything on anyone, there's money linked to it and we already know that the quality measures that we're getting from it are really fairly limited in their usefulness to actual improvement. So, if we are just now learning how to meaningfully use technology, can we not use this program to develop more meaningful measures?

It seems to me like that might be one of the better things we could do in this program. So, first of all, I will put that out there as kind of my own soap box but also to ask you guys if you agree or not and if you do agree, what might we do very concretely in Stage 3 to actually collect measures and advance the measurement process in ways that benefit everyone rather than just imposing more requirements that increase the resources required to achieve what we are after?

Phyllis Torda – Vice President for Strategy and Quality Solutions Group - National Committee for Quality Assurance

Floyd nominated me to go first.

Keith Boone – GE Healthcare

This is Keith Boone, I'd like to put my card up.

Eva Powell – National Partnership for Women & Families

Sure, okay, that was Rich?

Keith Boone – GE Healthcare

Keith.

Eva Powell – National Partnership for Women & Families

Okay, Keith, thanks.

Phyllis Torda – Vice President for Strategy and Quality Solutions Group - National Committee for Quality Assurance

A couple of reactions to your question, Eva. First of all I think one of the real opportunities that Meaningful Use offers is the ability to bring together the certification requirements with the measure reporting requirements and that is an opportunity to bring together different stakeholders to make sure that the EHRs can meet the needs of all the stakeholders in the programs, and that's a really important lever. With Stage 3 now, you know, Stage 2 more or less behind us, some people probably don't feel that way, but, getting there, we have the opportunity to plan and we have the opportunity to now look forward, I think, and take a very deliberative approach.

And then just one final comment. I think when we talk about testing, we all had limited time. So, it's really important to kind of disaggregate that concept. There is some testing that we need to do for new measures and it's regardless of whether they're e-Measures or any kind of measures and that goes to the basic properties of the measures, their importance, their reliability, their validity, those are independent of data source and then there are some aspects of testing that relate to data source. And we need to really think...disaggregate those when we talk about testing and as I tried to suggest in my remarks, think about what can be tested in a more laboratory environment and what absolutely has to be tested in actual sites, and try to separate those as much as possible.

Eva Powell – National Partnership for Women & Families

Great, thanks. And Keith or sorry, Floyd.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

...response to you as well, so I think when you ask for how can Meaningful Use in sharing information encourage better information, basically, if I interpreted it correctly, but one is by creating the ability to have standard value sets. I've heard this discussed in the other presentations. The Clinical Quality Workgroup of the Standards Committee Essential Components Tiger Team, I won't use an acronym for that because I don't have one, actually recommended on, I believe it was May 24th, that there should be a central location for value sets that they can be curated centrally, kept up to date centrally and I think that can help create a method to standardized how data are used.

I think it's also important, and I heard that addressed in other panels today, that there are essential components that are needed for really high priority, high impact conditions and issues. And again, it comes up that it's often ejection fraction, gestational age, cancer staging and there are others that have been suggested. So, if there were a standard data set that could be used across settings that would be helpful, it would also be helpful to learn from systems that do things well. What are standard elements that they use to do that. We currently at NQF have what we call an e-Measure learning collaborative where we look for collaborative input from all stakeholders to be able to have that kind of input. How does this work, how do you make this work? And I think those are things that the committees can assist with.

Eva Powell – National Partnership for Women & Families

All right, thanks and then Keith you had some comments?

Keith E. Campbell, MD, PhD – Director of Clinical Decision Support - Veterans Administration Office of Informatics and Analytics

Sure, yeah, let me just add that, you know, to reinforce the idea that a central location for standard value sets I think is something that we really should work toward. Today, you know, for example, with regard to

the pressure ulcer work that we've been doing, looking for where the data comes from, you know, some people are recommending a combination of clinical LOINC for stating question plus SNOMED for representing values and how does that fit in with the collections that we're supposed to be doing with ICD-9 CM or in the future ICD-10 CM, that makes it very difficult, you know, to decide what to pull together, how to pull it together given, you know, different ways that this data is encoded and if we put some effort on, you know, central locations for standard value sets, and there has also been some consolidation within the encoding standards areas as well with the international support for SNOMED, I know that there are good discussions going on between SNOMED and LOINC for example as to how they can interoperate better. There have been successful agreements with the World Health Organization regarding ICD and SNOMED as well as the general medicine device nomenclature organization as well.

So, I think that we've made tremendous progress here. And we're close to that goal, but I think just pushing, you know, into the end zone, if you will, on trying to get some centralized locations for standard value sets that are consistent and coherent with regard to our encoding standards would be a tremendous accomplishment.

Eva Powell – National Partnership for Women & Families

All right, thanks, Ferdie?

Keith Boone – GE Healthcare

Okay, I'm going to try to jump in again.

Eva Powell – National Partnership for Women & Families

Oh, sorry, that's Rich on the phone?

Keith Boone – GE Healthcare

This is Keith Boone.

Eva Powell – National Partnership for Women & Families

Oh, there are two Keith's, okay.

Keith Boone – GE Healthcare

Yeah, sorry, there are two Keith's.

Eva Powell – National Partnership for Women & Families

Okay, go ahead.

Keith Boone – GE Healthcare

On the issues being discussed in terms of measurement and some of the challenges with measurement, I liked what Floyd had to say about trying to push things a little bit sooner, you know, in the previous panel we heard how clinical decision support was supposed to implement and improve the processes. We also heard in the first panel about the fact that there was a lot of variability in the processes.

I think one of the challenges that we have in terms of measurement is that we need to look at how we actually define the clinical processes so that we can understand well what are the value sets that we need to capture, what is the data that we need to have to be able to measure whether we're doing a

good job?

I've spent, you know, more than two decades out of healthcare I've been in the software industry where I was deeply involved in process improvement programs like ISO 9001 and SEI CMM and it was all about making sure that you had a process to start with that you could measure and would have measurement built in so that you weren't trying to measure after the fact what was happening, but that the process itself was designed in a way that it was measurable and I think if we look back at, you know, the guidelines that

we're actually starting from and figuring out how to take those guidelines and turn them into value sets, and decision support rules, then the measurement piece would sort of just flow naturally out of that.

Eva Powell – National Partnership for Women & Families

Great, thanks and then Ferdie we'll go with you and then we'll go to Leslie.

Ferdinand Velasco – Vice President and Chief Medical Officer of Texas Health Resources – Chair HIMSS Quality, Cost and Safety Committee

So, first of all, I'm gratified that several of the co-panelists have reinforced our first recommendation which is the importance of the standardized value sets. From the provider perspective I'd like to take a different angle to your question, Eva, which is, you know, how can Meaningful Use and that policy process help drive what we've been talking about all day? And I actually kind of look at this from the glass is half full perspective and I think actually Meaningful Use has already made a tremendous amount of progress in this area.

From the provider perspective, we now have IT professionals, quality professionals, people doing CDS working together because of the Meaningful Use framework, because of the EHR incentive program and so I think the opportunity is to catalyze the progress that's been made to advance that further. When you think back to, you know, historically how things were done with manual chart abstraction or relying on claims, the traditional model has tended to silo those different constituencies and the Meaningful Use Program has helped to bring these different stakeholders together, and I think that's the opportunity ahead of us with Stage 3.

Eva Powell – National Partnership for Women & Families

Thank you. Leslie?

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

Hi, Leslie Kelly Hall and I'd like to really have the panel comment on something we heard earlier from Dr. Goldstein and it was really this idea that we cannot predetermine need. If we truly want to have quality measures be effective it needs to be in a moment of care and prospective, not analysis on population data, but with each individual at that moment of care. So, designing quality measures and CDS that allow you to take care and also not predetermine need seems to be a valuable response.

The work that Rich is doing with Query Health helps support that because then we have ability to gather what might be needed in a standardized way with standardized value sets but be able to retrieve that information on demand and so the comments that John made about innovation and use of data might be a good platform to think about designing for that future need rather than dwelling on so much retrospective use. We don't cure health populations at a time. We cure diseased patients at a time. So, I'd like comments from Rich and John specifically and then the rest of the panel as needed.

John Schrom - Epidemiologist - Rock Health

I would be happy to let Rich go first.

Eva Powell – National Partnership for Women & Families

Rich, do you have a comment?

Richard Elmore – Office of the National Coordinator – Query Health

Yeah, I mean think that there are two levels of care. Obviously there is care for the patient and I think that the country very much needs to be thinking about, you know, care for a population of patients. And a lot of times there are learnings from the population that can help with the care for the patient. So, there is kind of a virtuous cycle there. And I agree fully that we cannot predetermine need and one of the problems I think that we have right now is that we kind of agitate and cogitate over what measure and how it's going to be defined and all this rather than having kind of a learning system that allows us, as we are, you know, are in the moment and learn more about a particular disease, disease state or condition or epidemics, to be able to inform better the questions we need to ask and in rapid succession, rapid cycles to be able to get into improved answers.

Right now, each epidemic, each healthcare in this country is another major project because we have no way to ask the questions we needed to ask. It doesn't take complex and a lot of data to be able to ask a very important set of questions. But, we won't know what questions to ask until and unless we're at that moment. So, I think this whole notion of Stage 3 of improved outcomes of a learning healthcare system of the committee's keeping their eye on that prize, we need incremental improvement, no doubt, and I think that the recommendations we get that are incremental need to be considered as well. But, we need to make sure that we are making the change toward a dynamic ability to be able to ask questions and get answers.

Keith E. Campbell, MD, PhD – Director of Clinical Decision Support - Veterans Administration Office of Informatics and Analytics

Yeah, hi, this is Keith, can I comment?

Eva Powell – National Partnership for Women & Families

Sure.

Keith E. Campbell, MD, PhD – Director of Clinical Decision Support - Veterans Administration Office of Informatics and Analytics

I think one of the things that we need to do is to transition, you know, the quality measures that we're working with are course measures that are built up of a lot of smaller finer grained measures and that in order to be able to collect data effectively that we can then analyze for high level, sorry, you know, for aggregated measures that we didn't anticipate at the point of care at the time we were collecting data, we need to be pushing to finer and finer grained data about what actually happened at the point of care which then through queries or other aggregation techniques can then be used to develop these quality measures after the fact.

Eva Powell – National Partnership for Women & Families

All right, thanks and John, do you have a comment?

John Schrom - Epidemiologist - Rock Health

Yeah, I'll just piggyback off what Rich said and maybe even address a little bit of the question that was asked before this, but I was an epidemiologist at HCMC with Dr. Larsen and a number of other people here and I worked in the HIV clinic and I remember about a year or so ago there was a syphilis epidemic that had started in Minnesota and since I had access to all of the clinical information that existed in the EHR, which is something that's unique, that, you know, the Department of Health doesn't have access to, I was able to identify that there was an increase in our positivity rates, the types of people that were coming in more often and getting tested, and tested positive, and we were able to actually immediately change the kind of care that we were providing, that is test the people that needed to be tested two months before the Department of Health even caught on that there was an epidemic.

So, to your question about, I don't even know if I'm going to answer your question, but I'm just going to talk about syphilis, but I think having a more nimble system that's able to...you know, you sit around and

develop measures and that's a very important thing for quality long-term, but when it comes down to almost blending the quality measurement and clinical decision support systems to be able to say there is this change that's happening and here are the people, not high-level you should be testing people for syphilis, but here is a John Doe that's coming in today right now that needs to be tested, that's something that's really powerful, and I think one of the ways to do that is by changing the NQMC to be more dynamic, and be able to interact with information as opposed to just being in one standard place. I think that...I don't know if I'm answering your question at all but hopefully I'm hitting on some points.

Eva Powell – National Partnership for Women & Families

Thank you, Floyd and then we'll move onto Rebecca.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

So, I actually like the way this discussion has been going. I think I want to clarify a slight difference between the ability to query and look, and learn which I think needs to be on the same data model so that you can describe what you're looking for and create your query the same way you will for a measure. There is a slight difference between that, though, and what we want to use to evaluate provider's performance that gets used in value-based purchasing, and perhaps performance would be based on that provider's ability to access data quickly if that were a measure that were developed.

But, I think the same data model to do this, the same mechanism needs to be there. But, I think there's a difference between performance measurement for transparent reporting of performance comparing to what I can access because I need to know the information and it's often the result of the performance measure that tells you what you need to know as well. So, I think there are a number of discussions in that same group, but they all do need to be based on the same way to do easier queries to get data out and to use the same model.

Eva Powell – National Partnership for Women & Families

Okay, thanks. We'll move onto Rebecca?

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)

Yes, there's actually quite a few similarities in what needs to happen with e-Quality measures and with research, and I've been looking at this over the last decades, and especially when it comes to needing to do complex analysis being able to identify a core set of data, and being able to define it very clearly what you're looking for. So, I'm just wondering if you all could address what you've done to leverage the work from critical research and the development of clinical research standards which are open standards, and have been developed over the last 15 years.

Eva Powell – National Partnership for Women & Families

Go ahead, Floyd.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

I'll give a limited approach, this is from my personal experience I know that one of the reasons, a group called Integrating of Healthcare Enterprise, when it started a new quality domain didn't just call it the quality domain we called it, well I was there at the time, so I said we, but we called it the quality research public health domain feeling that through the analysis of the public health folks and research that the same data model should work across all, it's the same information we need in and out of the electronic record, should be the same value sets. So, from that perspective I think the same platform is important. And the more we can use the same value sets, the same registry I think the more we can support each other in this realm.

Eva Powell – National Partnership for Women & Families

Thanks. Others in response on the phone? Oh, go ahead Ferdie.

Ferdinand Velasco – Vice President and Chief Medical Officer of Texas Health Resources – Chair HIMSS Quality, Cost and Safety Committee

This is Ferdie Velasco, I think the exciting opportunity is because of that opportunity to leverage the same substrate for research and quality measurement, we have an opportunity as guidelines emerge from that research to almost sort of pre-populate or pre-identify the clinical measures that then go into

production, if you will, to then evaluate performances as you mentioned.

Eva Powell – National Partnership for Women & Families

Great, thanks, any comments on the phone?

Richard Elmore – Office of the National Coordinator – Query Health

I would just add that some of the Query Health pilots are in fact research oriented and there is one that is...the FDA is actually looking at use of Query Health standards to be able to address what kinds of questions of interest or post-market surveillance can be addressed by the systems clinical records and so that's one example, there are some others as well where researches are leveraging Query Health standards in these pilots and have been doing so in distributive ways prior but without the benefit of standards.

Eva Powell – National Partnership for Women & Families

Great, thanks. I just wanted to do a quick check, assuming that we went over by 10 minutes into this session we get to add 10 minutes? Is that correct or not?

Marjorie Rallins – Director of Measures, Standards and Informatics for the Performance Improvement Division – American Medical Association

I think that's the moderator's prerogative.

Eva Powell – National Partnership for Women & Families

Okay, well then we'll add 10 minutes, and so we've got then right around 30 minutes left and 1, 2, 3, 4 more comments. So, I just wanted to quantify that since we're talking about measurement. So, we'll go with Helen and just move down the line.

Helen Burstin – National Quality Forum

Great, glad we have more time. A couple of related comments and a question. So, I really liked Ferdie's language of leveraging the same substrate, I think that's actually the key here. I think one of the things I was struck by in the last panel, and I think perhaps in this panel as well, is the fact that while it's the substrate they don't need to be the same and I think we continue to think that everything we put in CDS needs to be measurement, and I think I'm hoping we start moving away from that. I think CDS is a great place to instruct on the process, say this is what's evidence-based go in this direction, because if we increasingly move measurement toward outcomes we get to the better measures we think matter that align with the National Quality Strategy, but we also don't burden I think the EHR down with so many of the exceptions and exclusions that we're currently I think really suffering under.

So, I guess my question there is, as we try to get to those measures that really matter, the ones that I think are perhaps more outcome oriented and certainly more meaningful, we're going to have this really tough interplay due to the fact that many of those EHRs won't have those data. So, I guess my question for you is we talked a little bit about testing and the importance of course, as Phyllis knows well, of testing the reliability and the validity of the data. So, I think there's a new piece of this that I'd like to get your thoughts on which is actually the feasibility testing.

What needs to be done to ensure that the measures we're bringing forward actually can be feasibly collected with the EHRs we have now or what's the path toward ensuring that the key data elements to get to the measures we need can actually be collected and I don't think we have standards for that. We've talked about this a bit with Kevin and Jacob, but I'd like to hear from the development folks.

Phyllis Torda – Vice President for Strategy and Quality Solutions Group - National Committee for Quality Assurance

Okay, so I'll start with that, you know, I think that we need more explicit policies about what we mean by the term feasibility. I don't think that we mean at this point in our evolution that it's feasible today, that the testing methods that we've designed or we've had to use out of necessity test whether something is feasible today, whether the data elements are collected or EHRs can easily be modified to collect them.

So, I think as a national policy in conjunction with Meaningful Use and maybe other initiatives as well, we need to define feasibility and if it's tested in a laboratory environment and if we know some types of sites can implement those measures it that good enough, you know, it's really a matter of what's good enough? Do we want to look that a range of sites can do it, any few sites, you know, the most advanced sites, a range of sites? We're never going to be able to test and again what can we...how can we...I

think feasibility in large measure can be evaluated in a laboratory environment that is then rolled out to the sites, but then there's some very specific pieces of information that need to be gathered. I had another thought, but I can't remember it so I'll stop.

Eva Powell – National Partnership for Women & Families

Okay, Ferdie?

MacKenzie Robertson – Office of the National Coordinator

Do you know also Eva that Robert McClure has a card up online?

Eva Powell – National Partnership for Women & Families

Okay, sounds great. Well, why don't we go to Ferdie and then to Robert, and then to Floyd.

Ferdinand Velasco – Vice President and Chief Medical Officer of Texas Health Resources – Chair HIMSS Quality, Cost and Safety Committee

Well you asked a great question, Helen and I agree with you, we do need to encourage and test for feasibility and I think that as a byproduct of moving toward outcome measures as opposed to process, I think that will happen. I think that we can certainly strive for more simplicity and I think as Floyd mentioned, as the focus shifts from retooling existing measures and really focusing on new measures, we have an opportunity to have that mindset up front and I know this committee uses the word parsimony a lot in terms of the number of measures, how about thinking about that in terms of the complexity of the measure specifications

And then the last comment I'll make is in terms of the testing of feasibility, you know, logistically, frankly

it costs organizations to do that whether it's EHR vendors or whoever is going to help facilitate that and, you know, in the care of field testing, providers really need to be incentivized and there are organizations, mine certainly would be willing to help pilot some e-Measures or field test them, but we can't do that on top of meeting our regulatory requirements and so that needs to be considered as well.

Eva Powell – National Partnership for Women & Families

Great and then on the phone, Robert?

Robert McClure – Chief Medical Officer - Apelon, Inc.

Hi, this is Robert McClure, can you guys hear me okay?

Eva Powell – National Partnership for Women & Families

Sure, go ahead.

Robert McClure – Chief Medical Officer - Apelon, Inc.

Great, I'm the Chief Medical Officer at Apelon and on one of the Quality Workgroups. First, actually a short comment on this last set of issues about what I would characterize as pushing. We talked about this in our quality group. Pushing the expectations in terms of meeting the ability of EMR systems to capture data that are important in the kind of what I think is being characterized as the small data issues as opposed to the big data that's happening across the road there and what we've found is that in many cases the kind of discrete information that's necessary to really drive meaningful impacts on care for particular patients, this small data issue which I think is absolutely critical, EMR systems don't collect that data and sometimes it's not because it's too complicated or very difficult it's just simply not the sort of thing that EHRs were built to collect. And so, I think we have a real, well dilemma is not the right phrase, but a real important activity about how far can we push that process by putting in place expected Meaningful Use measures that are going to require changes in EHR systems in order to be able to capture that?

For example, the ability to time mark things because it's common that certain measures require that activities occur in a sequence under certain time constraints. So, if certain activities occurring, as I say in a sequence, and often times that sort of information is not captured readily so that a system that would do

an automated analysis could actually get access to it. So, I think that's a very important dilemma that this group needs to address in terms of expectations on conformance.

But, I wanted to talk about something else and that was there have been a number of speakers who've talked about values and the importance of consistency, and access to value sets that. I find that very important also and so I'm wondering if the panelists could speak to whether they would find value and participate in some kind of system that allowed for open description of value sets, now, in my opinion, these would need to be tied to information models that, and in doing so create an open collaborative, and vetting process, and having done that, whether there would be interest, and even I say among some expectations that those value sets would then be used in their systems? In essence, I'm asking if the solution of value sets is to create an open and readily available source for very discrete model driven measure aligned value sets, if that's the solution. That's my question, thanks.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

I'll start, I'll let the panel...other comments. So, first of all I want to thank you because when my 5 minutes was up that was my next statement that I didn't make in talking about value sets, thank

you, Rob.

I think there are three things that were discussed basically in the Essential Components Tiger Team and they were development of the value sets based on the need and the intent, curation to make sure they're up-to-date, they don't use retired codes, they add new codes when needed, and they use the underlying code systems appropriately. But there was also validation and I think that's what you talked about just now and that is that among a broad set of stakeholders, publicly and transparently those value sets can be reviewed. The challenges with that is the governance for that needs to be clearly defined because it sounds like a good idea, but we need to know how that should be done.

There are questions about ownership that come into that, are the value sets owned and is it okay for someone else to force a change on someone else's own set? That's the governance issues and I think they can be resolved and Policy Committee perhaps can help us a lot there. There are other areas about speed, because if the value set is a component of a query or a measure and it takes a long time to get it validated and approved per se, if you use that term, then that's going to delay the query. So, we would want to make sure there was a very agile process for maintaining it. I think it's useful, but we have to think about making sure that we address it properly.

Eva Powell – National Partnership for Women & Families

Other comments? Okay, great, thanks to you all, we'll move onto Marjorie.

Marjorie Rallins – Director of Measures, Standards and Informatics for the Performance Improvement Division – American Medical Association

My question relates to, thank you, Eva, my question relates to alignment and coordination because I think this will be very important with standard setting and policy setting. If we're moving toward linking more closely quality measurement and quality improvement there needs to also be close coordination amongst the communities and stakeholders that are a part of the life cycle of quality measures, that's not an earth shattering statement.

But, let me give you an example, so there are...when we look at developing quality measures there are sort of three major communities and I apologize if I leave another one out, but there are those that conceptualize the measures, the measure developers. There are those that prepare the measure for implementation or specify the measures. And there are those that actually implement the measure. And within each of those communities there are surface recommendations.

So, for example, there has been a recommendation from the specification realm to limit granularity or pre-coordination and concepts. And then there is another recommendation to impart parsimony in data

elements, but, each one of the communities also needs to be aware of that. So, if the measure development community is not aware of some of the recommendations that come out of the other communities then we're never going to get I think the alignment that we're looking for.

So, I would ask the panel if you could speak to that. I know Floyd and Phyllis those are issues that you wrestle with as well. Go, ahead.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

I don't want to take the whole microphone, but I'll start. So, first of all there are two things that I can say about that, one is I think there needs to be education of all the communities collaboratively because guideline developers don't always understand what's really there if we're talking about EHRs and what's available and what's not. Measure developers are learning quickly because of often the Meaningful Use Program and other reasons. But I think there needs to be clear education and also collaboration. So, a learning type of collaborative to help people learn and identify issues.

We need to...if for instance we need to know a certain kind of information, then there may be folks out there in implementations that are already dealing with it, but we don't have to...we have to think about it differently. So, one of our HITECH our advisory committee to NQF members commented at our last call that there were a lot of requests being made for pre-coordinated terms in the US domain of SNOMED that didn't seem to fit with really what would be found and a lot of that was because, it's hard to tell, and I don't want to pre-suppose but a lot I believe is because those who want to know information don't know where else to find it. So, I think there needs to be give and take to be able to understand that more clearly.

And I'm really happy that John Schrom is on this panel because the other thing I heard that's always been something I want to think about is what is it that the patient gets into Facebook, into their Fitbit or that knows their exercise that could get to a record that could give information so we don't have to ask the physician another burdensome question. How can we encourage information that exists in the scale in the patient's home on the Fitbit, etcetera and I have no stock in Fitbit and I know nothing about...no disclosures needed, I do not own stock in Facebook either, which I think is a good thing right now.

But, I think we need to think about other sources that came up in other panels. We should, I've heard have people work at the top of their license. The patient should work at the top of the patient's license or the individual. So, just as a thought, how do we keep the education going and get people talking? I

think an open collaborative is a way to make some of that happen.

Phyllis Torda – Vice President for Strategy and Quality Solutions Group - National Committee for Quality Assurance

This is Phyllis, so just to reinforce your point, Marjorie, we fully believe that all measure development and implementation should take place in a multi-stakeholder environment and, you know, let me just, you know, I think this committee is an example of that, the other committees and many measure development activities, and NQF activities are examples of that, but you cannot understate the importance, you know, as I tried to suggest, we have been trying with enthusiasm and good faith to move forward on some of the measure recommendations that came from this committee actually for Stage 2, and run into some barriers, and we welcome the opportunity to come back, you know, and trying to do that today, share with you some of those barriers, and then have the various stakeholders put their minds together to address those barriers, because they're real, but I'm sure they can be overcome. So, I think you just can't overstate the importance of common understanding of what the state-of-the-art is and bringing together multiple minds to address barriers.

Eva Powell – National Partnership for Women & Families

And just kind of as a follow on, and maybe John has some input and it's jumping off of Floyd's point, too, is how we can better infuse patient's input into all that too as a major stakeholder?

John Schrom - Epidemiologist - Rock Health

I think a lot of this is happening with the development of patient centered medical homes and, you know, it's interesting. I don't typically think of measure development necessarily at this level, I think about it at a hospital level because that has generally been my experience and it is a multi-stakeholder process, and I've sat in rooms where patients are providing their input into the types of things that we're measuring too and so, more generally, I would wonder if there is a parallel process to take advantage of all of that work that's being done at a hospital level to...you know, if you everyone in the room, you have them making decisions, again if you can put all of that information in something that's machine readable, transmittable, sharable and then kind of let, I hate to use the term free-market, but let all the folks figure out well what are the good measures that Hennepin County figured out, what are the good measures that Stanford is working on, like what are...kind of moving in that direction, but, yeah to the point about patient...I think that's my comment.

Eva Powell – National Partnership for Women & Families

Great, thanks. Moving onto, is it Larry who is next?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Sure, I seem to have a question for every panel this time around. So, I want to pick up this notion of parsimony and also the thought of how do we kind of move forward a broad national agenda when, you know, we have very large data sets and very large vocabularies we're talking about and so the question I have comes out of some of this morning's comments. Could we...feasibility test with you guys, could we pick a very small like 1 or 2 areas to focus on and then look to the EHRs to actually granularly code just those things so we get away from the checklist kinds of measures which we seem to have had a lot of in Stage 1 and actually start to look at data models appropriately coded in the right standard languages and use that, if you will, as sort of the boot strapping method to get technology embedded in the EHRs that would enable a much more broad-based ability to handle coded vocabularies to allow for data to be in more than one place, you know, things could be on a problem list, they could be an assessment, they could be in a patient questionnaire, they could be in a demographic registration piece.

So, the data could be in a lot of places and I want to get out of this the data is trapped in one place in the record and actually get to the value traveling with the data. So, comments, thoughts about how we get focused and sort of get the wheels spinning?

Keith E. Campbell, MD, PhD – Director of Clinical Decision Support - Veterans Administration Office of Informatics and Analytics

Yeah, hi, this is Keith, can I comment?

Eva Powell – National Partnership for Women & Families

Yes, go ahead, go ahead.

Keith E. Campbell, MD, PhD – Director of Clinical Decision Support - Veterans Administration Office of Informatics and Analytics

So, you know, what you're suggesting, to take a small area and, you know, do it at a granular level is exactly what we're trying to do within the VA with the pressure ulcers and the deep venous thrombosis. A lot of that work has come out of us, some really good work in a number of nursing communities that have folks on it and I know that at least there has been collaboration between VA nursing, Kaiser nursing and several other bodies to the IHTSDO on this topic. So, you know, in short I think the answer is "yes we can" and actually we're starting in that direction.

Eva Powell – National Partnership for Women & Families

Others? Ferdie?

Ferdinand Velasco – Vice President and Chief Medical Officer of Texas Health Resources – Chair HIMSS Quality, Cost and Safety Committee

Sure, this is Ferdie Velasco, that's sort of a leading question, but I think its fair one and I would agree that the answer to that is "yes" that there is definitely an opportunity to do precisely that. I think an aspect

also, you know, sign towards parsimony is not just the value sets themselves but the complexity of the specifications. So, when I was asking, you know, the folks on my team that work on these e-Measures, what are some of the challenges that you face in trying to implement the Meaningful Use measures? And one of them is the complexity of the specifications. We have exceptions to the exclusions, you know, that you have to deal with.

For example, in stroke 3, I think that's the antithrombotic or anticoagulation for stroke patients, there has to be explicit documentation by the physician or the nurse that the patient has a bleeding disorder. Well that's already documented in the problem list and we're certainly encouraging the use of the problem list, why can't that be adequate for excluding those patients from the denominator? That's a legacy of our retooled measure is that has that kind of language built-in. Does that need to be preserved as we go forward with these de novo measures.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

So, just to make a comment on that, just because I think it's very valuable is that is exactly a legacy and that's one of the kinds of things that would be something that would not sound reasonable for someone to put in a new SNOMED US domain code to say physician said it was true when in fact you can find it on a problem list because it's a condition and I think the other answer to your question, though, is I did hear, through this morning's testimony, that there is somewhere between 5 and maybe a maximum of 25 key elements that are important in order to look for outcomes of care in really high priority, high-cost areas and I think some number between there certainly makes sense that if all EHRs could manage those data and pick data that have been really problematic to get and there are a number of items around that to know the patients are getting better, I think that could help move it forward quite well using specific value sets and handling it in a standard way.

Phyllis Torda – Vice President for Strategy and Quality Solutions Group - National Committee for Quality Assurance

This is Phyllis, if I could just add my two cents here. I think that we're throwing at you a variety of problems and they need to be bucketed, you know, based on our experience to date and then, we need to look at different types of solutions for different problems. Some of the early focus of Meaningful Use was really on primary care and getting at some of the major determinants of population health. There the issues may be less measurement oriented, but how to move from measurements to clinical decision support because we know that no matter what we think people still are only get the right thing at the

right time just over half of the time. So, those may be different type of issues.

Then, there are some of the issues that were referred to that were related to particular epidemics or, you know, public health crises, or more very narrow situations in which we're in a research and an evidence development stage so, I just would encourage you not to look to sort of one-size-fits-all kind of solutions, but to develop, and we'd certainly be happy to work with you, a typology of issues that we would now like to further explore solutions to.

John Schrom - Epidemiologist - Rock Health

I would just go back to...and this doesn't directly answer your questions, but getting more easily accessible data, if there is an API that's accessible then folks like me are happy to develop solutions to pretty much any problem that you can solve without having to go through an EHR, I mean and there are plenty of vendors that I think are sitting in the room right now that could do similar if they just had access to the information. So, when you mentioned focusing on a narrow area and perhaps having measures developed for that area and encoded in an EHR, you could just make it a really broad issue, but if the data is available, then I mean everything is possible if the data is available.

Eva Powell – National Partnership for Women & Families

All right, thanks, any questions on the phone?

MacKenzie Robertson – Office of the National Coordinator

Rich Elmore is on the line with a question.

Eva Powell – National Partnership for Women & Families

Okay.

Richard Elmore – Office of the National Coordinator – Query Health

Actually it was to an earlier question, but I do think that there are a couple of threads that come together, I think Ferdie mentioned earlier about the need to, you know, stay practical in terms of the measures and ensuring that there's some real world test of those measures. I think that that would be applauded by many of the different, you know, communities that are working collaboratively on this to make sure that in fact it is practical, that it fits in a providers workflow, that it's testable, I mean the numbers of combinations and permutations, the testability issues of some measures, you know, like asthma medications which have 33 different medications or so are counts, I mean it's almost impossible for it to be correctly tested. And so, you know, making sure that we're staying very practical in terms of what we're doing I think will make a big impact in terms of the results that we get from individual measures.

Eva Powell – National Partnership for Women & Families

Great, thanks. We've got, by my clock, if we're doing our 10 extra minutes, about 6 minutes, so Paul we'll go with you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I will be fairly short. So, Ferdie mentioned wanting to keep the queries simple and there was a previous panelist who said the simpler the query, the more the exceptions or the more the exclusions. I wonder if...I think they're both right. So, I wonder if we can find a simple query. So, we typically look at a problem...it could be a disease and you take the whole disease and of course nobody is alike. I mean there is no one-size-fits-all. Can there be one size that fits the right population?

So, there are high risk folks whether it's a condition or a prevention, there are people more at risk. Can we just identify those with essentially a narrow inclusion rather than taking a broad swath and then trying to find all the exclusions? Do you see the new paradigm I'm trying to see? And it's possible that small inclusion could be identified with structured data. What do you think about that?

Ferdinand Velasco – Vice President and Chief Medical Officer of Texas Health Resources – Chair HIMSS Quality, Cost and Safety Committee

It sounds pretty reasonable to me, Paul.

Phyllis Torda – Vice President for Strategy and Quality Solutions Group - National Committee for Quality Assurance

This is Phyllis, let me try to give you a couple of reactions. The narrower you go with a population of course the more likelihood you're going to run into a small numbers problem, so it's really important to think about what's the unit of accountability here and by going narrow are you going to get into a situation in which the measurement really isn't telling you anything because it's such a small number.

The other is we often include exclusions for face validity reasons because the clinician say, well you wouldn't do this for this patient and you wouldn't do this for that and, you know, you're sending a message. Sometimes we have found that basically with sensitivity testing that by showing...that including, making the exclusion really doesn't have that great of an impact and it doesn't change overall relative performance or the direction of performance you can then get rid of the exclusion. So, that's another tactic.

W

...follow up to Paul's question because I think it's a great one is that the other risk you take is you'll wind up with a population that's actually not very representative. So, you may recall for example we've had some measures that have come to NQF that wound up being such a small subset of the population of interest it's not relevant it's sort of like reading some of the clinical trials and the big journals where

they've chopped out every single patient who looks like my patient, so that's the danger. But, on the same hand if you actually have good rich data in an EHR you should be able to risk adjust and get to the outcomes and perhaps stay away from some of those process measures which are going to be more laden with exclusions.

Arthur Davidson – Denver Public Health Department

First, of all in terms of what Paul just asked, since Blackford brought it up this morning about having created rules for all of immunizations that might be an area, since you mentioned prevention, that might be an area where we could leverage some of the work and make that available on a widespread basis through EHRs. But, I have a question for Rich Elmore about clinical element data dictionary. I think you said that you had maybe three or four different sites in EHRs where that's been implemented. How long did it take to take data from those different native EHRs and put it into that CEDD? What's the level of effort there? And if we try to promote that, is that something that's scalable or reusable across many different sites? Have you done it in more than one site with NextGen or Allscripts and at each site is it different or is it...? Can you actually reuse the effort from the first one?

Richard Elmore – Office of the National Coordinator – Query Health

Thanks for the question. So, the pilots themselves are just starting underway now. So, the first kickoffs are happening now through the end of the summer. So, I'll have results on that to report back in, you know, the summer through the fall. There is not a presumption that the data will be moved into a clinical element data dictionary. The idea is that there is a means of being able to describe in a standards neutral way the data target that would be available for being able to ask a question and the implementation of that would be up to the individual EHR developer. So, once it's developed and once it's implemented into the EHR system, the expectation is that the time to be able implement into individual provider sites is very rapid. The timeframe for EHR vendors to be able or others, other clinical record systems to be able to do that will have a better read on over the course of the next several months. The reference implementation work has been done in a matter of a few months.

Arthur Davidson – Denver Public Health Department

Thank you.

Eva Powell – National Partnership for Women & Families

Thanks and I believe we're right out of time. So, I'll turn it back over to who...to Marjorie.

Marjorie Rallins – Director of Measures, Standards and Informatics for the Performance Improvement Division – American Medical Association

Okay, so thanks again for the panel for your testimony and then we will move on to panel number four moderated by...Panel four will be moderated by Floyd Eisenberg.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

Excuse me, now that the panel is seated, I want to be sensitive to time, so this is Floyd Eisenberg, moderator for the EHR vendor perspectives of necessary components of quality improvement. So, again I reference the bios that are in the handouts for folks to read. I won't go through those. What's interesting to me is this may be the last panel of the day, but everything we've heard of through the clinical decision support through the organizations trying to implement through measures it all depends on you. So, this panel should help to answer it all, it's how to get the data, how to standardize it, how do you manage the clinician workflow, how do keep your customers happy so they come back and how do you manage to export the information you need to? So, I wait to hear this. Thank you. Jason?

Jason Colquitt – Vice President - Greenway Medical Technologies

All right, thanks a lot. I want to thank both committee's the Policy and Standards Committee for the opportunity to speak. My name is Jason Colquitt I'm Vice President at Greenway Medical Technologies based out of Carrollton, Georgia. I know we all and you've heard throughout the day different lenses we all bring to the table in different vantage points, some positive, some negative, to the difficulty of these

tasks, I think that's a conundrum these committees have of how do we take all of these lenses meld them together and make everybody happy?

So, today in the beginning I'll kind of outline the lenses that I wear because I think you'll see that we all in this panel wear, even though some people say EHR and they think that's all one, we all bring different lenses to the table and where we sit within our prospective companies. So with that, kind of what's Greenway or what's the lens of Greenway? We are an electronic health record and practice management, and interoperability solutions, technology solutions. So, we are one, we've been one since the beginning. So, some people say EHR, not practice management. So, in our case we have all that in one database.

Our solutions are leveraged only in the ambulatory environment. There are various forms and flavors of that but that's the space in which we play. We have over 33,000 providers that use our solutions to capture clinical, financial, administrative information and represents 20 million patients or over 20 million patients. So, that's kind of the lens of Greenway. My focus at Greenway, where does that lead? I've been blessed to be at Greenway for 12 years. So, I've seen quite a bit of growth over those 12 years.

My current focus consist of leading a division, a data services division where we focus on analytics, business intelligence, care coordination, quality and research and we heard from Dr. Kush earlier about where does research fit into, I think again, back to the same cord that was hit, this is all important to figure all this out and don't want to be back in a research panel here talking about and starting back from the beginning, because I think a lot of the same questions are being asked across public health quality and research. So, that is kind of my focus at Greenway.

We have done Stage 1, 44 clinical quality measures, so my team has produced those so we have some focus and lens around that perspective of looking prospectively at that and retrospectively about where we've gone with quality measures. We're also a CMS qualified registry, we've been in the past PQRI, in the future now PQRS is the known, so we support 217 measures within that particular system, so we're looking through a lot of these same questions that are being asked here and how does our system portray that.

I also sit on various committees. So, Floyd kind of mentioned about the quality research and public health domain within the IHE integrating the healthcare enterprise, I've chaired that along with Floyd in the past. So, I bring an industry perspective. I also sit on the executive committee of the EHRA association. So, I talk with a lot of my colleagues across the board. So, in my written statement I kind of phrased a lot of stuff, I used the jeopardy method of I'm going to ask the question and you know the answer, some of these answers you'll say that's the \$500.00 question, we may already have answered but I kind of want to go through this a little bit and quickly, as my time is dwindling, but kind of say from our perspective looking back, so with all these lenses on clinical quality and looking backwards, and spring boarding forward what does it mean?

So, I think one of the first things I kind of hit on was the testing aspect, validation was key and I think we already heard that's an expense that we have to incur. Can we make that easier was my question? Are there standard formats? Are there manual set ups that we can avoid by automating a lot of these processes? Is there a test harness we can use to validate the output of this? Can we make this easier on ourselves? Can we use fully executable versus just, you know, just a custom written query that's going to produce these measure outputs?

The next reflection I wanted to kind of key in on my, again dwindling seconds, was that our providers leverage us and use us for a source of truth for these systems. So, we partner with them. I know on the earlier panels it was kind of the vendor is the enemy or not the enemy, but, you know, this party out here that's not interested in me. We see a totally different perspective from our stand-point and can tell you call after call where we sat on in and worked with a provider and their site through the system. We hit on the value set, so I'm not going to go there. The very important piece of this and as I have seven seconds, CDS, we've already had a whole panel on that. I think it's important to tie that back in to drive toward some of the questions or the data points that we need to have to in order to calculate these quality measures. With that I'll kind of turn it back over to Floyd and thank you for your time.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

Okay, well having been on a panel your five minutes always goes shorter than everyone else's. So, I'll move to Diane.

Diane Gilbert Bradley, MD – Chief Quality and Outcomes Officer - Allscripts

Thanks, Floyd. My name is Diane Bradley and I'm the Chief Quality and Outcomes Office at Allscripts and have been there in various incarnations for the last 16 years. As a physiatrist, a doctor who specializes in physical medicine and rehabilitation, the need to define quality outcomes with our patients and the importance of the interdisciplinary team in achieving those has always been a focus of my medical practice and has served me well as my biggest goal at Allscript was to work with the clients identifying the bright spots and then figuring out a way on how to disseminate that best practice. So, thank you for the opportunity to share with you today my perspectives on the quality improvement opportunities stemming from EHR adoption.

The delivery of healthcare in this country is evolving as we've heard all day and it's in a phase where providers and software developers alike must be integrating new processes and information into our systems and workflows and I just mean things need to be kinetic, they need to be fluid and one of the things that we can't do is cripple the innovation with our mandated quality measures, right? We've got to be able to move quickly.

So, from the vendor's perspective and it's something that affects our clients too, again we were talking today a lot the things have been mentioned in the different panels, but it's important to reiterate that there are systems like labs and radiology systems, and other EHRs that do not conform to the standard nomenclature like SNOMED and LOINC and we need to have those defined within the quality measures or else we're not going to be successful.

So, we have a lot of our staff that are forced to find alternative mechanisms to capture the required codes and the other thing that we're spending a lot of time on is education of the medical clinicians on what these measures are. So, we're finding that the implementation isn't just about the technology as it shouldn't be, but we're finding that there's a lot more interest from the clinicians and the clients about how to improve quality improvements. So, that's been a good thing for us for Meaningful Use.

In thinking about how we can collectively accelerate the quality lifecycle the obvious but nonetheless very important answer is analytics. We see analytics being applied retrospectively. We have clients who are now adopting both retrospective and the prospective, and then more importantly we're seeing as John was indicating in the panel earlier, accessed through the APIs to use other databases to do clinical decision-support in real-time, and we see that as a huge value add, and we're seeing more and more companies take advantage of that.

We have a startup called Rothman Healthcare that's been accessing the data and providing real-time decision support to the clinicians. So, that's the Holy Grail that we're all collectively working for and as this panel is about the vendors, I thought I'd share some thoughts about where we think we can substantially impact the effort to improve continuous improvement and that is in partnering with the client, and other vendors in implementing whether you want to call it evidence-based content or best practice, that there's a lot of information out there, and one of the things that we saw happen with Meaningful Use focus on stroke was taking the best practices from hospitals that had met the Joint Commission Criteria for stroke certification and then applying their best practices throughout. And then by definition they were achieving Meaningful Use on the stroke of measures.

And what we've seen in hospitals that have adopted a framework of evidence-based documentation through their interdisciplinary care plans, so if they're already doing the standard care for an orthopedic patient they're already doing the VTE prophylaxis, right, because that's standard of care. And what we're finding is that clinical decision-support that actually supports the critical thinking of all of the team members that says if you have a patient in the hospital in your bed that had a stroke, here are the 10

possible or the 10 common complications and you're looking for that and being very directed in the documentation instead of filling out a mandated head to toe assessment, we're finding that this helps standardize and that's really helping with the workflow of the clinicians.

My last point goes along with what John said in his last point which was that we have to allow for data capture and visual retrieval obviously, but the ability to access and download information from the patient is very key and our recent experience at the University of Massachusetts with a little company called My Care Team where they're taking the data from diabetic care and the patients are actually uploading that to their EHR has been very fruitful in terms of seeing the difference that that does in their care with the diabetes so that openness in the API that John was talking about is very important to us as we go forward.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

Thank you. Tom?

Tom Yosick – Software Developer - Epic

All right, thank you and good afternoon folks. I'd to thank you again for the opportunity to speak today. My name is Tom Yosick and I work in research and development at Epic we're a small Healthcare IT Company located in beautiful Madison, Wisconsin and in my role at Epic I'm a software developer by training. So, I'm a propeller head and what I do is help build capabilities into our software that allow our customers to clinical decision support at the point of care, but also then to take the data that they're capturing in Epic and use it for analytics and quality measurement.

As you've heard a number of panelist mention today we are blessed in some ways in the industry by having EMRs that collect a wealth of data. But, while we may be data rich I feel like we're sometimes information poor and that it's often times challenging to get data back out of the systems.

And as I talk to our customers who've implemented our EHRs I find there are a number of challenges that make reporting and analytics, and often time's clinical decision-support difficult when using EHR technology. And the first common theme I hear that has been mentioned a number of times is that often times we're being asked to measure data that's not actually captured in the EHR. And so as a software developer I don't have a magic wand and I'm not able to create analytics on data that's not captured.

So, part of our recommendation from a policy perspective is to make sure that when we're asking organizations to measure or proposing new quality measures that we try to focus on those data that are being captured ideally already in the course of clinical care or if not be thoughtful about adding new data collection requirements.

Now, often times even if the data are captured in the EHRs, as a number of people have mentioned, we see a lot of variability in how the data is captured sometimes for very valid reasons. Nurses and physicians, and specialists have very different workflows and they shouldn't all be forced to use the same tool, and so part of our opportunity as EHR vendors is to mask that acceptable variability so that when people ask questions of the data they don't need to understand the specifics of how it might've been capture because they're dealing with the information at a higher level.

However, we are often pressured by our customers to provide more flexibility and ways to allow them to customize and localize the way they use our EHRs. So, on the one hand we're being asked to provide more variability so that local customization can occur and yet on the other hand we're being criticized because it's too hard to get the data out.

So, again from a policy perspective, I think as you've heard other folks mentioned, the more we can institute common value set definitions, common metric definitions, that allows EHR vendors to build in the workflows to be able to capture the data in ways that are appropriate for different users and also for us to build in the kind of analytics to allow you to get it back out so that we're focusing on the appropriate level of variability, and not just tailoring to individual preference.

Now, one of the other challenges we also see is that there is at many organizations a chasm between IT who are the folks that often are the curators of the data and the end-users who actually understand the meaning of the data. Often times IT is viewed as a bottleneck and so end-users are demanding self-service access to the data. Now part of this is an organizational issue and that within an organization our experience has been those systems who have been able to bridge the communication gap between IT and clinical operations tend to be more successful at implementing analytic programs or at implementing effective clinical decision support.

Those who continue to treat IT and end-users as separate islands tend to struggle. There is only so much that technology can do to bridge that gap although there is a role to play in making data more accessible to end-users without requiring IT to become the gatekeepers to the data. However, most end-users aren't trained in many of the technologies that are currently used today to hold data in databases. So, it also pressures or opens up an opportunity for software vendors like Epic and others to build tools that allow end-users to serve their own data needs.

Now, I wanted to use this an opportunity to correct a possible misperception that I've often heard previously that EHR vendors are hard coding quality measure logic into their products and that's often time why it takes so long for these measures to take effect and in fact, calculating of quality measures is something that computers are good at doing, and that tends to not be the difficult part for us, the software vendors.

The real challenge for us is integrating at the right point in the workflow capture of the data elements so that we can actually perform the calculations. There has also been a proposal that if only we could extract the data out of the EHR and send it to some external system that we would be able to accelerate the deployment of quality measure calculations. As you heard on a number of panels before, quality measurement is only a part of the issue. In order to effectively implement quality improvement, you also have to integrate it tightly with point of care decision support. So, we as EHR vendors will need to do those calculations in our products even if we're going to do the quality measure calculation separately and I'll stop with that. Thanks.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

Okay, thank you. Michael?

Michael Stearns, MD – President and CEO - e-MDs, Inc.

Thank you very much I'm honored to be here. As background my name is Michael Stearns, I'm President and CEO of e-MDs an ambulatory EHR vendor but we mostly have clinics about 3-5, a lot of primary care, we have about 10,000 providers in the US. In the past I served as the International Director of SNOMED and worked with Marjorie Rallins very closely, she taught me everything I know about SNOMED, and then I'm also a certified professional coder, which is kind of a weird combination, neurologist, certified professional coder, and I've presented testimony to various working groups with the ONC on four cases in the past and then you invited me back again I'm surprised. Previously, I testified on safety, patient safety, patient privacy. We had a lot of fun with the PCAST model at that meeting and also I testified on the future stages of Meaningful Use last fall. I've also been involved in Texas, helped found a Not for Profit Organization focused on HIT Advocacy and Policy called the Texas e-Health Alliance.

There are six questions we were asked to address, I'm a little bit broader I think than the other members here because it's quality in general and not just the quality measures, CQMs. So, one thing that kind of sticks out now is Meaningful Use, the incentive funds are very front-end loaded and we got the easy one, Stage 1 was not particularly difficult for most of our users. Stage 2 and 3 are probably harder, but the incentives just kind of vanish. So, there could be a challenge there. So, I don't know what processes are needed but we probably do need to look at how we can realign the incentives so that there is a little bit more support for providers going to Stage 3 and 4 and 5, etcetera, because that's when we're really going to see the advantage of quality.

The CQMs, there's been some good work done with Stage 2 we're very happy with that. We do want to see expansion of Web services model so we can update them and use those models to actually provide feedback to providers at the point of care, I think most of the vendors are very interested in that.

Another thing I want to touch on is terminology issues. Having done the SNOMED project, having been a certified coder I am very interested in ICD-10 and it's not really designed to a clinical utility. I nicknamed it ICD-10 CMS because it's really a great fraud detection terminology if you've looked at it. It's got a lot of built-in things there. So, it's going to be a lot of fun to try to go through that.

We also have a lot of problems with HIE developers, HIE organizations and even vendors, and particularly providers with understanding the nuances of how information is going to flow in their communities because they don't really understand...points data and clinical data and there is not much clinical data out there, and not much reference material data available.

We actually also would like to see in a separate matter, we'd like to see an expansion to improve quality through HIT would be to accelerate access to legacy text data. There are a number of initiatives going on. You've been hearing now probably about the ability to go in and data mine legacy text which is almost like going back and ideally it would be like codifying data from the past and being able to act on it right now, so that's potentially very powerful.

Also we're hearing a lot of things around the country about business barriers developing interoperability where competing organizations are not willing to share data and we think that we need to take a look at that and also what the HIT initiatives have done to the business models of medicine is there a possibility that they're actually adding cost and reducing quality, and what needs to be done to reassess those?

We also need to look at the patient's role in quality improvement efforts. I think this was touched on a little bit, is what can they can do to help us? And then, also, case management is an area that hasn't really been fleshed out on the HIT side. So, the patients are managed by a care providers after discharge or...so there's a whole opportunity there for HIT to really make a difference, interoperability is going to be key.

And then order tracking which I really wanted to see us get in for Stage 1 is the number three reason in some reports why doctors get sued, other doctors agreed they were at fault for not tracking orders. Most of the systems have them in place, they were not a requirement for Stage 1. I'm not sure where they are at in later stages, but I would like to see that, personally since it's already there, we just don't have the doctors using it as much as they probably should.

We wanted to also touch on the role of HIT in research care related to genomic medicine. Genomic medicine is going to hit us like a tidal wave potentially if some of the things they're talking about come to fruition and HIT will play a very prominent role.

We also thought it would be good idea to focus on standards that facilitate the seamless transfer of patients from the hospital environment into the ambulatory environment, so in fact the orders tracking modules picks up yours as if the primary care provider wrote the order himself or herself. And then we also encourage, we looked very closely at the programs like the ACOs and PCMH and looked at how data can facilitate that.

And then, just to wrap up on CDS it has been shown as one recent report came out...a month ago, I'll stop in one second, that did show that it does improve compliance with guidelines, but they did not find evidence that showed that it improved outcomes yet, but I think it's just premature, we don't have enough data to show that. So, thank you very much.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

Thank you and Connie?

Connie Moser – Vice President – McKesson Provider Technologies

Great, thank you for the opportunity to provide testimony today. We commend this panel, the ONC and CMS for continued efforts on how we can collaborate to improve electronic quality measurement. I'm Connie Moser and I'm testifying on the behalf of McKesson Corporation. Today Health IT has limited ability to support clinical quality optimization for a few reasons. In a commendable effort, ONC has adopted standards available even when those standards may not be well-suited to that goal. For example, the quality data model is useful for organizing the elements of measure content but it is low utility as a certification tool.

In addition, the requisite standards and infrastructure remain immature. Until e-Measure specifications can be consistently computable and accurately parsed and interpreted without human intervention, EHR vendors will have to continue some form of hard coding. Lastly, the ONC has invested heavily in the S&I Framework and the Query Health Initiative for distributed population queries has shown tremendous promise. However, it should be noted Query Health is inadequate at this time for complex measures proposed for Stage 2.

The great promise of Health IT to better support quality measurement and improvement is its capabilities to create the learning health system. McKesson refers to this as a closed loop quality management process and this process supports the ability to leverage patient data, transform it into useful information, and deliver it to a constituent in a meaningful way so that they can change their behavior to improve the quality, the safety, and the efficiency of care.

In this process, data capture within the clinical workflow must not only support retrospective measures, but also comprehensive analytics that allow providers to assess and compare the care of patients who qualify for a given measure population as well as those patients who do not. Because providers need to understand the care process for the entire population we recommend considering export formats other than the QRDA1 which only includes patients who qualify for a given measure population. In addition, its only purpose is to support measure calculations. We believe it would be more extensible to consider using the summary of care record within the framework of the consolidation CDA.

Process improvements derived from complete analysis need to change the EHR workflow. Then, visual surveillance and clinical decision support tools will drive proactive compliance, and support best practice. The value of this closed loop process is illustrated most effectively by an IND in the Midwest. This IND has been so successful in using real-time visibility that they have virtually eliminated ventilator acquired pneumonia. While this condition is not in Stage 1 we will be working with providers to expand the same type of surveillance for Stage 2 measures.

The quality lifecycle can be accelerated by focusing primarily on standard setting work including establishing measurement priorities, evaluating evidence, reaching consensus, and testing validity. In addition, both controlled and field testing need to occur. The MITRE Cypress Project while a great start does not support inpatient measure testing.

Lastly, it is important to note that an MU measure such as medication reconciliation at transitions of care is a process measure. It should be specified as such using the same format as that used for clinical e-Measures. While Health IT vendors already play an active role, we believe we can also provide essential education and support to measure developers as they are not always knowledgeable about technical aspects and practical workflows of EHRs which hinders effective insight into measure development.

We also need to educate measure developers on EHR certification standards so that they can reference these standards rather than over specifying measures. The quality e-Measurement community is still in the early stages of transformation. Each measure development designs data models independently and debate is ongoing as it relates to competing approaches such as to whether to use an exception or an exclusion model. As a result, measures are not yet optimized.

In closing, we recommend the following, ensure we have robust and detailed standards that support consistently computable quality measurement. Resist the temptation to treat a successful proof of concept such as Query Health as a production ready concept for Meaningful Use. Aligned EHR

certification and measurement qualification processes so that certified EHR technology can be used by providers in the PQRI Program, as an example, without requiring a separate qualification process. And lastly, encourage a common vision for a Health IT measurement environment that fosters innovation by technology developers. Thank you.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

Okay, well first of all I want to thank the panel for a very nice set and very robust set of comments. And its interesting hearing the different approaches each of you took which is good. I think we have a nice mix of information. I will start with the prerogative of the chair of the moderator to start with a question. And I heard some requests from each of you. If I were to ask you what are the two most important improvements in the process with respect to data, what would they be to help you develop and implement your EHRs?

Connie Moser – Vice President – McKesson Provider Technologies

So, I guess I'll go first. The first one I would do is on standard setting obviously, the more we know about how to define a measure, how that measure is tested, how that measure is to be implemented, that will help us greatly identify where in an EHR those data elements should be placed to optimize workflow and also from an analytical creation or a measure computation that will be very helpful. We also believe we should play a more active role in measure validation and education to those measure developers so they can understand the practicality of EHR workflow and where we need to...what's practical, what's feasible, what's technical.

M

And I would just echo and actually amplify Connie's comments that what we're looking for is the creation of a common and standard set of high-value metrics that could be captured in an EHR ideally during the course of normal clinical workflow so that we're maximizing the amount of data that can be captured so that just like we talk about alert fatigue with clinical decision support, we can avoid potential measure fatigue where clinicians are being asked to fill out numerous checkboxes simply to drive the analytics downstream and so coming together as a community that includes not just the measure creators, but also clinicians, EHR vendors, patients where it's appropriate to take a look at those common data elements so that we as EHR vendors can then look at the appropriate place to include those in the workflow.

We've heard a lot of feedback about the challenges and importance of usability in EHRs. And part of our job is understanding that data elements that need to be captured and then building usable interfaces to be able to collect that from the right set of users. It's very challenging for us as vendors to build usable software when we don't know what data we are being asked to capture.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

So, one more.

Jason Colquitt – Vice President - Greenway Medical Technologies

What data is a big problem, I think. I think we heard from our earlier panel that we don't want to lock ourselves in. We want an extensible system that can capture any data and that's a nice thing so we can build a system that can capture any data in whatever vocabulary system, but when you try to start applying that to the work flow that's where it gets hard. So, us being informed on what types of data and then how that works into the workflow I think is something that we as vendors struggle with or at least Greenway does.

And then the whole value set issue. I can tell you, you know, where is that data and when it's updated, if it's not in a central place how do I store it and then get it out to everybody if it changes? Those types of struggles are things that we see. So, those would be the two things from our stand-point that I would say that is definitely needed.

M

Yeah, I'd echo the comments of the presenters. I would like to see us move to a concept oriented terminology for use. We had like V-codes were allowed but in the CQMs, the first round, it created a lot of problems. ICD-9 V-codes and then the second one I'd like to see focus on outcomes. So, we're not really looking at outcomes right now. We don't have really good proof that the CQMs are really going to generate improved outcomes except in isolated situations. So, there is an opportunity to do it on a broad scale.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

Did you want to answer, Diane or shall I move to a question?

Diane Gilbert Bradley, MD – Chief Quality and Outcomes Officer - Allscripts

Yes, I'll just do one. So, I would like to echo what Blackford talked about that we would really like to see a good way of sharing the guidelines. And so we're doing a good job sharing within the client base, but being able to extend that out so that we're not re-creating the wheel would be helpful.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

All right, so, let me move to...I was trying to watch the order that these cards went up, I probably got it out of order, but I'll start with Paul.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Okay, thanks, Floyd. I want to start with...responding to a couple of comments that Tom made just because I'm hoping there isn't a missed point here. You said you were going to correct an impression that people thought that hardwiring caused a slow retrieval and that's probably not the main point of the hardware comment, the main point of the hardwiring comment is it hardwires the workflow in a sense and that is very central to the problem we're trying to solve. So I want to make sure that you don't miss that or that your company doesn't miss that.

The other one you mentioned, you said to only use the data that's already in the EHR. I think that's another problematic approach. The Quality Measurement Workgroup produced these new concepts and they're motivated by measures that would matter to the patients and consumers, functional status, care coordination, a lot of things that are not in the EHR should be if we're going to tackle some of the main things. So, I would hate to get stuck in the legacy tethered by a tool. So, I want to make those comments.

Tom Yosick – Software Developer - Epic

Let me clarify, I wasn't proposing that we limit ourselves only to those data, but when we look at prioritizing how to define quality measures going forward make it so they will be thoughtful about quality measures that are going to require additional data capture requirements beyond what is already typically being captured in EHRs today and our experience to date has been that quality measures that were not designed with EHRs in mind often times didn't have that sort of EHR centric data collection philosophy.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Well, that's true but it also didn't really focus on what matters to patients and so we're trying to correct that problem and we need to all move there rather than fall back. Okay, so my main question is...many of you probably were at the first panel, usability came up a little bit and so ideas on how we can...what kinds of things can we build into Meaningful Use that would move us all in the right direction? I'm sure you want to go there. You do want to go there as well. What would give everybody credit for sort of making progress in that area? Is it a functional requirement? Is it some kind of a measure, metric that we can use? What are your best ideas for us to think about? It's a hard problem but we're a little stumped.

Diane Gilbert Bradley, MD – Chief Quality and Outcomes Officer - Allscripts

I'm going to...this is Diane, I'm going to refer to a study that was done at the University of, I think, Minnesota with a guy named Tom Clancy that did some time studies of report with nurses and just

studied where they went to get the information in the electronic health record and outside to do their handoff and compared that when they used the same electronic health record but now with a framework that was interdisciplinary and said, you know, if the respiratory therapist puts this information, you nurse, don't have to, you know, to copy that. And the difference was astounding and what surprised us was that it had really nothing do with the technology. It had to do with the framework that was put in place and the intentional design. And so when it comes to...and I'm not answering your question, but it was an interesting way of studying usability, which is how long did it take for somebody to do that task, right?

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

Okay, all right, so the order I saw the cards go up, I think Jacob was next.

Jacob Reider, MD – Acting Chief Medical Officer – The Office of the National Coordinator for Health Information Technology

I think Paul asked one of my questions, thank you, Paul. So, I'll ask two different ones. A, we heard from other folks earlier in the day about value sets as being valuable. Would they be to vendors? B, I was struck by some of the earlier folks talking about quality measures and clinical decision support as being sort of two sides of the same coin or inherently dependent on each other and I was actually struck by some of your testimony as focused more on quality measurement than I would have expected. So could you talk a little bit about that, the relationship between the two? Notice that we called this hearing quality improvement not quality measurement because of our perception that these things are very tightly aligned.

I heard yesterday at a different conference because they're all this week in D.C., it seems, a mention of clinical decision support actually being real-time quality measurement. And there was a metaphor of talking about FedEx and how that's what they do all the time and that's how they know that they're going to get their package to you because they had said after the fact, oops, it didn't work. Then they wouldn't have gotten your package to you, but in real-time they actually make adjustments because there is weather here or a driver who is out there and, therefore, they're able to do what they were intending to do, which is align with clinical practice guideline which might be get the package where it needs to get to. So, two questions, one is CDS real-time clinical quality measurement and would value sets be helpful?

Tom Yosick – Software Developer - Epic

Tom Yosick from Epic, absolutely yes to the first question, value sets would be very helpful. And also harmonizing value sets across different quality initiatives is a challenge that our customers face today and so that would be helpful if there could be some standardization of that.

We absolutely see clinical decision support and quality measurement, and quality improvement as part of a cycle in that you oftentimes use the outcome from your measurement activities to inform your clinical decision support interventions to decide whether they're being effective or not, to evaluate workflow, and where in the workflow or for what users is it appropriate to present clinical decision support, and then to evaluate as you modify and update real-time clinical decision support using those measurement tools on the back continue to continually improve. You called it real-time quality measurement improvement and I hadn't heard that before. I think that's a good way of looking at it.

Diane Gilbert Bradley, MD – Chief Quality and Outcomes Officer - Allscripts

Yeah, this is Diane. I would concur that it is real-time quality measurement or quality improvement because as the clinicians are taking care of the patients and we're providing them with the information and then suggesting, you know, have you thought of this or the patient hasn't done this in the guideline, would you like to order that, it's like we're helping that improvement of taking care of the patient right at that time instead of saying, you know, the patient's discharged and you didn't do that. So that's how we see that being very helpful in real-time.

Connie Moser – Vice President – McKesson Provider Technologies

This is Connie Moser and you probably don't hear a lot on clinical decision support from me because I am not a clinician nor will I ever profess to be a clinician, but I do run the analytics and enterprise intelligence

division within the McKesson Corporation. So, my perspective and in blending the perspective of those that run our clinical systems and the analytic side of the business, we do believe that clinical decision support means many different things. It means how do you communicate effectively and at what time? I think Joe Kimura, I think he left now, said giving the...oops there he is, the right information at the right time to the right person in the right way to change their behavior. I live, breathe and die to do that at McKesson. That's what we focus on. So, it's not just a CPOE clinical decision support system. It may be a visibility or surveillance tool that's on the wall that's saying, hey,

this swab needs to be...or the vent needs to be cleaned for ventilator acquired pneumonia and it's almost past it's four hours and by the way, the nurse that's responsible for that has just been pulled into a coding patient so she or he is not going to get to it, but Diane can go take care of that because she sees that communication, that is clinical decision support.

And it's also one of you, earlier about the patient, I think Norma, it was you had identified, look there's five or six different things that may be going on with the patient, will this surveillance type tool take those things into consideration? The ventilator acquired pneumonia is obviously a very simplistic example. But when you're looking at stroke or DVT or CHF, it is looking at those separate elements and saying, by the way, here is the care plan something has not occurred and you may need it to occur because of this particular patient and their diagnoses or their complications, and you need to take action, and if you can't, Diane can for you.

So I take it a step further. McKesson takes it a step further than just clinical decision support being the interaction of a clinician with the overall record. It may be a very specific communication that is occurring. And I do...we support value sets, I forgot to answer that.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

Jason did you want to comment?

Jason Colquitt – Vice President - Greenway Medical Technologies

Yes, Jason Colquitt, value sets already given that comment about we are in support of that. We use decision support to drive the data points that we don't currently get collected. So, that's one of the methods I see that...not that we've covered this topic, but in the ambulatory environment there are a lot of measures that depend on inpatient data that we may or may not have. So, that's another good use of decision support, patient fits the, you know, denominator, can I ask the question or use decision support to prompt to say capture that other additional data that I may or may not need. So, I think that's a good use of decision support and I think the two have to be used in tandem to drive to the quality that we want.

M

Yes, it's real-time quality improvement in general but we do have to deliver care. I've seen examples where there was overreliance in the technology and since they didn't get an alert they thought everything was okay, particularly in ePrescribing. So, we have to be cognizant of that, that there are certain things that may go wrong and doctors have to remember that they are still doctors and they have to practice even if they don't get an alert.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

Okay, are we ready to move onto the next question or do you have another comment?

W

You could tell, Floyd, my mind was just going. I just wanted to get back to the patient element because a lot of times we, as vendors, don't address the patient element and back to a patient is an integral part of a quality outcome, right? We absolutely believe that and we need to communicate and have them act as part of the process. So they, in that...but also it's not just clinicians. So, it's not just nurses and physicians, but it's that case manager who's got to do the admissions review within 24 hours to assist the clinicians in guiding or discussing, or debating the care plan, right? It's the person that's moving a patient

from one place to another so the EVS. It's how you effectively educate a patient before departure and are they getting it or are their families engaged?

So patient engagement solutions such as get well network. We integrate with those types of solutions to communicate effectively. Are pain levels too high? Have they received their education so they can be discharged appropriately? And do they effectively understand or does the nurse need to go over that with the patient? So, I think about it more broadly than just the clinical decision support.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

So, just a time check. We now have 19 minutes but we started late. So we could maybe go over 5, but I currently have 5 cards up. So if we can just try to be concise so we can get all this. Eva?

Eva Powell – National Partnership for Women & Families

Thanks. We've heard, I think, from every panel that standards is an issue and so clearly that plays a role in being able to exchange information. But we do have some standards and still information is not flowing as many of us would like for it to. So other than the standards component, I'm curious as to what each of your answer would be to what three things can the Policy Committee do to encourage greater transmission of information among care team members and across settings, particularly with patients and their family members and with providers who are not Meaningful Use providers such as nursing homes and home health? So three things that are not standard.

Diane Gilbert Bradley, MD – Chief Quality and Outcomes Officer - Allscripts

This is Diane from Allscripts. So, one of the things that we have had the privilege, I guess, the foresight is we have a home care system and we have a care management system. So we have had to work on the integration between either the ambulatory or the acute care through the different venues, but what I'm stumbling on is the three things that we need from you from a policy perspective besides the CCD and it seems to me that some of the innovation that we've seen through some of our academic places where they've dealt with a handoff tool that is very relevant to a clinician and standardizing that would be very helpful. So, not just the CCD, I mean ADT is good, but what is the clinician's needs and I'm just going to give you the one, because Floyd I'm trying to be concise.

Eva Powell – National Partnership for Women & Families

Yes, one is fine too, whatever you have to offer.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

Can I just add to the question, since you mentioned CCD? CCD can define sections that give you information but perhaps in measures or other clinical use in decision support you actually need structured data and it's not there today. So, are there specific areas of structured data that are not currently available that you feel would help you?

Diane Gilbert Bradley, MD – Chief Quality and Outcomes Officer - Allscripts

So, again as Allscripts is integrating two different systems, right? So, we have an acute care system that came from eclipse and we had an enterprise system, ambulatory system that was from Allscripts. So, we've been struggling with that. So, you know, how much of that data do you exchange automatically versus how much do you leave to the clinician to make a decision about whether it's relevant? And so I think that we could share some of the experiences that we've learned about that structured data because to do clinical decision support you've got to have that data in a structured manner. And, so that we've done I think we could offer up in written form for you, just some ideas of the valuable lessons that we've learned over the last six months.

Jason Colquitt – Vice President - Greenway Medical Technologies

Jason Colquitt, I'm struggling with Eva's question, because I'm in the standards world and I'm a technical guy like Tom so it's all like, you know, how do we figure this out from an engineering perspective so I'm struggling with that, but to Floyd, your point, I think the timing aspect, so that got brought up in the last

panel, that's a tough one. So, when there's timing elements within the measure itself and looking at the CCD and knowing what's there, there are ways in which you can do that but it's very difficult to line up what's the timeline for all these events to make sure I'm counting the patient appropriately.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

Okay, I don't want to leave it all to Diane, after all she is cleaning the ventilators associated pneumonia rooms, she's busy. Michael?

Michael Stearns, MD – President and CEO - e-MDs, Inc.

I'm having trouble too of breaking away from the standards, but at a policy level promote programs that educate people that value of these processes not just the providers but the patients, there is very limited awareness certainly in the patient population of the value.

And then another one that's kind of a safety issue is to make sure the context is preserved. So, if you do abstract data from EHRs we share them they can be corrupted as we know. So, data integrity is an issue that really needs to be looked at over and over again because various forms of data is collected on certain modifiers, negation, context, source, etcetera, the data gets corrupted downstream and that could be very negatively influential.

And privacy, privacy we just heard...I was over at the privacy conference for a moderated panel this morning and we heard about all over the world the challenges we've had with privacy and they didn't really take privacy seriously then and now they do, but it's really corrupted their HD efforts. The U.K. is probably the best example where it just fell apart because there wasn't that attention paid to privacy and patients became aware of it, and they really were reluctant to contribute, and were afraid to tell their doctors information that they were putting into the EHR, so thank you.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

Okay.

Diane Gilbert Bradley, MD – Chief Quality and Outcomes Officer - Allscripts

So, one of the...this is Diane again, we happen to have another conference here Tuesday and Wednesday with some executives and one of the Chief Quality Officer at Abington Memorial in Philadelphia was telling the story about how when he went to do the daily plan of care, so they have created a daily plan of care that they review with the patient every single day or the family members, and he was talking about how they catch errors, you know, the medications or allergies. But the story he told was finding that the patient was illiterate.

And so, you know, as we talk about all of these standards the idea that there is some standard information, as a physiatrist, you know, like how many stairs is that patient going to have to climb at

home? What kind of education do they need to be taught? That isn't talked about. And I think when you're going across venues you have to talk about how are you going to share that information. Because that to me is very important to the patient's quality, it may not be the quality measures we standardly talk about, but that practice interoperability is very important.

Eva Powell – National Partnership for Women & Families

And that gets to me what is really the issue here, which I'm not sure how we address that from a policy perspective. But early in your testimony you mentioned creating relationships either...I don't know if it was relationships, but you focused on relationship and agreement and working with your competitors or with other vendors. And what does that look like? Because I think from a policy perspective what I try to think about is what can we put in the requirements that is going to force people to work together? And I think that may be a dangerous place from a policy perspective because I'm not sure that we know, but at the same time I don't know another tool or lever for us to get that to happen and that's clearly what has to happen. I mean, otherwise the data is not going to be shared. So what does that look like in your work, Diane, since you all have done that?

Diane Gilbert Bradley, MD – Chief Quality and Outcomes Officer - Allscripts

So, for us...let's just focus on order entry because we've been doing that the longest, it's like we are agnostic when it comes is it zinc's order sets or is it Walters...or is it... severe and where we're focusing our time is how do you apply the clinical decision support at the right time, at the right place, to the

right person and not focusing on redeveloping that content. And so, we do the same on the interdisciplinary documentation.

And so when IHI came up with the bundle, to me it was like, okay, if I was the CMIO somewhere how would I implement that in the Allscripts software and that's the piece that we should be disseminating, right? Other people are talking about what's part of that bundle, but we're telling people how to use the EHR in the best way to support that process. Does that help?

Eva Powell – National Partnership for Women & Families

Yes, thanks.

Jason Colquitt – Vice President - Greenway Medical Technologies

This is Jason again. You keyed up I think some of the clinical quality measures actually hit to that forcing, if you will, the exchange of data because some of the measures say and I'm speaking from the ambulatory side, you know, patient was discharged. So there has to be some knowledge from the ambulatory environment that that patient was discharged and I have to have some data on that. So, I think some of the quality measures are sort of there to force that there is going to have to be some kind of communication, it might be via the patient at some point. But, you know, I think some of that is going to try to, you know, the quality measures can kind of force that.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

All right. So, let's move onto Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So, we've been talking a lot today about the very noble goal of rich data models and highly coded information. And I sort of see like we're on a path to success and convergence, but it might be 10 or 20 years to get there. So, let me ask the flip question, which is we're seeing a lot of really interesting innovative use working with unstructured data, unstructured text particularly in a lot of internet-based tools. And some vendor's trying to bring that into the clinical space.

So, do you have any sense that we can get good enough technology in place? And I use that advisedly because I think it will set people on edge. But, you know, the problems of we can't find the data in the chart because it was in a free text note leads to not very good decision support.

So, I don't know that we're any worse off if we start putting in place some tools that say you know what this is 95% good or even 60% good because it finds stuff we wouldn't have otherwise found. So comments about can we bring in a different approach to how we look at getting the information we need to be helpful?

Michael Stearns, MD – President and CEO - e-MDs, Inc.

Well, even if today we waved with a magic wand and everything was codified we'd still have major challenges, legacy data, text going back for years and so that's very valuable information. So, the ability to search that and pull useful information out is extremely important. And also, if you're looking at the value of the business model of HIE it's difficult to support. Around the world it's supported by the government in general or it doesn't work at all. So, the private mechanism isn't very solid. So, if we're looking at the ability for doctors to say, well I can't get access to information effectively, that to me would be a driver for HIE adoption from the provider's side for a quality of care metrics.

Also, if we're looking at research, I mentioned genomics, right now we're going to have the human

genome sequenced, wouldn't it be nice to go back and search legacy data looking for...expressions for medication responses, etcetera and be able to line it up? Obviously, it's a lot of research.

We're actually doing a pilot right now with one of our hospitals in California for this exact thing. We're exporting all the data from our EHR into a place that can be searched and with multiple providers' community and see if we can pull down stuff which is very relevant. There's been some interesting gains done in things like splenectomy patients who have not had Pneumovax, about 30% of the time I guess it didn't show up in the problem list. The doctor is not aware of it and they don't give a Pneumovax at that time and the patient is indicated. So, this is pulling it out of the legacy data, presenting it to the clinician in real-time and they take action upon it. And there are about 15 different clinical things we're looking at and that to me could really enhance care.

Connie Moser – Vice President – McKesson Provider Technologies

NLP, Natural Language Processing, getting at unstructured data is important over a period of time and I think there are advancements being made. We are obviously looking at it as a company, I'm sure all of us are looking at it to a degree and figuring how we can speed things up and make it usable. But there is a great deal of structured data that can be combined together for a particular patient to identify potential conditions that may be occurring or complications that are about to occur that we should look at that first because that's where we have access to the data already, whether it's the legacy data in a text format or in the current data that we have throughout our patient episode, a longitudinal patient record within all of our systems. But we do need to continue looking at it as it advances and continue to work with it.

Diane Gilbert Bradley, MD – Chief Quality and Outcomes Officer - Allscripts

So, this is Diane, one of the exciting things that we've seen in the last year has been around physician documentation. So, there were the earlier adopters who did a lot of structured notes to do E and M coding and then there were the folks who did a lot of the dictation. And what we're finding through our technology is the ability to take the structured data that is entered from somebody else and present it to the doctors so they're not having to reduplicate the documentation, but it stays in a structured format so then when they do the dictation, we're not losing all of that structured data and so it's like...it's a hybrid and that seems to be working well. So, we're exciting about the NLP technology and ready to use it, but we're seeing the hybrid use of both.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So, I wonder if that hybrid actually can go in both directions. So, you could take a free text thing and layer on some NLP to say these things look important, present that to the clinician and let them pick it and go from this is the best guess to, oh, now we can actually code it because we're getting you to pick through the coding structure.

Keith

This is Keith, I'd like to respond to that.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

If it's related to the current comment, go ahead.

Keith

Yes. So, I've had some experience in actually developing systems where we did pull out problems, medications, allergies and procedures at a previous employer, and we were actually coding the problems to SNOMED. One of the challenges that we found with that system is that actually, you know, presenting the information to clinicians was not an issue. But getting them to actually look at it, review it, validate it so that the system could actually improve in accuracy to the point where you could rely on it was an incredible challenge. And in part I think a lot of that has to do with the fact that it's just an additional step where a clinician has to look over something that they've already done to deal with the NLP aspects. I don't know that the technology is quite there yet for anything other than the hybrid approaches that were previously discussed.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

All right. So, this has been a good discussion. I want to make sure we get in our...we still have two more questions and about eight minutes. So, can we go to David, who was next, I think?

David Lansky – Pacific Business Group on Health – President & CEO

Yes, thanks. Building on both Paul and Eva's comments, I'm interested in where the vendors stand in a continuum of data sharing. So, particularly, as you know the Quality Measures Data Group and the Policy Committee recommended measure concepts that are now in development in various stages and they tackled domains like efficiency, patient engagement, care coordination. I think most of those will require linkages to data sets that are not in the purview of anyone EHR either longitudinally, across settings or across types of data like claims data or from the patient directly.

What do you think is...how do you foresee the extraction or integration of data from multiple hosts that will be used to construct this next generation of quality measures and how do your products anticipate being a part of a kind of ecosystem that shares data to produce those measures? Does all the data from other places come back to you to get computed? Does yours go to a third-party or to the other system to get computed? How are you anticipating the evolution of this space?

Diane Gilbert Bradley, MD – Chief Quality and Outcomes Officer - Allscripts

I can speak at Allscripts, this is Diane, from the claims data we tend to take in anything. So, we've done both the ambulatory and the different hospitals, so, we do really well there. On the clinical side we've tended to have the analytics products be very specific. So, an analytics on the financial system, an analytics on the care system, an analytics on the acute care, and so we've invested \$10 million dollars in a company named Humedica and that's kind of where we're seeing the aggregation of all of that information into wanting to do the clinical population health. And the strategy there is that there aren't very many IDNs that can say that the clinical data will be from one vendor. So, the idea that you have to be agnostic in bringing that in, we don't have internally that expertise. So, we've looked outside for that.

Tom Yosick – Software Developer - Epic

This is Tom from Epic. So, from an analytics and quality measurement perspective we see the exchange happening really both directions. There will be scenarios where bringing the data into our database makes sense or where we're feeding data out. But as we get back to looking at clinical decision support and the point of care it becomes more important that those data are hosted in a database that we have access to ideally in real-time. Now, there may be standards like Blackford has mentioned where we might be able to integrate with external decision support engines hosted in the cloud, but then those engines would of course need to have access to all of the same data that we do. And so, my sense is in cases where it's important to have real-time access to information we're going to need to find ways as vendors to get that data into our database.

Diane Gilbert Bradley, MD – Chief Quality and Outcomes Officer - Allscripts

And just to clarify, this is Diane again, so today we have the ability to query a third party database to use it in real-time for that clinical decision support. So, we find that it's usually large academic institutions or the cancer hospitals that are starting to use that capability. But every once in a while somebody will say I have this registry and are using that now.

M

I think there is a general consensus that there is need for interoperability, what's of interest though is that as things evolve there are business that are not really supporting interoperability which makes sense in a local community. Hospitals need to, they have competitive issues, etcetera. And there are sometimes, you know, pressuring their vendors not to open up their doors and do interface and all of that. So, I think that is a policy matter that is worth looking at from the stand-point of the business model in medicine that has evolved over time and are there any barriers in interoperability. When we do get into that point, though, I've been actually looking around the world for a place where they actually share data at a codified concept level and there really aren't any. Most of them have tried and they fall back to kind of glorified facts over concept.

I was in New Zealand a few weeks ago and 100% HIE since 2000, they're still not sharing codified data. So, there are a lot of challenges around how it's going to be represented. The challenge related to modifiers, certain modifiers gout, multiple sclerosis, you've heard that one before I'm sure from Jamie Ferguson, they're looking at using SNOMED attributes to connect things like gout and multiple sclerosis but that's a lot of work, incredibly labor intensive, but that needs to be addressed. And until it's addressed I do a lot of speaking and meeting with HIE directors on patient safety and HIE and right now I'm asking everyone to maintain a link back to the source document when applicable so that if the information is parsed out you don't make a bad decision because the information wasn't conveyed cleanly.

And that is what we're kind of taking a baby step now with interoperability if we're going to use codified data. And then as I mentioned earlier in order to get this to work so we can take advantage of the measure concepts ideas. We have to make sure that we do address privacy or it will shoot us down, thank you.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

So, we have one more question from Tripp?

Tripp Bradd – Skyline Family Practice, VA

This is Tripp Bradd, they've been kind of answered and parsed and re-iterated, but I wanted to come back to the gemba and that's the value and that's the patient. Most physicians will find everything, as has been mentioned repeatedly meaningless until they can meaningfully apply care to the patient. We talk about big data but really the small data at the point of care is what makes the difference and I'm glad to hear you've made progress. And, so I have heard some answers to that I'm not going to ask for any comments unless you'd like to comment on that. But, I can't tell you how many nondisclosure agreements I've had to sign to get at the data, okay, and I think the big elephant, from my perspective is the family physician that practices full-time is, the elephant is transparency and collaboration amongst the vendors, you can point at other people but if you guys work together with the Policy Committee it'll work. Thank you.

Floyd Eisenberg, MD, MPH, FACP – Senior Vice President of Health Information Technology – National Quality Forum

All right, so I want to thank the panel for excellent presentation and for excellent responses.

David Lansky – Pacific Business Group on Health – President & CEO

Thank you all and Floyd thank you very much for facilitating that and thanks to all the moderators today for taking on the extra work of guiding us through a very time managed process today. Thank you.

So let me take a couple sort of capturing comments to capture at least what I heard from the day and then let's take a few minutes among ourselves to just reflect on our two committees, what do we take away from today and where do we want to go from here as we start looking at our work ahead towards Stage 3 and then we'll have time for 10 minutes or so much public comment here just in a few minutes. I think that's where we're at.

So a couple things, first of all, I was very excited that there's a lot more consensus actually during the day than I might have expected coming in from a variety of constituencies and users and vendors, and all kinds of researchers and others, the list of kind of current state of the art, current problems, but also the amount of progress that has been made is really remarkable certainly compared to 5 years ago or 10 years ago, we've just come an awfully long way in the ability to measure and improve, and support quality activities through the technology. So, I think that was a very encouraging day.

What I think we have to do going forward and looking at what our roles are going to be to support that, part of it is figuring out the roles for federal policy because I heard several layers of intervention and action that are in play right now and we're trying to support that, those multiple layers. We're going to have quality measures for Meaningful Use which is one of the drivers we have...one of the tools we have available to us. Then there are quality measures for other payment programs that we don't control. What

CMS might do, what states might do, what private P for P programs might do. But those are externally created and everyone who came to us today has to react to those but we don't control them.

Then there is the quality improvement measurement enterprise within the enterprise where people want to drill down, slice and dice, add analytics to their own care processes. And it's an open question to me whether we should be speaking to that level at all as a federal policy body. Should we be laying out...right now we have 120 some measures in the stage 2 proposal, which a lot of them are process improvement measures. Is that really where our work should be? That's a discussion I think we have to have. Do we want to make more of those or go back to as someone said, maybe David Burton, early on pick the top 5, pick 5 measures in each and you're done, we'll do the rest. So, I think that's a discussion we need to have.

And then there is the clinical decision support, which is the tool kit to actually drive improvement against those measures. And I think it was very exciting to hear how much is going on there and it's a question, is that a place for federal policy? What is the role for federal policy to be speaking to clinical decision support, which as Helen said is a very precise quality process improvement specification. Is that something we want to be speaking to at all and if so, how and where? So those are really big policy questions I think we have to wrestle with.

But then I was very encouraged of how much collaborative standard setting and tool kit building is going on. And we heard today about the clinical element data dictionary, the CDS Consortium, some of the work IHE has done, Becky mentioned, to create some standards. We could wrap our arms around a lot of those initiatives and figure out what's...is there a coordination function, an integration function, a harmonization function that's missing? I sense that there is something missing. Is that a role for us to accelerate?

And my last comment I think is, all this sounds really good. We've made a lot of progress and yet the clock is ticking fast on the crisis in American Healthcare and the policy changes that are in play. We're going to see ACOs. We're going to see payment changes through the federal programs. We're going to see delivery system redesigns. We're going to see disruptive innovators like John Schrom talked to us about. How do we accelerate the good things we heard about all day today? Do we have a role in turning up the heat and can we use our EHR incentive program or the other tools that we have, the Standards Committee resources to dramatically accelerate the resolution and adoption of some of the tools that we heard about today?

So, that's what I came away with but let me pause here and let's take a few minutes, and just go around the table if people want to speak to either key findings and observations they had today or next steps they really want us to take among our two committees, and with ONC. Kevin, do you want to make a comment?

Kevin Larsen – Office of the National Coordinator

Yeah, I'll make a couple quick comments. This is Kevin Larsen from ONC. Something Jacob was going to mention earlier, there is a lot of active work in a value set repository and so that's the kind of feedback we've taken earlier and are actively working on. I think one of the kinds of policy questions that came up here and it really fits nice squarely between the two committees, there is this desire for outcome measurement but as my lens into outcome measurement has shown that the best outcome measures really depend on interoperability.

So, if we want really good outcome measures then we need to push interoperability and its real-time interoperability because that's what the users say they need that in order to take action. They don't want retrospective measurement. They want prospective or concurrent measurement. So, that means concurrent interoperability. If we don't think we can do that then we're back to process measures. And they also said that process measures are really helpful in a vision of change. And they're much less dependent on interoperability. So, to my mind that's one of the sorts of balancing tensions that I heard explored through the day.

David Lansky – Pacific Business Group on Health – President & CEO

Thanks, Kevin. Let me just go around and see if people have comments and put up your...cards I guess. Leslie?

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

I just would like to compliment all the panelists and maybe look to the future a little bit more in our design because we still are in relative infancy in all of these standard sets, and make sure that we include the patient as a participant in our initial design structure even if we do not see, as I think it was one of the physicians here said, we might still be immature in knowing how to use that, but we can certainly consider the patient and their family members in our principle designs as actors and participants in their own quality and in their own health.

And I think the place to test that initially might actually be in advance directives where we have a clear and very specific national imperative already mentioned within Meaningful Use 1 and Meaningful Use 2 where we could take patient-generated data as a source of truth and all of the complexities to go with that with very specific measures as reflected in the POLST Programs that get to very specific data elements right today as a test case for patient-generated and inclusion in shared decision-making.

David Lansky – Pacific Business Group on Health – President & CEO

Okay, thanks. Becky?

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)

I would like to say that I agree with your summary and I think we've just barely touched the iceberg on leveraging the standards that are available through IHE and CDISC. And when we create this value set repository I think those should be looked at before we start from scratch again because there is a lot available.

David Lansky – Pacific Business Group on Health – President & CEO

Helen?

Helen Burstin – National Quality Forum

Just that I agree with everything you said, David. I think you nailed it. I think we do need to better sort out quality measurement versus CDS. I think CDS has an important place here mainly because it is that same...as Ferdie said and the data is the data and that's really a good starting point for much of what we're talking about. I think we need to still think about how we move towards those better measures to truly understand what's available going back to Kevin's point. And, I think there's a real opportunity for us to think about what are the right concepts to move to, but then how to test the actual measures and systems that are real world. Because, I think there is a real challenge here of putting out measures for accountability use for other purposes that we're not confident can actually be adequately collected.

Eva Powell – National Partnership for Women & Families

Thanks. I was also struck by the number of times that the issue of transparency and also governance came up and I don't think you can separate those and that would seem to me to be a real point where policy would need to play an active role. And then the second thing, which didn't come up quite as often, but it did come up, and Leslie just mentioned it, the role of the patient. And I'm not sure what the answer here is. But it seems clear that the patient and their family as members of the care team from the privacy perspective and for a host of other reasons, that there is a clear role there that we must figure out to move things ahead. And I think some of it hinges it on the notion of patient preferences and I see that as having a connection to governance and transparency as well and really involving the patient in this process not just as a recipient of information, not just as a contributor of information but as a facilitator of the whole quality improvement effort.

David Lansky – Pacific Business Group on Health – President & CEO

Is that a commercial for tomorrow's hearing?

Eva Powell – National Partnership for Women & Families

Yes, it is.

David Lansky – Pacific Business Group on Health – President & CEO

Paul?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

I think I agree with you, David, about how...there was a lot of uniform feelings. Let me explain that, I think there is a lot of desire to do the right thing and I think it's just a let's help them make it possible. So, what's the role of public sector in doing that? One area is standards because nobody wants to do it first and you've got to have a level playing field. The other is to try to give a first move or incentive or at least remove some of the costs of being a first mover and by that I mean trying to give credit or perhaps extra credit for doing some of the things that we would want to have happen.

So in the standards area of course everybody has talked about value sets, and that is something we probably can facilitate one way or another. The other, like the first mover could be around some of the newer quality measures that matter to consumers and patients whether it's functional status or care coordination that don't exist now, but, gosh, do you have to do 125 and do something at your own expense? Can they get credit or even extra credit for doing that? So, can you have 6 folks that will, but 1 or even 2 categories really if you are contributing in a way that's really already been predefined as blazing a path in one of our new concepts, even if you have to develop it yourself.

So, there's two things. One it can help blaze the path on the development of these measures. And two, it could even feed into the testing or field testing for an NQF point-of-view. So, can't we give people credit for contributing to the public in a sense? So, those are two things. One, the standards and then the other one was...the other example of a first mover would be the real-time decision support or real-time reporting. A lot has to go into it but gosh, let's pay them to do that in the sense of credit against some other requirements. I mean, there could be some innovative ways we use the Meaningful Use Program to help that along.

David Lansky – Pacific Business Group on Health – President & CEO

Thanks. Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

So, I agree there was a lot of enthusiasm here today. That a lot of things are happening and things are moving ahead. I'm wondering if we can't do a better job of sort of learning from data in the wild or learning from experience in the wild. We're doing a lot around structured data and we obviously need to do that. So I don't want to stop that for a second. But I'm thinking about the discussion that we had last week on, for example, disabilities and some other status information where we're going. We don't have a good data set yet so we we're reluctant to put it into regulation.

But maybe what we could put into regulation is asking people to report what they're doing. So, not necessarily at a patient level, but what's the question you're asking and what's the answers that you're getting? And I don't care if it's structured data, unstructured data, code sets. Whatever it is, if you're collecting, you know, information about a functional status and we think that's important that we say we want to learn about this thing called functional status, so you give us the data. And so it's a new capability on the federal side to be able to receive this and do something useful with it.

But to begin...and maybe it's not to us as, you know, ONC or CMS, but maybe it's to one of the measurement development groups to say here is a data set on 300 million people that's 20,000 providers who've asked these questions and within that we'll apply some NLP and some smart search and we'll come out and say, hey guess what? This is the 90% question people are asking. So, using that question wouldn't be a stretch. So, I am wondering if we can't do some sort of out of the box things to kind of move in some new directions.

Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics

This is Liz Johnson. I think one of the things I want to share with the committee, this is from the standards perspective, taking the direction from the Policy Committee, so one of the things we're doing now, we just started this work, is the Implementation Workgroup that I manage, we must start doing clinical scenario testing against the actual measures for the first time. So, we're going to actually look at how do you start this process and move it all the way through because we've had these really silo'd testing. We go test functionality. We don't look at workflow at all, I heard that all day. So, I get excited when I think about the patient.

So, I ask the Policy Committee, and Paul you particularly with the Meaningful Use Group, give us some patient standards that we can do the same thing with and we'll work for you. We're there waiting to test those workflows. So, we'll be coming back to say we actually tested the way a clinician does their work and we were able to get there and meet several Meaningful Use measures at the same time. Let's do the same thing in quality and include the patient.

David Lansky – Pacific Business Group on Health – President & CEO

Go ahead.

Kevin Larsen – Office of the National Coordinator

This is Kevin Larsen. I just want to make a quick comment to that. We had a vendor Tiger Team for quality measures and they asked us for recommended work flows along with the quality measures. The developers felt that would be really helpful for them and helpful in their support of standardization at organization.

Elizabeth Johnson – Tenet Healthcare – Vice President Applied Clinical Informatics

... which is what we're about.

David Lansky – Pacific Business Group on Health – President & CEO

George?

George Hripcsak – Columbia University NYC

George Hripcsak, one theme was...a big theme was gathering data to feed quality measurement and improvement. In research when we want to have the right answer we hire a human being to read the chart and then type in the right answer and we're trying to do it larger scale so we're going directly to the raw data. So, I think data quality is actually much harder than the data standards side of this. And even if you ask the eligible professional to click off a box and say is this true about your patient, you have to measure how often that's true.

So, here's my conclusion for us. If you're doing a quality measurement, I think we should just measure how often we're wrong and accept that we're going to have a certain amount of time that we're wrong. If you want to really get it accurate then you have to go to the quality improvement and that gets back to the real-time theme because then if you're feeding it back to the doctor or to the eligible professional then they have a vested interest in getting the data right or yell at you because it's wrong as long as you're just doing measurement, it's a one-way thing and you don't see that you're screwing up. So, it's having that feedback loop that eventually improves your data collection whether you use NLP or check boxes or whatever you want.

David Lansky – Pacific Business Group on Health – President & CEO

All right, I think we've made it around and we're probably at about our time, yes, perfect. So, first let me just again thank all the people who traveled and came to spend time with us today we really appreciate your...yeah we're coming back...your time in coming to join us and thanks to all the committee members for the same contribution of your time and great creative questions and probes and with that we will turn to the public and see if there are any additional comments.

Public Comments

MacKenzie Robertson – Office of the National Coordinator

Operator, can you please open the lines for public comments? And if while we're waiting for the phone comment, if there is anyone in the room, if you could please come up with the table.

Alan Merritt- Altarum Institute

If you would like to make a public comment and you're listening via your computer speakers please dial 1-877-705-2976 and press *1 or if you're listening via your telephone you may press *1 at this time to be entered into the queue.

Marjorie Rallins – Director of Measures, Standards and Informatics for the Performance Improvement Division – American Medical Association

And if you could just identify yourself before you speak, please. Go ahead.

Laura Heermann Langford – Intermountain Healthcare

Okay. I am Laura Heermann Langford from Intermountain Healthcare and I appreciate you taking time for some public comment at the end. I've been listening with a lot of interest today. I had comments even prepared before I came today but I've kind of adjusted them as I've listened to your conversation. And things that I'd like to add that I don't think I've heard yet throughout the conversation today is I really support the standard terminology and standard value sets. I guess I put terminology before the value sets. The value sets are incredibly important but I have found with some of the work that we've done through emergency department data sets and also some pressure ulcer data sets that until we really bind that to a common terminology it still is not quite enough to really get that standardized exchange and even an understanding of what's happening with the patient. There is still an interpretation that happens between your value set and your terminology and so we need to drive it all the way into that very deep level of detail.

The other thing that I wanted to address is how important it is to get the clinical decision support integrated and embedded into workflow, and that's not a trivial thing to do. We have done a lot of decision support at Intermountain Healthcare and I was engaged in a study that took some of our protocols into 11 other hospitals across the country and its human nature that people look for kind of the shortest route around. And so work arounds are quite common with clinical decision support. And so, you can even say that, yes, we have decision support. We have this many rules. We have this kind of an outcome but until you know that you're following it as intended you don't really know if you're getting the quality as intended because of those workarounds. And that even comes to the data entry pieces.

We have talked today about how important it is for the data that's collected is feeding the decision support. And so, again, if we don't help people understand how important it is for their data that they're entering and how that is impacting the decision support and the quality, there are workarounds that happen with the data entry, which is why we see a lot of free text and items that are not quite as usable to us.

So, that leads me to the idea that came up also today as related to cultural changes and how important it is, and how I believe that through quality measures we can impact the culture, and that is that we need to instill in the very youngest, most novice bedside clinician a value for decision support, a value for the quality that decision support is trying to get to, and also that they trust it because we still have a culture in our health care where my experience is almost more than what I am being told by the clinical decision support system or the quality measure. I saw this in 10 patients, I believe this is better than what that no name person has told me through a quality measure or through a decision support system. So, we really need to start learning or looking at how can we instill confidence, trust and value into what we're trying to get to here. Thank you for your time.

MacKenzie Robertson – Office of the National Coordinator

Thank you, go ahead.

Evelyn Knolle – Senior Associate Director of Policy – American Hospital Association

My name is Evelyn Knolle I'm with the American Hospital Association and I'm actually standing in for our expert on HIT at AHA who is traveling, but I just wanted to echo a few of the comments that I've heard today. The AHA is committed to automated quality measurement and we understand that to be useful it's got to be feasible, it has to provide reliable and valid data, and it has to provide a real benefit. And we agree that we are not there yet. We heard in Stage 1 from our members a lot of who had problems with the e-Specifications and the known errors in the e-Specifications. We also heard some concerns about the validity of the data being reported out of EHRs. And we have come to really appreciate the need for robust field testing, which has been commented on a lot today and we fully support that.

One of the panelists mentioned adding new measures in Stage 3 and I think we would say that before we add new measures we need to do right with the measures that we have. And Stage 1, as we like to say, was about getting started and now we need to work on getting it right. And the AHA looks forward to working with CMS and other stakeholders to do just that.

MacKenzie Robertson – Office of the National Coordinator

Thank you very much. Are there any other public comments in the room? And seeing no public comments on the phone, David, I'll turn it back over to you.

David Lansky – Pacific Business Group on Health – President & CEO

All right, thanks MacKenzie, thank you all, thanks for these last comments as well. And we are adjourned, we get to go home early. And some of us will see you back here tomorrow for the patient generated data hearing. Please come or dial in if you can. Thank you all.