Patient Safety: Why It's Getting More Visibility
Alliance for Health Reform
April 7, 2006

[1] kaisernetwork.org makes every effort to ensure the accuracy of written transcripts, but due to the nature of transcribing recorded material and the deadlines involved, they may contain errors or incomplete content. We apologize for any inaccuracies.

[START RECORDING]

ED HOWARD: Good afternoon. My name is Ed Howard. I'm with the Alliance for Health Reform and on behalf of our board of directors chaired by Jay Rockfellow and vice-chaired by Bill Frist, welcome to this briefing on a topic that really touches tens of millions of lives every year in this country and that is patient safety. Our partner in today's program is the Leadership Association of the RWJ, Robert Woods Johnson Foundation, executive nurse fellowship program. you will find a sheet describing both the Fellowship program and the leadership Association at the back of your packets at the right hand side. So, you get a sense of who these folks are and what they do. You will hear more of that from Cindy Percelli [misspelled?] who is representing the Leadership Association this afternoon.

Patient safety is a topic that we tend to take for granted but we sure shouldn't. Yesterday for example, I was recruiting a speaker for a briefing that we are doing next month but the potential speaker was unsure of her availability because she was nursing her husband through a staff infection that he had acquired at a local hospital sometime while he was in there for surgery. Well, that kind of story could be multiplied by millions each year. Everybody agrees that not improved patient safety; I mean nobody is against it. Right. But when it gets down to what to do about today's problem there is less than antinomy. There are questions about what kinds of

errors get reported, whether the reporting is voluntary or mandatory, how to structure the incentiatives that might make safety a priority, how to foster the leadership that does that in individual institutions. A whole multitude of questions on which there is something less than consensus. And we are going to explore as many of them as we possibly can in the next hour and forty-five minutes.

Last year as most of you know Congress passed some patient safety legislation and we will hear something today about how that new law is being implemented. And I hope we are going to explore what other steps might be needed either in the public or the private sector to bring about improvements in the area of patient safety.

A quick logistical digression, in your packets you are going to find a lot of background information including the slides from our speakers and speakers bios that are more extensive than I will have time to give them. There are by the way two versions of Mary Ann Fuchs' presentation, one in which are the cliff notes version she will actually give, so be aware of that. And by close of business today you will be about to watch a webcast of this session on kaisernetwork.org. In a few days, you can go back to that or to our website and look at a transcript along with most of the materials that you see in your packets so that you don't have to hang to the hard copy if you don't need them. And those of you who are new to this

process, you wont be as bored as the rest of you when I ask you that at the appropriate time you can fill out green question cards for our speakers, you can go to the microphones that are set up in the audience for you to ask questions orally and there is a blue evaluation form in your packets that I hope that you will fill out to help us make these briefings better for you.

We have with us today representing the RWJ's executive Nurse Fellowship Leadership Association, Cynthia Armstrong Percelli who is associate dean of the West Virginia University School of Nursing. She is also a former RWJ Nurse fellow and she is on the board of directors of the leadership Association. She firs got acquainted with the Alliance and vice versa when she was that nurse fellow in the office of senator Jay Rockfellow, our chairman, so we are happy to welcome you back, Cindy.

CYNTHIA ARMSTRONG PERCELLI: Thank you Ed and on behalf of the Robert Woods Johnson Executive Nurse Leadership Association we are please to be able to be here to c0-sponsor this briefing. I just wanted to say very briefly that the Executive Nurse Leadership Association of the Robert Woods Johnson Nurse Fellows Program is a group a nurses who have been fellows in the RWJ Executive Nurse Fellows program who really work at the inner section of health policy of patient care, of research, and education. And really as senior nurse executives

have the opportunity to impact on issues like patient safety. So we are pleased to be here to be able to talk about and talk with experts and that the area of patient safety to look at how these policy implications really affect the point of care. You will see members of the alumni group throughout the room and they have nametags like this one. Please feel free to ask them more about this group.

We are also, both of our organizations are happy to be a part of the Robert Woods Johnson Foundation and a part of groups that they sponsor. We are pleased to be able to also introduce some of the leaders in the program, in our program: Marilyn Chow, who is the program director for the Robert Woods Johnson Executive Nurse Fellowship is here. And Marilyn is a senior leader in her own right. Also, Dr. Ed O'Neil is here. Dr. Ed O'Neil is the principle investigator for Robert Woods Johnson Executive Fellows. So thank you for being here. I am going to turn this back over to Ed for introductions of our panel.

ED HOWARD: Thanks. I think it's pretty clear that this program wouldn't have occurred had it not been for the vision and tenacity of Cindy Percelli. So, we thank her for that.

[Applause]

I should note by the way in light of the relationships that Cindy so carefully plotted for us amongst the various entities that we are going to be exploring this issue further

in May looking at the explicit connection between patient safety and nursing in partnership with Robert Woods Johnson Foundation in some of the projects that they have funded on this specific topic. We are hoping to schedule sometime during National Nursing Week which is May 8 – 12 or something like that.

We have today by the way just an incredibly good line up of speakers to help us understand patient safety, medical errors. It is also more numerous group than we usually have so I apologize for trying to keep us on course, on schedule so there is enough time for discussion and questions. Having said that, we are going to sort of violate it in the very first instance because our first speaker is Carolyn Clancy who recently marked her third year, completion of her third year as Director of the Agency for Health care research and Quality, the HRQ. Carolyn is an internist by training, one of the country's outstanding health services researchers. We are happy to have her back even if we can only have her for a little bit. So, we are going to after her remarks take a few questions and then we will go on to the rest of the panel. Carolyn thanks so much for making time for us.

CAROLYN CLANCY, M.D.: Thank you very much. Good afternoon everyone. Really delighted that you could get here when the weather wasn't entirely cooperative. I am still waiting for that sun. I also want to tell Cynthia in particular

but many people in the audience that I am very proud to have serviced as a mentor for one of the Robert Woods Johnson Nurse fellows who couldn't be here today but she sent me about three e-mails to say she was sorry. She hoped that it went well and was feeling quite deprived that she couldn't be here. I have to leave early today because my advisory council is in today discussing some of these very same issues. So, I apologize for jumping in and out.

So just a few words about the Agency for Health Care Research and Equality, we are a research component of the Department of Health and Human Services. Our mission is to improve the quality, safety, efficiency and effectiveness of health care for all Americans. In contrast to NIH, that focuses on biomedical and these days, sort of submolecular research to prevent, diagnosis and treat diseases. In the Centers for Disease Control that focuses on population health and the role of community based interventions our focus is really long term and system wide improvement of health care quality, safety, and effectiveness.

Now the Commonwealth Fund did a really terrific survey this past fall of sicker adults in six countries. You can see here the United Kingdom, Germany, New Zealand, Australia, Canada and the US. So, what you got here are developed countries with very different health care systems. This is on the health affairs website. What I found quite striking is for

sicker adults none of our country systems have figured out how to do it very well but I was particular struck by this as well. According to respondents in this survey, a higher proportion of folks in the US noted the occurrence of any medical mistake, error, or test error in the past two years. Now again remember these are the sicker patients, the people for whom we tend to spend the most money and provide the worse care. So, issues of errors cut across that population as well.

Since the Institute of Medicine published their report and I think you will all know what an incredibly strong role Janet Corrigan played in that report, in late 1999 to ***Err is Human***? We have really had an incredible opportunity so any of you who had anything to do with this appropriation since 2001 for us thank you again. We have been able to fund over 225 patient safety and related health IT projects since 2001. Very recently, we awarded over eight billion dollars in funding for fifteen partnerships in implementing patient safety. Early on, states told us that they have lots of data but they don't have human capital. So, to that end we are now just about to graduate our third class of the patient safety improvement corp. these are health professionals from multiple disciplines who come to Washington or another site for about three weeks of really intense preparation. They do most of their work at home so its mostly distance learning. We do this collaboratively with VA. We get to take advantage of VA's expertise in patient

safety. They get to see to what extent their methods are applicable and to the rest of health care system, which tends to be a little messier and more chaotic than the VA system. We are also working closely with defense, CMS quality improvement organizations and so forth. So, our portfolio from the offset has tried to span a spectrum that includes identifying, learning more about safety and issues outside of the hospital where our knowledge base is not so well developed, all the way from that end to working in partnership with multiple organizations who can implement what we know to make health care safer as rapidly as possible.

In 2007, the president's budget gives us 84 million dollars for a combination for patient safety, which includes our investments in health IT. Our big push for 2007 is going to be ambulatory patient safety. What do we know about medical errors and making health care safer in ambulatory settings? That same commonwealth survey found that actually most of the respondents in all countries reported a very high proportion of errors in out patient care. If you think about the opportunities for poor coordination, transitions, and lost information, its not terribly surprising so there is a lot of opportunities for improvement.

Right now, we know that current private and public sectors of patient safety programs focus largely on the care for hospitalized patients. And that is important. If you follow

Suttens [misspelled?] law that is where a lot of expensive care takes place and where there is a lot of opportunity to have big impact results. But this investment is now going to turn our attention to ambulatory settings. Our primary over arching focus is going to be improving the safety and the safe use of medications. That will be a strong role for health IT or the effective use of health IT to improve safety in outpatient settings.

So those of you who might be from Virginia, any appearance that makes you think of the mixing bowl is entirely consequential here. This you know, little figure is supposed to actually focus your attention that our efforts are focused squarely on the intersection of safety and quality in health IT. So far, we haven't been able to support diffusion of health IT to 38 states with a primary FOCUS on rural and underserved communities. We estimate that this has the potential to impact the care of up to forty million Americans. Very importantly, we have also been working very closely recently with the community health centers.

To put this in prospective for HHS's health IT efforts, where the security in the American health in the nation and community are focused on policy and the questions of how can we accelerate the adoption of health IT and how can we deliver value to the American health care consumer and the office of National coordinator is focused on building a nationwide health

information infrastructure or what might be referred to as the pipes. Our FOCUS is really on providers. How can providers use health IT in hospitals and ambulatory care settings to improve the quality of care and patient safety. You might think that those two statements go together immediately. In fact, with vendors in particularly people trying to implement health IT will tell you is that the hardware and the software is about one third of the answer. The rest is all that really messy stuff about human behavior and people working so that the health IT can deliver the value that it promises. This is what Secretary Levitt refers as the sociology rather than the technology.

What I want to turn to now is just to describe the patient safety bill. This bill has been in the making for quite some time and was signed into law by the president in July of 2005. The purpose of this act, it's the Patient Safety and Quality improvement Act, is to provide for the improvement of patient safety and to reduce the instances of events that adversely affect patient safety. As Ed just noted a couple of minutes, everyone is for this. And I think the enthusiasm behind this bill reflects that broad scale recognition of the importance of patient safety and also the importance of promoting any efforts to make health care safer.

What's the problem that this bill is intended to address? Providers fear that patient safety analysis can be

used against them in court or in disciplinary proceedings. So for example, if all the hospitals in the District of Columbia wanted to get together to work on a common safety problem, they could do that. But any additional information that they generate by way of looking at patterns of errors, or near misses or evaluating the impact of strategies intended to reduce the incidence of those errors and near misses is potentially discoverable. That tends to have a fairly chilling effect on that sort of collaborative activity. State laws really offer inadequate protection so for example, some of the large systems like Trinity or Premier or pick your favorite that have institutions in different states, pretty much have been advised by their lawyers, do not share. It's one hospital at a time.

In patient safety, improvement is hampered by the inability to aggregate data. Imagine if hospitals and other providers, health care organizations could work together collaboratively, we could learn from their results so we wouldn't have to keep replicating some of the same incidence of errors and so forth. Not only that we could get to a place where patterns of failures could be more rapidly identified. So, the issues the Act addresses, it authorized the creation of an entity that we refer to as a patient safety organizations. These organizations can enter into contracts with providers to assist them in analyzing threats to patient safety and

Correcting or preventing them. So, in other words, multiple health care organizations can work together. They may or may not be geographically located. A hospital in DC would be working with one in California or Hawaii for that matter. But the point is working under the construct of a patient safety organization that additional work that they generate, that additional work product – you can tell I have been lots of time with lawyers – is protected. No one loses their rights to sue that they have right now, but that additional information would not be discoverable. The law further requires that PSOs work with more than one provider so that those patients' safety organizations can aggregate data across providers and with other patient safety organizations. And the law provides federal confidentiality protections for these analyses and significantly limits their use in criminal, civil, and administrative proceedings.

So we are now in the heavy throws of trying to figure out how to get out a regulation to make it incredibly clear to people what is effective patient safety organization, what is going to be require to become certified as a patient safety organization, and what precisely are the boundaries of that protected space because if we are not clear about that, this bill will not have its intended impact. There is no money in this bill. It remains to be seen whether there will be a business case where people were to participate with patient

safety organizations but we have got to be as clear as possible about what is the protected space.

We are going to be focused on the efforts and learning from input from those who are involved at the sharp end. That is to say the front lines of delivering health care. we are also going to be building on existing work done by the private sector and previous conceptual work done by the Joint Commission and the National Quality Forum and others. We are going to be working very closely with our partners in the Department with the Veterans Affairs and DOD. We are going to be hoping to use IT to the maximum extent, practical. At the end of the day, though our guiding principle and every meeting we start with this guiding principle is to keep it simple. We want the lightest possible regulation but we need to make it as clear as possible what is that protected space, what do you need to do to be patient safety organization. So, we have just finished having three listening sessions. We had several hundred people at each of these listening sessions, incredibly helpful questions. I have never talk about this to an audience where somebody didn't pose a question where – I didn't say this publicly but inside I was thinking oh, we didn't think of that. So, that's exactly why you have listening sessions.

We are currently developing regulations to govern the operations of the program and have been compiling for a while now again based on a blueprint, pretty much provided by the

Institute of Medicine in their report in November 2003. We have been compiling an inventory of operational patient safety reporting systems. The reason we have been doing that is that the law allows the Secretary to disseminate common formats for reporting events and threats to patient safety. These would be voluntary, they are not required but I think most people would like to know if I am going to be collecting information, for example, on medication errors, I would like to know I am using the same definition as somebody else. So, I can sort of compare what our results look like to someone else's. In addition to that, so that will focus on patient safety incident definitions. The law also allows the department to create or work with promote the creation of network of patient safety databases. Okay, you don't just want to be reporting stuff and put it all in one big pot because you would then be creating what one of my colleagues refers to as a data graveyard. So, we are going to need something that builds on the [inaudible] textomy and whatever systems have already done to make it easy for people to report errors and near misses.

Before I close here, I do want to alert your attention as a part of celebrating national patient safety week a couple of weeks ago, for the next couple of weeks, for the past month we have had this poster on various trains in the Metro system so I would hope that you would keep an eye for it. This is a poster from a campaign that we launched with the American

Medical Association and the American Hospital Association, five steps to safer health care. This was to let the public about steps that they could take right now to make sure that they got safe health care. Please understand that this was not about saying we can't figure it out so it's up to you now. But more to let people know that they too have an important role so the steps are pretty straightforward. Ask questions if you have doubts or concerns. That sounds real self evident, does it? on average people ask about 1.4 questions per clinical encounter, that includes questions about parking. The second step is to keep and bring a list of all the medicines that you are taking. We are working very hard particular around the – now that the Medicare drug benefit is becoming real to work with AARP and others to get this message out. The third is to get the results of any test or procedure that you have done. And most doctors have their own internal code except they don't always even think to tell you what it is. Some assume that you know that they think that no news is good news; others contact you no matter what. You don't need to know the code; you need to know the results. The fourth is to talk to your doctor about which hospital is best for your needs. And the fifth is to make sure that you understand what happens if you need surgery or have another procedure done, what precisely is done to you. as a doctor, I can tell you often times people simply don't know the details of what happened to them which is really too bad when

we need to make some decisions that would be highly informed by knowing the details.

So, with that let me thank you for attention. And I am really very excited to be here today.

ED HOWARD: Thank you very much, Carol.

[Applause]

All right. You now have the opportunity and the time to ask slightly more than 1.4 questions but you have to do it. And if you will go to — if you have a question on a card for Dr. Clancy you can hold it up real quick but I urge you to use the microphones because we don't have much time. Let me just take advantage of the lull here to ask a question that was submitted in advance, if I can, Carol. And that is someone who is concerned about and notes the juxtaposition of the quality and disparities portfolios that AHRQ holds and I guess the question would be how do you use the interest in alleviating disparities as a way of dealing with patient safety.

CAROLYN CLANCY, M.D.: Well, I think a common theme there for both is that you can't improve what you can't measure. This issue of having common definitions and so forth would be very important. We have done a little bit of work with some tools that the Agency developed, these patient safety indicators to look at selective aspects of hospital care to examine disparities as it pertains to patient safety. And it's pretty much a mixed picture. Now it's a mixed picture in the

context of the fact that many states don't have good data on the Hispanic population. So I would say our information is pretty limited. Interestingly the Kaiser Family Foundation did a survey a few years ago and people who are African American or Hispanic believe that they have a higher chance of experiencing unsafe care. So, I think that perception alone ought to make sure that we try to connect the dots as much as possible.

FEMALE SPEAKER: Thank you. As a pro—

ED HOWARD: Do you want to identify yourself please?

SHARON STRAITCEE [misspelled?]**:** Okay. Thank you. Sharon Straitcee from the state of Florida in public health. As a public health nurse and administrator, are we looking at anything in school health or home care. You talked about in-patient and out patient settings, is that part of what you are looking at as well?

CAROLYN CLANCY, M.D.: So far our investment for 2007 and this is literally the discussion we are beginning to have with our advisory council this afternoon, is pretty wide open in terms of what are the boundaries of ambulatory care. I could imagine lots of interesting issues that come up or opportunities for dropping the ball if you will in coordinating between school health, either the nurse or teacher making a recommendation to a clinician about what a particular kid needs or the fact that that school health entity needs to be helping a kid with who needs to take medication or get treatments

during the school day. So there is no reason that that wouldn't be part of it. We also have some additional authority in the Deficient Reduction Act, which urges us to work closer with CMS on the needs of people living at home who have disabilities and chronic illnesses. So, that is definitely going to be on our radar screen.

MARLIYN PARK: Marilyn Park, American Federation of Government employees represents the Veterans Administration employees, which is a large number in the Veterans health care settings. There is currently a major of reorganization of IT going on and a lot of our front line health care nurses and other professionals are concerned because if the unique sort of interface that has made VA health care and patient safety so good, now centralized. We ought to be concerned about the impact on that whether we will be able to ensure that the changes don't impact our abilities to deliver health care in the safe way. I think we do that very well. And I just wonder if that had been looked at all because I know the VA is such a needer in this area.

CAROLYN CLANCY, M.D.: My understanding from colleagues at the VA is that they too share that concern and want to make sure that it has the least possible impact on front line providers. In other words, as this system is being reorganized that you know the primary FOCUS is making sure that the front line folks can actually continue to deliver health care safely

and as effectively as possible. But frankly this is a big issue for the portfolio projects that we are funding that go under the heading of health IT but are actually very much about patient safety because again all of the issues that relate not to the hardware and software – hardware and software don't cause problems but people misusing them or not using them as intended do. And that's the part where we have got to keep getting it right and build a better evidence base for getting it right.

MARLIYN PARK: Right on the radar screen. Thank you.

ED HOWARD: I think that we have time for just one more question depending on Carolyn's advisory council's insistence on her presence. Yes, go ahead.

GREG SHUCKMAN [misspelled?]: My name is Greg Shuckman, I am with the University of Central Florida. A couple of weeks ago we just got approved to have medical school so we are anticipating all the challenges that there will be associated with that. The question I have for you and you have spoken to this before a little bit was about the role of stimulation. How do you see that evolving in terms of being able to use? Recently more team stimulations of team training and how that can improve and adapt to safety in medical.

CAROLYN CLANCY, M.D.: First of all let me just note that I happen to live, this is just consequence, a couple of blocks from the annex to Walter Reed, which is in Silver Spring

and at the annex to Walter Reed there is the most incredible stimulation laboratory. And they take the broadest possible definition of stimulation, which I think is great. Everything from using trained actors NSAID which students learn to do interviews and do physical exams, up through – I mean totally amazing life science fiction like gizmos that involve people working on responses, preparing to respond to mass causalities even though they are working in very remote locations, so it's all there. They have got the headsets for the 3-D surgery and all of that. I think that it is an incredibly exciting opportunity for the future. I know more and more medical centers are actually taking advantage of that. The day I went over to this – it's the Uniform Services University, the health sciences of the military medical schools through stimulation lab – when I went over there I saw about three different groups touring around because they want to start that on their own. I think it would be a great thing to build in from the ground up. I would just encourage that you take a very broad view of what is meant by stimulation. It is not just the machines but it encompasses the whole range of strategies that includes stimulated training for teams and so forth. The other thing I can say is watch our website. You will see something soon. That is all I can say right now or I would have to shoot you.

ED HOWARD: Well shoot me then but Carolyn thank you so much for making time to do this. I think we will inform the

rest of the discussion. Good luck with the advisory council.

[Applause]

Let's take the best advantage that we can of the rest of our experts who we have. Let me introduce them en masse if I can so that we don't disturb the flow of the conversation once we get started. We are going to hear next from Janet Corrigan whom Carolyn Clancy actually complimented institutionally talking about the force and importance of the Quality Forum of which Janet is now the President and CEO. It's a private organization, one of the most respected voices in the quality arena and just recently brought about the merger of the Quality Forum and the group she had been heading for the last year, The National Committee for Quality Health Care. Many of you know Janet from the key role she played as Carolyn mentioned in this series of influential quality studies done for the Institute of Medicine.

Then we will hear on Janet's left, from Tom Nolan who is the co-founder of Associates in Progress Improvement and also a senior fellow at the Institute for Health Care Improvement. Tom's frankly given most of the credit by Don Berwick [misspelled?] and others at NIH for the hundred thousand lives campaign which most of you have heard about and about which Tom is going to tell us some more today.

On my far right is Steve Mayfield who will speak next. He is newly appointed senior vice president for quality and

performance improvement at The American Hospital Association and director of the AHA Quality Center. Steve has got a wealth of real world experience in improving patient safety much of it from the state of Georgia. He is a winner of the prestigious Denning [misspelled?] Medal from the American Society of Quality.

Then finally we will hear from Mary Ann Fuchs who is the chief nursing and patient care officer for both Duke University Hospital and Duke University Health Systems where she is responsible among other things for managing almost six thousand nurses system wide. She is also, no consequence here, a former RWJ Executive Nurse fellow.

So, let's get started and hear first from Janet Corrigan. Janet thanks for being with us again.

JANET CORRIGAN, Ph.D., M.B.A.: I hope you received – I have to apologize though. There are two handouts and we didn't get them to the Alliance on time to make it a packet but they were available outside so hopefully you have those. Please excuse our tardiness. This is actually my first week on the job as at the National Quality Forum. So, it's a little bit chaotic at this point. But it is a real pleasure to be here. I appreciate the offer.

As Ed indicated, NQF is kind of a unique organization. It was established back in 1999 following up on a recommendation of the Presidents Commission on Consumer

Protection and Quality. It is a non-profit organization. But it is a public/private sector partnership entity. The primary purpose of the organization is to endorse performance standards and other types of tools that will help to facilitate the reporting of performance information whether that is on safety, effectiveness, consumer centerness, equity, a whole range of indicators and to facilitate being able to make comparisons and everybody being able to understand that information.

The organization has about 325 members and they come from all different stakeholder groups, consumers, purchasers, providers, health plans, researchers, QIOs. The board of directors is a mixed of both public and private sector individuals. Carolyn Clancy and Mark McClellan are both a part of the NQF Board. The consensus process that we have in place for the endorsement of standards, that process meets the requirements of the National Technology Transfer and Advancement Act, which means once standards have been endorse by NQF they are the ones that should be the first choice for the federal government in its various programs.

Over the last five years or so, NQF has developed a set of tools, safety specific tools. These are tools that should be very useful to those patient safety organizations that we all hope will develop rapidly as the result of the recent legislation. There are also tools that are useful to particular providers and for any forms of public reporting systems.

I am going to touch on three of them today: a set of safe practices, adverse event and patient safety enbenched classification system. There are three reports that have been produced in each of these areas: safe practices for better health care, serious reportable events in health care and standardizing the patient safety taxonomy. We will be pleased to provide you with copies of any of those if you would like to see the full reports. But I will give you quick summary today.

In 2003, NQF identified and endorsed thirty safe practices. These are practices that if they were adopted by all health care provider organization we believe that they would significantly reduce the risk of harm to patients. Harm from the various procedures, systems, and environments of care. These are practices where there was a strong evidence based. They are also ones that are generalizable across various settings and types of patients. They are ones where we know what to do. We have a good knowledge base as to how to make improvements so we know that there are currently not – have not been adopted by many health care organizations but we know that there is a strong evidence base and we know how to put them in them in place so we should be able to have a significant improvement on patient care.

These thirty practices fall into five major categories: creating and sustaining a culture of safety, matching health care needs with service delivery capability, information

management and continuity of care, medicine management, and informed consent and disclosure. Now one of the handouts that you have today is a one pager that lists the thirty practices. And they include things like having an explicit protocol for adequate level of nurse staffing. They have had institutions of patient mix and they are experience in training of their nursing staff. It also includes things like when verbal orders are taken; they should be immediately recorded and read back. You should have computerized order entry systems for medications and other orders. Referring patients to high volume providers, whether there is a significant evidence base that those procedures obtain better outcomes when done by high volume providers, but you can read through the entire list yourself. They are very reasonable and as I said, evidence based practices that should be adopted by every health care provider now.

The second tool that is in the NQF toolbox is a set of twenty-seven serious reportable events. These are events that could be reported to the patient safety organizations that would likely develop as a result of the law. There are events that are well defined. They are preventable. And when they occur they generally result in very serious injury to patients. These events were identified in response to a call form measures, which is how the NQF process is conducted. And they were six types of events that are included in this list. Some

of them are surgical events like wrong side surgery, performing surgery on the wrong patient. Some of them are events that relate to products are devices for example; a patient is injured as a result of a contaminated drug or device. Others have to do with patient protection, patient suicide or disappearance. Care management, for example, advance stage pressure ulcers for patients who are institutionalized in institutional settings. Maternal death, others have to do with the environment, deaths associated with patient falls, and last but not least, criminal events such as sexual assault. You also have a full list of these serious reportable events in your packets today as well.

Now the third tool that I want to mention that the NQF has endorsed is a patient safety taxonomy. It's very important to adopt a particular taxonomy that all of the patient safety organizations should use. The taxonomy is a standardized way to classify the events that are reported. It also includes a detailed instrument for recording information on the various events that will be reported to the databases. NQF endorsed the JACHO, patient safety event taxonomy. There are efforts currently underway to harmonize this taxonomy with one that is used on a wide spread basis within other countries in European countries. Ultimately, we would like to have a taxonomy that is used worldwide so that we can compare these data, we can aggregate them into various categories and look at trends over

time. That is a very important part of getting the most out of the kind of information that we will be reported to these patient safety organizations. And this taxonomy that essentially enables that mapping of these events, the aggregation, the analysis, and real learning from what will likely be tens of thousands and over time hundreds of thousands of events that are reported to patient safety organizations. Taxonomies also help to facilitate the prioritization of these events. If you talk to some of the folks that have had patient safety reporting systems in place, one of the problems that they frequently have is that they are inundated with reports and they don't have adequate staffing to be able to analyze, conduct a root cause analysis, and frankly some events are probably much more important to analyze than others or that we can prioritize and FOCUS our attention on those that are likely to point to very significant problems where systemic solutions can be found and put into place. The particular taxonomy that NQF has endorsed has five domains that will be reported for each of these events: discovery, events specifics, axillary information, causal analysis and lessons learned. It also has standardized definitions and various principles for improvement.

So, in summary, NQF has put together a safety agenda, which is being advanced in partnership with many other organizations. Those thirty safe practices have been

implemented by many health care providers across the country. They are also currently being update and will soon have an additional report that provides more detailed guidance to health care settings on how to implement those safe practices. There are various mandatory reporting systems in place across the country. About a third of the states currently have mandatory reporting systems. Some of them, about a dozen, those that have put them in place in more recent years do use the adverse events, the reportable events that NQF has endorsed. The Tri-Care system of DOD has also adopted and requires its managed care organizations in health plan that have been in contracts with to use the serious reportable events that have been endorsed by NQF. We think that these events and the taxonomy will be particularly useful to the patient safety organizations that are currently working with ARC and others to hopefully ensure their adoption by those organizations as we move forward. Thank you.

ED HOWARD: Thanks very much Jan.

[Applause]

Now let's hear from Tom Nolan.

THOMAS NOLAN: Thank you. I am Tom Nolan, senior fellow at the Institute for Healthcare Improvement and IHI is a not for profit organization based in Boston. Our mission is to help accelerate the rate of improvement of quality and safety in health care.

In December 14th, 2004, Dr. Donald Berwick [misspelled?] the CEO of IHI announced the hundred thousand lives campaign that I am going to give you a brief overview of that campaign. As part of our work, we have programs that bring together health care organizations be they clinics, doctor's office, or hospitals around common aims such as medication safety, chronic disease management, delays in waiting times. And typically, there would be thirty to eighty organizations that might enroll in such a program around the common aim and over six month to a year period, they would develop and test changes based on evidence. But we were becoming frustrated with the pace of national change. We might have fifty hospitals in a, what we call a collaborative but there are five thousand hospitals in the United States so that that's a pretty slow pace. So during the time where we were concerned about this the 2004 presidential campaign was raging and we got to be thinking perhaps some campaign thinking be applied to improvement and then as the results of that we consulted with some experts who run campaigns and got some ideas from them.

The campaign's objectives were to save a hundred thousand lives starting December 14th and ending June 14th, 2006. Now we must be explicit about what do we mean by saving a hundred thousand lives. The campaign is focused mostly on hospitals and nurses and doctors and hospitals day in and day out save lives.

What is the campaign about? The campaign actually is about accelerating improvements in health care systems so that nurses and doctors work in better systems and do even a better care for patients. So for example, our baseline is 2004. So if a hospital had ten thousand admissions in 2004, a campaign hospital. And they had a mortality rate; death rate of three percent then three hundred people would die in that hospital in 2004. Assuming about the same severity of illness, similar volume of ten thousand in 2005, if their mortality rate was 2.5-percent, down from three, then 250 people would die in 2005. So, the difference between three hundred the baseline and the 250 we would count fifty lives saved. So, across all of the organizations that's a little bit more complicated than that but that is the basic idea of how we are making the count.

Our other objective was to enroll more than two thousand hospitals. As it turns out, we are up over three thousand hospitals now enrolled in the campaign, and to build what we call a reusable national infrastructure for a change that we could use for other topics besides mortality in hospitals and to raise the profile of the problem. The problem being the gap between what is known in the literature and what systems in hospitals can provide. Here is a map of the enrollees in the campaign. It's a little over three thousand as I mentioned. We have every state represented in the campaign.

So, what is that they are doing in the campaign? Well,

we have campaign platform with six clients or interventions. Those six can include some of the things that Janet mentioned. Actually there is quite an overlap between these and the things that Janet mentioned. One is the deployment of rapid response team. By this it means a nurse or a doctor or respiratory therapist whose on a regular medical surgical unit, if they see a patient deteriorating and don't have help immediately available to them, can call a team typically to come from a nurse and a doctor from the ICU to help them out, evaluate the patient, and decide on disposition. Second, delivery of reliable evidence based care for heart attacks. Prevention of adverse drug events, certainly drugs can be very helpful but they can also cause harm if the doses are not right or if there are interactions between drugs. In particular, we focused on reconciliation of drugs. You come in on certain drugs, those drugs maybe doses or different drugs, you change while you are in the hospital, and its hard to keep track of all of those and it can result in some pretty serious harm. Prevention of central line infections is another one we focused. Patients who need frequent intravenous medications or blood or for other reasons may have a central venous catheter or a line inserted in one of their veins. Those lines are often helpful but also bacteria can grow in those lines and cause infections in the bloodstream. There are known interventions to reduce those infections. The sixth point was prevention of surgical site

infections. Infections in the part of the body where the incision was made and finally, prevention of ventilator associated pneumonia, very sick patients who need help breathing are on ventilators but those ventilators can also cause pneumonia. So, we asked people to work on those six planks. We gave them some ideas on how to actually make progress on those so three thousand hospitals are at work on some or all of those planks.

We made a projection on what the savings would actually look like. Given our calculation, you can see back at the end of last year we have a little break where it's say well, if things just proceed linearly where would we be, up around seventy thousand but if they accelerated, that is the hospitals got better and better at making these improvements, which is often the case, when you start an incentiative, you start slow and get better. That's the second line. And I think we are – right now, we believe that the accelerated line will be a better predication of where we will end up June 14th.

The campaign participants so far we have had tremendous support from the American Nurses Association, The American Medical Association. There have been large systems such as SSM Healthcare and Ascension have been part of this effort. Federal agencies such as the Agency for Healthcare Research and Quality, Dr. Clancy's organization, has been fantastic help and others that you see here. So, we have actually put together

endorsements from a large variety of groups and also got some technical help from a large variety of groups.

The actual campaign structure itself looks something like this. We have IHI campaign leadership, which we started, introduced, and got the campaign organized, have ongoing communications and coaching of the three thousand participants. Then in the middle there we have what we call nodes, approximately seventy-five of them. We knew we couldn't coach all three thousand hospitals but for example, the North Carolina Hospital Association is a node and the National Association of Public Hospitals is a node for public hospitals. They have their own programs that they help support and coach the individual point so we're starting out there. And of course all of the facilities now which is over three thousand.

So, the campaign this phase will be complete in June 14th. We will announce the number of lives saved then in Atlanta at a meeting we are having. And the possible ways forward here, not all the organizations are working on the six planks so there is some next steps we could think about of having them expand their efforts. We could work on different topics. We could work on school-based health that someone else worked on because we have a national infrastructure now, we could choose topics and deploy some of these things much more widely. So, we are still with some help of advisory groups trying to decide on what the next topic will be. So, thank you and I wait for your

questions later on. Thank you.

ED HOWARD: Thanks very much Tom.

[Applause]

Thanks very much. Let's move on to Steve Mayfield to begin.

STEPHEN MAYFIELD: Thank you Ed. I am very honored that Ed bestowed on me the prestigious Denning [misspelled?] Award, which I do hold in high esteem. I should point out though it was Mr. Thomas Nolan who actually received that award and we should be grateful for that.

ED HOWARD: My apologizes.

STEPHEN MAYFIELD: Similarly, I have not won the Nobel Prize, nor the Congressional Medal of Honor. [Laughter]

You have been hearing a lot about policy and approaches. I am going to drill down a little bit both at the thirty thousand foot level for hospitals and also to very micro levels. I am going to jump back and forth between the two. So, the next few minutes, my goal is to talk about what are we doing to help hospitals improve quality in patient safety. American Hospital Association has about five thousand hospital members and there are little over six thousand hospitals in the United States. We are working hard to support their efforts to improve quality and safety. I am going to talk a little bit about how we are doing that.

What are we trying to accomplish? We are trying to

improve through put in hospitals so that when patients arrive, they get served quickly and they get served efficiently. They get out quickly because people are sick in hospitals and their infections are flowing around so we would like to reduce length of stay. We would like to reduce readmissions, going to improve the patient matching identification process. When you first show up to the hospital you get identified one time, every thing after that subsequentially fifty or a hundred steps just matching your initial identification to a order. We want to make sure that happens appropriately because right now people can get blended records. We want to reduce health care associated infections. We are working on improving medication safety, incidents of falls, topical process that you read a lot about in the paper, congestive heart failure and acute myocardial infarction, pneumonia, as well as surgical site infection. And finally, if we do all those things the cost per adjusted discharge comes down.

So, what are we trying to help hospitals do? There are really three main things. I am going to talk about process. We want to remove waste from processes, eliminate defects and reduce severibility. I know that is something that is very near and dear to Tom. Our work is a system. Every system has processes and every process has waste. So what I am going to do is I am going to drill down into the very detailed layer quickly just to show you the basic process that almost all

hospitals share in common. This is a busy slide but you have it in your handout. I am a patient and I show up at the ED. There is information about me available. My arm hurts. — You want me to speak more directly, how that — My arm hurts, I have a grey pallor, I am sweating, my chest hurts, it's hard for me to breathe. Physician looks at me. He is going to make a clinical decision. He says I suspect Steve is having a heart attack. He has made his decision or she has made a decision. She turns that decision to the system, which then initiates a care process, a number of steps. The care process in this instance might include an aspirin for me, a beta-blocker if appropriate, a twelve lead EKG, draw lab specimen, send it to the lab for the results to come back. That acts on me as a patient and returns information to the physician for the next decision.

One of these things that you will notice here is there is a lag between these decisions. That is the opportunity to improve the process. The lab results come back, EKG results come back. The physician makes the next clinical decision and says your EKG indicates and the trichromium levels in the lab are up, I think you are having a heart attack, acute myocardial infarction. My next decision is to do a catheterization on you. They return that decision to the system that starts the next care process that acts on me as a patient that returns the next information to the physician for the next decision, so forth until I leave healthy and well without having had an infection.

Those are the basic four things that happen in a hospital. Patients show up, we have information, physicians make decisions, nurses and axillary care providers act on the patient, the patient returns new information back to the physician, the patient flows through the system. We are helping hospitals on those four things. And many of the things that you heard from Carolyn earlier, and from Tom earlier are about those safe practices and about those six aims we are trying to institute those evidence based practices.

Quality Center at the American Hospital Association helps hospitals with eight main things: leadership, the business case for quality, engaging physicians and our workforce, patient FOCUS for care, the right of improvement of methods and strategies, fostering communication, and finally measuring and reporting and information technology is the back bone to that. That is another busy slide but it's the same one that I showed you. It's just in blue but this is the opportunity for innovation for reliable care.

One of the things we want to help hospitals do is ensure that this identification and matching at the very beginning is accurate. We want to ensure that the physician with computer order entry can put those orders back in the system quickly without error. We want those reports to come out electronic medical record and order generation to come out accurately and quickly. We want labs to be returned. We want to

know where the patients, radio frequency identification as the patient flows through the system. We want to turn all of that into improving our processes by working on reliability and a high degree of confidence.

So the three things we want to do are remove waste, eliminate defects, and reduce variability. There are eight types of waste. And waste is sort of an engineering term, so it's really over production, waits and delays, fuse, bottlenecks, transportation that you don't need, inventory, under utilization of both staff and equipment. Those are the eight areas that hospitals are working to improve these processes so that care gets more safe.

Now I am going to drill down at a really detailed level real quickly. I come to the hospital, one of the first things that happens to me is I get a lab draw. The physician gets that information to make the next decision. That sound like a pretty simple process. That is a diagram of it. Here are the five main steps. Physician writes an order and it prints in the lab. They retrieve that, they print a lab, they go to the patient, they collect the specimen, take it back to the lab. Five simple steps, that sounds pretty easy? Yes. Here is an actual picture working with the hospital where a 147 steps to make those five things happen. That's the opportunity for hospitals to work on safe practices and process improvement so that we make this reliable and effective.

So how can the Quality Center help? It's going to be a web presence predominantly that facilities can go to and find tools, information, case studies. They can drill down on each on these levels. For instance if you are CEO or administrator you might want to be interested in leadership, you can drill down on that, takes you to a new page, gives you information and resources, it can connect you with other hospitals and content leaders like the Institute for Healthcare Improvement or ARC or CMS. And then you can also do searches on this website to get more information and finally, you can contact us and we are doing four things to help hospitals. We are consolidating information in one place. Leaders and administrators and physicians are very busy people. We want to make it easier for them to find the information that they need so we are going to consolidate that for them. We are going to connect them with each other so we can share success stories about those hospitals that are doing a great job through the Institute of Healthcare improvement Incentiatives. We are going to convene hospitals and learning labs and collaboratives so that we can share those lessons. And then finally we are catalyze all of this so that care gets better and safety improves.

So, in summary, hospital continually improves process. It requires innovation so that systems become reliable. They pursue that relentlessly and we at the American Hospital

Association Quality Center are going to a resource for that.

ED HOWARD: Great. Thank you so much Steve.

[Applause]

Before I recognize Mary Ann let me just apologize to Steve that we didn't get all 147 steps reproduced very well on the versions that we have in the kits. Let me also apologize to Tom for taking away his Denning Award. [Laughter] I don't know who wrote those biographies –

THOMAS NOLAN: No apology needed.

ED HOWARD: I guess I did so. No, I am very sorry. It is one of the most prestigious quality awards in this country so I don't want to misappropriate and I am sure there is one in your future Steve.

Yes, Mary Ann, thank you very much for your patience. He

MARY ANN FUCHS: Well thank you for the opportunity to be here today. And just a short amount of time I want to tell you so much that I could spend an hour on each of the topics that is listed in my slide. And like was recognized before, you did receive a handout around our patient safety program at Duke Hospital and I had asked you to take a look at that and if you have questions ask at another time because I will not be spending my time talking about that but I believe it is our of organizations most significant accomplishments, making our organization safer.

So as we started, as I started to think about this presentation I looked back in a timeline for our organization really focusing on safety and quality efforts. While we would always say that we have really good processes and practices and different things in place, in 2002, we had a new CEO come into our organization who actually had been our chief medical officer. His name is Dr. William Fulkerson, an incredible pulmonologist and critical care medicine physician. It really was his goal to help our organization improve from a quality and safety prospective. Early in his leadership we spent a lot of time restructuring processes, looking at new performance improvement techniques and engaging in every safety incentiative that we could through partnership with various organizations, etcetera. And we actually felt we were quite effective and felt that we had a safe system.

Then on February 6th of 2003, we transplanted a set of mismatched lungs and a heart into a sixteen-year-old patient of ours, Jessica Santeton [misspelled?] and this is Jessica's picture. And I am sure many of you have seen Jessica's picture because Jessica's picture was everywhere in the United States and outside of the United States because this really became a public event. We really didn't understand how that could ever happen to her or how this could happen in our organization. And we learned quickly to understand that while we were focusing on those high volume, high risk quality and safety procedures that

you are told to FOCUS on that we couldn't forget the low volume ones that were high risk in addition. We learned just how much we were relied on others both internal and external to our organization for important information regarding patient care. We learned that when we assume we take great risks that others have completed the necessary due diligence both internal and external. We learned just how much we needed to improve the safety in our organization and how we needed to improve how we work as teams to provide the best care for our patients, families, and staff. We also learned that several other organizations had made the same mistake but they didn't feel like they were in a position to talk about it until our situation became public. We learned that we could impact national policy. And we became active in various groups and various organizations to make changes, The Joint Commission, United Network of Organ Sharing and our local organ procurement organization.

So, at this time we thought we were really doing a very good job. We felt we were addressing our safety culture and we thought we had redesigned our performance improvement process and structures to be able to address and to provide the safest. So we knew we had some work to do. We actually did a lot of work in our organization and actually evaluated the entire organization from the top to the bottom of the organization and made multiple changes. And some of those actions started at the

highest level of our organization while our board was well aware if we have various programs and activities related to quality and safety in our organization, they weren't as actively engaged as they could be. So, we have a strong presence now, a board subcommittee led by a physician who sits on our board external to our organization who actually – this group now participates in all of the monitoring and benchmarking of our organization safety and quality activities. They actually participate in patient safety rounds on an ongoing basis.

We had patient safety officers in each of our health systems organizations. We established a role for a health system patient safety officer. That individual is actually first trained nurse, then physician, Dr. Karen Thurst [misspelled?] whose main responsibility in our organization now is to make sure that all of our incentiatives are coordinated across our health system so that we are actively sharing that information that we learned and lessons learned along the way.

Our new chancellor also appointed a new vice president from medical affairs whose primary purpose in the role is to FOCUS on quality and quality incentiatives. So together partnered with our patient safety officer, we have consolidated all of our quality and safety structures in order to enhance our ability to improve. We have been actively engaging in a safety structure a new patient safety structure, which I

mentioned in the presentation in the handout before to really try to address the best way to be able to engage providers at all levels. And from that prospective at the point of services where the patient care decisions are made, we have to establish and make systems appropriate so that the best decision can be made, the best and the safest decision can be made. And in developing that culture of safety, we really recognized that safety affects every individual in our organization, not just the bedside providers but also everyone. Its safety extends well beyond the walls of our organization in all our clinics and those types of areas. And that culture change in the end requires a change in individual behavior and individual mindfulness and their accountability in managing those processes. So, we really made changes but we continue to make other types of multiple changes.

In our organization, we actually used Kaplan and Norton's balance scorecard, Harvard Business School model to measure organizational success. If any of you know the model, there are four quadrants. One of those quadrants is to measure business or clinical quality in our case, a customer prospective work culture and finance prospective. What we have done with this model is actually established the framework for organizational evaluation and performance evaluation from this most senior leader in the organization down to the bedside. So we have common goals, objectives written specifically that

incent our behavior on an ongoing basis in order to improve our organization success. And we feel that having these common goals and indicators and measures have been very helpful to help us achieve where we are today as it relates to our safety and quality environments in the organization.

We spent a tremendous amount of time and energy and have been very successful in information technology experiences in our organization. These were not just to measure quality in our organization but also to assure the safe care processes that were developed. And some of these do include the development of a voluntary reporting system. When we really looked at it, we had twenty-three different ways that you could report an incident in our organization and they were all on paper, different pieces of paper. With the development of the voluntary reporting system, we actually have now an online function that is spread across our entire health system that has enabled us to achieve great impact as it relates to managing errors. We actually have a grant-funded system that looks at adverse drug events now that has been very helpful at detecting those events that aren't able to be reported. Actually there is a recent article just published in the Journal of Clinical Outcomes Management by Dr. Peter Keilbridge [misspelled?]. This system we hope will be taken outside of our organization and used in a much broader fashion.

Then we have an ongoing process where we measure

culture and culture, not just from a safety prospective from our bedside staff but our chancellor feeling that the entire organization, our senior leadership team is engaged in that entire process so we have active engagement of activities from all those prospectives.

So, we spent a lot of time strengthening data analysis resources, adding up to ease to be able to analyze some of the data that we have had. We work with various organizations and we are involved in every single one of those hundred thousand lives incentiatives and I don't know how many we have saved but I could go back and find out for you because I do know we are tracking that information. We have had a lot of involvement and active engagement of medical leadership in administrators, nursing staff, staff from across the entire organization in these processes. We have adopted Sick Sigma as the performance improvement methodology as I can almost didn't hear the words from Steve a minute ago but its exactly what he was talking about in reducing wasted and looking at all those processes. We have built into every system committee and process in our organization a way to measure ongoing performance indicators. If you do not measure and monitor and you heard Carolyn, Dr. Clancy say this before, you will never know if you improve. So we actually monitor this in various components in systems and committees along the way keeping it in front of us at all times.

We have also spent a good amount of time implementing different ways to share lessons learned. That is one of the biggest concerns. You heard mentioned before people do not share their stories. They feel afraid to share their stories because there is a fear that that story will be used against them as opposed to improving future behavior or making a system more safe. So, we're developed various mechanisms in our organization for those components and sharing them. And we have developed actually a patient safety center which actually is a center led by our chief patient information officer who is developing research processes as it relates to various components. You heard about team training, we actually have three different areas in our organization undergoing crew resource management training. And I have high hopes for some of that work. And are doing work with some of our schools in the local area via various grants to train students in safety and performance improvement techniques.

And so we still have some ongoing challenges however; and I think these challenges, you heard some about today. Some of that balancing of the regulatory or compliance incentiative with being able to share a lesson learned or share that you have had a concern in your organization, be able to change that, not just internal to your organization but to share it on a broader basis. These incentiatives are on ongoing basis are very resource intensive and we need a lot of assistance of

things like a common infrastructure for taxonomy, for definitions as well as technology to be able to set the platform for us to be able continue to improve and then finally I would say that when I went to nursing school, I didn't learn necessarily about patient safety incentiatives or performance improvement technology or methodology or understanding some of those things. And actually, they are not a core component of any curriculum of our schools of medicine, our schools of nursing or allied health. So, we have a great opportunity there. And with that, I say thank you.

[Applause]

ED HOWARD: Thank you so very much Mary Ann. As we move into this question phase let me remind of your green card opportunity – this has nothing to do with the immigration debate – the microphones in the back and if you do have to leave sometime before the end of the program we would love you to fill out the blue evaluation form as a way of helping to improve these programs. Yes, I think you were first. You want to identify yourself and we will take the questions from the microphone first.

ALLEN GLASS: Allen Glass for Senator Binds office. Two questions, first is about hospital safety. It is my understanding that the main external oversight over what hospitals do is the JACHO. My question is you got incentiatives coming from AHA, IHI, NQF and others, are these being funneled

through the JACHO in some fashion so that that can be incorporated into their oversight scheme? My second question concerns the role of individuals, the patients, in patient safety. Are we doing enough to involve the patient in patient safety? Yes, we ask people undergoing knee surgery to point to their bad knee but such low technology things like if you put a color picture of a pill on each bottle of medication then the patient could check to see if what is suppose to be in there, is the Right thing and of course things like fall prevention you can have all the high tech systems in the world with computers and resources, that is not going to stop a patient from falling unless you actually get involved with the patient. So, those are my two questions about JCAHO and about the involvement of the patient in patient safety.

JANET CORRIGAN, Ph.D., M.B.A.: I can say that in the case of the state practices that NQF has endorsed, we currently have an effort underway to update those safe practices and as a part of that effort we have worked in a very partnership fashion with JCAHO, NCMS and others that have regulatory or accreditation requirements that relate to safe practices. What we have been doing over the last year is to work very aggressively to harmonize all of those regulatory and accreditation requirements pertaining to safe practices and hopefully in the next volume coming later this year, you will see there is more consistent definition and synergy of how

organizations are approaching the oversight area.

MARY ANN FUCHS: From a hospital prospective, I would say that there are various incentiatives and activities going on in different organizations. I know of no real way to share that globally across the country for different incentiatives. For example, when I described briefly patient safety rounds. Patient is part of the patient safety rounds. The patient and family are queried along the way as it relates to different concerns or issues that they might have and actually engaging their thoughts and ideas about things that we could improve to enhance. So there are different things going on out there. We are probably just not as comprehensive as a nation, if you would with collecting those areas.

KAREN HILL: My name is Karen Hill. I am from Lexington Kentucky from Central Baptist Hospital and I felt lead to raise the issue as a private hospital trying to meet all of these accreditation standards. We submit data to over fourteen databases as one private hospital we have 371 beds. We face several issues that make it difficult and cumbersome in trying to meet these national accreditation standards. One is supportive of the gentleman's comment about the databases. Right now none of those speak – we submit to CMS, Joint, American Cancer Society, ACC, Anthem, I mean I could go on and on. And I would love to see a national forum where the power brokers that had the authority over these organizations could

get together and in one forum agree on the indications, agree on the definitions and agree that there is one place for a provider to submit information where you could all share it and slice and dice it in whatever way you want, but where we would be able to send our resources back to the patients and the patient safety instead of having – and in my hospital for example, we have over thirty nurses that work in different areas of the hospital that collect and abstract charts and this information to feed into these kind of systems. That's my first one.

My second comment is in that roundtable I would love to see a national mandate for universal bar coding for both medications and for medical supplies. They have had it grocery stores for years but we can't get it in medicine and yet when we try to implement things like an automated medication administration systems, our patients have to wear two and three armbands because the vendors wont agree on universal barcoding for medication administration, for example. So its just very frustrating as a provider to try to meet these standards and be the best when the vendors haven't been forced to cooperate and have interfaces and barcodes and things that would make our life a lot easier in trying to promote safety.

[Applause]

ED HOWARD: Okay. I think we have struck a chord here. Who would like to take on any or all of that?

MARY ANN FUCHS: I can't take on an answer but I have the same concerns as a provider.

ED HOWARD: Fair enough. Steve, do you have – want to give this a shot here.

STEPHEN MAYFIELD: I will give part of a response and I agree with you. Coming from a hospital, I understand the multiple reporting requirements and the different databases and the new accreditation standards and trying to satisfy everybody who wants something. One of the things that is happening right now with the Hospital Quality Alliance and Janet as well as others, ARC, CMS, Joint Commission, they are all coming together to work on the same indicators, to count the indicators the same way, to measure them the same way. We are making good progress with that. And that is certainly one of our goals at the American Hospital Association that we come up with a unified set of indicators that are representative and useful to hospitals and patients, that we can all track them and define them in the same way and that we get useful data that is comparable. We can determine how well we are improving our performance.

JANET CORRIGAN, Ph.D., M.B.A.: Steve is absolutely right. The Hospital Quality Alliance has been a step forward. I mean I think its about two years old now, a relatively new alliance. What it tries to address though are those performance measures and reporting requirements that are at the

institutional level, not reports on individual adverse events that would go into the patient safety centers. So for example, you would perhaps find an indicator of the hospital infection rate or thirty-day mortality for a CABG patient. Those are the kind of aggregate hospital institutional level measures that are reported into – that are part of the hospital quality alliance. Hospitals may well report individual patient reports which hopefully will come to a central repository at some point. They are already reporting into CMS at the patient level. But then we calculate overall level indicator for that institution for purposes of reporting out in the hospital compare websites that CMS maintains.

The difficulty we have is that we now have multiple alliances operating though so it isn't quite as clean as it looks. There is a separate cancer alliance, which is propagating and selecting particular measures rated to cancer care. There is also an ambulatory health care alliance, which has many different speciality and subspecialty groups participating in it. And they will begin I think to bleed over into some of the measures that affect hospitals. Last but not least, there is a proposal on the table by CMS to develop a medication alliance. So we are now seeing a little bit of fragmentation in these various alliances so I am not sure that we are quite going to come together to the point that we were trying to get too which really was to have common reporting

requirements.

Once again, there is – those measures are a little bit different from the individual patient. The individual reports on adverse events that occur that would go into the patient safety organizations. If we are going to get standardization there at that level, it will be if we develop that common taxonomy, hopefully the NQF endorsed taxonomy. And if we define those adverse events and have a common set, they have to be reported or required to be reported into those patient safety organizations. And that is really what the NQF is about. It's trying to encourage to have a common set of endorsed measures, reporting requirements and taxonomies that hopefully would be used by all centers and stakeholders that had need for access to that information.

ED HOWARD: If I can I would like to take the viewpoint of the person who wrote this green card question to followup on what we have just been talking about. They might ask Janet how long is all of that going to take? Because here is what they actually said. Could the panel address the role of policy in improving patient safety? That is the coercive power of government. For instance, should any of the thirty safe practices where the six hundred thousand lives steps be mandated by government or should government increase incentiatives to adopt these. In other words, how can we get some movement or do we have enough movement already?

THOMAS NOLAN: Connected to an earlier question, the Joint Commission for accreditation in health care organizations has been a tremendous partner of ours in the campaign and Dr. Dennis O'Leary [misspelled?] and our CEO, Dr. Bergwick [misspelled?] are in weekly communications. The partnership that we have established with the Joint Commission is one in which as we are working with individual hospitals through our program and field testing some of these ideas, we are then conversing with the Joint Commission on things that this is proven enough, it ought to be written into the standards. So at least in the area of the Joint Commission, we have joint conversations on what seems to be working in the field and what should be a standard.

We also have some — Steve Janes from the CMS is a fellow at the institute this year and trying to make closer connections there. So, those are a couple of examples of moving experience into regulation or policy.

STEPHEN MAYFIELD: May I answer that? The question had to do with policy or mandates being an effective way to accelerate this improvement. And my response would be that one of the great things about the United States is our ability to be innovative and creative. Once we start mandating specific processes then we limit the ability of hospitals in their own environment and their own community to come up with creative ways to kind of that same enter or even better so there is a

balance between that. We need policy to support the appropriate movement but I would think that the incentiatives would move everybody in the right direction.

JANET CORRIGAN, Ph.D., M.B.A.: I think we do need strong federal leadership to move this area forward. And that federal leadership needs to be done in partnership with the private sector. We have a very diverse health care sector. The federal government is the largest purchaser, the strongest regulator and operates some of the largest delivery systems.

So federal leadership is absolutely critical in health care but then you also have to recognize that there private sector leadership that has to be brought on board because to harmonize this concoctive of requirements and reporting and measures that we have out their we have to bring the public and the private purchasers together in pursuit of a set common aims and goals and we have prioritize and decide what measures we are going to use, what types of adverse events we are going to FOCUS on. Health care providers can't FOCUS on every thing so we are at the point now with the proliferation of many different measurements, sets and reporting incentiatives that some degree of prioritization and harmonization is needed that will require federal leadership in conjunction with leadership in the private sector.

Whether or not the federal government takes a carrot or a stick approach I don't think it makes that much difference.

You can get there either way so pick the approach that you think is the one that you are most comfortable with and begin to move forward. Right now on this administration, we had a strong carrot approach I think and that's just fine. we are beginning to really encourage the reporting of information at least to reward that financially, that is the first step towards getting providers comfortable with reporting our performance information and potentially linking the pay for performance down the road.

KATHLEEN SULLIVAN: Hi, good afternoon. My name is Kathleen Sullivan. I'm from the central coast of California. We touched briefly – I have two comments and one evolving into a quick question. Primarily to begin with Dr. Nolan, we touched earlier in a question that Dr. Clancy about the direction of taking strategic partnering with home care as we work on improving health care quality in this country. Dr. Nolan, in your slide on the six steps in your campaign, one of them in their talks about preventing central line infections. Certainly in the article that came out of ***Modern Health Care*** that is expanded to talk about improving, eliminating infections in ventilator acquired pneumonia. In my past professional lives, I have at any given time had over a hundred patients, children primarily on home ventilator assistance and I would suggest that probably at any given time although its not quite the same infection issue, the majority of central lines are managed in

the community. So, I would really encourage all of you as you engage in your work to look to the home care industry to be a very strategic partner.

Secondly someone along the – a little bit of a different question. There is and I think we all recognize this. Often times, a disconnect with all of this good work on making recommendations to improve health quality certainly you have engaged the work on improving the pace of making that improvement. But the disconnect I am asking about trying to form a question about is we make these recommendations but then on a parallel process we have various government agencies and regulatory and the administration sometimes doing things that appear to be totally contradictory. Case in point, when I read through – last time I read through the IOM reports, I think it might have been the second one; the one specific recommendation to improve quality in the home care environment was to eliminate paperwork, to cut down on the paperwork. That was the number one barrier to improving quality in the home care environment and yet as of May 1, a massive undertaking in home health advancement beneficiary notice takes effect, which will only add to that paperwork burden. Any advice on how we cut down that kind of disconnect.

THOMAS NOLAN: Well, besides the home care industry we could have probably represents of other components of health care systems. In my view, the primary problem in the US health

care system is we have components that don't work together as a system. If you go to Sweden or England or many other European countries they have their own problems in health care but most of them work quite well as a system. In fact you might say that as a society we like three aims from our health care system, good patient experience, better population health, the population of Washington D.C. or some company, and a control of per capita costs. So as a society, we might say those are three aims that we are interested in. however there is almost no health care organization in the United States that has those three aims and in fact the way payers both government and private pay for care, they almost assure that the business models for these components will be set up so that those aims are separated. So number one, putting the components together in a system and two, where payers both federal and private can help is paying for the overall system and not just the components.

JANET CORRIGAN, Ph.D., M.B.A.: And I can't resist taking the opportunity to make a comment that it really is time for the health care sector to go electronic. The paper needs to go. There is simply no reason for it. For all of this paper. I know it doesn't completely solve the problem but it does help a whole lot. Those electronic health records should be put in place. We need to achieve the president's goal of a ten-year plan to bipartisan work to try to advance a significant agenda

on electronic health records systems and conductivity.

ED HOWARD: We only have about fifteen minutes left and we have a bunch of people at the microphones. We are going to ask you to be brief in your questions. We ask our panelists to be brief in their responses. And urge you if you have written a question on a card, to get up to a microphone because that's the only way you are going to be assured to get to it. Yes, go ahead.

JOANN REED: Joann Reed, North Carolina. Three of the four remaining panelists at least represent the hospital perspective and the reality is most of health care takes place outside of hospitals. I haven't really heard that addressed very much but you know I know in my state almost five years ago, we did a study of adult care homes and found an 80-percent error rate in medication. That means we only got it right one time out of five. So I would be interested in Janet's perspective on input from other settings to the indicators and event tracking and those kinds of things in places where you know other types of settings are really trying to implement this.

JANET CORRIGAN, Ph.D., M.B.A.: It is a really important point. We, I think in many ways are — you have a silo health care delivery system. And the communication doesn't take place across the various settings. The paper, the information doesn't travel. Unfortunately our approach to measurement and

reporting is also turning out to be one that is quite siloed so what you will find when you see some of the measures that are coming forward out of various alliances is that you will have a smoking sensation measure that has a different numerator and denominator and specification for the hospital side than it does for the ones coming out ambulatory.

And oh, by the way, there are even other measures that are specific to diseases and conditions that are being brought forward by various specialty groups. There is an incredible need to harmonize these measures across settings. If there is no need for pain management to be any different whether the patient is in home health versus nursing home versus the hospital, and in some cases there may be a legitimate difference in how the measures are specified but in a lot of cases, there is no reason for that measure to differ across settings.

Our approach for developing performance measures and reporting systems should be patient centered. It should start with the patient, not the provider or the setting and until we make that conceptual leap that paradigm shift, we are going to continue to repeat the same mistake that we have on the health care delivery system in all of our measurement and reporting processes, which is to approach them from a provider perspective and a silo perspective rather than a patient perspective.

BARBARA MARON: My name is Barbara Maron [misspelled?] and I represent the College of Emergency Physicians. I will keep my comment short since you just addressed it primarily Dr. Corrigan. And that is in our zealot try to get everybody under the tent before Congress passes some law about paper reporting, pay for performance for physicians, all these issues around patient safety and quality where we really need to work to get together collaboratively in teams instead every of the 24 medical specialities is rushing out to try to get measures developed and discussions take place at MedPak and other public policy forums about who owns the patient, whose is going to deemed, who is going to get the incentiative and its becoming more chaotic than collaborative or effective, it seems. I think it makes it more difficult in this environment.

JANET CORRIGAN, Ph.D., M.B.A.: I am sure it seems that way. Let me point out though that there are some very positive things about the development that has taken place in the last year or two. I have been working the quality measurement area for almost twenty years and what we had seen is a C-change in the last few years. In terms of the engagement of leadership from the medical community, the nursing community, pharmacy community. We have tremendous leadership on the clinical side at the table now in terms of quality and safety improvement, measurement and reporting incentiatives. And I view that as a real plus. I also think that the kind of momentum that we are

getting trying to move forward with public reporting. It is a huge transition especially for all these small practice settings to begin to get on board. So, I applaud these efforts to try to push us forward whether it's with paper reporting or pay for performance and to seize the opportunity to be able to advance that agenda.

At the same time though, you are pointing to a really critical issue. And what we need to do to address it is to put in place a process where we are identifying key goals at the national level. A limited set of goals that we are going to achieve that in turn will be translated into our agenda for developing and prorogating performance measures. We need to be putting in place a parallel process that in three years from now we can bring some rational order to all these despaired efforts that are currently underway.

I would also point out that you really do hit on a critical point because the kind of measures that we really want going forward are composite measures that look at whether that heart patient, patient with a heart condition, received all of the necessary services that they should have within a six month or a nine month period. We are treating a chronically ill population and we need to have the capacity to look and measure quality longitudinally over a period of six, nine months, a year and to have joint accountability. All those providers – the typical patient have multiple chronic conditions and see a

half of dozen or more providers during that time period. It may cross various settings. All of those providers have some accountability there. They are jointly accountable for that patient's outcome. So, we got to somehow figure out how to get the composite measures and then sets of measures that we would use in our reporting system and how to jointly ensure the accountability or joint accountability on the part of the various providers.

DONNA RAY JACOBSON: Good afternoon. My name is Donna Ray Jacobson. I am a physician who specializes in preventive medicine. I currently work in the office of Public Health and Science over in HHS. I don't work in quality and it's a slightly different take on this session here. a few years ago I worked in a resident workforce reform and I haven't heard a lot recently about sort of the quality of the workforce and sort of being over taxed and over worked and retired. I think that other than the American Medical Student Association which took an advocacy role against OSHA a few years ago, OSHA bumped it physicians again to sort of regulate ourselves. I think we are one of the last specialities to really not do that well. I think there are some improvements. I don't think its ideal yet. I am wondering your take sort of on not just residents in the teaching hospital but at places where you are going to have a tired staff and the areas related to that.

MARY ANN FUCHS: The first thing I would say about our

experience with the change in the resident work hours is that we lost a lot of different ways to continuity of care of patients so it is causing another whole set of issues around care coordination and the handoff of information that is becoming now risky and in some ways, for our patients, putting things in place to better address those things are key components. I think your point is a good one as it relates to what other health providers are potentially having the same type of issues that relates to fatigue. And I know North Carolina we have actually done some work and actually Brenda Leary [misspelled?], you are in the audience there, you might want to chime in on this as it relates to looking at work hours of nurses. And actually, it had conversations with our state board of nursing, center for nursing, other organizations starting to look at this. And from an organization perspective right now internally to the organization of which I work I will tell you that we done an evaluation around work hours and we tried to – to determine there are increased number of adverse events over time but we don't see that data or that information coming out of our organization. That doesn't mean it is not there yet. But I think we are really just starting to look at it in many ways.

ED HOWARD: There will be more on this specific topic at our briefing in May as well. You are person that was summoned. [Laughter]

BRENDA LEARY: Brenda Leary [misspelled?] from the North Carolina Center for Nursing. It's a state nursing workforce agency. Just feed you back on what Mary Ann has said, that really came out in our – we have a state level institute of medicine. Many of you probably know Gordon DeFreese who was the director for many, many years. Now it is Pam Silverman. We had a task force on the nursing workforce. And we looked at preparation; we looked at well workforce environment. But we really picked up on IOMs, national IOMs more recent work on looking at what happens after about twelve hours and that became part of that report. We also made it very clear that it doesn't matter if it's voluntary or mandatory. A lot of times we kind of advocate for being able to do it if we want to but not being made to do it. But it didn't really matter that there was still a safety issue. So, I think hopefully that will help everybody look more carefully about the number of hours that nurses work.

PATRICIA BUTTERFIELD: Thank you for the opportunity to comment. Patricia Butterfield, I'm on the nursing faculty at the University of Washington. From a process perspective, the prevention of an adverse event can happen at various phases in the process. One of the things that prevention science tells us is that in many ways the way to prevent an event is not to do it all. There are many examples of this in health care, AA, and ChartQ has been a leader in this area looking at things low

back care, where successive surgical interventions lead to poor clinical outcomes for patients, early treatment of prostate cancer we are watching and waiting. It may be a very appropriate response. How do we integrate our goals for patient safety with parallel events that are really looking at clinical practice guidelines and the reduction of unnecessary procedures? Thank you.

ED HOWARD: We have to bring Carolyn back. Anybody wants –

MARY ANN FUCHS: I can comment on what we are trying to do with our computerized physician order entry system because that is a prime way to be able to look at data and aggregate and to be able to determine if some of the decision making was appropriate at it related to various items or drugs or procedures that might ordered. And actually, we are just in pretty much in a very preliminary mode with the implementation of decision guidelines in trying to determine from those guidelines where the variances are. Now, that is individual, one organization obviously data set but in our organization on a daily basis over 22,000 orders are entered into our computerized physician order entry system so there is a large dataset there that we have the opportunity but haven't had the – haven't completed the analysis or really intensely completed the analysis and how we can use some of that. But that would be one example of what an organization can do.

JANET CORRIGAN, Ph.D., M.B.A.: There is quite a little bit of work underway in the performance measurement area that is trying to get at that issue of clinical waste in some cases, where there are unnecessary services or the one the patients perhaps would have been better without, that exposed them to more potential harm than good or the overuse area. I would point to two. I think the work of John Winberg [misspelled?] and Elliot Fischer the geographic variations in per capita expenditures and finding up to two fold differences in per capita expenditures per Medicare beneficiaries, probably everyone actually but the works that I have read have been on Medicare beneficiaries. And that is a real important indicator in some of the more recent work that they have published have also showed that in those really high expenditure areas, high per capita expenditures geographic regions you actually see that decoratum in quality that begins to result from patients churning around to providers and setting and getting services that really are over used. Expose them to more potential harm than good. That is one of the reasons we need in our whole – in developing performance measures to think outside the wall of an individual episode or encounter because where you often pick up the excess use is when you are looking over time where patients are getting redundant services from one provider to another. That is one part of the puzzle.

And there is some good work underway to develop those

sorts of measures. There is also some good work underway that Judy Herborn [misspelled?] and some of her colleagues are working on which is to measure whether in an encounter between a patient and a clinician is the patient given an opportunity to share in decision making. Are they provided with adequate information, the risks associated with a procedure as well as the potential benefits, adequate information on alternatives to less invasive alternates, watchful waiting and things of that nature?

Of course we know from Weinberg's on the videos with patients that you – patients are more inclined to go for watchful waiting typically than the physician especially a surgeon which is of course is the particular intervention that they know really is the procedural intervention. so it is important at several levels that we look overall at the community level, and whether there is perhaps too many resources and particular types. You see the impact of a fee per service payment system, which really is to generate more volume and also to look at those individual encounters in ways that we can encourage more reform to patient decision making. Because that will probably help as well.

THOMAS NOLAN: Dr. Clancy had a slide on the patient safety quality and improvement act and part of that was to indicate how we can aggregate data and begin to use it to that mass of intelligence. That is one of the purposes of that act

so that the facilities have safe harbor to share their information so that we can then begin to look at those probabilistic models that indicate and support evidence based medicine decisions. So, I see that as a great opportunity to patient safety act that will allow us to share that information. We intend to tease out those things that work best for the patients.

ED HOWARD: Cindy, can we squeeze in a question from a card here before we have to close things down.

CYNTHIA ARMSTRONG PERCELLI: Take a question about the business case for inspiring safety and quality. There is much in the literature about the lack of economic incentiatives for providers or systems to improve care. I am wondering if the panel could speak to that from the business model.

STEPHEN MAYFIELD: Well, I can jump in on that. The business case for quality has got two sides to it. One of which is the reimbursement schedule and you see a lot of that with the pay for performance and the possibility and the actual demonstration projects with a differential of one and two percent for facilities that meet certain criteria.

Actually the greatest opportunity to the business case for quality is working inside the organization just as Duke University is doing, working on removing waste, reducing variations, and eliminating defects because the Gerran [misspelled?] Institute and the American Society for Quality

and others have demonstrated that the opportunity to remove those extra steps, the reworked, the extra movement that goes on represent thirty to forty percent of the opportunities. So there are great opportunities for the business case for quality that will actually reduce the cost of care.

JANET CORRIGAN, Ph.D., M.B.A.: We are making a good deal of progress. We have a hundred private sector efforts on pay for performance underway. We have dozen or more demonstration projects within CMS and we have the pay for reporting incentiatives that are trying to counter what really are very toxic incentiatives. The fee for service and DRG based payment system in many cases.

I want to caution you though. We don't know what the impact of these are and how effectively they will lead to improvements in quality. The early results are quite promising. We are beginning to see some improvement especially on those particular areas that are being measured. But we are very, very early in the game.

The other problem we have with these efforts is we do not have a good evaluation system in place. So five years from now unless ARC is appropriate to funding and puts in place a strong program for comprehensive evaluation of these efforts we may be sitting here five years from now and asking the same questions even though we had all of this innovative activity underway.

And very quickly, one last comment. That business case for quality looks a whole lot better when you start looking across settings. The opportunities to really, really pull out waste in the system and get a higher payoff for our dollar are much, much greater when you look at a chronically ill patient over six months, nine months, across settings.

THOMAS NOLAN: I am certainly interested in the control of inflation and per capita costs and Maureen Bisono [misspelled?] who is the CEOO of the IHI and I recently had an article in *The Journal of Health Care Financial Management* on the business case. Our view is this that we are looking for high value health care but improvement of quality should not also have on its back that it takes out waste or cost. In many cases, it does. We think there are two complimentary efforts: the improvement in quality and safety and the reduction of costs. Those are complimentary but separate efforts. What is happening now is in part I think because doctors and nurses say its about quality not about costs, that its hard for executives of health care organizations to say you know there is waste in this system and we ought to get out after the waste and excess cost, take that out which would actually allow some more incentiative end resources for quality improvement. So, I wouldn't put all of the cost reductions on the quality improvement agenda.

ED HOWARD: Well that is a pretty good last word. Thank

you for hanging in there through some very difficult materials. Thank you also for helping me thank the panelists for what I think was a very good guide through that very difficult material.

[Applause]

[END RECORDING]