ALLIANCE FOR HEALTH REFORM

Disclosure and Apology: A Win-Win for Patient Safety and Medical Liability?
Ascension
Alliance for Health Reform
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ED HOWARD: Good afternoon, my name is Ed Howard, I am with the Alliance for Health Reform on behalf of Senator Rockefeller and Senator Blunt and our board of directors, I want to welcome you to this program today on so-called communication and resolution programs. CRP's. People are going to be using that – it's not quite an acronym, but that group of letters over the course of the next hour and 15 minutes or an hour and a half and you have to have that in your head. Now some of the most heated discussions in Alliance briefing history have involved medical liability questions and of course the key question, how do you protect patients from adverse events while you help practitioners have some piece of mind while they deliver the highest quality care they can? Now some states have responded, trying a whole variety of responses to that question and today we are going to take a close look at one of those, that is encouraging the disclosure of what you can call "unexpected outcomes" to patients. Some pilot programs along those lines that have been in place now for several years and we are going to examine how those programs are structured, what results they have yielded and what the potential is for these CRP's. These communication and resolution programs. We are pleased to have as a partner today, Ascension Health, the nation's largest non-profit health system and not coincidently, designer and operator of one of those pilot programs that we were talking about. And we are going to hear from Ascension's Ann Hendrich in just a moment.

A couple of housekeeping chores – if you are in a Twitter mode, note that the #patientsafety and if you need WiFi, the instructions on how to do it – I don't know if we had an instruction on the table, but we have the credentials on the screen right now and you can take a look. Feel free to tweet about the program and join in the conversation. There are some good pieces of information in the packet, including speaker biographies that are more extensive than I am going to give our panelists today. There is also a one page materials list in your kits, along with copies of the Power Point presentations. A lot more background available on our website, allhealth.org. One important resource I want to call to your attention, thanks to our colleagues at Health Affairs, we have included in your packets copies of a couple of really important articles on this topic from a recent Health Affairs issue and we are very grateful for their help in getting those reprints for you. If you want this whole issue, which I would commend to you, you can get it at an attractive discount using the flyer that is in your packets as well. Actually, I would suggest that you subscribe to the Journal if you don't already. It's really the single best source of a wide variety of health policy analysis and you will get your money's worth. There will be a video recording of this briefing available in a couple of days, followed by a transcript a few days later, both on our website, allhealth.org. At the appropriate time you can ask our panelists a question either by filling out one of the green question cards in your packets, by coming to one of the microphones that you see on the floor here or by tweeting the question – we are monitoring the Twitterverse, if you will. So you have no excuse for not getting into the conversation.

And at the end of the briefing we are going to ask you to fill out that blue evaluation form in your packet so that we can make these programs even better in the future. And if you

are on Congressional staff, we would be especially appreciative of your filling out that evaluation form. Actually, from the very beginning of the Alliance's existence, our founder Senator Rockefeller had it clear in his mind and made it clear to the staff of the Alliance that our main purpose is to serve the information needs of the Hills staff, so tell us what you need and we will try to deliver on it.

I want to note the presence, without putting him on any sort of spot to actively address you, the Senator from Rhode Island, Senator Whitehouse, who is off to our left. He is one of the most thoughtful students of health policy – I was going to say in government – but in America today, I would say. Always asks good questions and if you find one that you want to add, we will recognize you immediately.

So enough housekeeping. Let us get to the program. We have a wonderful group of speakers whom I am going to introduce in block to avoid interrupting the flow of the presentations. And we are going to start with Dr. William Sage. He is a member of the law faculty at the University of Texas at Austin where he teaches several health law related courses. He is working now on a study of our subject for today, as a matter of fact, patient safety and disclosure. And another project on consolidation in the healthcare industry. And he is Dr. Sage not just because of his JD degree – a lot of us have that – but he's got an MD degree as well, both of them from Stamford and I'm glad you made it from Stamford to Texas – from Maine to here, in order to be part of our program. Bill?

WILLIAM SAGE: Do you want to do the other introductions?

ED HOWARD: Dr. Sage has pointed out that I didn't do what I was planning to do, which is to let you know who the other panelists following him are. I'm nervous, what can I say? Dr. Raymond Cox on my immediate left is the Executive Director of the volunteers in Medicine Clinic on Hilton Head Island. Formerly he served as the Chief Medical officer at Providence Hospital in Washington and as Chair of the Obgyn Department at St. Agnes Hospital in Baltimore. He has spent most of his career caring for underserved populations with an emphasis on maternal and child health. At my far right is Ann Hendrich, the Senior Vice President, Chief Quality and Safety and Nursing Officer for Ascension Health. And serves as the Executive Director of Ascension's patient safety organization and she is a nationally respected scholar in areas including geriatrics, patient safety and organizational change. At the other end of the panel is Jean Rexford. She is the Executive Director of the Connecticut Center for Patient Safety, where she has represented the patient voice since 2004. Her mission, that of the Center as well, is to promote patient safety, including the quality of healthcare and protect the rights of patients. And she is an active member in a number of national patient safety initiatives.

Now, as I prematurely said before, we are pleased to turn to Dr. William Sage.

WILLIAM SAGE: And thank you, Ed and thank you all for being here today. So imagine that you go to a hospital to have surgery. You would expect your doctors to tell you all of the risks of the procedure that you are going to undergo and all of the alternatives and to go through those very carefully with you so that you understand what might happen to you and indeed, as a matter of ethics and law and business practice, that will generally happen. If you are told about what might happen to you, the risks of your medical care, wouldn't you also think you would be told about what did happen to you if something went wrong during the medical care? You would be surprised to learn that there has not been nearly so much a consensus about that simple fact. Communication and resolution programs are a rather acronymed way, institutionalized way, of filling that gap. I have been asked to give you a very brief overview and that is really what I'm going to do and I'm going to save most of my comments for the questions and discussion where I can really be responsive to your concerns. Communication and resolution programs have very simple goals. Tell patients what happened to them when it's something unexpected, try to make things better and improve safety for the future. Because as you might imagine, if healthcare systems are not accustomed to tell patients what happened, and why it happened, oftentimes they probably don't know themselves. And if they don't know themselves, how can they improve safety for the future? Communication and resolution programs have a long history. There has been some adverse attention drawn recently to the Veterans health system, but it was the Lexington, Kentucky Veteran's Hospital in 1987 that pioneered the very first communication and resolution program, although it did not talk about it in those terms. It described it as disclosure, apology and then an opportunity for compensation. Various large organizations, the Institute of Medicine, the Joint Commission, NCQA, others in the '90s and some very large healthcare delivery organizations instituted systems that were basically systems brought within healthcare organizations. Not independent physician practices, but typically hospitals, typically associated with the provision of acute care, that if something went unexpectedly wrong, patients would be told, some explanation and investigation would be begun and ultimately some effort to put things right with the patient would be made as well as some feedback to improve safety for the future. Different models of this have emerged, but that is the core features.

Why are we here? Well, I am partly here to talk to you about what those are in the world of healthcare and I'm also here partly because you all here in Washington DC and in state legislatures, have opportunities to contribute to the good sides of this. And in fact, legal issues do intrude on communication and resolution programs with the expected regularity that you would think they do, give the long overhang of medical liability as a policy under political concern. So although this is an ethical and practical commitment to patients – to be honest, to try to put things right, to have it not happen again, there is fear of litigation, there are various barriers to the patient's participation and then there are the understandable concerns of healthcare professionals, which tend to fit in a mixed way into categories. Those that really center on reputation. What is these providers' self image and image in the world and then what are the economic consequences of that reputation

and of other forces to the providers. And law influences and often constrains many of these factors. I'm going to divide law very briefly for you, into two categories and this will almost partition along committee jurisdictions. There is the things that have to do with civil liability and tort reform and malpractice and there is the things that have to do with healthcare and healthcare financing. And they are both really important.

I am going to talk more about the healthcare and healthcare financing things because they are probably the things that you didn't come here expecting to here and subsequent speakers I think will focus more on some of the liability issues. In your readings is an article that we published as a group effort from the ARC project back in the January Health Affairs that describes these in much greater detail. In the liability world, we are talking about things that you tend to think of as tort reform and then some other things that have to do with civil litigation. So first question you probably have is, well is tort reform good for communication and resolution programs or bad for communication and resolution programs? My personal answer? It doesn't matter a lot, but it's generally better for being open and transparent and kind of adopting a new ethical paradigm in business, paradigm in healthcare. If you have some incentive to change, but you are not too afraid to change. And so a moderate liability climate tends to work the best for communication and resolution programs, which exist and thrive in states ranging from those with very strict limits on tort damages to those with no limits at all, but I would say, if there are challenges, the challenges are at both extremes. In Texas, where there is so little chance of malpractice litigation these days, that only a very progressive institution will take on the challenges of building on of these programs and maybe at the other extreme, a state like New York, where people are so afraid of litigation so often, that they are afraid to change their existing practice because they don't know what will happen. But basically my message is that this isn't a reform that is linked either pro or con to damage caps. But other things turn out to be pretty important. For example, have some breathing space, some cooling off period between when events happen and when lawsuits are filed. Having the various providers who are involved in these, roughly in the same page in terms of their legal and economic incentives. So when you have highly selective immunities that apply say, to a hospital but not to a physician, or to a public provider but not to a private provider. It may be that it's harder to get them to work together as indeed they do need to work together to have the communication and resolution program succeed. To be in an organized fashion, be honest, make things better and make it better for future patients as well. A lot is often said about apology protection laws, that you can't use an apology in subsequent litigation. My experience, very few people actually want to use an apology in subsequent litigation in healthcare at least. It just makes your physicians seem caring and compassionate and concerned with your welfare. Not typically if you are in court, what the plaintiff's attorney is trying to demonstrate. But indeed, people who are worried about their statements being used against them and an apology protection law may actually turn out to be very useful. And something that you might have thought of, even if you are doing this voluntarily in complete cooperation with the patient, our experience is that the patient still needs some sort of legal

representation. And shifting the expectations and the framework of the plaintiff's bar to participating for compensation in these types of programs is I think a very important challenge.

The pieces that you probably wouldn't think of, are things that really aren't about litigation and more about the business and payment environment of healthcare. I will just point out two of the three on these slides. One is the National Practitioner Databank and other ways in which over the years we have passed laws at both the federal and state level, to require the reporting of payments made to patients in connection with possible negligence by physicians. These were enacted against a backdrop of traditional litigation and silence and a deny and defend approach on the defense side that is not what CRP's are. We are talking about being honest and open and there is a significant need, in my opinion, to revisit some of the data bank practices and some of the state licensing authority and reporting practices here, because otherwise physicians were quite reluctant to participate because of the damage they perceived to their professional reputation and their professional livelihood. And then for those of you who might have Medicare and Medicaid jurisdiction as part of your portfolios, one of the biggest practical changes in litigation surrounding medical error, has been the aggressive ways over which in the past few years, Medicare now asserts its right, its legal right to place a lien on payments made to patients that reflect in some way money that Medicare has spent on the care that the patient needed following an error. So right now if a settlement is reached with a patient, Medicare is entitled to get back from that settlement, every last dollar that it contributed to the patient's subsequent medical care, following the event. These practices certainly have legitimacy to them, but they are really not well aligned with the needs of the communication and resolution approach. They do not serve the provider incentives well, they do not serve the patient incentives well and they really lead to very unnecessary delays and something that I think strongly needs to be revisited is the way in which Medicare subrogation recruitment and lien assertion interact with this much more cooperative and pointive care approach to dealing with medical error.

And then this last slide is kind of the summary slide and I'm sure it's not quite legible, but in your take home copy, at least gives you not only the bullet point category, but my opinion of what's most important to know about, so is this a significant movement? Yes, it is. I think the movement towards transparency and honesty associated with error is just as ethically significant as the movement associated with informed consent was, two or three generations ago. This is a big deal. This is not a trick of the tort reform side, a trick of the trial bar or something that is kind of a fall back, because neither side gets what it thinks is really important. No, this is about better patient care and I think professionally, it is very significant to both physicians and patients and as a matter of fact, new generations of physicians expect to do this. They expect to be supported in doing it, but this is something they think is important. It's worth understanding that this approach to safety improvement is a transparent approach. It is not a – we will only be honest about what has happened if we work to fix it, just ourselves, in a back room and issue a quiet

technical report. Many of us thought that had a role 20 years ago; I think we have all gotten very skeptical about that. Transparency is good, CRP's contribute to transparency. This is about hospitals and organized health systems, not so much about individual physicians, except in so far they participate in the systems – individual physicians tend to be very, very concerned about individual reputation. This becomes a very difficult thing to do, just by yourself; it's a very good thing, in my view to attach to an organized system of care in which the professionals are supported. And what are often called "care for the caregiver" programs, after medical error have turned out to be one of the very, very successful aspects of the CRP approach.

I would also urge you not to think that just because a hospital now has a whole bunch of errors that are disclosed, that that is a bad hospital. A hospital that has a CRP program in place, that has a lot of errors disclosed, is probably a really good hospital. Just because you see the errors doesn't make it a bad hospital. It was a bad hospital when no one saw the errors.

How much law do we need? This is, at heart, a self help initiative, but as we have said before, law has an important facilitative and non-obstructive role and then I will save any comments about politics and tort reform for discussion. What I would urge you to do is look at this material, whether it's from me or from other people, with the least jaundiced view that you can bring to it. Don't regard this as something coming from the usual malpractice constituents. Certainly in my writings, you will see things that seem to fit the tort reform page, mixed with things that seem to fit the trial bar page. But that is because this really isn't a civil justice initiative; this is a patient care initiative. Thanks very much.

ED HOWARD: Thank you Bill. We turn now to Ann Hendrich from Ascension.

ANN HENDRICH: Thanks very much. I'm going to move us quickly from the policy perspective, directly to the patient care level. It's my pleasure, really, to share with you the Ascension Health experience around research findings from a multi site, very large study, around this topic of disclosure. I want to quickly mention what Ascension Health looks like, because I think it really denotes that if Ascension Health can do this, really any healthcare system can, given our diversity. We are a large system, we have over 1900 care locations in some 23 states, all of which have different tort reform or not. And we chose to center this study in five of those states. We have more than 150,000 associates who work hard every day to make care as safe as possible to those we serve with healthcare that works, healthcare that is safe, healthcare that leaves no one behind. So again, the reason I mention the size and complexity of Ascension is because I think that these study results demonstrate what is possible when a structure/disclosure program is put in place at any healthcare system. We believe so much in this that we have put forward a challenge to the healthcare industry that this should be an accepted standard of care by 2018 for every healthcare system in the country and we are moving aggressively toward that own goal at Ascension Health.

Let me now share with you a little bit of background before I share study results with you. For the last many years, we have had a very focused in the area of obstetrics because it's a primary concern for us for our patients' safety, for both mother and the infant. You may know that most of the time, during the birth process, things go well. But when they don't go well and there is unexpected events, they can go badly very quickly. Our obstetricians and nurses have developed a program that we call HANDS, you see the logo in the upper right hand quadrant of your slide. It stands for Handling All Neonatal Deliveries Safely. And what this is means is that we realize, much like in the safety industry, without the characteristics of high reliability, which means that we must train our obstetricians and nurses to anticipate the worst even possible, be trained for that and then respond as a cohesive team. And they have done exactly that. So they practice on high fidelity mannequins that this young audience would relate to. These mannequins actually birth an infant and they do things unexpectedly. So it's truly testing the behavior and the competency of the clinicians. We also have online modules that test the competency around fetal monitoring, which means monitoring the baby's heart rate during labor to predict the fact that the infant may have non-reassuring heart strips that could suggest that there is pending trouble ahead for the mother and the infant. They also have been through cause analysis training, so when that unexpected event occurs, our team has been trained to go in and look at what just happened here? What can we learn from it? How can we become a highly reliable organization in this high risk area know as obstetrics? So when the agency for healthcare research quality announced this call for proposals, it was music to our ears, because here was our opportunity to put together this package of interventions known as HANDS and couple with it this issue of medical liability and start to solve to that in a cohesive approach and to build a formal research study around it. So the results that I'm about to share with you, come from that study. There were over 20,000 mothers who enrolled themselves and their infants at one of the most precious times in life, which is impending birth. So think about what that means from a patient perspective. During labor and delivery, they were willing to say yes, I want to be part of this study looking at safety, looking at disclosure, because should something happen, this is what I want for myself. So very high levels of patient engagement. The – as I mentioned, the study sites, there were five of them. They included the states of Wisconsin, Michigan, Maryland, Florida and Alabama, all very diverse, but employed, non-employed physicians in these sites that we did this study and I want to quickly review with you at a high level, the five hypotheses and you can read more about these in the Health Affairs article that was just mentioned. Also there is an info graphic in your packet that has a lot more detailed information.

Let me quickly review most importantly, the results on the right hand side of the page. Again, keep in mind; this is 20,000 mothers and infants. Even though birth trauma and unexpected events are rare events, they do happen and all of those were tracked and measured in the 20,000 mothers. We predicted that there would be a decrease in shoulder dystocia births, simply put, this is where the infant does not progress as we would expect,

through the birth canal. It can result in a lifelong consequence called a brachial plexus injury. A permanent partial or temporary paralysis of the arm. Dr. Cox will share more with you about that, but it's a devastating injury for a healthy newborn infant and the mother and family. During this program, we saw 48% decrease in the severity of those births from a bundle that was put together by our obstetricians and nurses. Secondly, we said that there should be a change in the delays of treatment. When there is impending trouble or a crisis team needs to assemble, that we should be able to do that very quickly and get the infant out very quickly, much like in the safety industry. And in 98% of these births, those infants were delivered in three minutes or less. Now, this may seem like an obvious statement, but let me share with you. In most delivery rooms, that time is never clocked. So these physicians and nurses actually started a stopwatch at the moment trouble was recognized and the study tracked that intervention. That is being spread now to all of our delivery sites and we deliver more than 80,000 babies a year. Look at the percent of compliance n that area alone. The third hypothesis is that we believe that there would be a reduction in the severity of claims and also in the settlement amounts, if this worked, because we were doing everything we could to prevent to clinical complication, but in the event that unexpected event occurred, we would fully disclose, once the event was investigated by the team, what just happened here. We saw 57% reduction in the rate of actual and potential liability claims. Those are human lives. Those are infants and mothers who are seeing less birth trauma events in what is really considered a rare event analysis. Then the last two, an increase in the reporting of serious safety events. This really speaks to the culture. All of us have worked in a culture where you did not feel comfortable stepping forward and disclosing something. This meant, at these sites, that nurses, unit secretaries, housekeepers, anyone felt comfortable bringing a safety issue forward. We saw another 48% increase there. Finally, we predicted that there would be an overall decrease if these interventions worked. We didn't know if it would work or not. And again, keep in mind these are rare events, so when you use a rolling 12 month average, in other words, an event will not drop off for another 11 months, we continue to track that in rare event analysis. We saw an 18% decrease. So a simple summary. This had very significant reductions in all of the areas that we wanted to test around safety, high reliability and disclosure.

Let me move now to, how did the disclosure process work? Because this is really the key takeaways. It is very doable and again, we are encouraging and challenging healthcare systems in the country to adopt the same principles and many – many already have. First of all, that immediate reporting. Time should not lapse, because we will forget or envision things happen differently than they actually did at the point of care. So immediate reporting to get the highest accuracy possible and we call these "trigger" events; things that should trigger an immediate investigation. That is the continuous cycle of learning. What just happened here? How can we prevent this from happening again? That expedited investigation to look at cause and also to evaluate, is there liability? Was the outcome that was unexpected, preventable? That is the key headline for us. Then also all of these events are logged not only for study purposes, but for ongoing data mining.

We have a patient safety organization at Ascension. We track all of our events. We mine those and through patient safety work product, we transparently report them and send out alerts to all of our clinical and administrative leaders. So that same event will not happen in the same way at another facility. That is what will make healthcare safer in this country.

Finally, ongoing communication. I want to say something about disclosure. It is not disclosing an event once. It is never enough; because that was unexpected. It is a conversation. We need time to think, reflect on what you just said to me. I will have questions after you leave the room. I will go through a grieving process potentially and we need to allow that individual to have time and space to do that. So we teach our clinicians that this is something that you must give time and space to. We will all respond differently. Finally, the resolution through communication. If we determine through the investigation that the unexpected outcome was preventable, we want to resolve this issue as quickly as possible to regain the trust of the family and also if settlement is warranted, that we are moving toward that. We do not want to see any infant or other situation where resources could have helped the family to intervene more quickly.

Let me quickly show you. This is what our event response team looks like. It includes the obstetrician, almost always the obstetrician who delivered the infant. The nurse. The risk manager. The neonate provider and then a coder. Let me talk quickly about that. The reason we want a coder involved is for accuracy so that we can do ongoing research and data mining around the event. So in summary, this can be described as what we call CORE – communicate openly, resolve early. Transparent disclosure of unexpected events and we plan to implement and sustain a proven model for talking with patients. We are now spreading this research from the five demonstration sites to every one of our delivery sites, which is 64 in total. You can imagine that is quite an enormous undertaking as well as beyond OB. This is not limited to just OB, so it is how we work here. We believe it will reduce the likelihood of contentious and expensive litigation by doing the right thing at the right time for the patient. Thank you.

ED HOWARD: Thank you very much, Ann, and we turn now to Dr. Cox.

RAYMOND COX: Good afternoon and thank you for inviting me to come speak with you this afternoon. As you can tell from my bio, my day job is running a large, free and charitable clinic in Hilton Head Island, South Carolina. But by training and by calling, I'm an obstetrician/gynecologist and I'm excited and pleased to be here to talk to you about the wonderful work that is being done not only by Ascension Health, but by many other systems across the country. This work that was done through our research project was largely engineered and directed by Ann Hendrich, Ziod Hadar and all of the hospitals – the five hospital sites that were involved in this project, had a very particular role to play in making sure that this project had the wonderful outcomes that you saw today.

What I'm going to try to do over the next couple of minutes is to personalize for you the information that you heard from both Bill and Ann. Twenty-five years ago, I delivered a baby who would go on to have a permanent brachial plexus injury. It took me about seven minutes to deliver this baby, I'm not quite sure how long it took because back in those days, we didn't time the delivery, we didn't keep track of the time involved. We didn't have a coordinated structured team response and of course we didn't do simulations to practice being prepared for those high risk, low frequency events. And afterwards, we were advised that we should not talk to the patient and family because that would increase the likelihood of liability by speaking directly with the family after the delivery to discuss this adverse event. So I decided to break the rule after this delivery and I met first of all with the parent and then with their family members – there were about 15 family members that we put together in a conference room, to not only explain to them what happened at the time of delivery, but also to give them the opportunity to ask any questions they might have about how this delivery took place and why their child had this outcome. We formed a bond with that family and over the next four or five years, they actually sent us pictures of this little girl. This is not the little girl, by the way, but I wanted to give you a picture of what brachial plexus palsy looked like in a child after delivery because sometimes particularly as ob/gyns, we don't see this type of follow-up. What was very important and very touching to me was that the family stayed in touch with me to make sure that I knew what the outcome of that child was and by the time that child went to school at age five, this palsy, this injury, had resolved spontaneously. And the child went on to have a normal childhood.

Let's fast forward to what we have done through this AHRQ study. The work that we have done and the physician response to that work has really been truly remarkable. We actually started this journey about ten years ago, as Ann mentioned, through the HANDS program and a lot of the work in getting the physicians to buy into the disclosure process, was really set up by the work that we were already doing through simulation. So getting the physicians and the nursing staff involved in simulation was really one of the first hurdles that we had to overcome, because the nurses and the physicians would run the other way whenever we pulled out the simulation mannequin. But over time, they began to understand how important this was and they also began to understand that as leadership for the hospital and for the system, that this was not something that was going away. That we were committed to reducing birth injury and these were the programs that were putting into place in order to make sure that we could reduce the birth injury. So once we got their buy-in, they were actually excited and involved and even made many suggestions about how we could improve this process. Not only in terms of the simulation training, but as we then had to address disclosure we ran into a different set of issues. It wasn't just that some of them had buy-in on disclosure, and the ones who were easiest to get buy-in, were those who were employed by the hospital. But we had many physicians who had their own commercial insurance and those commercial insurance companies didn't want their physicians involved in a disclosure process, because they felt that that would increase their liability. So we really went through – and this didn't just

happen at St. Agnes, it happened at several other hospitals across our system, one in particular. So there was that issue to overcome. Many people felt very uncomfortable about apologizing for events that took place at the time of delivery, but one of the ways that were able to get through that and I'm going to give you some of the responses from St. Agnes, was actually by working with the OBERT team, the ob event response team. The risk manager, the physician lead, the nurse lead who had been trained in disclosure – all of the physicians, by the way and all of the nurses had undergone discloser training. But these were the leaders in terms of helping physicians, the physician who did the delivery actually start the conversation with the family. Initially they were uncomfortable with that, over a relatively short period of time, the physicians, 85% of the OBERT or disclosure responses were actually initiated by the physician over time. Which is a very encouraging result. The feedback that we got – I'm going to give you an example of the feedback that we got from one family that was involved in this, it is a little difficult to talk about. But one of our patients – we had a maternal death of a patient who was actually a colleague of ours. And the concern that I had as the chairman of the department at the time, was that two of my physicians and three or four of my nurses who were involved in caring for this patient – it is such that they came to my office and said that they were resigning their practice. They didn't feel that they could practice ob/gyn any more. They didn't feel that they wanted to be in maternal child health nursing. It was through the work of the Ob of that response team and through supporting those doctors and nurses as well as supporting the family, that allowed us to get through this situation. It was extremely difficult because we had to sit down with the family and explain to them what happened. Now, in this case, this was not a preventable event. There was nothing that we could have done that would have changed this very unfortunate and this very tragic outcome. But what it did do was to allow not only the family to heal because the family was brought in on several occasions to communicate with them at every opportunity that we got new information, if there was anything that could have been differently, what the results of the pathology tests were, etcetera. So that process that we developed not only helped in our relationship with the family, but it also helped to save the careers of three fine ob/gyn physicians and four wonderful ob/gyn maternal child health nurses. At the very least, that in itself was a save from this group.

Because at the end of the day, what we want to do is provide a situation where we have a baby who comes out perfectly healthy, ready to take over the world – not yet, not yet – sorry Dexter. Who is ready to take over the world. Mother is sitting there reading about this little tyke, there are rockets going off and cherubs standing around and storks flying and the nurse is standing there making sure the doctor is doing the right thing – now, Dexter – but we want to make sure that we will know that we have reached high reliability when this woman and her baby have the same outcome as this woman and her baby. Now, here is my ask. There are a couple of things and Bill already mentioned some of them, that I want you all to focus on as part of the congressional staff. One is that we need to federalize apology laws in a way that makes it easier for physicians to feel that we are enclosing them in a just culture. We are trying very hard to get away from the

blame and shame environment and create an environment where we can begin to look at this adverse events and learn from these adverse events. And the current environment does not allow us to do that. The other thing, from a legislative perspective that would be very helpful, is by ensuring that liability providers – malpractice insurance providers – understand the role that they have to play in making sure that by changing how they address these adverse events, it makes it easier for physicians to participate without feeling like it would lead to loss of reputation and make it difficult for the few solo practitioners who are left in practice, to not feel that they are risking their practice by participating in these types of events. Thank you very much.

ED HOWARD: Thanks very much, Dr. Cox. And we turn now to someone who directly represents a consumer interest, patient interest and that is Jean Rexford.

JEAN REXFORD: I represent all of you as healthcare consumers, as – you know, for your mothers and your grandmothers and your children. It is a system that is currently not working for the individual patients. Congratulations to Ascension and to what you are doing, Dr. Cox. These are what I call "islands of excellence" and if we could replicate these through the system, we would actually still have a lot of problems and I'm going to talk to you a little bit about them. The way it is currently set up is cruel and I'm glad you talked about the providers. It's cruel to the providers and it's definitely hard on patients. My original board was made up of – one man was George Meader, his daughter, who was four, had a tube put in her ear and she died. No one acknowledged any wrong doing. It went to trial and six years later, everybody was still blaming everyone else. And George kept saying, but my daughter is dead. Another board member, Gus, lost two legs. This is when I learned, minor surgery only happens to other people. Lost two legs during minor surgery. The physician left Connecticut and went to another state. That of course was litigated. But no matter what the financial end to all of these stories, Gus will never walk again. So we have a system that is not working for patients. We have a system that is not working for physicians. I recently was up in Massachusetts. They have seven hospitals that are now doing the apology. What struck me as they were talking about their first year experience doing this was the physicians who had participated were traumatized. They were living with – as your health group did – they were living with the consequences of an action that harmed people. So if it's hard on the physicians, we can imagine that it is hard on the patients and their families. There is so much that happens to patients that doesn't bump up into the category of errors. Errors happen one at a time, so it could be in Maine, California, in Kalamazoo – but it's three jumbo jets of people, every single day, who die because of medical error. And yet, because it's not a single jet, we are not paying enough attention to the problem. So Ascension Health is just – they have been great and Susan Davis who was at St. Vincent's Hospital in Connecticut, worked with the hospital association in my state and everybody is doing this high reliability work, which is exciting because the engineers from nuclear and aviation industries are in there and they are saying, this is the reality of the care you are providing. And people react the way we all would, with, oh my heavens if that's – I want to do it differently. So these safety

huddles that they are doing are a wonderful way to change. The change is beyond the safety or the needs to change is beyond the safety huddle.

I was a panelist last year at the Board of Radiology Foundation and for two days they worried about the over use of CT scans, especially with children. This will create cancer. And so for two days they talked about it and I, like today, was the last speaker and I said, not once did any of you mention conflicts of interest. If we have a new machine, it will be used to pay for that new technology. So we have – and let's think about competition between hospitals. If somebody is doing a new kind of surgery – the robotic surgery was purchased by one hospital in Connecticut, then another one had to do it and people were using this without enough training and people were being harmed. So somehow, the capitalism within this system is not necessarily working for patients. So we have a medical device industry. 90% of the medical devices that are implanted in patients are not tested. So the hip that was causing so much trouble – I think it was the metal on metal hip, we don't have a national registry that keeps track. So within a hospital system that was actually doing really well on safety, that patient could have left the hospital – is the physician tracking that patient? When that goes wrong, to whom does that patient call? We have one of the second leading problems for errors is communication and yet if you have ever been ill or had your going out with your mother or your father from a hospital on the directions that the hospital provides as you are leaving, you know that the communication is not clear. There are so many things that could be done if we involve patients from the beginning. Patients are smart, we care. Right now we trust a system that is not necessarily trustworthy.

ED HOWARD: Thank you Jean. We now get to interchange among the panelists, I would encourage that, and you get a chance to join the conversation with questions, which I remind you, you can accomplish either by coming to one of the microphones, filling out a green question card or tweeting at #patientsafety. Let me start off with just a clarification question for Ann. You referred in one of the parameters that you had in the chart, to a reduction in actual and potential liability claims and I wonder, how do you measure potential liability claims to be able to get to a single digit percentage reduction?

ANN HENDRICH: Good question. So I mentioned there are some trigger events that were unexpected. These are the events that don't necessarily cause an unexpected outcome, but they were unexpected in the situation or the practice. So we also monitored those as well. This is often what is called a near miss in the safety industry and we wanted to have twice as many near misses being reported as we did actual, unexpected events. That really is one of the best measures of a safety environment.

ED HOWARD: I should point out that we started early compared to our usual time slot of 12:15 to 2:00 and we are going to end the discussion no later than 1:30, so you had better get your questions in now. Some folks submitted them in advance and I'm going to start with a couple of those if I can. We heard reference particularly from Dr. Cox about

the importance of the role of the insurance companies and both he and Bill Sage talked about this. The question wants to know whether disclosure on apology programs can be successful without protecting the apology from the threat of a lawsuit. That is, can doctor/patient communications be truly open when anything that the physician says can be used against him or her in court?

WILLIAM SAGE: So the question was about the need for apology protection. I would say that most of the programs that are already in operation and most of the physicians who are already doing this, whether they are in a state with an apology protection law or not, they have become pretty comfortable. But if you really want this disseminated widely, one is dealing with skepticism and occasional paranoia and that instance – this type of a legal change is one that I think has very little downside, but can be reassuring. One of the great challenges in many areas of health law and policy of course, is that it is a professionally driven endeavor with great social and economic consequences. Professionals are people, people have perceptions, a lot of things and a lot of dollars depend on their perceptions. So often in the world of medical liability, you are dealing with very strong perceptions. Some are empirically justified, many are not. But none the less, there are instances in which accommodating the perception can have significant benefits for the public and apology protection is probably one of those.

RAYMOND COX: Let me just add to that a little bit. There were several studies done a few years ago in the UK, Australia and in the United States and it was interesting because they were all consistent, that showed about 12% of all preventable adverse events ended up as a claim. Now, that 12% figure – so then the question becomes, well, why is it that only one out of seven preventable adverse events ends up as a claim? The typical reason why people sued, was to find out what really happened. They felt like they were not being told the truth, that things were not being disclosed to them. One of the reasons why we are so interested in this issue of disclosure and transparency is because it helps to re-establish and maintain the physician/patient or the health system/patient relationship. So that is a very important part of why these disclosure and apology laws are so important. A lot of physicians – like the example that I gave you initially, take the risk, so to speak of divulging what happened at the time of an event. But a lot of times that takes not only courage, but it also takes the support of the hospital leadership or the health system leadership. If the health system leadership is on board, then that makes it easier for the physician to feel safe in reporting these apologies and disclosures.

ED HOWARD: Ann, you talked about Ascension's geographical spread – 23 states. Dr. Cox made the recommendation that we have to get the insurance companies on board in this apology business and I wonder what your experience is from state to state in that area?

ANN HENDRICH: It is variable with the medical malpractice insurance carriers, as was said earlier. We are being very transparent about this. Some of the insurers actually said

to the obstetricians that they had insured for more than 20 years, that if you disclose a serious event to the mother, we will not insure you anymore. Now part of this is the learning and building the knowledge and that is where the research comes in and the more studies we get like this to demonstrate, it does not increase liability, then we can get the insurance industry on board with us. In fact, we did, in this short lifespan of just less than three years within the study. By the time we finished, we had moved to the insurers actually offering premium reductions for the physicians who went through the full training. So again, it demonstrates – it is about culture and perceptions and we can change those with facts.

JEAN REXFORD: What I have learned is that everybody at the end of the day thinks they have done a good job, because at the end of the day, we are all tired. And when it's efforts like Ascension that stop to look at data, then they can see, oh, we are not doing as well as we thought we were going to do. I think some of the things that are happening now around transparency can be transformative. Many states are setting up [unintelligible] claim databases that are going to be providing, with the Affordable Care Act, they are going to be providing data on care and quality and costs. So there is exciting change out there, but its state by state and it's not universally packed in.

ED HOWARD: I have a question from one of the cards and also directed to you, Ann, at least initially. They ask if Ascension is using simulation with the new IT system implementation. Since new system implementation is a high risk time for clinicians and patients and actually there is another question that came in advance, asking all the panelists to address HIT safety and errors, given that there has been so much in the news lately about HIT safety and breaches and the potential for errors that could affect a whole lot of patients at the same time.

ANN HENDRICH: I love the question and the short answer is, yes, we are. One of the things that we are doing now is we are bringing human factor engineers in to work with us. What we don't realize is that a lot of the medical device products that have been built, are not necessarily intuitive for the clinician and they can contribute to medical error unintentionally. So before we buy any new piece of equipment now, we have not a few, but frankly hundreds of clinicians who are – it's one of the principles of high reliability, deference to expertise. They are the experts, they are the ones that should be testing and determining whether or not this piece of equipment or the EHR is constructed in such a way that it represents my work flow. So yes, we are. We need to do more of it though.

WILLIAM SAGE : I will give a little plug for my home institution, UT Austin. We have a grant, it's since expired from [unintelligible] coordinator for HHS to set up University based health IT training and one of the things we did in connection with building that program was we created an EHR learning laboratory that now has a lot of unusual features, including having a mock – simulated, I should say, health information exchange. So it goes outside of any one provider organization and one of the new initiative areas for

our program right now is patient safety and it's interesting because it's both a process of testing the systems that are in place and the information they provide, but also being quite attentive to the information they don't provide. A lot of the things that are required to improve safety and to improve quality are not found in any health information system at present.

JEAN REXFORD: It's a little mind boggling to me that we don't have a single gauge. We figured out with railroads in our country that for railroads to get everywhere we had to have a single gauge. We have not done that with health and information technology, so the patient is many times at a loss. Yale now has a giant system, buying up practices. But if a patient were at Danbury Hospital, that is information that is not transferable. And yet, in a mobile society, we are always moving. We are in other states, we are in other places. Somehow we have to figure this out and quickly.

ED HOWARD: Yes, would you identify yourself, please?

AUDIENCE MEMBER: Yes, my name is Lisa Somers; I'm the Director of Policy and Advocacy at the Center in Healthcare Institute. I'm trying [unintelligible] and so I had to get up here and say, thank you very much because this is just incredibly important work and as somebody who had an experience much like Ray's, early in my career, I really want to thank you. And my question is about a topic that often comes up in health reform discussions and at these briefings, and that is the topic of overuse and over treatment. Particularly in obstetrics, we think a lot about overuse of electronic fetal monitoring and overuse of cesarean section. And often there is a sense that what drives that is fear of liability. That is what is driving particularly the c-section rate. So I'm wondering if you can share anything about, through your work in this area, do you think it's having an impact on that question of overuse or over treatment?

ANN HENDRICH: Let me give a primary example and again, thank you for the provocation behind that question. One of the things that we focused on is early elective deliveries at Ascension Health and Dr. Cox and others really led this pioneer work long before the rest of the nation was looking at it. Now, you may not know this, but many, many mothers in this country are induced prior to the 39th week of pregnancy with no medical indication. So we are not talking about inductions that are required for a medical reason, but the mother is simply either tired of being pregnant, the mother in law is coming in or convenience, frankly. And it's more complicated than that, I'm just using simple examples. But these inductions are costly; they often result in a cesarean section because the mother was not ready to give birth, even under the best circumstances. Right now, our rate for early elective deliveries prior to 39 week is less than 1% in those 80,000 births. Our obstetricians have not stopped there. Our committee just adopted now, going to 40 weeks 6 days, because it is not until the 41st week of pregnancy that the risk of stillborn or complications goes up. This is not a hardened fact, because as Dr. Cox will tell you, this is medical intuition and science together and only the physician and mother

can determine, but we are using that as a system standard. So that is one example where over utilization of induction contributes to poor quality, safety issues and needless cost in healthcare.

RAYMOND COX: Lisa, to follow up on that, we thought we were gonna see a significant reduction in cesarean section rate when we implemented this early elective delivery bundle. We really haven't seen that yet. What we have seen is a significant reduction in admissions to the neonatal intensive care unit, particularly from babies who weigh over 5.5 pounds, which is a significant savings and obviously a significant reduction in risk to those infants. But we continue to search for ways to understand what makes up that cesarean section rate and how various opportunities for overuse can be ameliorated through standardization of care. One of the things that we are committed to doing is part of our [unintelligible] journey, is making sure that we are standardizing those events or those practices that can be standardized. And that is something that we are very committed to.

JEAN REXFORD: 45% of what we do everyday is from habit and I would have to say, probably with healthcare, it's even higher. So you – so what you will see when there is transparency are their practices that that's what they do, early deliveries and cesareans. So the data becomes critical for all of you as you try to change this. They don't know that they are outliers. I think on the overuse with CT scans, the whole choosing wisely program is going to be also transformative and exciting because we keep treating illness, sickness and not health and it's way too expensive.

WILLIAM SAGE: I asked the organizers to include two of my writings in your packets. One is the CRP and law health affairs article that we have talked about, the other is a book chapter about the relationship between liability and healthcare costs. Things like overuse and it's called both symptom and disease, meaning that liability does have some effects on its own, but for the most part it shows the inadequacies and perverse incentives in the healthcare system more generally. I think Ascension is very much to be commended for having policies in place to prohibit early elective induction. If you were to get honest responses from many, many providers about why they don't have such policies, you would hear things you really don't want to hear. You would hear from hospitals that they really don't want to take on their obstetricians who by the way, are not typically their employees. They don't want to chase them to other hospitals by telling them what they may not do. And you would hear even some hospitals that say that they can't afford to lose the revenue associated with having a child born with significant complications that needs NICU care. These are not things that we want to hear, but they are out there and I think the more general lesson, if you will let me retreat into kind of the academic policy space that I inhabit, is that often what we are buying and selling in healthcare are not real products. And as a result we don't pay for them or produce them in the way that just makes sense. What you want is a safe delivery and everyone involved in that delivery should be on the same page and paid all together to create the product and

warranty it against these types of complications and we don't do that. We pay for process steps, we pay separately for each component and we get what we pay for and it's often overuse.

ED HOWARD: Can I just ask, Bill, in developing these bundles, these products if you will, is that an alternative to kind of evidence based standards that might stretch beyond a community which is kind of the standard of care that is now being used in liability cases? Is there a way to take the work that we are hearing about there, generalize it, standardize it, as Dr. Cox talks about, so that there is less reluctance to do some of the things that we know could help improve both cost and quality?

WILLIAM SAGE: Absolutely and I won't take too much time to elaborate, that is a different talk, Ed. But if one is thinking just logically about what you want to buy, you want to buy something that makes sense to you to buy. A medical outcome, a period of treatment for something that you have chronically. Having a baby and having it all turn out well. You want a warrantee associated with that or you want to be able to measure at the end of the day whether you got what you paid for or not. And our healthcare system is just not set up to do that. The more we can move in the direction of setting up our healthcare system to do that, it's not a matter of a new list of real products. It's not a matter of cookbook medicine, it's saying that, no, everybody who is providing these real products will figure out how to do it right. And Ascension in many ways is figuring out how to do it right.

ANN HENDRICH: I just wanted to add, one area where I think we are seeing rapid innovation is through the CMS hospital engagement networks, which is 3800 hospitals, if you have not had a chance to peruse the website there, we are a hospital engagement network and the choose wisely program is spreading, so I think we are seeing early signs of what is possible with rapid spread over just a couple of years and it is having dramatic effect on hospital acquired conditions and over on this over utilization issue.

ED HOWARD: There was a question submitted in advance by one of the congressional staff folks. It takes a different approach to some of the questions we have been talking about. It's noted in the initial briefing paper, the questioner writes, that a potential avenue of achieving the goal would be preliminary disclosure of potential risks and unanticipated outcomes of medical services in question as well as a potential agreement between the patient and physician for monetary compensation in the event these outcomes come to fruition. Would you liken this approach to a prenuptial agreement within the medical field? And how would monetary compensation value be determined prior to the medical services being administered, given the wide range of potentially negative outcomes possible.

WILLIAM SAGE: Do you want me to grapple with that one a little bit? Okay, so here you guys will get to realize that I'm kind of a liberal Democrat who loves markets, go

figure. Markets are actually really resilient. We have had a long tradition of law in this country, predominantly at the state level, that says that you are not supposed to be able to bargain with your doctor in advance for under what conditions he can hurt you and what you get if he does. Again, that has been kind of a theoretical literature on why contracts make sense, but while all of this goes on, actually the real world has figured out some good things to do. So there is a big field now of medical tourism. You know about where people go get complicated medical treatment abroad. Well, most of the places they go abroad don't have the American tradition of civil liability and in fact there are companies that will sell you a first party policy of in essence, medical liability insurance and you will buy that as a patient before you go abroad and someone who sells you the package here may incorporate that. This is an interesting legal and regulatory problem, but in general, why not? It is showing a market emerging to do exactly these sorts of things. I'm not sure about the analogy to a pre-nup.

ED HOWARD: Question for Ann from one of the audience members, in the study, what percentage of those who participated in disclosure discussions, continued on to lawsuits and why, if studied, was an offer of compensation rejected?

ANN HENDRICH: Again, we can refer to the Health Affairs article, someone to say about the obstetrical claims is that it's often one of the longest lag times for claims or trial or a settlement because of the very issue that Dr. Cox spoke about, is that until the child misses the first developmental milestones and it's proven that that is not going to be reversible, you don't see these claims. So we have a whole actuarial analysis set up around these 20,000 mothers. We continue to monitor in the info graphic, you saw that the baseline period was in excess of 7 million. During the three year study period, it is less than a million. And to date, that rate of improvement continues because there is overall reduced events occurring – again, rare events but serious, and also then therefore less claims are following both because they are not occurring, but also because disclosure. So be watching for additional papers for us coming out. We will keep the data set open for another three years after this study has closed in 2013, to make sure we are capturing the final outcome based on age of the children that were birthed in that last year.

JEAN REXFORD: When I was up in Massachusetts, they were, after a year's experience, they were thinking that it is critical for the patient to have access to a lawyer early on to help with the negotiations. So that the patient and the family can feel well represented and not overwhelmed. When bad things happen, you are so right, it takes a long time for people to sort of adjust themselves to a world that is very different and so it is not quick, it is complicated and I think legal support on both sides is critical for a good outcome.

WILLIAM SAGE: I just want to strongly agree with that. Most of the programs that I am aware of that operate these CRPs not only prefer that the patients be represented, but they

go out of their way to help the patient find good competent non-conflicted representation. It's definitely a change in how the plaintiff's bar does business because it's not long delay, it's not high expense, it's not high risk that would justify a high contingent fee. It's compensation. It's a different type of law practice. But I think it's very fulfilling to the people who do it and it's evolving slowly in the different states that have providers that are doing CRP's.

ED HOWARD: As we go into the last few minutes of our program, I would ask you to pull out the blue evaluation forms and fill them out as we hear the last few questions, one of which will come from the gentleman at the microphone.

AUDIENCE MEMBER: Thank you, Mike Stenson with PIAA, representing the medical liability insurance industry. I just want to make one very brief point because I don't think it's been represented here, is that medical liability insurers have actually been leading and innovating on some of these programs for many years and in fact PIAA sits on the executive committee of the collaborative of accountability after medical injury, which is aggressively advocating for these programs across the country. Kind of following up on the comment you just made, Dr. Sage, I wanted to get Miss Hendrich's perception on whether or not the idea of bringing attorneys into these proceedings – whether you have experienced that and whether or not that is helpful. It would seem to me that that would immediately change it from a cooperative procedure between the patient and the provider to one of more of an adversarial nature. Have you had any experience dealing with that in Ascension?

ANN HENDRICH: [inaudible] counsel, is that your question? Always. And we have expertise here that can comment as well, but we encourage that. In fact, I can safely say we would not go to resolution without that representation.

WILLIAM SAGE: I would have to add here, in just my personal opinion, I think PIAA and its member institutions have been leaders in collecting data that bears on patient safety and patient safety improvement over the years. I think they have been laggards in sharing that information.

ED HOWARD: Question about timing – how quickly after an event do you talk compensation with patient families? I suspect that is both in actual experience and analytical terms when you are trying to devise these programs.

RAYMOND COX: I will make the first comment on that – again, from a physician perspective, there is a lot of difference between an apology and a full disclosure and you heard Ann talk about the fact that a full disclosure includes not only initially meeting with the patient and their family to explain the events surrounding the adverse event, but then apologizing for whatever that adverse event was. And then stating to the family that you will make a determination as to what caused that event. And then in a timely manner,

get back to the family or back to the patient and let them know what your findings were and what if anything needs to be done to prevent this from happening again. When we talk about federalizing laws for apology, we are actually talking about federalizing laws for full disclosure because that is the safe environment that we want to create, that is the umbrella that we want to create to make sure that we are able to establish a just culture that will allow us to develop these relationships – redevelop these relationships with our patients that we used to have a long time ago before all of this complexity came into this. So essentially what we are actually talking about is creating that type of environment.

ANN HENDRICH: I would just add that it is difficult to give you an exact number because they are so highly variable depending on the complexity of the case. What I can say is that it's gone from years to a few months or weeks, compared to how it used to work. Again, we want to be thoughtful about the investigation, given the family and patient time to work through disclosure with the providers that they trust and it is much shorter than it was previously.

ED HOWARD: Does the compensation discussion necessarily involve admission of guilt? We have heard over the years of programs that covered immediate medical bills and use that as a device to try to get to an early resolution to some of these claims.

WILLIAM SAGE: This is just a good clarification for the people in this room who actually have a longer history with this general area. One of the first well known programs for immediate disclosure, apology and compensation was through the Colorado Physician Insurance Company or CPIC, it was called their 3R's Program. It was a very successful program, but it was not highly formalized in the sense that it wasn't legalistic. Patients didn't release their claims, there was never actually a demand made in writing and the amounts that were paid, were paid to help the patient and the family with their immediate financial needs, with freedom to sue afterwards, but it was typically administered for relatively low dollar events. The communication resolution programs that we are talking about now and the ones that are growing up at the major institutions tend not to follow that model. Instead they do require release of claims, they tend to be able to do deal with higher dollar events and for that reason, representation of patients by lawyers is extremely important and everyone acknowledges that. So if you are thinking the 3R's program, great program, and there are other ways to do that in kind of a really non-adversarial context, but what we are talking about here tends to be the larger events, the higher dollars and it does have to be somewhat more structured and legally formal.

ED HOWARD: I think we have come to a good stopping place in this conversation. We haven't quite solved all of these problems, but we have some evidence of progress in a variety of places and we have a topic that we are going to keep an eye on and try to come back to as those developments warrant. Thank you for your active participation in the program. Thanks to our colleagues at Ascension for both contributing Ann Hendrich's

expertise and co-sponsoring the event and I would ask you to join me in thanking the panel for a really good exposition of some tough issues.

[applause]