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PATIENT SAFETY: INSTILLING HOSPITALS WITH A CULTURE OF CONTINUOUS IMPROVEMENT

HEARING

BEFORE THE

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

OF THE

COMMITTEE ON
GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

JUNE 11, 2003

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WEDNESDAY, JUNE 11, 2003

U.S. SENATE,
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS,
OF THE COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 9:05 a.m., in room SD–342, Dirksen Senate Office Building, Hon. Norm Coleman, Chairman of the Subcommittee, presiding.

Present: Senators Coleman, Levin, Durbin, Carper, and Pryor.

Staff Present: Joseph V. Kennedy, General Counsel; Mary D. Robertson, Chief Clerk; Kristin Meyer, Staff Assistant; Caroline Lebedoff, Intern; Elise J. Bean, Democratic Staff Director/Chief Counsel; Laura Stuber, Democratic Counsel; John Myers (Senator Specter); Marianne Upton and Krista Donahue (Senator Durbin); Wendy Want (Senator Lieberman); and Tate Heuer (Senator Pryor).

OPENING STATEMENT OF SENATOR COLEMAN

Senator COLEMAN. This hearing is called to order. I will begin my opening statement and then turn to the distinguished Ranking Member of this Committee, Senator Levin, and then we will go to the testimony of the witnesses.

Good morning and welcome to today's hearing. In the 19th Century, Edward Jenner's discovery pushed the boundaries of germ theory and disease. The use of antiseptics and anesthesia in surgery increased public health levels and sanitation. And in the end, the simple act of washing one's hands transformed modern medicine by saving lives by preventing the spread of disease.

The topic that we are dealing with today deals with how we can reduce errors that negatively impact patient safety. It is not just about systems. In fact, it is a basic discussion of how do human beings interact with the systems that are created to underscore the primary obligation of medicine, to protect the safety of patients.

I want to repeat that we are going to talk a lot about systems today, but in the end, we are talking about people's lives. We are talking about lives being lost and there is a human component that sometimes when we talk about systems in an antiseptic way we forget about, and that has to be at the forefront, that we are dealing with people's lives and we are dealing with lives, deaths that could be prevented, and accidents that shouldn't have happened.

To be sure, there must be strong, dynamic, and rigorous systems in place to ensure the safety of the patient from the moment they enter our Nation's hospitals to the time they leave. There is an opportunity for us to discuss that today, and even more importantly, for us to implement systems that will accomplish this task.

This opportunity was pointed out in a study issued by the Institutes of Medicine 3 years ago entitled, "To Err is Human: Building a Safer Health System." Today's witnesses are at the forefront of the effort to achieve these improvements.

However, before we get to the discussions of systems, we need to recognize the one of the key ingredients of the future of our health care system in a single word, and that is confidence. Americans must have complete and total confidence in their health care systems if we are to ensure progress is made in this Nation, keeping our people not only safe but healthy.

Americans must have confidence that not only is medical technology among the best in the world here, but that the people who are using it are the most highly trained and skilled. Americans must have confidence that their health care providers, doctors, nurses, and others are not only equipped to manage their care, but they are committed to the highest standards of medical professionalism and ethics.

Finally, Americans must have confidence in the institutions of health care. We must be certain beyond a shadow of a doubt that every possible attempt is being made to ensure that we emerge from a health care experience at a hospital or clinic in a better condition than when we entered it. The basic premise of the Hippocratic Oath, to do no harm, must reflect not just the deliberate efforts of health care providers, but must also extend to the practices and procedures they implement to ensure the totality of the health care experience is safe, from beginning to end.

From the onset of washing hands to the discovery of drugs to prevent disease and pestilence, medicine has been constantly improving and always innovating. Such improvements must continue to be the hallmark of our health care system. First, it is obviously a critical component of patient safety and health. Improved care saves lives.

Second, it increases the quality of care, of speeding recovery and improving outcomes.

Third, it reduces cost, allowing more individuals to afford quality health care.

Fourth, it eases the acute shortage of health workers, such as nurses and lab technicians that many areas face.

This subject could not be timelier for Minnesota. Last week, the Minneapolis paper reported the tragic death of 2-year-old Brianna Baehman. Brianna died as the result of a hospital error. Ironically, this mistake happened in one of Minnesota's best hospitals, a hospital with an excellent record of quality improvement and a firm commitment to improving patient safety.

Our first witness today will also remind us that the consequence of error can often be fatal. They will also do something else that they have done repeatedly since this great tragedy: Help us recognize that a failure occurred and that improvements must be made.

I applaud them for not only accepting those failures, but for admitting that there is a critical need for improvements.

Today's hearing is not meant to focus blame or to concentrate on tragedies for the sake of sensationalism. On the contrary, these tragedies are painful reminders that human error is a function of human growth. We must learn from our mistakes. Unlike most of us, doctors and nurses are in the unenviable position where their mistakes can easily have fatal consequences. While we can never achieve perfection, the good news is that we can do much better. We can develop a system in which errors are prevented and the consequences minimized. However, the reality is that we will never conquer human fallibility.

As I said, today's experts are at the forefront of the Nation's efforts to install a culture of quality and implement a system of continuous improvement. I believe that their success or failure will determine the level of confidence Americans have in the health care system and, thus, the future of our health care system.

At its most fundamental level, today's topic is the key to the future of our medical system. How do we ensure confidence and patient safety in our health care system through better performance from the Nation's health care system, especially its hospitals? There are proven management practices that have many names, including lean manufacturing, balanced scorecards, and Six Sigma. Although Japanese companies such as Toyota and Sony made many of these practices famous, they were originally developed by American experts, such as W. Edward Demming. Today, most of the world's leaders in productivity are American companies, such as GE, 3M, and Honeywell.

The experts we hear from today will tell us that we can get these same improvements from the health care sector if we adopt some of the same management practices. Like any other institution, hospitals are basically human endeavors. While we cannot legislate away human error, we can develop systems for minimizing the chance of error by improving communication, standardizing practice, and learning from mistakes.

Doing this depends on a number of things, however. One is the willingness to study and eliminate barriers to better performance. These barriers may take the form of human resistance to change, the lack of a team culture, or liability concerns about sharing information. By themselves, each barrier may make sense, but when they stand in the way of better health care, we need to examine their usefulness.

Second, we need to work with those institutions or organizations and agencies that are prepared and committed to go that next step towards ensuring ongoing confidence in the safe care of patients in our health system. I am pleased that one of those people who are here today to talk about what they are doing to ensure a system that will provide for monitoring and improvement of patient safety in Minnesota is the Commissioner of the Department of Health, Dianne Mandernach. The State of Minnesota is one of the first in the Nation to begin implementing a system of data collection, working with the Minnesota Hospital Association to ensure accurate reporting of information related to patient safety. I want to thank the Commissioner for being here today and for the work and leadership

she has provided on other issues, including SARS, in the State of Minnesota.

In the end, in every area such as long-term care, medical practice, and product development, we need to and can do better, and the tools for doing so are already at hand. The health care industry can and must undergo the same type of transformation toward a culture of quality and system for continuous improvement that the manufacturing sector has recently experienced. Our experts are here today to tell us that this is being done, and with our help, it can be done faster.

[The prepared statement of Senator Coleman follows:]

PREPARED OPENING STATEMENT OF SENATOR COLEMAN

Good morning and welcome to today's hearing.

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The topic today deals with how we can reduce errors that negatively impact patient safety. It is not just a discussion about systems—in fact, it's a basic discussion about how do human beings interact with the systems that are created to underscore the primary obligation of medicine. To protect the safety of patients.

That is, in my mind, the premise of our discussion today, and the testimony of our witnesses.

To be sure, there must be strong, dynamic and rigorous systems in place to ensure the safety of a patient fromt he moment they enter our Nation's hospitals—to the time they leave. There is an opportunity for us to discuss that today, and even more opportunity for us to implement systems that will accomplish this task.

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Americans must have confidence that not only is medical technology among the best in the world, but that the people who are using it are the most highly trained and skilled.

Americans must have confidence that their health care providers—doctors, nurses, and others—are not only equipped to manage their care, but they are committed to the highest standards of medical professionalism and ethics.

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The basic premise of the Hippocratic Oath, to do no harm, must reflect not just the deliberate efforts of health care providers, but must also extend to the practices and procedures they implement to ensure the totality of the health care experience is safe from beginning to end.

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Such improvements must continue to be the hallmark of our health care system.

First, it is obviously a critical component of patient safety and health. Improved care saves lives.

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Ironically, this mistake happened in one of Minnesota's best hospitals, a hospital with an excellent record of quality improvement and a firm commitment to increasing patient safety. Our first witness today will also remind us that the consequence of error can often be fatal.

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While we cannot legislate away human error, we can develop systems for minimizing the chance of error by improving communication, standardizing practice, and learning from mistakes. Doing this depends on a number of things, however. One is the willingness to study and eliminate barriers to better performance. These barriers may take the form of human resistance to change, the lack of a team culture, or liability concerns about sharing information. By themselves, each barrier may make sense, but when they stand in the way of better healthcare, we need to examine their continued usefulness.

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Senator COLEMAN. With that, I would like to turn it over to the Ranking Member of this Committee, Senator Levin.

OPENING STATEMENT OF SENATOR LEVIN

Senator LEVIN. Thank you, Mr. Chairman. Thank you for convening this hearing. It is a very important subject and your intense interest in it is critical to continuing progress in the area.

Health care in the United States is among the most advanced in the world. Our doctors are trained in the newest techniques and medications. Our nurses undergo rigorous training, and our hospitals provide life-saving emergency care, diagnostics, medical equipment, and sustained support to return patients to health. But even top-caliber hospitals cannot escape medical mistakes that sometimes result in irreparable damage to patients.

We have all heard the painful stories. A few years ago, a man in Tampa had the wrong leg amputated. Last summer, a young Dallas woman died because she got the wrong liver transplant. A North Carolina teenager died earlier this year after receiving transplanted organs that did not match her blood type. A young man in Texas underwent surgery for a stomach ulcer and continued to experience severe pain afterwards and learned during an emergency room visit some time later that a 13-inch surgical instrument had been left inside of him during the original surgery.

The Centers for Disease Control estimates that over the last 5 years, as many as 15,000 people have had foreign objects left inside their bodies after surgery. The problem of medical errors is an old one. The Chairman has referred to a major milestone, a report that was issued in 1999 when the Institutes of Medicine, a federally chartered research agency, released the report called "To Err is Human," and that report estimated that between 44,000 and 98,000 Americans die each year as a result of preventable medical errors, including diagnostic mistakes, equipment failures, infections, injury related to blood transfusions, and misinterpretation of medical orders. The report said that hospital deaths due to preventable adverse medical events are the eighth leading cause of death in the United States, exceeding deaths attributable to motor vehicle accidents, breast cancer, and AIDS. The report estimated that those medical errors cost the American health system between $37 and $50 billion a year.

I remember when the report came out, it was information that shocked not only the public, but the health care profession in terms of the scope of the problem and how hidden it was and how little was being done to address it, and to their credit, the health care profession responded, not by denying the problem but by taking up its call to action, and there was a real break from the past that resulted due to concerns that ranged from patient suffering, professional pride, liability admissions, and legal costs. Many in the health care field could not or would not admit to individual or systematic or systemic medical errors, but the fact is, it took courage then and now for any medical professional to admit that mistakes happen.

By making it acceptable to admit the truth, the health care professions have been able to move into a new era of identifying problems and designing best practices to overcome them. The key first step in this process has been to conduct a root cause analysis of a troubling incident to determine what happened and why, not to assign blame, but to find out what went wrong and what can be done to avoid similar problems in the future.

The resulting best practice recommendations cover a wide spectrum of hospital procedures. Some of those recommendations are high-tech solutions. Some of them are very low-tech, just to avoid

patient identity mix-ups by requiring patients to provide a very clear name, birth date, and doctor, which sounds awfully simple, but until recently has not been done in many places. All three types of information being required have led to fewer cases of mistaken patient identity. And read-back requirements, to read back to the patient the information that patient gives over the phone, has been important to reducing errors.

One of the leaders in this effort is the National Center for Patient Safety, a small Federal program that began operation just a few years ago, to improve patient care at the 173 hospitals run by the U.S. Department of Veterans Affairs. This program focuses on prevention, not punishment, to eliminate system vulnerabilities, and it has become a model for both public and private hospitals. I welcome testimony from the Director of the center, Dr. Bagian, who lives and works in Ann Arbor in my home State of Michigan.

The Chairman is right. We are dealing here with real people, real victims. We are not just dealing with statistics, although we all use them, and we are not just dealing with processes, although we must study them. But his point is the real one. We are dealing with real people who hurt, and major errors not only hurt particular patients who suffer the immediate effects, but their families, their loved ones. They hurt the doctors and hospitals that have to deal with the consequences of those errors. They increase overall medical and hospital costs. Those errors divert taxpayers' funds from other Medicare and VA health needs. They contribute to medical malpractice costs. They burden our legal systems.

So it is in everybody's interest to improve patient safety, and again, I commend Chairman Coleman for convening this important hearing.

Senator COLEMAN. Thank you very much, Senator Levin.

I would now like to welcome our first witness to today's hearing, Roxanne Goeltz from Burnsville, Minnesota. I want to thank you for your attendance today and thank you for your courage in speaking out. I have had a chance to read some of your writings. I can only imagine how difficult it is, how great the pain is. But your courage in speaking out, describing the circumstances of your brother's death and your insights into how patients can participate more effectively in their own health care is important and we certainly want to hear your testimony today.

Before we begin, pursuant to Rule 6, all witnesses who testify before this Subcommittee are required to be sworn. At this time, I would ask you to please stand and raise your right hand.

Do you swear the testimony you will give before this Subcommittee will be the truth, the whole truth, and nothing but the truth, so help you, God?

Ms. GOELTZ. I do.

Senator COLEMAN. Thank you. We will be using a timing system, Ms. Goeltz. Please be aware that approximately 1 minute before the red light comes on, you will see the lights change from green to yellow, giving you an opportunity to conclude your remarks. While your written testimony will be printed in the record in its entirety, we ask that you limit your oral testimony to no more than 5 minutes.

Ms. Goeltz, you may proceed.

TESTIMONY OF ROXANNE J. GOELTZ,[1] BURNSVILLE, MINNESOTA

Ms. GOELTZ. Good morning, Mr. Chairman and Members of the Subcommittee. Thank you for the opportunity to speak to you today.

I am in front of you today because of the love I have for my brother, Mike, who died in September 1999 of medical error. One week later, a Minneapolis newspaper ran a three-part series on errors in hospitals. One-and-a-half months later, the IOM report came out stating 98,000 people a year die of medical errors in hospitals alone. In my profession as an air traffic controller, that would equate to crashing an airliner with 250 people in it every day.

I needed to get involved for my brother, for myself, and for all the other loved ones being harmed needlessly. I want to share with you the story of my brother, Mike.

Before September 22, 1999, I did not have a clue what the term medical error meant or that such a thing existed. Almost 4 years later, I still do not have a clear definition of what it means. What I do know is that needless harm is coming to people that enter the health care system.

On September 21, 1999, my brother had gotten up, showered for work, and as he was getting ready to leave became light-headed and then experienced severe pain in his stomach. Mike went over to my parents and asked if he could spend the day, that he thought he had the flu. By 4 p.m., he was in so much pain that he could not speak and agreed to go to the emergency room.

My dad took him, and after Mike was checked in, Dad went home. That was the last time my dad saw his son alive, and he will never forgive himself for leaving. But he had always been taught that you are safe and cared for in a hospital.

Dad called around 6 p.m. to see how Mike was doing, but he was still in so much pain, he could not speak. Mike was eventually admitted to the hospital and given a self-drip morphine infusion for his pain, even though they were not sure what was causing it. Around 3 a.m., the next morning, my parents received a phone call telling them that Mike was not doing so well and would they come to the hospital. On the way there, they decided to take him somewhere else, not realizing he was already dead.

When the elevator door opened on the second floor, the whole staff was standing there whispering. They stopped abruptly and my mom looked into the eyes of one of the nurses and she knew. She turned to my father and said, "He is dead, Ray." This is the part of my story I have the hardest time getting through. It is the picture my parents have of their son every morning as they get up and every evening as they go to bed.

Screaming, my parents ran down the hall to Mike's room. They stood in the doorway, staring at him lying in the bed, his arm hanging over the side with the IV still in it. My mom and dad traveled that space from the doorway to their son with a horrific feeling of failure, the failure every parent fears that they will not protect their child from harm. They felt guilt for trusting someone else

[1] The prepared statement of Ms. Goeltz appears in the Appendix on page 53.

with this task and now they experienced the ultimate mistake that could not be undone.

My dad tried to put Mike's arm under the sheet, but was unable to bend it. They leaned over their six-foot, 200-pound son and hugged and kissed him. He was so cold. Mike was never cold, and he certainly could not be dead.

When people die in airplanes, their families are brought to a site where the parts of the plane are gathered so they can attempt to begin the process of closure. They have grief counselors and supporting family members with them. An investigative process is begun immediately to try and find answers as to why the tragedy occurred. The families are kept informed and told what is found.

My parents were allowed to go to the body of their dead son with no one there to support them. They were made to feel they deserved no answers as to what happened to their son, as if dying under the care of the medical profession relieves the profession of any accountability. No one would talk to them about their son's last hours alive. My parents were treated with silence and compassionless statements. The death of my brother was a tragedy, but the treatment of my family is what makes that tragedy horrific.

I am often asked, what was the error that Mike died from? Mike was given a drug for pain, left alone, unmonitored and unchecked for over 4 hours. He died during this time. Is this the error, or was the misdiagnosis the error, or the treatment of my parents after he died the error? Mike died because we had been taught to trust our health care system and all will be well. This is not the reality of our system now.

I can give another example. A friend put her mother in a care home after she had brain surgery. My friend was concerned about whether the facility could care for her mother and stated so to the floor nurse. The response was, "Don't worry. We will take good care of your mother." In the next 36 hours, her mother sustained three separate falls which resulted in brain damage. The caring words said by the nurse have become a blatant lie to this family.

What could the nurse have said? How about the truth. How about, "We will do the best we can to care for your mother, but we cannot watch her all the time. Falls are a danger for patients and I can show you what we do to minimize them. If you would like to stay or have other family and friends stay with her, we welcome your help."

As a family, we take part of the responsibility for Mike's death. We left him alone and we should have been there to speak for him when he could not. Maybe he would have died anyway, but he would not have died alone.

I envision in the new world of health care that Mike would have taken a more active part, as well. He would have known of the aneurysm history in our family and how his own history of high blood pressure could contribute to his risk of having one. He would have been more aware of the risks and educated to the symptoms.

When I began to understand the enormous task of patient safety, I became overwhelmed by it and had to decide what contribution I could make. I believe in the need of involving the consumer in whatever directions the industry takes. Consumers are key players

on the team and all the efforts attempted in health care will be for naught if the consumer is not educated in their role. We need to help the public understand it is the system that is failing them and not the health care workers.

The individuals here today represent the movement that is taking place that will make our health care not only the best in the world, but the safest in the world. AHRQ has already made important contributions to patient safety in general and in the role of consumers in particular. Among other projects, AHRQ is supporting a workshop in October that will bring consumers who are frequent flyers in the system together to mine our experience for lessons learned in being constructive, proactive partners in our care.

Facilitated by the Institute for Alternative Futures and the Partnership for Patient Safety, I am involved in the development of this grant and want to commend Carolyn Clancy for her agency's commitment to the notion of a patient and consumer-centered system. AHRQ's work in this area has just begun, and as a consumer, I urge the Committee to support it with appropriate resources so this kind of work can continue.

I hold a special place in my heart for the National Patient Safety Foundation, since it was their outreach to a nagging family member that allowed consumers to be at the table by establishing the Patient and Family Advisory Council, on which I have the privilege to serve. I want to commend Robert Krawisz's leadership and NPSF's efforts in creating a national database of patient safety information, which is crucial to the education needed about this issue.

I believe the Leapfrog Group, through its call for patient safety reforms and advocacy on the behalf of employees, is one of the most important patient-centered forces in health care today. Among other resources, the Leapfrog Group's ability to use its member companies' human resource departments to educate consumers about their roles and responsibilities is enormous. The Office of Personnel Management is an honorary member of Leapfrog and should step up to the plate to support this group's efforts of reform.

I have personal knowledge of the Fairview Health System's dedication to patient safety under Dr. Page's leadership because I had the opportunity to bring to his attention a family who had experienced a system failure and were very angry about it. While I cannot discuss the details, I witnessed how his staff agreed to meet with this family, listen to them, and responded by telling them what Fairview had learned from them and was going to investigate. It was not an easy meeting for Fairview, but the difference between this approach and the way my family was handled after Mike's death was night and day.

Consumers are ready to work with leaders like Dr. Page who respect us and show it in the way their organizations operate. I think we can accomplish great things by working together in partnership.

There are several things I believe could be done to further the culture changes needed in health care and society. The first would be to require disclosure in a reasonable time frame of any bad outcomes. Since facilities are required to sign contracts for care to re-

ceive Medicare and Medicaid funds, I urge you to consider whether this could be a condition of participation.

Another important step would be to prohibit the confidentiality agreements that seal the records when a medical liability claim is settled. One of the great disparities between aviation safety and patient safety is that we widely publicize our lessons learned and use them as safety tools. Allowing the facts that produce accidents to be hidden, as health care routinely does, means health care repeats the same mistakes over and over again, as each hospital and clinic climbs its own carefully hidden learning curve.

Finally, let us start educating the public about the true cause of errors. We need to stop scapegoating individuals and look at the system that is failing them and us. We should inform health care consumers not only of their rights, but just as importantly, their responsibilities as partners in care.

My own experience has led me to join with these allies in a movement that can make patient safety a reality rather than a dream. We could use help from Congress and Medicare, and I have a number of suggestions about what our government can do to further the culture needed in health care society.

The first is to require disclosure of medical errors, as I have said. Finally, there is a need to educate the public about the sources of medical errors. These occur because our systems fail and the corrections will need to be systemic. Rather than a "blame system" that seeks to find individuals and hold them responsible, we need a learning system. The Institutes of Medicine has published two reports showing how we can create systems changes.

I would like to leave you with a short story about a friend who learned I was coming here today, and we have had my conversations about patient safety in the past 4 years and her daughter was in the doctor's office getting a dosage of medicine for an illness that she had. It was being measured in grams. This woman, who has never spoke up before, asked them to double-check the dosage and to show them how they came up with the information.

This is not a difficult mother. As family members, we are often labeled that we are when we ask questions. What we are trying to be is partners in our care. Our government can and should help educate people about their responsibility. Thank you.

Senator COLEMAN. Thank you very much, Ms. Goeltz.

When you talked about the death of Mike in the early part of your testimony with great sadness and a little anger, and as I listened to your testimony, maybe it is your own personal journey, but there seemed to be a bit of hope that if individuals can be treated with greater respect, if there is a cultural change, if there is more information, that we can make progress. Are you hopeful today?

Ms. GOELTZ. Very hopeful. I, in the last 4 years, would never have imagined the attention and the dedication that has come about this issue.

Senator COLEMAN. Talk to me a little bit about responsibility for culture change. There are two parts to that. On the one hand, I listened to you talk about the system culture, which I think you are talking about, but then you also quite often make reference to pa-

tient responsibility, or family responsibility. Talk to me about both those cultures.

Ms. GOELTZ. Well, more of my heart is in the patient responsibility. As a consumer, I feel that on my own journey in health care after Mike died, I was diagnosed with cancer, and the struggle that I had in getting the people in the health care system to listen to my input and give credence to what I was saying was evidence that they felt they needed to be the only ones to care, that I didn't have the information to provide.

I think that we need to educate the consumers about how important it is that we have rights as patients, but with those rights, we also have responsibilities, such as knowing if you have a history of aneurysms in your family, as my brother did not, knowing if you are a diabetic what kind of medications might react with the insulin that you are taking, and not just rely on the individual that is caring for you in health care to have that information or be aware of it.

Senator COLEMAN. Last question. On a couple of occasions, you have referred to the difference between aviation safety, something you are familiar with as an air traffic controller, and patient safety, obviously from the tragic death of Mike as well as your own journey, do you have any insights as to why the difference? It appears to me as I look at aviation safety, when an accident occurs, everything, from the first step of dealing with families to the investigation, is thorough, complete, every detail checked out, and then report published. And yet in hospital safety, we don't seem to have the same thing. Help me understand from your perspective why we are not there.

Ms. GOELTZ. I believe in aviation, about 12 years ago when they started to look at the cockpit management and how it used to be the captain was always the last word when things were happening in the airplane, they grew from that and anybody that was in that cockpit had input, and if the lowly engineer in the back said, "We are not taking off," they wouldn't take off. That was the start, where aviation started to look at it as a team effort rather than an individual who ends up being totally responsible.

In health care, they are taught both in school, and as they are going through their training, that they are responsible and that it can only be one person to be responsible because if they have numerous people giving input, there would be mass confusion and nothing would—the patient would die as they were arguing, basically.

The importance is not necessarily to take away one person making a decision, but ensure that that person is listening to all the input around him to make that decision and not just basing it on his own experience, because there is a lot of experience in the room, for example, in a surgery room when you are doing something, than just that one individual. And so it is the team effort that is important, and I believe that attitude towards that has to change.

Senator COLEMAN. Thank you, Ms. Goeltz. I appreciate your very insightful perspective, as well as the great compassion that you bring today. Thank you very much.

Senator Levin.

Senator LEVIN. Thank you, Mr. Chairman.

Let me add my thanks for coming forward. It is very difficult for you to do that, to recount a very painful chapter of your life. You have obviously used it for constructive and positive purposes, to help others, and we thank you for that, as well, because you tried to turn a tragedy into something which would have a positive impact.

I am interested in your thoughts about holding people responsible or accountable for failures, errors, or mistakes. There is great emphasis on that in our world. I am wondering both about you individually, how you personally feel about that—I gather from what I know that you did not bring a lawsuit against the hospital, for instance, and if you feel comfortable talking about your thoughts about why not.

I am also interested in your thoughts about whether there is too much emphasis on blaming or holding people accountable or holding people responsible for errors and whether or not that has a negative effect on what we are trying to do, which is to have people admit mistakes, and whether the organization that you are a member of or associated with, the National Patient Safety Foundation, has any views on that. I know you are not here representing them, but if you are aware of their position on that issue, it would be helpful for us to know that.

Ms. GOELTZ. First, the fact that we did not pursue suing the hospital, it is not that we didn't do that initially. Initially, the anger and the hurt that came out of what happened to my brother and the fact that no one would talk with us, I did go with my parents to a lawyer to see if we could get answers for what had happened to Mike. Basically, what he told my parents after many weeks of encouragement that he was going to be able to get answers for them was that it wasn't worth his time. He could not make enough money. That was another slap in the face for my parents.

At that point, I realize that was not the route that I wanted to pursue and I ended up finding the National Patient Safety Foundation on the Internet and attended a forum where I heard them compare aviation safety to health care safety, and that was my connection with looking at it from a system standpoint rather than trying to blame the doctor or the nurses that were involved, because I started to learn what they were working with and in, with staff shortages and an attitude of complacency. It was a small rural hospital, which is also a factor in the possibility for medical errors.

Because of that, of my knowledge of how I do things in my work, and I have been in air traffic control since I was 20 years old, it is the way I think. I don't blame individuals. I try to look at it from a standpoint of what is their background.

As an example, I had a trainer when I was an air traffic controller. No one else could work with him. It was very difficult to work with this man, but I tried to understand what it was about his information that he was providing me, and he had been a sole survivor of a unit that came out of Vietnam and he viewed things very differently than other people. And it was by trying to understand that background that I was able to work with him, and I believe that is what I do when I look at errors. I try to understand

what is behind the error, not the individual that was there when it occurred.

As far as NPSF, they have always been about not blaming and punishing. That was the message I heard when I first met with them in October 1999 and they continue to support that.

Blaming individuals does not get us anywhere. It is what we have been doing in health care for years and this is where we are at. It is time to change and look at what we can do to help the individuals work better in a system that is failing them.

Senator LEVIN. Thank you very much. If you have a chance to either stay for the panels, or if you are not able to, to perhaps read some of the testimony, I think there may be at least some reassuring testimony that things, indeed, are happening in the field along the lines, I think, that you are talking about, which is openness and acknowledging mistakes rather than trying to assign blame. So I think some of the later testimony this morning could be reassuring to you that there is movement in the direction that you indicate. Thank you very much for coming.

Ms. GOELTZ. Thank you.

Senator COLEMAN. Thank you. I would like to call our second panel of witnesses at this time.

We welcome our second panel at this time, Dr. James Bagian, Director of the National Center for Patient Safety for the U.S. Department of Veterans Affairs in Ann Arbor, Michigan; Dr. Carolyn M. Clancy, the Director of the Agency for Healthcare Research and Quality at the U.S. Department of Health and Human Services in Rockville, Maryland; and finally, Dr. Dennis O'Leary, President of the Joint Commission on Accreditation of Healthcare Organizations based in Oakbrook Terrace, Illinois.

I thank all of you for your attendance at today's important hearing. I look forward to hearing your testimony this morning and your unique perspectives on what the Federal Government and accreditation agencies are doing to foster a climate of continuous improvement in our Nation's hospitals.

As I noted earlier, pursuant to Rule 6, all witnesses who testify before the Subcommittee are required to be sworn. At this time, I would ask you all to please rise and raise your right hand.

Do you swear the testimony you will give before this Subcommittee is the truth, the whole truth, and nothing but the truth, so help you, God?

Dr. BAGIAN. I do.

Dr. CLANCY. I do.

Dr. O'LEARY. I do.

Senator COLEMAN. Thank you. Dr. Bagian, we will proceed first with your testimony. We will then hear from Dr. Clancy and finish up with Dr. O'Leary. After we have heard all of your testimony, we will turn to questions. Dr. Bagian.

TESTIMONY OF JAMES P. BAGIAN, M.D., P.E.,[1] DIRECTOR, NATIONAL CENTER FOR PATIENT SAFETY, U.S. DEPARTMENT OF VETERANS AFFAIRS, ANN ARBOR, MICHIGAN

Dr. BAGIAN. Thank you. Thank you, Senator Coleman. It was a pleasure to hear both your comments and Senator Levin's because I think it really set the stage, as did Ms. Goeltz's.

What I would like to talk about is kind of reemphasis some of the things that were said and talk about some of the experiences we have had at the VA as we have done some of these things, because I think there are some useful lessons, both as barriers to be overcome and avoid and maybe successful ways to go about looking at this.

As you have already stated, the problems of patient safety are significant and we know worldwide, not just in the United States, that anywhere from 4 to 9 percent of all patients who come into a hospital end up being a hurt incident to their care. That is quite a huge number.

In 1997, well ahead of either of the IOM reports, the VA embarked on the quest to try to improve patient safety and Dr. Kizer, who was the Under Secretary for Health, really is responsible for getting the ball rolling.

In 1998, I was first involved with the VA as we looked at this and it became clear to me from my background as an engineer and a pilot and an astronaut for over 15 years and being a member of the Challenger Accident Investigation Board and now even on the Columbia Accident Investigation Board that the culture in aviation was much different than it is in medicine. It is like night and day, as you heard from Ms. Goeltz. I can't agree more.

The real point was culture and how do we look at things differently, and I think one of the things, and maybe a slight clarification of what has been said to now, is that people talk about it is about preventing errors, and I would say that is not what it is about. That is a tool. That is not the goal. The goal is to prevent harm to patients. That sounds like a subtle difference, but it is important because many things that harm patients are not traditionally viewed as errors, and yet they need to be corrected, and if we have time during the question period, I will be glad to give you some concrete examples of that.

But we find that preventing harm is the big deal. It is about preventing harm and how do you do that. We will all agree what harm is. We might not all agree on errors.

The barriers are several. One is leadership in this area. For a number of reasons, in many places, leadership has been lacking. Our leadership has been viewed as if we write an e-mail, make a policy, that is going to change things. Things don't change by e-mails and policies. They change by leading people. You manage things, you lead people, I think that is a very important thing.

Another is the difference, and you heard it already, it is about having a learning system, not an accountability system. We have numerous accountability systems. They play a role. They play a vital role. They are not sufficient. They are necessary, but not sufficient. We need a way that people can learn. People don't learn at

[1] The prepared statement of Dr. Bagian appears in the Appendix on page 61.

the point of a gun. They don't. By saying, we are going to subject you to penalties if you don't learn, that doesn't make people do it better.

These are accidents. These are not deliberate acts. Caregivers do not start out to hurt patients. They don't. That is the worst thing that can ever happen to a provider, but yet it happens, and we heard some examples this morning already.

The fact is, how do we set it up so they can learn from these? It has to not be viewed as a punative system. It has to be looked at as a fair system. If the people involved in delivering health care, and this includes the patients, as well, if they look at the system as punative, they are not likely to candidly participate.

Aviation has shown this. Going back over 25 years ago, an accident approximately 40 miles from where we sit killed 92 people on TWA 514. It came out that the information what caused that accident, had been known 6 weeks prior and was never adequately disclosed because of fear of punishment. That led to the confidential reporting system that NASA runs, the Aviation Safety Reporting System. It is very important that they have confidentiality for reporting. If they don't, people don't report things because they are afraid they will be unfairly treated.

One of the things we need to change, and it is not just medicine that does it, the first question people often ask is, "Whose fault is that?" and I call fault the "f" word in medicine. It is not whose fault is that. The question is, what happened, why did it happen, and what do we do to prevent it? These are the things, and if you don't end up with what do we do to prevent it, then you have really done very little.

We think what you have to do is look at how to get people comfortable with that. How do people get comfortable with saying, things went wrong, things aren't just right? We know from surveys there is a difference in culture between aviation, for example, and medicine. When a cohort of pilots were asked, if you were told by your superior to do something you thought was wrong, would you question it? Ninety-seven percent said yes. I am surprised it wasn't 100. Among physicians, less than half said yes—quite a difference. It is a different culture.

The big question is, how do we get there? How do we change this? And we think there are a number of things.

One, you need to develop a systems approach. People have to understand what is blame-worthy. We have done this in the VA and we have shown that by clearly establishing what was blame-worthy, that is: Criminal acts, things that are criminal, purposely unsafe acts, and acts involving substance or alcohol abuse on the part of the provider; these acts deserve to have boards of investigation with full disclosure, discoverable, and possible punishment, if that is appropriate. If it is not one of these type of acts, then we look at it in a confidential way to come out with what real systems solutions are and then implement them.

By doing this, we have seen reporting in the VA, which was always thought, even by the Joint Commission in the past to be good, went up 30-fold. Our close call reporting went up 900-fold. That is 90,000 percent. Close calls are reported in very few facilities in the United States today outside the VA today. We require investigation

of those. Close calls are things that almost happened but didn't actually result in injury. That is a way to learn. That is the way human beings learn, yet institutionally in medicine and many other industries, we just mop our brow and say, whew, glad nothing happened, and then we go and do it again the next day until somebody is hurt. That is the foolish way to proceed. We need to look at things differently.

We provide tools to people, where we have actually embedded systems approaches, because the changing culture doesn't happen overnight. We develop tools that are human factors engineered that teach people how to look at systems very thoroughly. When they find these tools are successful, they adopt these behaviors as their own, not as some artifice, as their own, and then that changes their attitudes. And then when attitudes change, then culture changes.

We have done this. We have seen this now being adopted, like Australia has done it, taken our tools and converted it into Australian, changing words that we think are English that they don't, for example, change schedule to roster. We see here it is translated into Danish. Australia has adopted our system for the whole country. So has Denmark. Sweden is in the process. So is Singapore and Japan. Canada has looked at it, New Zealand, and others.

We believe, along with these tools, it is not just giving people tools, it is involving the whole system, which includes the patient. You see on this poster how we ensure correct surgery. We have pamphlets go to the patient to do the same exact thing.

The bottom line is that what we need to do is get away from the misconception or fallacy that it is just reporting. We have reports. It is also good to have people feel safer with reporting. The important thing is what we do about it, without creating an environment where it is safe for people to report, to really examine these thoughtfully and candidly, nothing will change and without creating, and that is what I think Congress can do. And while the VA has the ability to do that and some States do, it is inconsistent across all States.

Federal legislation which has already passed out of the House in H.R. 663 and is in the Senate under consideration needs to be acted on, I think. There are some changes that need to be made. It does not let local facilities be their own patient safety organization. If you remove the ability to improve things from the front line, you remove the ability to be tightly coupled and fix things. You need both central and at the front line where the work really happens, and I would strongly encourage you to look at that, because creating that environment will allow it to go forward at a meteoric rate, I believe. Thank you.

Senator COLEMAN. Thank you very much, Dr. Bagian. Dr. Clancy.

TESTIMONY OF CAROLYN M. CLANCY, M.D.,[1] DIRECTOR, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ROCKVILLE, MARYLAND

Dr. CLANCY. Good morning, Mr. Chairman and Members of the Subcommittee. I am very pleased to be here today to discuss the important issue of supporting hospitals and other health care organizations in their efforts to build and sustain a culture of continuous quality and patient safety improvement.

Hospitals and other health care delivery systems provide millions of Americans each year with important and frequently life-saving care. But as we all know, medical errors and patient safety issues are an epidemic. And as we have seen from recent news headlines, no institution is exempt and everyone who uses the health care system is at risk. This is about all of us.

However, there is good news. Our health care system is committed to improving the quality and safety of care provided to our Nation's citizens. This issue is a very high priority for Secretary Thompson and for the Agency for Healthcare Research and Quality, or AHRQ. Thanks to the vision of the U.S. Congress, over the last 3 years, AHRQ has had the opportunity to invest $165 million in patient safety research and is now the leading funder of this research in the world.

My written statement describes how we have invested that $165 million and also describes the lessons we have learned from other industries which have made major strides in safety.

I would like to mention very briefly an exciting proposal that we have for fiscal year 2004. AHRQ is requesting a total of $84 million dedicated to patient safety activities, of which we propose to invest $50 million to help hospitals invest in information technology, or IT, designed to improve patient safety with a special emphasis on the needs of small community and rural hospitals.

Today, I would like to focus on how AHRQ translates the findings of the research we support into the information and tools that help hospitals, health care professionals, patients, and others improve the safety of health care. The research funded by AHRQ addresses two major challenges facing the health care system as it deals with patient safety.

One, the key message we have heard again and again this morning from the Institutes of Medicine report and its sequel, "Crossing the Quality Chasm," is that it is the system. Health care professionals, as you mentioned, Mr. Chairman, are human. Humans are prone to mistakes. We need to make sure that these professionals work in systems that are designed to prevent mistakes and catch problems before they occur.

The second is that we need to shift away from naming, blaming, and shaming as a way of responding to errors. The correct response is to learn so that they don't happen again. If you punish people for reporting, they won't. This is not an easy thing to do, to learn from errors so that they don't happen again, but it is what we need to do. Related to this is the need to create a system that allows

[1] The prepared statement of Dr. Clancy appears in the Appendix on page 66.

people to discuss and report errors without fear of recrimination or being sued.

I would like to give you a quick example of an organization that could teach us all a lot in health care about preventing mistakes. The next time you go to Starbucks for a latte, notice how many people read your order back to you after you place it. Then look at the checkmarks on the cup made to back-up the verbal order. In health care, this is called read-back. Obviously, making a latte isn't nearly as complex as health care. On the other hand, many of the lessons from Starbucks apply. We need to build that kind of redundancy into health care and it isn't there right now.

To meet these challenges, AHRQ has funded an ambitious patient safety research agenda that was formed through extensive consultation with the users of our research, consumers, health care providers, hospitals, and others. We feel very strongly that supporting research that meets the needs of its ultimate users is what will make a difference in patient safety.

As you pointed out, Mr. Chairman, when you welcomed the National Patient Safety Foundation to Minneapolis in May 2001, in the end, success will not be about what leaders and CEOs do. They provide direction. Success will be tied to folks on the front line who have the vision and incorporate the message and carry it out well. That is how you will be successful.

The goal of our patient safety initiative is to develop the information and tools that can be put to use immediately to improve health care safety and quality. For example, the health care system has long decried the lack of good measurement tools to identify where problems exist and solutions for solving them.

So to fill this gap, AHRQ has developed a free web-based tool that can help hospitals enhance their patient safety performance by quickly detecting potential medical errors in patients who have undergone medical or surgical care. This tool is called patient safety indicators and it will be a tool that is ready and waiting for the proposed patient safety organizations if the pending patient safety legislation that Dr. Bagian just mentioned is passed by this Congress.

We also know that health care professionals need information based on the latest scientific evidence and strategies and techniques to improve patient safety. In health care jargon, this is best practices. AHRQ supported the development of an evidence report titled, "Making Health Care Safer: A Critical Analysis of Patient Safety Practices." This report identified 79 potential practices and rigorously reviewed the evidence underlying those. We then turned that report over to the National Quality Forum, a private consensus-building organization, which then developed 30 patient safety best practices, which were released 2 weeks ago in Los Angeles.

However, providing information on best practices and patient safety is important, but certainly not enough. Therefore, AHRQ is poised to begin two exciting new programs under our patient safety initiative. The first, in which we will be working very closely with Dr. Bagian, is the development of a Patient Safety Improvement Corps. This initiative was developed in response to States who say that they needed more people to help them actually address the problem of medical errors and patient safety. The Patient Safety

Improvement Corps will be a cadre of specially trained patient safety experts who can provide technical assistance to States, local governments, and health care institutions, learning from errors and helping to prevent them from happening again.

The second program is a series of Safe Practices Implementation Challenge Grants. These grants are intended to help hospitals and other health care institutions assess safety risks to patients and devise ways to prevent them, as well as to implement safe practices that show evidence of eliminating or reducing known risks and harms.

I would like to tell you about an exciting AHRQ-funded project that is helping to promote learning from medical errors and near misses so they don't happen again. We have developed a website modeled on the format of morbidity and mortality conferences that are routinely held within individual hospitals across the country. The AHRQ web M&M site is an online, peer-reviewed patient safety journal aimed at improving patient safety through analysis and discussion of submitted cases. These are submitted anonymously and these are near misses and also include an analysis of why this occurred and what could be done to prevent it.

We also offer training and education about errors and patient safety to policy makers through our User Liaison Program, or ULP. Patient safety has been a big feature of our ULP workshops recently. For example, we had one in Minneapolis in July 2001 and recently had one in Seattle last week on patient safety. This is a great deal of interest among State and local policy makers in this topic.

I would like to thank you again for giving me the opportunity to discuss the very important issue of medical errors, patient safety, and furthering a culture of continuous quality improvement in hospitals and health care organizations. Working together, we can improve the patient safety, enhance health care quality, and give the American people the best, safest health care system possible. Thank you.

Senator COLEMAN. Thank you very much, Dr. Clancy. Dr. O'Leary.

TESTIMONY OF DENNIS O'LEARY, M.D.,[1] PRESIDENT, JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS, OAKBROOK TERRACE, ILLINOIS

Dr. O'LEARY. Good morning. Thank you, Mr. Chairman and Members of the Committee, for inviting the Joint Commission on Accreditation of Healthcare Organizations to testify this morning.

The Joint Commission, like others, is deeply concerned that the number of serious medical errors remains unacceptably high, despite the focus of significant national attention on patient safety in recent years. As part of our own intensified efforts to improve patient safety, we have created a Sentinel Event Database that today is this country's most complete record of the full range of serious medical errors and their underlying causes. This database, combined with knowledge gained from working directly with health care organizations to address their patient safety problems, has

[1] The prepared statement of Dr. O'Leary appears in the Appendix on page 84.

given us a deep understanding of the interplay of factors that contribute to health care errors.

In this testimony, I would like to briefly outline six strategies for addressing the medical errors problem.

First, health care organization leaders must be encouraged to create cultures of safety in their own settings. A culture of safety is characterized by an open atmosphere for reporting and addressing errors. Adopting such a culture is the overarching strategy that is necessary to the support of all other solutions to the problem.

The culture of an organization emanates from all of its leaders, particularly the CEO. However, investments in patient safety, while a moral obligation, usually provide financial benefits predominately to payers and purchasers rather than to the organization. Further, it is a hard reality that public payers pay the same reimbursement for unsafe care as they do for safe care, a point not lost on stressed organization leaders. If there is no business case to drive the creation of cultures of safety, as most would now agree, a new pay-for-performance business case needs to be established, as we later recommend.

Second, one of the Joint Commission's most important contributions to patient safety improvement efforts has been to incorporate into its accreditation requirements a systems approach to managing risk that is borrowed from engineering and quality control principles used in the manufacturing world. Individuals will always make errors. However, adverse events usually occur when internal systems fail to keep human mistakes from reaching patients.

The Joint Commission now requires accredited health care organizations to engage in both after-the-fact and prospective risk analyses that assess weak points in their systems of care and then to redesign these systems "to build safety in."

Third, we need to educate and train health care professionals who are proficient in systems thinking. Today, we educate physicians at length on content unrelated to patient safety and lead them to believe that they will know how to do everything by themselves. By contrast, nurses, who are on the front line of the most complex health care, are educated for 2 to 4 years and receive brief postgraduate supervision that averages 30 days before they assume full responsibility for patient care duties. As a result, many nurses leave patient care because they feel unprepared to deal with today's high-acuity patients and actually fear that they will make critical mistakes in caring for patients.

So today, we have a severe nursing shortage and a corresponding severe patient safety problem. Data from the Joint Commission's Sentinel Event Database demonstrates that in 24 percent of unanticipated deaths and serious patient injuries, inadequate numbers of nurses is a contributing factor.

Last year, the Joint Commission published a major white paper on the nursing shortage which urged Federal funding for post-graduate nurse training. This is a *de minimis* investment in patient safety. Additional funding is also needed to supplement the extremely modest dollars allocated to last year's Nurse Reinvestment Act. Appropriations under this act are essential to the funding of faculty in nursing schools, which today must turn away hundreds

of qualified nursing applicants. This is an untenable situation in the face of a major and growing nursing shortage.

Fourth, information technology can become a vital asset in reducing medical errors. Unfortunately, the health care industry lags far behind most other industries in the use of information technology, and there remain significant impediments to broad-scale adoption of available technologies. Therefore, we are particularly pleased that Secretary Thompson has made the attainment of a National Health Information Infrastructure a priority of his Department. Now, the Congress, too, must prepare to make the capital investments necessary to facilitate rapid adoption of appropriate information technologies by health care organizations and to rapidly close the gap between what is possible and where this country is today.

Fifth, I would observe that behavior change is best achieved when there are incentives that reward desired actions. I would like to mention two powerful incentives briefly.

The first incentive lies in targeting the expectations of the health care oversight framework. To this end, the Joint Commission has now set a series of discrete national patient safety goals around documented safety problems and has incorporated assessment of compliance with these goals into the accreditation process.

The second type of incentive involves rewarding behaviors through payment. There is now a growing imperative to determine how payment incentives can be aligned amongst payers, purchasers, provider organizations, and practitioners toward the goal of improving the quality and safety of care. Patient safety improvement must be part of the "pay-for-performance" equation.

Finally, the passage of patient safety legislation must become an urgent priority of this Congress. Federal confidentiality protections for reported adverse events and their underlying causes are inextricably linked to the efforts to create a culture of safety inside health care organizations. Such protective legislation would establish a solid foundation for leveraging the sharing of information and mutual problem solving.

Thank you for the opportunity to testify today.

Senator COLEMAN. Thank you very much, Dr. O'Leary.

Let me ask first a general statement for the panel and then some very specific questions. Both the distinguished Ranking Member and myself made reference to the Institutes of Medicine report, "To Err is Human." It made recommendations for a 10-year program to reduce adverse events in the medical system, the medical industry. Just a brief comment. How are we doing? We talk about reports, reports are out there, but are we making—talk to me about the level of progress. Dr. Bagian.

Dr. BAGIAN. Well, I think I can certainly speak from the VA's standpoint. We had adopted—not adopted, we had already done the things when the IOM report came out, so we read it and said, well, this is an affirmation of what we were doing.

I think one of the things that was not correct about that report, quite frankly, was the 50 percent reduction, and I always kid about 50 percent of what? The reports you have are not reality. You have to understand that self-reports will never absolutely and accurately represent what happens. That would be like saying the number of

speeding tickets issued today on the Beltway around D.C. is indicative of the number of people that speed. It isn't true.

What reports do is they identify vulnerabilities that you need to then attack and solve, and we can show one. For instance, we found pacemakers that are used in intensive care units that have been out 8 years and the most widely used pacemaker in the world had a problem where they were having numerous problems a month where they would lock up and not work. We looked at it based on just a close call. No one looked at it as an error. They thought it was just a close call. We actually looked at it, understood it, talked to the manufacturer, worked with the manufacturer to change how they trained, how they labeled, and ultimately change the software so it can't occur. A much more effective solution than just telling people to be careful.

So there are a number of concrete ones we can show. We can look at things like preventing incorrect surgery. We showed by thorough root cause analysis that it is not just the wrong side. In fact, approximately 36 percent of cases the wrong patient is operated on. That means the solution is slightly different. And yet by very small things, and you alluded to some of them, about how to identify people and things of that nature, are small, critical things and yet make a big difference and show the incidence goes down dramatically. So yes, I think there are definite advances. But, we can do better.

Senator COLEMAN. Dr. O'Leary.

Dr. O'LEARY. I think we have made huge advances in our knowledge about why these things happen and steps that can be taken to prevent them. But I think the reality is also that we are running behind the power curve. This is a moving target.

We have addressed a lot of the issues identified in 1999, but each day, we are introducing new drugs, new technologies, and new procedures. As they are introduced into our health care settings, there is no mindset as to how the systems involved in their use can be designed so that bad things won't happen. This is all about the need for a culture of safety in health care organizations. It is just not the No. 1 or No. 2 priority of the leadership that it must be.

I don't think you can underestimate the importance of the Federal legislation that is working its way into the Senate now, nor the importance of pay-for-performance incentives. If you want to capture the attention of the leadership, major change is essential.

Jim is right. Fifty percent of what. Some people have said that the IOM were far too high, but some of us believe those were substantially underestimated. We have a very big problem, and we have not gotten on top of it yet.

Senator COLEMAN. I am interested, and Dr. Clancy, as you respond, I just want to add another question to that, because you talked about a number of reports. There is a lot of reporting going on, a lot of stuff that AHRQ is doing. But I am interested in translating that data into reality, into what does it take to—you have got best practices, identified them. How do you ensure that those best practices are instituted?

Dr. CLANCY. Well, first of all, just let me build on the comments of my colleagues. I agree that the VA has been doing a terrific job and the Institutes of Medicine report was probably a serious under-

estimate. It doesn't, for example, address avoidable harms in outpatient care, in nursing home settings and all kinds of settings, or in children and so forth. I think the awareness has increased dramatically and that is a good thing.

We have now begun to pull together information about best practices, and I wanted to reinforce just for a moment why that is so important. In the wake of any highly-publicized error with a tragic outcome, what happens is that health care institutions do something immediately. Now, they don't necessarily have a lot of knowledge about whether that is effective or not, but it stimulates great action.

I think the strides that AHRQ and others have been making is to give health care institutions and leaders a sense of where the evidence is, where it makes sense to make those types of efforts, and where we maybe need to learn more.

Having said that, I think that a big focus of our research initiative this year is to challenge institutions to work with us. They actually do have to contribute to these Patient Safety Practices Implementation Grants, to take what we know already and put it into practice because it is urgent that we do so.

And the last reason I am a little bit optimistic is that there are more and more consumers knowing that they have to ask questions, that their role is vital.

Senator COLEMAN. Great. Thank you.

With that, I will turn it over to the Ranking Member, Senator Levin.

Senator LEVIN. Thank you, Mr. Chairman.

I would like to talk about the reporting questions, as to whether or not medical errors should be reported, whether that ought to be a voluntary or mandatory issue, and then the bill which I have just been looking at for the first time, I must confess, that passed the House, H.R. 663, which I think a number of you referred to, relative to patient safety.

But first, on the reporting issue, Dr. Bagian, tell us about your views on mandatory versus voluntary reporting of errors.

Dr. BAGIAN. Yes, sir. I think we have to define the term. By mandatory, we think by having legislation or rules that way you must report. If we interpret that to mean that everything will be reported, I think we are delusional, quite frankly. There are numerous examples in aviation and other industries where there have been mandatory reporting and things don't get reported.

For example, the one I mentioned a little bit earlier briefly, about the accident on TWA Flight 514, not far from here, where 92 people were killed. It came out that 6 weeks before that particular accident, another crew had had the same problem, did not report it. This came out in the investigation and they realized that while they were supposed to report, it was mandatory, it didn't get reported. Once they furnished a safe harbor to talk about honest mistakes, those things helped and it is due to confidentiality.

Places that have tried to do this and then gone back on the confidentiality, for instance, New Zealand is a classic example. That happened over a decade ago. They promised the confidentiality and then violated that promise. They got no more reports, zero.

During my testimony before the Senate, Arlen Specter's Committee back in January 2000, he asked the same question about mandatory versus voluntary and I quoted Dr. Charles Billings, who started the NASA Aviation Safety Reporting System. He said, in the final analysis, all reporting is voluntary. You can legislate whatever you want, but if you think that means everybody reports, that is not the way it is. People report either what they can't get away not reporting, or they report the things they altruistically think are worthwhile reporting.

We disagreed a little bit on opinion during that hearing and I wrote a little essay for Senator Specter. He went and looked at so-called mandatory systems in his own State of Pennsylvania and came back and said, "I agree with you. It doesn't work."

So if we are really interested about learning, mandatory isn't the issue. It is how do you have an environment where people tell you what vulnerabilities exist, and then how do you then implement, as I think both my colleagues here at this panel have said, how do you then act on those reports, because that is the key. There is not a lot new under the sun, I must tell you. You can look at incidents that happened today and they happened last year and they happened 10 years ago and nobody—I won't say nobody, but seldom have they been effectively dealt with, and I think the key is how do we create an environment by which they can do that.

And I think there are ways and we have to get past the solution that we often see, and I think Dennis and Carolyn can probably verify. Very often in the past, people will say, "Tell the nurse to be more careful." You know, duh. There is a Nobel Prize winning suggestion. Yet, you see it again and again, rather than here is how we design a system so even when somebody makes an error it does not translate to the patient being hurt. So I think it is critically important not to worry about mandatory versus voluntary for accidental acts but worry about how do you deal with it. How do you disclose, not the report, disclose what the problem was so other people can learn from it and what the solution is, which is vitally important to actually help the patient.

Senator LEVIN. Do either of you have a comment on the voluntary/mandatory reporting question, how we define it?

Dr. O'LEARY. Like Jim, I think you are kind of kidding yourself about a voluntary system. The fact is, people will report what they are going to report, and you don't know what you don't know. Even in places like New York that have strong systems, there is clear evidence of underreporting.

Most importantly, mandatory systems create a confrontational stance. However, we are trying to solve enormously complicated problems. If we don't work together—that is the Congress, accrediting bodies, the private sector, payers, everybody—if we are not working together, we are not going to get there.

Let us take wrong site surgery as a case in point. We have issued two sentinel event alerts on this, and we just held a wrong site surgery national summit to draw additional attention to this. We know what the problems are. But the Joint Commission, on a voluntary basis, receives five to eight new reports of wrong site surgery every month—something that should never happen.

Now, I think there is probably an answer to this. We are going to advocate for the development of a universal protocol, and we are going to get the surgical societies to buy into this and urge their members, the surgeons, to do this. The point is that everybody has to play in the solutions, and if we have confrontational or adversarial systems, we are just not going to get there. We will just drive reporting underground.

Senator LEVIN. When we talk, or you talk about mandatory versus voluntary, this is a report to whom? We are not talking about legislation. We are just talking about internally, inside of a medical facility. Don't you all believe——

Dr. O'LEARY. Oh, well——

Senator LEVIN. Define the word "mandatory."

Dr. O'LEARY. We all ought to have a common understanding.

Senator LEVIN. Right.

Dr. O'LEARY. I completely agree with you. We do have requirements in our standards that the organizations define serious adverse events and report them internally. That is an accreditation requirement. That is very different from requiring reporting to a State agency or to a Federal agency, with or without public disclosure. That is where we get into the adversarial situation.

Senator LEVIN. I just wanted to get that on the record.

My time is up, so I had better pass. Thank you, Mr. Chairman.

Senator COLEMAN. Senator Pryor.

OPENING STATEMENT OF SENATOR PRYOR

Senator PRYOR. Thank you, Mr. Chairman. Thank you for having this hearing today on this very important subject matter.

Let me try to get inside the numbers, and I think I am following up on some of Senator Levin's questions here, and that is in preparation for this hearing today, I have reviewed a few statistics. In 1991, two reports in the New England Journal of Medicine found that adverse events occurred in 2.9 percent of the hospitalizations in Colorado and Utah and 3.7 percent of the hospitalizations in New York. And then some follow-up statistics based on that.

I also have a statistic that says in January 2000, a GAO study said it was uncertain how many deaths occurred as a result of adverse drug reactions, but one study projected that it was as many as 106,000 deaths that occurred in 1994.

I guess what I am asking the panel is, do we really know the scope? Do we really have a handle on the numbers and what is really going on out there?

Dr. BAGIAN. I would say the answer is no, absolutely not, and I think when they have done prospective studies, which are different than the ones you have cited—they were chart reviews. We know doing chart reviews, that is inaccurate. Everything that occurs doesn't appear on the chart. I think we all know that, and that causes underreporting. We do know by prospective studies that the complexion can be much different.

However, I think to try to take a bookkeeping view of it, to say exactly what it is, we can spend a lot of effort doing that and that is not helping patients directly. What is really important is the things we know about we haven't even corrected, which is really the inadequacy we first need to deal with. As we have more trust

in the system, and I think we have seen that in the VA system, where we have seen a 30-fold increase in reporting, that it gives the ability to identify problems.

And I would say that we have seen examples of a report where we have had only one in our reporting system. We go out and prospectively look and it is happening in every hospital, and yet people become so inured that that is just the way things are, instead of saying, why don't we change it and we change it and the thing goes away. And yet, if you looked at reports, you would say, not an issue at all.

So I think the reports aren't the primary issue. People have to feel safe and you have to show them the report has resulted in improvement, and that is what primes the pump to get people to help you. That is the key. If you don't translate the results, you are dead in the water.

Senator PRYOR. Do you two agree with that?

Dr. O'LEARY. Absolutely.

Dr. CLANCY. Yes.

Senator PRYOR. Do you have any follow-up comments you would like to make on that?

Dr. CLANCY. I would just want to underscore the comment that Dr. Bagian made earlier, which is that we can all agree when there are harms. There is some legitimate controversy at times about which of those harms are avoidable, but the aim of medicine should be to do no harm. That is a fundamental tenet of the Hippocratic Oath.

In addition to that, I would say that there are two broad areas of avoidable harms. One is all about systems that has nothing to do with the knowledge problem, and you can pick any publicized incident you want. This is not about we didn't know that the donor and the recipient were supposed to match. We didn't have a system in place to double-check and make sure that it couldn't possibly happen that that mismatch occurred.

Then there are some knowledge issues that I think the Chairman spoke about at the beginning of this, and we have a lot to learn in both areas.

Senator PRYOR. Dr. O'Leary, would you like to add anything to that?

Dr. O'LEARY. No. I agree.

Senator PRYOR. OK. That is a great answer. [Laughter.]

I am not trying to say that we have to have tempirical data on this, but do we have a sense at least of, say, the numbers of wrong site surgeries or incidents related to the wrong dosage of medication? I mean, do we have any sort of sense of——

Dr. BAGIAN. I would say what Dennis said before. You don't know what you don't know. We can look at the New York data, we can look at our data, and it shows us what we think are incidence of reporting rates, but we know that is the floor. It is probably more than that. There are some that are missed because it is not realized that it is a problem, or frankly, people are embarrassed or ashamed or afraid for whatever reason to report.

But I think the big thing is, there are so many things we know about today, that if we could fix just those, we would be a long ways along. And I think more than that, it is sort of the thing, do

you teach people to fish or do you give them fish? It is one thing to say, do this, this, and this. That tells us about the problems we know. But if we are talking about systemic change, it is how people think, how they solve from a systems approach. You need to give them that, because then as new unanticipated things come up, they are solving problems right there and they are nipping them in the bud.

Senator PRYOR. That is good. Let me ask one last question, and I am almost out of time here, but that is I understand the paradox that health care professionals are in where if they do report, they may get punished in some way. They may get sued. Their insurance premiums may go up. There are a lot of bad things that can happen when people are genuinely trying to make health care better. We have some proposals here in the Congress relating to medical malpractice tort reform. We have a lot of people in my State, rural hospitals and other hospitals are concerned about how much their liability and exposure is when things go wrong. But they are, I think, trying to do their best to try to provide the quality health care they should.

But where is the balance there? I mean, how do we, I hate to say expose the problem, but I will use that word. How do we expose the problem and address it, but at the same time not punish the people that sometimes do, and we all admit, I think, cause real harm to people? I mean, there is no question that some of these medical malpractice problems cause very severe harm, even death, and cause great hardship. So where is that balance?

Dr. O'LEARY. Well, let me make a couple of comments. First of all, I think this is, oddly enough, one of these true-true unrelated kinds of issues. Of all of the medical errors and serious adverse events, something in the range of 3 percent of people sue, and of the cases in which there are lawsuits, most of those are probably not with merit. Those are well-established figures.

Now, that does not in any fashion excuse the delivery system and all of us who participate in it from paying attention to medical errors and doing everything we can to address them. That will help the problem, and at the very least is a good faith effort if we are going to deal with tort reform on the other side.

One of the places in which this interdigitates is the issue of sharing information with patients and patients' families when adverse events occur, a point very poignantly made by our first panelist this morning. We now have a requirement, and it is based on studies out of the Veterans Administration system, that requires the organization and the physician, in particular, to tell patients and patients' families when something bad has happened.

And the interesting aspect of this, and Jim knows more about this than I do, is that the liability exposure goes down and the overall expense is much less. There are legitimate settlements, but you are not spending a lot of money on legal costs and so on.

Dr. BAGIAN. May I follow up to that? I think that Dennis has hit the nail right on the head. It is too true and unrelated. The fact is that the specious argument is made that by having confidentiality for safety system, that you take away the ability for the patient to have adequate redress for damage done to them, and I think nothing can be further from the fact.

The fact is that we need to do things in a different way. It is sort of the Einstein quote about insanity, doing the same thing over and over again but expecting different results. If we don't allow there to be a learning system in parallel to the accountability systems, little will change.

In the VA, for well over a decade, we have had where you inform the patient that they have been injured, or their family, whatever is appropriate, tell them how they can have redress financially both for pension and tort, and do that. We show overall, which is not really important, that our losses are less, but that wasn't why we did it. We did it because it was the right thing to do. That goes on one side. We take no arrow from the quiver of the plaintiff's attorney or the patient.

However, the other data that would never be available, that is where people say, hey, here is what happened, here is how we can prevent it, that will never come forward if you stay the way it is in most places right now. So we will continue to hurt people, we will continue to pay them, and then we will do the same darn thing tomorrow because we think it was Dr. X, and if we fix Dr. X, that is the problem. Well, you know what? There are thousands of Dr. X's and there are millions of Nurse Y, and to think that we are the only individual and we are the only one that made that mistake is not true.

We have to say, what are the systems issues to help well-meaning Dr. Xs and Nurse Ys not cause the problem, and I think the parallel thing, we have confidentiality for safety, and make it clear that is different from the other accountability system. For one, they still get all the stuff they get today, all of it. It is to give us another tool to make things better. If you don't, then things will be like they have been, which I believe we all think is unsatisfactory.

Dr. CLANCY. Just a quick comment. Fear does not actually follow rules of logic. [Laughter.]

Even though, as Dr. O'Leary said, most of the times when people are harmed, they don't sue, that doesn't mean that fear of malpractice doesn't have a very chilling effect on people's ability to come forward and say, look what happened here, I can save you from doing this. I believe that is what we really need to turn around to make a positive culture.

Our research has shown in the experience of the VA that when patients are harmed, they want an apology, they want an explanation, what happened, and they want to know, what are you going to do to make this better? Doctors want to provide that information, as well, and they are terrified because of fear.

Senator PRYOR. That is one reason I asked the question, because it is hard to find that balance on the best approach, I think.

Mr. Chairman, can I ask just one more very brief follow-up?

Senator COLEMAN. Absolutely.

Senator PRYOR. Back on the statistics and the numbers and the reporting, do you all have any sense about whether the problems with patient safety are more pronounced in rural areas versus urban areas? Do you all have any sense of that?

Dr. CLANCY. We don't, but we are actually funding some research in rural areas right now with the Health Resources and Services Administration.

Senator PRYOR. Thank you.

Senator COLEMAN. I want to do a second round of questioning, a follow-up to Senator Pryor talking about the paradox. I certainly understand the fear of liability, but one of the things that I am sorting through here is, on the one hand, Dr. Bagian, you have a system of close calls, I mean people reporting those, and that needs to be done in a way in which there is no fear of some kind of retribution.

On the other hand, and I use the wrong site surgery, something that should never happen. There is no reason for it to happen. There should be a protocol to prevent it from happening. If folks aren't following that protocol, then how do you punish them? What do you do? Dr. Bagian.

Dr. BAGIAN. Well, I can talk about our own system. We talk about, as I mentioned before, the intentionally unsafe act. Violation of a rule by itself doesn't mean there is wrongdoing. We all know that there are rules that, under certain circumstances, aren't appropriate. If you make people lockstep, do the policy like an automation, then we don't need people, we will have computers do it. The fact is, we pay health care professionals to use judgment.

If somebody has done something in basically a reckless or a careless manner and basically said, well, I don't believe in marking the site, so I am just not going to do it, there will be sanctions about that and we consider that an intentionally unsafe and that will be dealt with in a discoverable way where discipline can and probably would be meted out.

On the other hand, if there is an accident, when you examine it and say, this could happen, there is some judgment there, but I think you have to look at, is this a systemic issue? If it is something you can see, here is what is set up under this particular circumstance, you can understand why it happened.

There are a number of examples. I can give you one. It is not a VA. It was a trauma, a motor vehicle accident. You don't have time to talk to the patient. The patient can't talk to you. So the normal things where you ask the patient to tell you who they are and the site isn't appropriate. They went and actually operated on the wrong side of the chest—this wasn't a VA. Do you think they deliberately did it? No. When you looked at it, you understood the setup, and that was so unique and idiosyncratic that the fact they couldn't follow the procedures is understandable and we had to say, how can you do that better?

The fact is, while it theoretically can happen, sir, it is not the major issue and I think it is not a problem to deal with that.

Dr. O'LEARY. Our six new National Patient Safety Goals, which we implemented for the first time this past January, each have two specific requirements and one has one. We now survey organizations for compliance with those requirements. Of the 11, three relate to wrong site surgery prevention. Organizations not in compliance with any of these can lose their accreditation. So we do have some teeth in these expectations for the first time.

These are stand-alone steps. However, the universal protocol that I talked about rolls several of these requirements into a series of interrelated expectations that organizations will be held accountable to meet. In a sense, that is a punishment-oriented mentality,

but I think at some point, you have to tell people that you mean it and they really need to do these things.

Senator COLEMAN. And that is my question. On the one hand, we are talking about systemically wanting people to understand that if something went wrong, you ought to report it. In part, and it was a good point, it is not just, by the way, for what you are doing there, but 20 times over somewhere else.

But how do you develop that system when, in fact—I will use the simple stuff, again, the wrong site, obvious, basic. This is stuff we know. This is not chemical interactions. There should be a protocol, like pilots, before they start or get on a plane, every time, they walk through the protocol.

How do you encourage reporting of something that you know is going to lead to some sort of sanction?

Dr. BAGIAN. I would say it doesn't always lead to the sanction. It depends. I mean, it really does depend. But I think what the Joint Commission does is correct, just like they do for root cause. You don't have to report it, but you are expected to act on it. If it comes out you haven't, you pay the piper.

We have done the same thing, and we have written in *Annals of Internal Medicine* about this, is where the ultimate buck stops is at management and leadership. Leadership either creates an environment where you are expected to follow the protocol, and if I am the CEO of a corporation and we have physicians that are privileged at my hospital that aren't doing it, then it is not just them. It is, who is the captain of the ship? If the leadership does not make sure it is done, there is where the primary responsibility is. If you ask me, I think a CEO responsibility has to be very up front about this.

Dr. O'LEARY. Let me give you a case in point here. I am going to talk to you about the American Academy of Orthopedic Surgeons, and I don't think I am speaking out of school here. They have had a "sign your site" program for several years now. Until recently, 40 percent of orthopedic surgeons refused to "sign your site," just refused to do it. Now, if you are the hospital CEO and the orthopedic surgeons who bring a lot of your business to your hospital are blowing you off, what are you going to do about that?

So they came to us and said the Joint Commission needs to get on board on this. Help us lean on our members. And that was really a lot of the thrust of the wrong site surgery summit that we hosted, to get all of the surgical societies on board. It is a way of linking hands together to deal with a problem. At the end of the day, we expect to have a universal protocol that is going to be signed off on by organization after organization saying this is the right thing to do. That is how we advance the ball down the field.

Senator COLEMAN. Let me ask one last question. It is really in follow-up to, I believe it was Senator Pryor asked the question of whether greater incidence in rural hospitals of concern here. Each of you talked about technology, and I am wondering, is technology the great equalizer? I mean, the reality today is, no matter where you are, you have got access to all the information you need. Talk to me a little bit about how you are using technology to better educate, to cut down the incidence of these kinds of problems. Dr. Clancy first.

Dr. CLANCY. Well, I guess I will brag for Dr. Bagian on behalf of the VA. A week or two ago in the *New England Journal,* there was a terrific article showing how the VA's efforts to reengineer health care, which included a substantial focus on information technology, led to quantum leaps in quality of care that the rest of the health care system has simply not been able to achieve. This is a good news story and actually underscores that IT is an important part of the solution. It is not the whole solution, and people do get a little carried away in their enthusiasm at times.

We have some very exciting projects underway right now looking at a variety of technologies, everything from the proper use of bar codes—and I am told by the folks in Wal-Mart that health care is way, way behind in our use of this fairly straightforward technology—to hand-held devices for electronic prescribing and so forth.

I think the trick is making sure that it gets used. The software and hardware is pretty easy. There are some excellent examples of times when organizations were given software and hardware free, but weren't given any support in terms of how to use it. I think the challenge is how to incorporate information technology into the culture of work and making sure that it works for you rather than giving other health professionals another job to do.

Dr. O'LEARY. It is not a panacea, but very simple things like access to just-in-time information about a patient are very important. A patient comes to the emergency unit; he's never been seen before; no one knows anything about him or what medications he is on. The patient may not be mentally clear. Being able to tap into that patients information is really critically important in being able to provide safe, high quality care.

Also, having computerized systems that identify medication interactions and inappropriate medicines and dosages, which is basically the thrust of computerized physician order entry, obviously reduces errors and saves lives. It is not a panacea, but it gets us further along than we have been before.

Dr. BAGIAN. If I could just echo some of the things that have been said, it is not a panacea. We are very fortunate at the VA to have a very robust electronic medical record so when a patient shows up, you can see all their outpatient information, you can see their chest films right on the screen. Just click, click, click, there is a chest film, there is a biopsy specimen, whatever.

The thing is, though, I think one of the barriers for most folks is that we don't have yet well-recognized standards. So if you go with one vendor and things change, it is not transportable, and I think that is where there can be help. Where there are standards that are standards for the United States, then it is like tires. Suppose tires for all cars were different, so you have to have a special tire for a Ford and a special one for the Chevy. It would be much tougher. We know that 15-inch tires are 15-inch tires. If we had the same thing for our patient data sets, that would really, I think, jumpstart people to go to electronic medical records.

The single biggest thing I would say in the VA, the results that Dr. Clancy talked about, having an electronic medical record to be able to identify problems and really know, this diabetic isn't on the right dose of insulin, whatever, that allows us to see oversights and

deal with them very directly, to have decision support, as Dr. O'Leary said.

But right now, I think it is not conducive. If I were a CEO of a private hospital, the investment I would have to make for electronic medical records, not knowing if I would be orphaned next year, I think would probably be imprudent in most cases. It would be heroic to do it, but probably imprudent. And I think by having standards, you can make it the prudent thing to do. It is good patient care. It is actually good economics. It is good all the way around.

Dr. CLANCY. I also would just add that rural institutions are one particular challenge, which is why we are very excited about our investment for 2004 which will be giving them a particular emphasis.

Another area is outpatient care, in general. The number I have heard thrown around is about 8 percent of outpatient practices have electronic medical records. Having practiced in an institution that had computerized physician order entry, which is now one of the pioneers in the area. I can tell you that you still have significant challenges with transitions in care if you don't have something in the outpatient setting or a way to address those gaps.

Senator COLEMAN. Thank you. Very helpful. Senator Pryor, any questions of this panel?

Senator PRYOR. I will defer to Senator Durbin.

Senator COLEMAN. Senator Durbin.

OPENING STATEMENT OF SENATOR DURBIN

Senator DURBIN. Thank you, Mr. Chairman. I apologize to you and the panel, I'm trying to juggle committees, and it is not fair. I wish I could park myself here, because I am really fascinated and am trying to focus on what you have to say.

Dr. O'Leary, thank you for coming out from Illinois to join us today with Mr. Krawisz, also from my home State. Thank you, Mr. Chairman, for inviting them.

Over the Memorial Day break, I flew overseas and ran into the bookstore and picked up a book and started reading and it was one of the best books I have read on this subject and I recommend it to you if you haven't seen it yet. It's called "Complications." It was a National Book Award finalist.

Dr. CLANCY. Yes.

Senator DURBIN. Written by Dr. Gawande, who is a surgical resident in Boston. I don't think I have ever read a book that gave me as much insight into the practice of medicine and learning the practice of medicine and all of the challenges associated with it. It is, I think, extremely insightful and well-balanced. Every Member of Congress interested in this issue should read this book, and I commend it to you if you haven't. I just think it says so many things that are so meaningful and give such great perspective.

Let me tell you one or two things that he said that stuck with me. He dedicated an entire chapter to what he called bad doctors. He said, it is not the bad doctors who engage in criminal behavior or make egregious mistakes that are the big problem. It is what he calls the everyday bad doctors.

He talks about one doctor who everyone long admired, a hard working surgeon, did good work until 1990 when he started making mistakes, ignored obvious symptoms, declined to do surgery when it was necessary, refused to fix his mistakes when patients returned to the office. It took 5 years of injured patients, ignored reprimands, and malpractice lawsuits before he was finally suspended in 1995. Why? Here is how he explains it.

There is an official line about how the medical profession is supposed to deal with these physicians. Colleagues are expected to join forces promptly to remove them from practice and report them to the medical licensing authorities, who in turn are supposed to discipline or expel them. It hardly ever happens that way, he says, for no tight-knit community can function that way. When a skilled, decent, ordinarily conscientious colleague whom you have known and worked with for years starts popping Percodans or becomes preoccupied with personal problems or neglects the proper care of patients, you want to help, not destroy, the doctor's career.

There is no easy way to help, he writes. In private practice, there are no sabbaticals, no leaves of absence, only disciplinary proceedings and public reports of misdeeds. As a consequence, when people try to help, they do it quietly and privately. Their intentions are good. The results aren't. As is often the case, the people who were in the best position to see how dangerous this doctor actually was were in the worst position to do anything about it—junior physicians, nurses, and ancillary staff.

He describes the research of Marilyn Rosenthal, a sociologist at the University of Michigan, who has examined medical communities around the world. She gathered data on what had happened in 200 specific cases, ranging from family physicians with a barbiturate addiction to a cardiac surgeon who continued operating despite permanent cerebral damage from a stroke. The dominant reaction, Dr. Rosenthal found, was uncertainty, denial, and feckless intervention, very much like a family that won't face up to the fact that Grandma needs to have her driver's license taken away. How do we change the culture?

He talks about a lot of things, but I want to really come to this point with you. Over and over again, each of you have told us we have a serious problem with medical errors and patient safety, and I think we look at it in terms of the global issue, and I think Dr. Clancy said medical errors and patient safety issues represent a national problem of epidemic proportion.

And then we take a look at it from the viewpoint of the victim, the patient victim. What is the recourse for the patient victim? If they are one out of 50 that decides to file a lawsuit, they have their day in court. But 49 out of 50 don't file lawsuits. They are victims and either don't know it, or knowing it, decide not to pursue their legal recourse.

Now we are in a debate about whether to limit the opportunity for a patient victim to recover in court. That is our debate now. And let me ask you this. If the current threat of litigation has not forced reform in the medical system and doctor conduct, how can insulating those doctors and hospitals and medical providers from liability in court do anything but encourage further bad conduct?

Dr. BAGIAN. Can I try first? I mean, it is an interesting question. We talked about it a little before you stepped back in the room, but to repeat, I think the evidence is fairly clear, certainly from the aviation industry, when they thought that by mandatory reporting and public exposure was a way to make it safer, it didn't happen and there were many deaths because of that.

When they went to having a parallel, not a replacement, and I will emphasize that, you have your accountability system and ability to redress, which we think is appropriate, but when you have a parallel learning system, it gives you a place where you might learn other information that otherwise will never be reported, period.

And if you look at over 500,000 reports in aviation by ASRS, many things that were never, ever recognized by the so-called mandatory system, like runway incursions, like wings that sweep over the main runway as a 747 taxis back to the ramp and they would never report because that is the only way they could get back to the ramp, and if they reported they did, it was a violation and they would lose their license, so instead, they just did it. Look, nobody is looking, let's do it because I need to get the job done. When they made that available, for instance, in the ASRS, those things were then addressed and the problems were fixed.

Senator DURBIN. Let me follow through, then, because we often hear that. That is not an unreasonable conclusion you have reached based on the evidence you presented to us. But then we hear the other side of it. Oh, the threat of lawsuits has created all of this defensive medicine. Doctors are ordering tests they never would have ordered to make sure they cover themselves.

So at one point, you are arguing—not you, but the profession is arguing that there is a consciousness of the threat of litigation which is literally affecting the practice every single day, and then the opposite conclusion is being argued, but wait a minute, to be honest with you, the threat of litigation isn't causing people to reform the system. How can it have such an impact, if it does, to create defensive medicine and not have an impact to create this appetite for reform?

Dr. BAGIAN. Well, I think partly it is the dislocation of penalty versus reward in the way the system is set up among the profession. I think as Dr. Clancy pointed out, fear is not necessarily based on reality. People's perception of their risk, and I am talking about physicians as well as the patient, affects their behavior. However, I think the big issue is not the malpractice issue here. There needs to be—certainly, malpractice is important. That needs to be available.

But I think when you look at solutions, as you talked about the bad doctor, as you classified it from this book, the fact is that if you have systems in place and encourage those, and we deal with these and I can give you examples, where you see, for instance, the physician popping Percocet, as you gave as a hypothetical or whatever, if you look at that, the question is, how does your privileging and credentialing work within the hospital? How do you show proficiency? How do people demonstrate that have had a stroke, as you made the example of a cardiac surgeon? How do you make sure they are proficient?

I think right now in many of our hospitals, we don't do it as in aviation, where pilots have to demonstrate their proficiency on an ongoing basis. It is not once you are a pilot, you keep flying. You come back and you fly in a simulator. We give you challenges and you pass or you don't. We don't do that in a methodical way in medicine. I think if you do that and hold the organizations responsible, not just the individual but the people that manage them, to say, hey, what is it, and it is not just Dr. X. The fact is, I would challenge you when you find one of these bad doctors, if you look in a systematic way through your whole staff, there are many others that have the same problem, and that is where you get the leverage to really make a difference in patient care.

Senator DURBIN. I am sorry to cut you short. I thank the Chairman for giving me a few extra minutes. Let me just say a couple things in closing.

One is, this does not create a situation—this book does not create a situation in the mind of the reader that is anti-doctor. I mean, there are heroic things that this surgical resident describes that he has done on a daily basis, and any one of us who has had a loved one or family member in a hospital or doctor's office wants the best and the brightest right there feeling that they can help us.

But I do believe that we have to try to come to some balance here. When a hospital administrator in Decatur, Illinois, tells me that their hospital pharmacy writes 50,000 prescriptions a year, and when they went in looking for errors they only found 20, it just boggles the mind. Human error is going to argue there are many more than 20 in the course of a year. They are afraid to even talk about it.

When a system is built so that colleagues, junior colleagues have to report on a bad doctor to stop him from malpractice, the system is not working. I really think that we have to look at the medical malpractice insurance crisis from the perspective not only of what happens in the courtroom, but what happens in the operating room and what happens in the board room of the insurance company. All of these things have to come together for an honest appraisal.

Thank you very much, Mr. Chairman.

[The prepared statement of Senator Durbin follows:]

PREPARED OPENING STATEMENT OF SENATOR DURBIN

Thank you, Mr. Chairman, for holding this hearing. The debate over how to best ensure patient safety has been going on for 4 years and I hope this hearing will help move the process along.

Rarely is there an opportunity in the health policy arena to help prevent so many injuries and deaths. I am very pleased to see that there are two folks from Illinois here today: Dr. Dennis O'Leary from Oakbrook Terrace and Mr. Robert Krawisz from Chicago. Welcome to both of you.

There is a fascinating book called *Complications: A Surgeon's Notes on an Imperfect Science* by Atul Gawande. Dr. Gawande is a surgeon in Boston who took time off during medical school to work on Clinton's health care reform plan. He brings a unique perspective to this issue and I want to read you some excerpts from his book because I think it illustrates how complex and multi-layered the challenge of ensuring patient safety is.

He dedicates an entire chapter to what he calls "bad doctors." He says that it is not the bad doctors who engage in criminal behavior or make egregious mistakes that are the big problem. It is what he calls the "every day bad doctors."

He describes a doctor named Hank Goodman whom everyone long admired. He was a hard working surgeon who did good work . . . until 1990 when he began making mistakes. He ignored obvious symptoms, declined to do surgery when it was

necessary and refused to fix his mistakes when patients returned to his office. It took 5 years of hurt patients, ignored reprimands and malpractice lawsuits before he was finally suspended in 1995. Five years of dubious outcomes before he was stopped. Why?

In trying to explain why, Dr. Gawande gets to the heart of the challenges we face. He writes:

> "There is an official line about how the medical profession is supposed to deal with these physicians: Colleagues are expected to join forces promptly to remove them from practice and report them to the medical-licensing authorities, who, in turn, are supposed to discipline them or expel them from the profession. It hardly ever happens that way. For no tight-knit community can function that way."
>
> "When a skilled, decent, ordinarily conscientious colleague, whom you've known and worked with for years, starts popping Percodans, or becomes pre-occupied with personal problems and neglects the proper care of patients, you want to help, not destroy the doctor's career."
>
> "There is no easy way to help, though. In private practice, there are no sabbaticals to offer, no leaves of absence, only disciplinary proceedings and public reports of misdeeds. As a consequence, when people try to help, they do it quietly, privately. Their intentions are good; the result usually isn't."
>
> "As is often the case, the people who were in the best position to see how dangerous Dr. Goodman had become were in the worst position to do anything about it: Junior physicians, nurses and ancillary staff."

Dr. Gawande describes the research of Marilynn Rosenthal, a sociologist at the University of Michigan who has examined medical communities around the world. She gathered data on what happened in more than 200 specific cases ranging from a family physician with a barbiturate addiction to a cardiac surgeon who continued operating despite permanent cerebral damage from a stroke.

The dominant reaction Dr. Rosenthal found was uncertainty, denial and feckless intervention—very much like a family that won't face up to the fact that grandma needs her drivers license taken away.

How do we change this culture? How do we encourage doctors to help each other but know when their help is not enough?

Dr. Gawande talks about more than bad doctors. He describes the pressure of the profession and how human his colleagues are. He says, "Plain old mistakes of execution are not uncommon. We have only begun to recognize the systemic frailties, technological faults and human inadequacies that cause them, let alone how to reduce them."

He goes on to describe another layer of the problem: Consistency in procedure. He says "important knowledge has simply *not* made its way far enough into practice. Among patients recognized as having heart attacks, for example, it is now known that an aspirin alone will save lives and that even more can be saved with the immediate use of a thrombolytic—a clot dissolving drug."

"Yet, a quarter of those who should get an aspirin do not, and half who should get a thrombolytic do not. Overall, physician compliance with various evidence-based guidelines ranges from more than 90 percent of patients in some parts of the country to less than 20 percent in others."

According to a study by a Dartmouth physician, the likelihood of a doctor sending you for a gallbladder-removal operation varies 270 percent based on the city you live in; for a hip replacement, the variation is 450 percent, and for intensive care during the last 6 months of your life, it varies a whopping 880 percent. A patient in Santa Barbara is five times more likely to be recommended back surgery for back pain than someone in the Bronx.

All of these things demonstrate how complex this problem is. It's not just about bad doctors. It's about consistently practicing evidence-based medicine, and it's about changing the culture of medicine.

I'm very interested in hearing the solutions our witnesses will present today. Thank you.

Senator COLEMAN. Thank you very much, Senator Durbin.

I would like to excuse the panel, then, at this time. Thank you.

I would like to call our final panel of witnesses. We welcome our final panel, David Page, President and Chief Executive Officer of Fairview Health Services of Minneapolis, Minnesota; Dianne Mandernach, the Commissioner of the Minnesota Department of Health, St. Paul, Minnesota; Robert E. Krawisz, the Executive Di-

rector of the National Patient Safety Foundation of Chicago, Illinois; and I anticipate that we will have a final witness, Dr. Suzanne Delbanco, the Executive Director of the Leapfrog Group for Patient Safety in Washington, DC. I understand Dr. Delbanco is coming from another engagement in the city and hopefully will join us soon.

I want to thank all of you for your attendance at today's important hearing. I look forward to hearing your testimony this morning on how the private sector is working to improve the performance of our Nation's hospitals.

As you have heard, pursuant to Rule 6, all witnesses who testify before this Subcommittee are required to be sworn. I would ask you now to please stand and raise your right hand.

Do you swear the testimony you are about to give before the Subcommittee will be the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. PAGE. I do.

Ms. MANDERNACH. I do.

Mr. KRAWISZ. I do.

Senator COLEMAN. Thank you. We will be using a timing system. Please be aware that approximately 1 minute before the red light comes on, you will see the lights change from green to yellow, giving you an opportunity to conclude your remarks. While your written testimony will be printed in the record in its entirety, we ask that you limit your oral testimony to no more than 5 minutes.

Mr. Page, we will have you go first, then we will hear from Ms. Mandernach, then Mr. Krawisz, and if Dr. Delbanco comes, we will finish up with Dr. Delbanco. After the panel has testified, we will then turn to questions.

Mr. Page, if you will begin.

TESTIMONY OF DAVID R. PAGE,[1] PRESIDENT AND CHIEF EXECUTIVE OFFICER, FAIRVIEW HEALTH SERVICES, MINNEAPOLIS, MINNESOTA

Mr. PAGE. Thank you, Chairman Coleman. Thank you for this opportunity to speak to this important subject. I am President and CEO of the Fairview Health Services, which is a system of 18,000 employees serving seven separate communities in the State of Minnesota. I am also on the board of the National Patient Safety Foundation, an organization dedicated to improving the safety of patients all across this country. And I am here to talk about cultural change and process improvement.

As we have heard before, there is no institution, no matter how gilded its quality reputation is, that is immune from the sorts of issues that we are talking about this morning. I have an example here of yesterday's *New York Times* Science section where the headline is, "When Her Heart Failed, A Pump Gave Her Life." This is a headline of yesterday's *Times* Science section featuring one of the Fairview institutions. I also have a newspaper here of less than 2 weeks ago where the headline reads, "Hospital Error Cited in Report on Two-Year-Old's Death."

[1] The prepared statement for Mr. Page appears in the Appendix on page 92.

We recently had a tragic loss at one of our facilities, the one that was cited in the second newspaper I just shared with you. A 34-month-old girl named Brianna received a ten-fold overdose of a powerful blood thinner called heparin. This was following her liver transplant. She later died. We are not certain how or whether the overdose may have contributed to her death. We are certain that our systems allowed a ten-fold overdose and failed a conscientious staff, a patient, the patient's family. We are incredibly sorry for this event and I would be pleased to tell you what we have done to make sure that the event doesn't reoccur.

We have standardized heparin concentrations throughout that hospital. We have instituted a safety checklist that occurs at each shift change, citing certain particular drugs that are on the medical administration list. And we have implemented another double-check on the signing off on drug administration on high-risk drugs, of which heparin is one. We have committed ourselves to make sure that this particular episode does not reoccur.

I am here today to describe to you what Fairview is doing and must do to make health care safer, and we need your help and the help of the other organizations here this morning.

But if you remember anything from my conversation with you this morning, I would have it be this. To become safer in health care, we must learn from other industries that have confronted similar safety issues, and they have created cultures that focus on high standards, on safety in a compulsive fashion. They have created open communication atmospheres where all can be reported without fear of reprisal or threats to income. And finally, and of equal importance to the other two, they have embraced continuous process improvement.

Our goals at Fairview, and I think reasonably transferred for goals for the health care system in general, we need to do three things. We need to embrace a bold vision and focus of the sort Paul O'Neill did at Alcoa Aluminum, where employee safety was a daily issue, and he brought safety records down to the lowest in the industry by leadership from the top and focus.

We have a history of that focus at Fairview. We have made it part of our vision. We have created senior executive positions focused solely on that. We have made safety part of executive goals on an individual basis. And we are developing a culture of process improvement where we can continually take a look at how we perform the systems and processes that serve our patients.

I would point out to you that the State of Minnesota was the first State in the Union to have 100 percent of its hospitals reporting in the Leapfrog website of what their record is on patient safety, in patient safety systems. We also have in our State a medical database, and you will hear later from testimony on this panel about an adverse health care event reporting system recently passed in the State.

Second, teamwork and open communication is the second piece of where we must go on this, including anonymous reporting. I know of institutions that over a decade ago had the capability of having anyone in their care system or the family write down a concern and, almost like a suggestion box, put the concern into a system that was available throughout the hospital that would say, "I

wonder about this," and it might be a physician, a nurse, a drug administration. That is an open process. It did work. And Congress can help us here by helping to support an atmosphere of full and open disclosure, not only to the patients, their families, but in and amongst the systems as we try to learn from our mistakes and see that they don't happen again.

Last, we must implement a rigorous process improvement system of the sort 3M, Motorola, Toyota, and others in the industry have in place. After Fairview's management visited Motorola in 2001, we came back and started to work on implementing a scorecard system that would give us the ability to track and, most importantly, measure the things that we had that surround the delivery of care, our systems and processes.

If you don't understand the capabilities of your processes and systems, you will not be able to measure them and measure their performance. If you can't measure them and their performance, you will not be able to change their outcomes. It has been said earlier this morning on previous panels, more often than not, by a large factor, what has failed to protect human failure has been our systems and our processes.

These challenges are larger than any one institution or delivery system can address, and I encourage you from the public policy to support the things that have been mentioned by others here, certainly the open and faultless reporting, I think the reimbursement for quality of care. It was said earlier this morning that from the standpoint of payment, there is no difference on bad quality and good quality and that should not be. I think insofar as the largest purchaser of health care in the country, the government, we really ought to have a distinction made for when quality is present, can be identified and measured, and have a payment that recognizes that.

In winding down, I will tell you that Fairview has implemented and is in the process of continuing to implement an electronic medical record. This electronic medical record allows us to bring to bear clinical data about patients at all sites in our system, in our clinics, in our emergency rooms, in our intensive care units, and depending upon the physician's capability at home, in his home, on a concurrent basis, including in-line, on time lab reporting.

We are spending about 4 percent of our top-line revenue in information systems. The health care industry's average is 2 percent, and industry in general ranges between 5 and 15 percent. You can help us with this area by helping support this investment, this capital investment, by something of the sort that might be a capital pass-through of the sort that was in the reimbursement system for major capital investments. Have a capital pass-through for investment in information systems that are in the clinical environment.

Senator COLEMAN. Mr. Page, I will have you please sum up your testimony.

Mr. PAGE. I will close by saying, we must work together to create the culture of relentlessly high standards for patient safety. We must create an atmosphere of open communication and disclosure without fear of reprisal that encourages error reporting. And most importantly, I think from my standpoint, we must measure and consciously improve our systems that support those individuals

who are at the bedside, and your help in this will be indispensable for us.

I thank you for this opportunity to meet with you here this morning. Thank you.

Senator COLEMAN. Thank you very much, Mr. Page. Commissioner Mandernach.

TESTIMONY OF DIANNE MANDERNACH,[1] COMMISSIONER, MINNESOTA DEPARTMENT OF HEALTH, ST. PAUL, MINNESOTA

Ms. MANDERNACH. Thank you, Mr. Chairman and Members of the Committee, for providing the opportunity to participate in this very important hearing.

Today, I am pleased to share with you some very exciting steps that the State of Minnesota has recently taken to establish a process for the mandatory reporting of serious adverse events, commonly referred to as medical errors. These efforts go beyond the mere reporting of the events to include the review of information on the underlying cause of the events, the review of corrective actions taken by the reporting hospital, dissemination of information regarding these events, and public reporting by type and location of the event. This law integrates many of the recommendations of the Institutes of Medicine, but more importantly, the law provides for accountability within hospitals and to the public.

Before discussing the specifics of our legislation, however, I would like to make a few general comments on the issue of patient safety.

Since the 1999 release of the Institutes of Medicine's landmark report on patient safety, "To Err is Human," we have been flooded with information on this issue from a variety of sources. However, the issue of patient safety has been one of my core values for many years.

As a former CEO of a small hospital in Northern Minnesota, I was very aware of the need for assuring that systems were in place to promptly and accurately identify both errors and potential errors, the ones referred to as near misses. It was my responsibility to assure that steps were taken quickly, fairly, and objectively to review any incident and then make sure that corrective actions were implemented to minimize the occurrence of similar events.

The need for ongoing, continuous quality improvement within every institution is a theme that we have heard repeated today. I strongly support the initiatives that are being undertaken by the groups represented here today. However, as the topic of the hearing suggests, instilling hospitals with a culture of continuous improvement, we must understand that the efforts taken within the hospital will always be the most important, the most direct, and the most timely to truly minimize and prevent the occurrence of medical errors.

As Commissioner of Health, I am ultimately responsible for assuring that the care and services provided in State-licensed facilities protect the health and safety of our patients. Every media story reporting on serious consequences of medical errors reinforces

[1] The prepared statement for Ms. Mandernach appears in the Appendix on page 110.

this need to assure that there is public accountability and follow-up on these serious events.

The formation of the Minnesota Alliance for Patient Safety, MAPS, was one of Minnesota's key responses to the IOM report. MAPS was jointly established by the Minnesota Department of Health, the Minnesota Hospital Association, and the Minnesota Medical Association, with a mission to promote optimum patient safety through collaboration and supportive effort among all participants of the health care system. MAPS now consists of over 50 health care-related institutions.

MAPS has become a collaborative forum to discuss the implications of medical errors in the health care system, to provide education and training programs, to disseminate the successful efforts undertaken by hospitals to reduce errors. The public-private make-up has provided opportunities for frank but open discussion on many of the sensitive issues, many of which were referred to this morning.

Without this collaborative process, passage of our mandatory reporting law would have been much more difficult, if not impossible. As Chair of the Hospital Association, David Page played a pivotal role in convincing other hospitals to actively participate in MAPS. The need for and development of a mandatory reporting system was one of the more controversial discussion topics undertaken by MAPS. Concerns were raised about the benefits of mandatory versus voluntary reporting, types of events to be reported, the ability to analyze information to identify trends, the ability to provide appropriate follow-up and recommendations for change.

A subgroup of MAPS was established to review the provisions of Minnesota's current law and then to move forward to include any reporting system and make recommendations to be introduced in the 2003 legislative session. I am very pleased that these efforts led to the bipartisan sponsorship and passage of our Senate File 1019, the Minnesota Adverse Health Care Events Reporting Act of 2003.

One of the key attributes of this law is the inclusion of the reportable events recommended by the National Quality Forum. This list of 27 "never events," that is, events that should never occur in a hospital, such as wrong site surgery, represented a consensus of many interested parties as to what should be included in any mandatory reporting system. This list provides an effective starting point for a medical error reporting system. It is our understanding that Minnesota's law is the first ever in the Nation to specifically incorporate the NQF recommendations. This list was and is consistent with the criteria established by the IOM, that a mandatory reporting system focus on serious adverse events and that the events reported be defined as clearly as possible.

However, in order to take steps to provide patient protection, any reporting law must go beyond the mere collection of statistics. We have heard that repeatedly this morning. Our reporting law mandates that information be reported as to the cause of the error as well as the corrective actions taken by the facility. These crucial elements address our concerns as to the internal and external accountability and assure that appropriate actions are taken in the facility to protect patient health and safety.

In addition, the law directs the Commissioner to review the information to determine whether trends or system problems are being identified and to also furnish information to all providers to assist in the improvement of their patient safety system.

While Senate File 1019 made significant changes to the reporting law, the legislation was discussed, debated, and enacted in an environment of consensus. As with every piece of legislation, the fine points of the law were debated, but there was no serious opposition to the need for the law or the value of its enhancement to patient safety.

There was one major stumbling block and that was the fiscal impact at the time that we were attempting to address a major budget deficit. That allowed for a transition plan. So the key provision was the agreement that the Department would not be required to implement the law until sufficient non-State funds were obtained. The bill proponents and especially the Minnesota Hospital Association believed that the initial start-up funds of approximately $125,000 could be obtained either from private sources or through grants. The willingness of the hospitals to secure the necessary funds to implement the transition fees was strong recognition of their commitment to this process.

There are some recommendations and suggestions that I would like you to consider in the future. We would encourage a national system that would focus on the mandatory reporting of these specific events. I realize that this will generate some problems for States with existing reporting systems. However, this is the only way that we can get a national perspective on the true extent of this problem.

The collection of clearly identified events across State lines will also assist in the identification of trends, the identification of system problems, and will encourage more collaborative responses to improving patient safety. As part of this recommendation is a request to obtain funding to support the efforts. We realize that funding is always a concern, but if steps can be taken to minimize the extent of medical errors, the price paid for these systems will be money well spent. Funding could be directed at the development of demonstration projects or pilot programs to allow for an analysis of the effectiveness of various State systems. However, we are well past the time for continued discussion and debate and systems need to be put in place as quickly as possible.

There is one final thing and that is, we would encourage that steps be taken through Medicare and Medicaid survey and certification programs to address both the internal and external reporting of medical errors. Regulations and regulatory agencies should balance the need for public accountability and safety with the need for internal quality improvement efforts. Consistent expectations for the reporting and monitoring of these events and funding for these activities is a critical component to provide accountability to the public we represent. Thank you.

Senator COLEMAN. Thank you very much, Commissioner Mandernach. Mr. Krawisz.

TESTIMONY OF ROBERT E. KRAWISZ,[1] EXECUTIVE DIRECTOR, NATIONAL PATIENT SAFETY FOUNDATION, CHICAGO, ILLINOIS

Mr. KRAWISZ. Thank you, Mr. Chairman and Members of the Committee. I am Executive Director of the National Patient Safety Foundation in Chicago, and prior to that, I served as a senior manager for the National Safety Council and also the American Society for Quality. My comments today will focus on instilling hospitals with a culture of continuous improvement.

In a recent study, the Juran Institute indicated that the cost of poor quality and safety exceeds 30 percent of all health care outlays. With the national health care expenditures of $1.4 trillion, the 30 percent figure translates into $420 billion spent each year as a result of poor quality and safety. Performance improvements can provide important benefits, such as greater patient satisfaction, significant improvements in patient safety, and dramatic cost reductions that can be shared with purchasers and consumers.

A question that is often asked is, how long does it take to change the culture and performance of an industry? Are we making progress in patient safety? We heard that just a little while ago with the other panel.

I think we can turn to the transformation of occupational safety and quality in the United States for part of the answer. The change cycle consists of five stages: Problem recognition, the introduction of solutions, growth, maturity, and integration.

The problem recognition phase usually lasts about 10 years as an industry struggles with denial. Once there is a commitment to find solutions, the length of the change cycle depends on the amount of support that is provided and on the strength of the economic business case. It took about 25 years after the formation of OSHA to change the culture in occupational safety and secure dramatic performance breakthroughs.

The quality transformation in the United States was faster, with major improvements in place in the mid-1990's following the Baldridge Act of 1987. We simply can't wait that long in health care. The stakes are too high. With your support, we have the ability to complete the change process a lot faster.

Where are we today? We are near the end of the search for solution phase. The patient safety movement is gathering steam and moving into the growth stage of the change cycle. We know what to do to start the improvement process, but we need resources to get the job done.

The National Patient Safety Foundation established the Patient and Family Advisory Council to provide guidance and patient perspectives on all of its activities. In March, we released a national agenda for action to support patients and families. It provides a high-level road map for action in four areas: Education, culture, research, and supportive services.

The first step is to raise awareness of these issues. The second step is to address how these actions should be implemented and funded. A detailed agenda is included in my written testimony.

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[1] The prepared statement for Mr. Krawisz appears in the Appendix on page 113.

There are several evidence-based strategies that are starting to produce dramatic quality and patient safety improvements. I think the challenge is to close the gap between what is known and what is being practiced in most hospitals.

The National Patient Safety Foundation's dissemination strategy plays an important role in closing the performance gap. Examples of breakthrough strategies include the following. The Baldridge health care criteria provides an excellent framework for managing the enterprise and securing performance improvements. Hospitals can set their sights on winning the award or simply following the criteria.

SSM Health Care in St. Louis is the first award recipient in health care. Results include significant improvements in safety and quality, cost reductions, and improvements in their market share.

A full disclosure policy provides the information essential for identifying problems and developing breakthrough solutions, and we have heard a lot about that today. There are two axioms of disclosure. No one makes an error on purpose, and no one admits an error if you punish them for it. Full disclosure provides data to analyze problems and find solutions, improves patient and family satisfaction, and reduces malpractice litigation.

SSM Health Care, the Baldridge winner, established a blame-free zone for staff to report errors and near misses. This has led to numerous system improvements. Many other hospitals have also adopted effective disclosure policies.

Another important strategy is engaging patients and families to develop new perspectives. They experience the gaps and fragmentation in the health care system. Patients and family advisory councils help health care professionals and leaders, keep them honest and grounded in reality, and they provide timely feedback, new ideas, and additional creativity. The result is improved quality and safety and reductions in malpractice allegations.

There are also numerous process improvement tools that hospitals can use to evaluate processes and identify solutions. Examples include process mapping and analysis software, failure mode and effect analysis, root cause analysis, design of experiments, and comprehensive Six Sigma programs.

Six Sigma has set a new standard for organizations in a variety of industries that are reducing errors to only 3.4 per million opportunities. Froedtert Hospital in Milwaukee utilizes the Six Sigma methodology extensively to reduce process variation. Successes include improving outcomes with high-risk medication and reducing the variability of PCA infusion pumps, cycle times, and analyzing lab specimens, and reductions in patient falls.

The Joint Commission released 6 goals and 11 evidence-based requirements in January. The National Quality Forum released 30 evidence-based safe practices in May of this year. Hospitals can secure dramatic improvements in quality and safety by adopting these practices now.

What can hospitals do to close the gap between what is known and what is being practiced today? I think a major lesson learned at Occupational Safety and Health is that organizations need a formal program to organize and focus their activities before rapid im-

provements can take place. The elements of an effective patient safety program are also included in my written testimony.

In closing, there are a number of ways Congress can encourage greater effort at continuous improvement in health care. These include the following: (A) providing funding to support the national agenda for action for patients and families, including development of a patient and family resource center; (B) supporting a central role for the Agency for Health Care Research and Quality and coordinating a multi-faceted, multi-industry national patient safety initiative—this should include sufficient funding to carry out research and development activities to support and advance public and private patient safety initiatives across the Nation; (C) creating financial incentives for hospitals to support the business case for safety; and (D) supporting patient safety legislation aimed at protecting confidentiality and promoting disclosure, such as H.R. 663, which passed the House by a near-unanimous vote in March, and also S. 720, which currently awaits Senate action. Thank you.

Senator COLEMAN. Thank you very much, Mr. Krawisz.

Mr. Page, when we invited Fairview to be here, it was a number of weeks ago that we put this together and invited Fairview because they are acknowledged as one of the leading institutions in Minnesota and your leadership in this area. Certainly, the very tragic circumstances of last week probably bring to mind that we can do all the things that we intend with systems, but there is still human error.

Are we looking at training issues? Are there workload issues? I am trying to understand the nature of human error, and when we are talking about life or death, which we are talking about here, how do we make sure that we are doing everything possible to minimize it?

Mr. PAGE. Chairman Coleman, I appreciate that question because I think it is one of the key questions. A very short answer to that is that within the circle of institutions and people trying to deal with patient safety, we developed a graphic, a concept. It is called the sharp end and the blunt end and it is literally a sidewise-drawn arrow, a big broad-band arrow with at the very sharp end of the arrow, a patient, nurses, physicians, and technicians. That is the sharp end.

And everything behind that in a widening gap are the systems that support the delivery that occurs at the sharp end. We have the knowledge that the vast majority, and I am talking about the 95 percent-plus of occurrence, of failure to protect from human error, occurs in the blunt end in our systems. And in the event that recently occurred and one of our institutions reported on last week, we looked at the sharp end and the blunt end and find most of our learnings are on the blunt end. But the good news is, those learnings allow us to do things with the processes around that sort of care that will keep that from happening again.

So training, yes. I think, really, the investigation of the cause of the factors, root cause analysis that has been mentioned here this morning, the learning from that and then the realization of those learnings into your other systems and processes.

Senator COLEMAN. Thank you very much, Mr. Page.

Commissioner Mandernach, I am interested, you talked about the ease of the bipartisan manner in which Minnesota enacted its particular statute, I think you said Senate File 1019. Was the issue of liability raised during the course of this discussion?

Ms. MANDERNACH. It was raised during the course of the discussion, but I give credit to the MAPS group that really championed this and brought it forward. There had been a great deal of work done around the issue of liability and in the final analysis, it was looked at again as the right thing to do in the interest of patient safety. Knowing that, there are still going to be issues of liability and we are not taking away the patient's ability to exercise their options. This is to make tragic situations not just reportable but that we all learn to make sure that it doesn't happen again.

Senator COLEMAN. Thank you.

Mr. Krawisz, in your written testimony, I know you talked about the Internet. Internet use is the second-leading force inhibiting hospitals from installing management practices designed to improve patient safety and quality, but then you also talk about the power of the Internet to inform.

Mr. KRAWISZ. Yes.

Senator COLEMAN. I am interested in this area of technology and are we using it and particularly in dealing with rural areas, where I always see it as a great equalizer, the opportunity to get whatever information you want no matter where you live. Can you talk about patients who use the Internet, what does the National Patient Safety Foundation recommend?

Mr. KRAWISZ. Well, I think the Internet is a fabulous resource. If you look at the numbers, last year, more than 20 million people went online to research medical conditions and their treatment. I think that this perhaps is a double-edged sword. A danger might be of the patients making their own decisions on their treatment. It is certainly good for them to use the information and then to go to their physician and to ask a lot of questions. Those are the things that we are recommending.

We also recommend they use the Internet to communicate a lot of information to patients on the extent of the problem and what they can do to protect themselves. As an example, on our website currently, we are receiving more than 400,000 visits each month. Most of those are from patients that are researching what they can do to protect themselves and to be safe. We have a number of fact sheets for patients, and these can be easily downloaded for their use.

So I think it is a valuable tool, and another thing that we are doing, we have a grant from AHRQ to produce web-based education for physicians, nurses, and also patients, and this will be offered free and it will be on our website by the end of the year.

Senator COLEMAN. Thank you very much.

Dr. Delbanco, we indicated that you had another engagement and would hopefully join us. I am going to forego swearing you in. I do want to turn to my colleagues for questioning, but I will give you an opportunity for a very brief statement, just a summary, and then I will come back to you after my colleagues have had a chance to raise some questions. But I will give you this opportunity right now to make a very brief statement.

Ms. DELBANCO. Thanks. And when you say brief, can you specify so I——

Senator COLEMAN. Two or three minutes. Thanks.

TESTIMONY OF SUZANNE DELBANCO, PH.D.,[1] EXECUTIVE DIRECTOR, THE LEAPFROG GROUP, WASHINGTON, DC.

Ms. DELBANCO. I think that I will just talk. Rather than read from my notes, I will just speak and then I can hand in my written testimony.

The Leapfrog Group is an organization of about 140 large employers and other large health care purchasers, like State agencies and labor unions and others, who have come together to try and make big breakthrough improvements in the safety, quality, and overall value of health care for Americans. What brought the group together was really frustration about seeing how much health care costs were rising, learning about how health care quality varies tremendously from provider to provider, and feeling like from the buy side of the market there was very little control over what it was that purchasers were actually purchasing.

So the group felt the need to look in the mirror as purchasers and ask themselves how they could reform their own practices and behaviors to start sending a stronger signal to the health care system that quality improvement and safety improvement is actually incredibly important, not just cost containment; although, of course, that is a primary concern to employers today.

So the group came together about 3 years ago, received sponsorship and founding from the Business Roundtable and has grown from its initial 7 founding members to 140. What brings the members of Leapfrog together is a common commitment to two major activities.

One is to informing and educating employees, so the 33 million Americans that our 140 members represent understand about how quality can vary and how important it is to make informed decisions.

We are starting very specifically with some recommendations around improvements that hospitals can make in the area of patient safety. They are largely process improvements where we are advocating a change in the way that health care is delivered, first through the use of computerized physician order entry systems, where doctors make medication errors via computers that are linked to error-prevention software.

Second, through particular staffing in the intensive care units where patient care is managed by doctors with special training in critical care, known as intensivists. The research suggests that when you have this kind of staffing, the odds of dying in the intensive care unit are reduced by 29 percent, which is quite tremendous.

And then last, we advocate that patients who need certain high-risk surgeries or who have certain high-risk neonatal conditions, be referred to hospitals who we know, based on a variety of sources of evidence, are going to produce better outcomes for those pa-

[1] The prepared statement for Ms. Delbanco appears in the Appendix on page 128.

tients, because these are elective situations where patients are going in for procedures that actually can be very dangerous.

So that is the focus of our employee education and information. In order to actually provide relevant data to consumers that they can use, we have a voluntary online hospital survey where we invite hospitals to report their progress towards implementing these practices, which today are still quite rare.

To reinforce the efforts of providers who try to implement these practices, which are not easy to do, we also are working on helping employers find ways to reinforce in the marketplace, through positive incentives and rewards, the efforts of health care providers who have fully implemented these practices or who have made significant progress. So whether those approaches include trying to shift market share by educating patients to seek care at those institutions or by directly providing financial bonuses or different payments to hospitals that have these practices in place, we are trying to start aligning the incentives properly so that there is a difference between how we pay health care providers who do a very good job versus those who may not be trying as hard.

So together, we have gathered data from about 810 hospitals across the country. Those data are available publicly on our website, www.leapfroggroup.org, and are disseminated by many other partners, health plans, and others.

Our philosophy about what it is the private sector can do and what even Congress could help us do is: We need to have a more transparent health care system, where we have an ability to gauge health care performance, whether it is along safety or quality or efficiency measures or others, so that we can know about how to educate consumers and we can know what should be the basis for rewarding providers differentially.

And in addition to that, we need to experiment a lot more with how to create positive carrots and even sticks in some cases so that we can reinforce the efforts to continuously improve the way that health care is provided.

So I will just stop there.

Senator COLEMAN. Great. Thank you very much, Dr. Delbanco. Senator Pryor.

Senator PRYOR. Thanks, Mr. Chairman. I know we have a vote going on right now, so I am going to keep my questions very short.

I guess this is mostly for you, Mr. Page, but I would like to hear everyone else's analysis of this. What impact on patient safety has the advent of managed care had? It seems to me that it is one of the great developments in health care in the last several years here in this country. I just wonder if there is any correlation to managed care and patient safety.

Mr. PAGE. That is a good question. I am not sure I have a clear answer. I can opine two things. Managed care, in its process to trade off the economics of premium and the cost for control of the delivery in a more rigorous fashion, gate keepers and those sorts of things that HMOs would have, I think has at least given the promise of having control of the sorts of clinical sets and check lists and things that would be used in the delivery of care. From that standpoint, I think it could be viewed as a positive element.

Unfortunately, I think the down side of the managed care is that often when it has a profit motive, the delivery of care becomes second to serving the interest of the investors if it is publicly held, and from that standpoint it has probably not been a very positive impact.

Senator PRYOR. Do you all have any other comments on that, managed care?

Ms. MANDERNACH. I would agree with David.

Mr. KRAWISZ. I would, also. It has not had a very positive impact and I think people are moving away to looking at different systems, incentive-based systems.

Ms. DELBANCO. I would just add maybe a slightly different comment, which is that employers who designate a lot of their responsibilities to health plans, whether they are managed care plans or less restrictive plans, have had more success with managed care plans in terms of their ability to educate patient members about making informed choices. We have seen a lot more uptake among those types of plans when it comes to sharing performance data and reinforcing the role of consumers making informed decisions.

Senator PRYOR. Thank you, Mr. Chairman.

Senator COLEMAN. Thank you, Senator Pryor. Senator Carper.

OPENING STATEMENT OF SENATOR CARPER

Senator CARPER. Thank you to our witnesses. Welcome. Thanks for being with us today.

I have one question, and the question involves, if you will, an intersection, not like an intersection of streets but the intersection of policy issues that confront us here pretty regularly. One of those is health care safety, which you have been kind enough to speak to for us. Another is health care cost containment. A third is all those folks in this country, 40 million or so, who don't have any health care coverage. A fourth is the advent of new technology, some of which Dr. Delbanco has spoken to. And the fifth is the Medicare reform legislation which we are going to take up in the Senate next week.

I am wondering if any of you would just share with us your thoughts. I picked up on some of what Dr. Delbanco was talking about in terms of automated prescriptioning of meds, not through written prescriptions but electronically. It may be less expensive, lead to fewer errors, and fewer negative outcomes for patients. That is the kind of solution I am looking for.

We are going to have a chance to, not reinvent Medicare, but to change it rather significantly. One of the ways I hope we will do it is by the use of technology to help us on the health care cost containment side, help us on the safety side, and maybe if we do a good job there, then we can have a few dollars to address those folks who don't have any coverage at all. Do you have any thoughts, advice for us, if you will, as we take up this legislation in the Senate next week?

Mr. PAGE. I would offer two points. One is that the computer application information systems in the clinical context does have tremendous capability to reduce error and make safer care, which has real costs. Now, the costs aren't always attended to the institution, but I think from the national policy standpoint, the emphasis on

moving towards systems that can reduce the error rate can save a tremendous amount of cost.

I think one of the other issues that you mention is the intersection of those who don't have access to the system and that has real costs to the system, because oftentimes they come to the system late in their health care issues and are a much more difficult problem clinically to deal with. It is logical for the national policy on a cost basis to try and get these people into the system rather than have them on the fringe of the system taken care of by what we now call the safety net hospitals. I think that is a reasonable, appropriate, cost-driven public policy approach to take.

Last, I think the Congress should probably recognize that the demographics of our population are changing. People have, almost one in five in this population have chronic illnesses, defined by being an illness that persists longer than 3 months, and this will change how we will take care of health problems going forward in the future.

Ms. MANDERNACH. The only comment that I would add, and I would wear my former hat as a hospital CEO of a smaller facility in smaller Minnesota, as you talk about the policies, I would ask for a sensitivity to the rural structure that is very fragile at this point in rural hospitals. As we talk technology, it is not a lack of desire, it is a lack of funds available, and as we begin to establish standards, we need to be very sensitive that there are great sums of people who live in Northern Minnesota, in rural areas across the country, in addition to the fact that we are a very mobile society. And so even if we live in big cities, we often travel in rural communities and we need that infrastructure.

Mr. KRAWISZ. I think technology certainly works. The VA under Ken Kizer has really proven what can happen with both bar coding and computerized physician order entry. However, it is very expensive. I think we should find a way to allow all hospitals to be able to participate.

As you all know, many hospitals are plagued with significant financial losses and low margins and they really don't have the money, especially I would believe in rural areas, to adopt these sophisticated technological solutions. So I think maybe with your help and the right incentives, we can move in that direction, and which I believe is the proper direction.

Ms. DELBANCO. I will speak again from the employers' perspective. I think employers, especially those, let us say, who are manufacturers, are frustrated with the processes that are being used in the health care system and see a lot of waste. One of the reasons why the Leapfrog Group initially started by advocating structural or process improvements is because the feeling is that if we root out the defects, if we get rid of the mistakes that are made, we will be much more cost effective in terms of the health care dollars, the limited health care dollars that we use.

And so I think the two points that I would make, which are similar to what I said at the end of my remarks, are that we believe it is incredibly important to have publicly available health care performance information so we can gauge how effectively our health care dollars are being used, and that one of the only ways to collect that information or report it in a cost-effective manner is to have

an underlying clinical information system that hospitals and other caregivers put in place across the country so it is economical to gather data and to report it.

So it is a little bit of a catch-22 situation, but our goal, at least as private sector purchasers and some public sector purchasers working together, is to try to jump-start that process and not sit back and wait for incremental improvements.

Senator CARPER. Thank you all. Thank you.

Senator COLEMAN. Senator Carper, thank you.

We have to go vote. I do want to thank the panelists. I want to note that due to time constraints, the Subcommittee was unable to invite all of the parties affected by this issue to present oral testimony. This week, we have received written statements from the American College of Obstetricians and Gynecologists and the Alliance of Specialty Medicine. Without objection,[1] these statements will be included in the written record, as well as the prepared statements of all the witnesses.

Again, I want to thank you, and this hearing is adjourned.

[Whereupon, at 11:34 a.m., the Subcommittee was adjourned.]

[1] These statements will appear in the Appendix as exhibits.

APPENDIX

TESTIMONY OF ROXANNE J. GOELTZ
Automation Specialist, Federal Aviation Association, Minneapolis, MN
Member, Patient and Family Advisory Council of the National Patient Safety Foundation
Member, Advisory Council, Partnership for Patient Safety
Co-founder, Consumers Advancing Patient Safety

Hearing on:

PATIENT SAFETY: INSTILLING HOSPITALS WITH A CULTURE OF CONTINUOUS IMPROVEMENT
Wednesday, June 11, 2003
9:00 AM
342 Dirksen Senate Office Building

Good morning, Mr. Chairman and members of the Subcommittee. Thank your for the opportunity to speak to you today.

My brother Mike died of medical error in September of 1999, one and half months before the IOM report came out stating 98,000 people a year die of medical errors in hospitals alone. In my profession as an air traffic controller, that would equate to crashing an airliner with 250 people in it every day.

Mike's Story

I want to share with you the story of my brother, Mike.

Before September 22, 1999, I did not have a clue what the term "medical error" meant or that such a thing existed. Almost three years later I still do not have a clear definition of what it means. What I do know is that needless harm is coming to people who enter the healthcare system.

The only thing Mike wanted from life was to have a family, spend weekends with them, cook great meals and watch the Packers. Unfortunately Mike never found a person with whom to share his dreams. I last saw Mike in August, on his way through Minneapolis with friends going to the Sturgis Motorcycle Rally. We sat on the deck eating homemade pizza and drinking beer. Mike was gone on his motorcycle trip for two weeks. It was a tense two weeks for my parents, because my brother Craig had died 10 years earlier in a motorcycle accident. They did not know that one-month down the road Mike's life would be taken by something even more dangerous than riding a motorcycle.

Happiness filled the air when he stepped into my parents' living room in full riding gear and with a big grin on his face. "It was great Mom, so beautiful". He gave her a big hug. That memory now tears at her heart every day.

On September 21, 1999, my brother had gotten up, showered for work and as he was getting ready to leave he became light headed and then experienced severe pain in his stomach. He went over to my parents and asked if he could spend the day, because he thought he had the flu. By 4:00 PM he was in so much pain he could not speak and agreed to go to the Emergency Room. My dad took him and, after Mike was checked in, Dad went home. That was last he saw his son alive. He has never forgiven himself for leaving him there alone, but Dad was always taught and he believed that you are safe in the hospital.

Dad called around 6:00 PM to see how he was, but Mike was still in so much pain he could not talk. He was eventually admitted to the hospital and given a self-drip morphine infusion, even though they had not determinined where the pain he was having was coming from. My parents received a phone call from the hospital shortly after 3:00 AM on September 22, 1999, telling them Mike was not doing so well and would they come to the hospital. On the way there they decided they needed to take him somewhere else, not realizing he was already dead. When the elevator door opened on the second floor the whole staff was standing there whispering. My mom looked into the eyes of one of the nurses and knew. She turned to my father and said, "He is dead, Ray." This is the part in my story I have the hardest time getting through. It is the picture my parents have of their son every morning they get up and every evening they go to bed.

Screaming, my parents ran down the hall to Mike's room. They stood in the doorway and saw Mike lying in the bed, his arm hanging over the side with the IV still in it. My Mom and Dad traveled that space from the doorway to their son with a horrific feeling of failure, the failure every parent fears that they will not be able to protect their child from harm. They felt guilty for trusting someone else with this responsibility, and now they live with the ultimate consequences of their mistake – one that cannot be undone.

My dad tried to put Mike's arm under the sheet but was unable to bend it. They leaned over their 6 foot 200 pound son and hugged and kissed him. He was so cold, Mike was never cold, and he certainly could not be dead.

Beginning a Journey as a Consumer Concerned about Safety

When people die in airplanes their families are brought to the site where parts of the plane are gathered so they can attempt to begin the process of closure. They have grief counselors and supporting family members with them. An investigative process is begun immediately to try and find answers as to why the tragedy occurred. The families are kept informed and told what is found.

My parents were allowed to go to the body of their dead son with no one there to support them. They were made to feel they deserved no answers as to

what happened to their son, as if dying under the care of the medical profession relieves the profession of any accountability. To this day, no one will talk to them about their son's last hours alive. My parents are treated with silence and compassionless statements. The death of my brother was a tragedy but the treatment of my family is what makes the tragedy truly horrific.

The doctors told my parents that Mike died from blood around the heart. When my parents asked how it got there, the answer was they did not know. And there were excuses. A car accident had happened that afternoon, and the emergency room was busy. That is the last thing a family wants to hear -- that someone else was more important than their own son, and therefore that they did not care for him. If the hospital was so busy, why not tell the family so they have a choice to take their loved one somewhere else?

The first thing we did was blame – the doctors, the nurses, anyone we felt should have cared for Mike better. They said Mike was misdiagnosed, and that the doctor made a mistake. A mistake! He never even tried to help Mike. Was any of the information my mother passed to the nurse even given a second thought? My parents left the hospital after this meeting, still in shock over the fact they actually trusted their son to these people. Oh, the guilt, anger, betrayal, disbelief they were experiencing. "Just give us one more chance God, we will do better."

A community in shock, Mike has so many friends, they want answers too, they are angry. Those that could give some answers hide behind the hospital doors. The hospital administrator, who attends church with my parents, offers no condolences. Is this the kind of person who is in charge of caring for their community's health? We are able to forgive mistakes but not indifference, not denial and hiding. So many people calling and stopping in to see my parents, trying to understand, offer condolences and support. Mike is gone and we cannot understand what happened, the hospital has no explanation, no apology, no condolences, and no help to try and deal with the loss. Why are the family members ignored, shunned and treated by the responsible facility as if they are at fault? Mike did not need to die? In an age of medical miracles he was not even given a chance. He was quieted with a drug and left alone.

Our initial reaction was to get a lawyer, so we could get some answers. I went with my parents to the first and only meeting with an out of town lawyer because no one in town would touch it. We were still in a great deal of pain during this visit. I decided it would not be the route I would go to try and deal with my pain. I did not trust this person who was not displaying any compassion towards my parents or I for what we were going through. Over the course of the next few weeks I tried to convince my parents to see someone else but they just did not have the stamina. The lawyer eventually sent them a letter saying with out a more thorough autopsy (he knew Mike had been cremated) he could do nothing and the money that could be gotten was not worth the work he would

have to put into it. That sealed it for me. Another profession that advertises they help people but forget to tell you only if they can make a profit.

I began spending much of my time trying to find answers or help to deal with the grief, injustice and murder of our trust. I searched the Internet for medical error and came up with one hit. It was to the National Patient Safety Foundation (NPSF) web site and there I found a regional forum that was going to take place in Milwaukee the end of October 1999. I wrote the contact via email and asked if I could attend. I told them I had recently lost my brother to a medical error and I wanted to see what was being done about the problem. They said yes.

It was a surreal experience. When the keynote speaker got up and began comparing the aviation profession to the medical field a light of understanding started to glow in my mind. I was in aviation, trained as an air traffic controller. I began to understand how what happened to Mike could have occurred, but unfortunately understanding and accepting were two different things. I ended up in front of the forum telling what little we knew of my brother's death and how we just wanted to be talked to honestly and for someone involved with Mike's death to validate our loss.

During the drive to my parent's house after attending the forum I started to realize how dangerous healthcare was and the struggle that was going on to bring out the errors to learn from them and do something about them. I started to think about what happened to Mike and wanting to work with the hospital to correct the flaws in the system that failed him and those entrusted to care for him. I slowly began to realize I was going to have to forgive so I could work with the healthcare system to make a change. This was a great struggle for me. I felt as if I was betraying my brother to want to work with people I felt had not cared for him. I had to come away from trying to blame an individual in Mike's death to looking at the system that failed all of us.

I tried to approach the subject of the system failing with my parents but they cannot remove the last image they have of Mike in that bed. An image that was preventable if those involved had been trained by the system to handle such a situation with compassion instead of fear. My parents have a great deal of anger in the loss of their son and I cannot deny them their feelings and pray every night their hearts can heal.

One lesson I took away from my brother's death is that you should never leave your loved one alone in the hospital. Patients are very vulnerable -- both emotionally and physically -- and need the support of family or friends. They may not always believe that themselves, and it is very easy to talk yourself out of the fact that you need it. But I was soon to learn first hand how important it was.

Learning to be a Partner in My Own Care

On July 20, 2000 I underwent open chest surgery to remove a tumor next to my heart and lungs. It had been diagnosed as a malignant thymoma. I put into practice what I had been preaching to family, friends and co-workers -- and that was to have someone with you at all times while in the hospital. I called this my "24/7 Team." My team was great; they worked with the healthcare staff, making themselves knowledgeable about my medications and when I was to get them. They also supported me emotionally. Anytime I opened my eyes someone I recognized was sitting there.

I suffered a pulmonary embolism my second day in the hospital. Many nurses have tried to convince me it was the fault of the RN on duty that day. I do not believe that for one minute. She was covering twice the number of patients she should have, and I was not educated to the fact of how important it was to get up as soon after surgery as possible. Later, a doctor specializing in this area indicated to me that this clot was waiting to happen and the surgery just hurried it along. I was fortunate to be in the hospital when it happened. The nurse should not be blamed for this outcome. I believe the system failed her.

The journey I am having in the healthcare system is very different than the one I would have been on if Mike had not have died the way he did. My little brother's death opened my eyes to the fact that consumers need to be partners in our healthcare. I also realized that our healthcare workers are not infallible gods, and that we should not rely on them to be miracle workers. They are human just like me, they work in complex system just like I do, and they need our help to do their job well and make our journeys as safe as possible.

In my attempt to understand medical error, I began looking at the parallels between healthcare and air traffic control. I looked at the decisions that are made by controllers in the normal course of a day and how they could mean the life or death of someone. We do not work in a vacuum where our decisions and actions are completely our own. Instead we work in a complex system where every decision made or action taken becomes part of a history that results in a particular outcome. There are times we must distance ourselves from the image of our customer to accomplish the job and at the same time communicate with them in a professional, humane manner to instill confidence and trust in our abilities. As humans in both aviation and healthcare we make mistakes and must learn from them to improve.

Having made the comparison, I could also see the contrasts between the professions. We split in the way we address error. I asked someone at my facility who was recently involved in the evaluation of an error what he thought punishment accomplished in dealing with errors. He said, "punishment does not prevent error it prevents the reporting of it."

The system healthcare workers function in is failing them and their patients. We have been blaming and punishing the individual and it has not made healthcare safe. It has actually built a wall of distrust and misunderstanding between healthcare workers and their customers, it is this wall that prevents the communication and honesty that is needed to identify and correct the flaws in the system that are contributing to errors.

Now, well along in my journey, I firmly believe that the key to improving the system and making it safe is that we all must do our part to make it work. Responsibility for safety needs to be shared from the top down to the bottom, and that includes the consumer. I know there is concern that if we take the responsibility for an error away from the healthcare workers in the system, there will be no responsibility taken at all. I dispute that. If we work as a team, the concept of teamwork actually increases the responsibility for each individual to do their part.

It takes a lot when you are in a profession where mistakes take peoples lives to admit and deal with the fact that you are capable of making mistakes. That's true in air traffic control as well as medicine. In healthcare, you are told you have to be perfect and cannot make mistakes. Therefore, when they do happen the culture of perfection and blame prompts you to hide them, deny them and even ostracize those who have made them as if you would never have made the same mistake. In air traffic control, our approach is very different. Our culture acknowledges that we are human and constantly reminds us that we can make deadly mistakes at any time, prompting us to be vigilant at all times.

As a family, we take part of the responsibility for Mike's death. We left him alone and should have been there to speak for him when he could not. Maybe he would have died anyway, but at least he would not have died alone. I envision in the new world of healthcare that Mike would have taken a more active part in, as well. He would have known more about the medical risks in our family, and how his own history of high blood pressure could contribute to his risk of injury. He would have been more aware, and alert for the symptoms of a medical problem.

The Important Work of Educating Consumer Partners

When I began to understand the enormous amount of work need to improve patient safety, I was initially overwhelmed. I had to decide what contribution I could make. I now believe in the crucial importance of involving consumers in healthcare improvement, whatever direction it takes. Consumers are key players on the team and all the efforts attempted in healthcare will be for naught if the consumer is not educated about their role. We need to help the public understand it is the system that is failing, not the healthcare workers in it.

The individuals here today represent the movement that is taking place that will make our healthcare not only the best I the world but the safest as well.

AHRQ already has made important contributions to patient safety in general, and the role of consumers in particular. Among other projects, AHRQ is supporting a workshop in October that will bring consumers who are "frequent fliers" in the system together to mine our experience for lessons learned in being constructive, proactive partners in our own care. Facilitated by the Institute for Alternative Futures and the Partnership for Patient Safety, I am involved in the development of this grant and want to commend Carolyn Clancy for her agency's commitment to the notion of a patient- and consumer-centered system. The AHRQ's work in this area has just begun, and as a consumer I urge the committee to support it with appropriate resources, so this kind of work can continue.

The National Patient Safety Foundation is also to be commended. I am grateful for the opportunities they afford consumers to be "at the table," by establishing the Patient and Family Advisory Council, on which I have the privilege to serve. The NPSF's efforts in creating a national database of patient safety information are crucial to the education needed about this issue.

I believe the Leapfrog Group, through its call for patient safety reforms and advocacy on behalf of employees, is one of the most important patient-centered forces in healthcare today. Among other resources, the Leapfrog Group's ability to use its member companies human resources departments to educate consumers about their roles and responsibilities is enormous.

I have personal knowledge of the Fairview Health System's dedication to patient safety under Dr. Page's leadership, because I had the opportunity to bring to his attention a family who had experienced a system failure and were very angry about it. While I cannot discuss the details here today, for confidentiality reasons, I witnessed how his staff agreed to meet with this family, listened to them, and responded by telling them what Fairview had learned from them and was going to investigate. It was not an easy meeting for Fairview, but the difference between this approach and the way in which my family was handled after Mike's death is like day and night. Consumers are ready to work with leaders like Dr. Page who respect us and show it in the way their organizations operate. I think we can accomplish great things by working together in partnership.

There are several things I believe could be done to further the culture changes needed in healthcare and society. The first would be to require disclosure in a reasonable timeframe of any bad outcomes. Since facilities are required to sign contracts for care to receive Medicare and Medicaid funds, I urge you to consider whether this could be a condition of participation.

Another important step would be to prohibit the confidentiality agreements that seal the records when a medical liability claim is settled. One of the great disparities between aviation safety and patient safety is that we widely publicize our lessons learned and use them as safety tools. Allowing the facts that produce accidents to be hidden, as healthcare routinely does, means healthcare repeats the same mistakes over and over again as each hospital and clinic climbs its own, carefully hidden learning curve.

Finally let us start educating the public about the true cause of errors. We need to stop scapegoating individuals and look at the system that is failing them and us. We should inform healthcare consumers not only of their rights, but just as importantly their responsibilities as partners in their care. A friend said to me just before coming out here that if it were not for conversations we have had she would not be the consumer she is. When her daughter was being given medication in grams and being weighed in kilos, she asked them to double check the dosage amount and explain to her how they arrived at the answer. This is not a mother being difficult, as family members are so often labeled. This is a mother trying to be a partner in her daughter's care. We should encourage and celebrate that. If there were more mothers like her, we'd have a stronger safety net and fewer bad outcomes.

So, let me leave you with this invitation to healthcare and those who fund healthcare research: First, work with us to educate consumers about the real risks of healthcare and our responsibility to work in partnership with you to keep our loved ones safe. Second, listen to consumers when we try to talk to you. We see things that you often don't, and we want you to use what we learn to help keep future patients safe. Third, always tell us the truth, and the sooner the better. Otherwise, we cannot trust you. Finally, be transparent. Talk publicly about system failures, so we can all learn from your analysis of accidents. The airline industry doesn't bury accidents, and neither should healthcare. Going public may feel frightening to you, but educated consumers will praise you for your honesty and trust you more when you do openly share what you've learned. Thank you very much.

Statement of
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Veterans Health Administration
Department of Veterans Affairs
Regarding
"Patient Safety: Instilling Hospitals with a Culture of Continuous Improvement"
Before the
United States Senate
Permanent Subcommittee on Investigations
Committee on Governmental Affairs

June 11, 2003

Mr. Chairman and Members of the Subcommittee, I am pleased to be here today to discuss the vitally important topic of patient safety and the critical factors for success needed if our hospitals are to succeed in this effort. In particular, I will discuss some of the critical elements for success that the VA has identified as we have implemented an aggressive, system-based, patient safety program throughout our healthcare system.

Inadequate patient safety is a critical worldwide problem in healthcare. In the U.S., estimates of the lives lost due to factors related to patient safety exceed that of the lives lost due to motor vehicle accidents, breast cancer, or AIDS (IOM, To Err is Human). In order to reduce medical errors, programs must first identify the underlying causative factors so that they can be understood, and then implement effective preventive strategies. Unfortunately, most healthcare systems and regulators have not modified their tactics to focus on prevention. The systemic problems that are associated with medical errors and close calls persist; namely the misguided belief that accountability systems and punishment are the primary and most effective means to achieve improvement in patient safety. While accountability systems play an important role in health care organizations, they cannot do all things. Albert Einstein once observed, "Insanity: doing the same thing over and over again and expecting different results." This is where we seem to currently find many individuals and organizations in their quest for patient safety improvement. Put another way - the health care system punishes providers without giving them the tools to improve patient safety.

An over-reliance on punitive accountability systems is a major stumbling block to improvement because it does not encourage identification of potential problems

and provides disincentives for reporting. This state of events is not peculiar to healthcare and has been encountered by other industries. Aviation recognized that further improvement in safety could not be achieved by putting in place yet another accountability system. Instead they introduced a system whose purpose was learning, whose goal was prevention not punishment, and most importantly was viewed as both beneficial and non-punitive by the end-users or those from whom reports are sought. Today in medicine there is no dearth of accountability systems but there is a scarcity of systems that are viewed as non-punitive reporting systems.

To address these needs, the VA developed and continues to implement an innovative systems approach to prevent harm to patients within VA's 163 medical centers. VA recognized that individual human behavior is seldom the basic reason for medical adverse events - adverse events are usually due to the complex interaction of known and unforeseen vulnerabilities in health care delivery. Innovations were necessary, since no one had ever instituted a comprehensive systems-oriented safety program for large medical organizations. VA combined lessons from industrial settings such as aviation and nuclear power with the theory and body of knowledge from human factors and safety engineering to fashion systems that would better contribute to prevention of unintended harm to patients. (Human factors engineering was cited by the 1999 IOM report as the discipline most often overlooked by health care when designing safety systems.)

VA implemented nationwide internal and external reporting systems that supplement the many accountability systems we already had. The new systems' sole purpose was for organizational learning and improvement. Said another way, the objective for reporting is to identify vulnerabilities that can then be mitigated, not to serve as a counting exercise as counting in itself is of very little value. They were constructed to encourage maximal reporting of potential and actually occurring problems by non-punitive methods that would then be converted into corrective actions. This was essential because, without the ability to identify system vulnerabilities and to analyze their root causes for common systematic problems, our ability to achieve meaningful and sustainable patient safety improvement is limited. We sought to design reporting systems that would identify adverse events that might be preventable now or in the future. In addition, we sought systems to identify, analyze, and most importantly correct situations or events that would have resulted in an adverse event if not for either luck or the quick action of a health care provider -- we call such events "close calls." We believe that "close calls" provide the best opportunity to learn and institute preventive strategies, as they will unmask system weaknesses before a patient is injured, thus enabling preventive actions to be taken. This emphasis on "close calls" has been employed by organizations outside of health care with great success. It has been said that experience is the best teacher, however it is also the most expensive. In the case of medically related experience, that cost can be expressed in terms of tragic consequences. "Close calls" enable us to

learn and institute preventive actions without first having to pay the costly tuition born of human tragedy.

One method VA employed to better understand how to make these systems optimally function was to first conduct surveys and focus groups of both VA and external healthcare workers to better understand their concerns and the characteristics that would help make our program effective. The use of punitive actions was a point of concern. Specifically, health care providers' view of punitive actions extended beyond typical administrative punishment to include factors such as shame, embarrassment, and negative impact on professional reputation. Protection from these factors was essential if we were to receive any reports from which we could then learn and proceed to undertake improvement and prevention efforts. This information convincingly demonstrated that confidentiality is pivotal to assuring the non-punitive intent and potential of your learning system to the personnel from whom you wish to receive reports and who you wish to subsequently implement corrective actions.

The importance of confidentiality has been shown in many safety systems ranging from military aviation safety programs to the NASA - Aviation Safety Reporting System (ASRS). The success of the ASRS program has been cited in numerous venues including the IOM Report 'To Err Is Human.' For more than 25 years, the ASRS has handled over 500,000 reports without compromising the confidentiality of its reporters. Maintaining this level of trust has been essential to allowing the ASRS to identify problems and systems vulnerabilities that were subsequently dealt with, which otherwise might have resulted in catastrophic events. There are also examples of other aviation safety systems patterned after the ASRS, such as the one in New Zealand, that were initially successful until they divulged the identity of a user resulting in the cessation of reporting and effectively the end of their system. In fact, after the passage of several years they tried to re-establish their system but failed to do so due to their inability to ensure that confidentiality would be maintained. This experience demonstrates that once trust is violated it can be extremely difficult or impossible to restore. Ultimately, public safety suffers because problems cannot be identified early and corrected.

Confidentiality is the common element that enables a safety system to be effective. It is important to recognize that making patient safety information confidential does not deprive any of the pre-existing internal or external accountability systems of information that they require. The two systems are mutually independent; that is, data reported and developed in the course of a patient safety activity is in addition to, separate, and apart from events identified to oversight reports. Voluntary reports on close calls and other problems would not otherwise exist were it not for a confidential system. Currently, the statutory protection for this type of information varies from state to state and does not permit the confidential and privileged sharing of information across state borders. If individual institutions do not have this confidentiality protection, their ability to

effectively run a patient safety program will be substantially hampered. Furthermore, confidentiality for patient safety information, if uniformly available, will facilitate the sharing of information between institutions in a particular locale as well as on a national basis. Without it, the fear of shame, embarrassment, as well as the fear of other punitive measures stands in the way of dissemination of information that will improve the quality and safety of health care and benefit patients everywhere.

Experience in the VA system has shown that reporting of events and especially close calls increased dramatically after clear definitions were enacted as to what constituted a confidential patient safety issue. This has resulted in the identification and mitigation of system vulnerabilities not just within the VA system but globally. Without confidentiality the same results could not have been achieved. Reports and information concerning systems vulnerabilities can be thought of as the fuel for the patient safety improvement "machine". If the hospital/healthcare environment is not appropriately constructed with regard to creating a non-punitive approach towards reporting and systems improvement, little will change. This 'environmental' change must occur not only at a national but at a local, frontline, level as well. In the final analysis, the actions that ultimately improve patient safety and prevent harm to the patient occur at the level of the patient. If the systems that are implemented, the non-punitive approaches employed, and corrective actions taken aren't translated to solving problems at the frontline where patient care actually occurs, all will be for naught.

Organizational leadership that is meaningfully and visibly involved is another component that is absolutely essential if the patient safety improvement effort is to be successful and sustainable. This requires more than merely issuing directives and emails. In the VA this type of leadership is exemplified by our medical center directors who personally meet with every root cause analysis team to understand the vulnerabilities that were studied as well as discuss the suggested systems improvements that will be required to prevent future problems. Leadership means becoming personally involved, it cannot be delegated to others, and the drumbeat must be relentless. CEO's and healthcare systems boards must have patient safety be part of the way they evaluate their performance. Patient safety is the foundation upon which quality patient care is built. A health care provider can't begin to say that it delivers high quality patient care if it isn't first safe. Without this commitment at the top little can or will change. Leadership by itself while essential is not sufficient in and of itself. There must also be a safety infrastructure that enables the course leadership sets to be converted to action. The VA National Center for Patient Safety designed its patient safety system with a number of tools that overtly require or subtly encourage employees at all levels to identify problems, analyze them from a systems-based perspective, institute human factors oriented systems-based solutions, and track these interventions to assure their effectiveness, all with an eye to preventing harm to the patient which should be the real overall goal of any patient safety program. For example, 31 VA medical centers working in a

collaborative project reduced their major injuries due to falls by more than 60 percent. This is important because major injuries after falls can lead to premature deaths and increased health care spending. For example, more than 20 percent of nursing home patients experiencing a hip fracture due to a fall will die within a year, and hip fractures cost Medicare almost $3 Billion per year. Other VA patient safety impacts include pacemakers and defibrillators in worldwide use whose designs were changed to make them less prone to failure in use as a direct result of the VA patient safety improvement system, and technology applications such as barcodes used for medication administration to virtually eliminate the misadministration of medication to VA patients.

Interest in improving patient safety is at an all time high. Very early, VA identified improved patient safety as a high priority. Our systems now serve as benchmarks and are being used and emulated by others both nationally and internationally. In the last two years alone, the VA has trained individuals from over 30 domestic heath care systems or providers such as Vanderbilt, the University of Michigan, and Dartmouth. Internationally we have trained representatives from 9 countries including Denmark and Australia, which have subsequently implemented national programs based on ours. It is important to remember that patient safety is not a destination but rather a never-ending journey and commitment to self-examination that relentlessly and skeptically challenges the way we do things in the quest to prevent our patients ever being harmed while they are under our care. Uniform, unambiguous, and assured confidentiality of patient safety information is essential underpinning for these efforts to flourish and succeed. We must approach patient safety in a way that permits and encourages all healthcare providers to aggressively pursue patient safety initiatives and emphasizes and celebrates prevention, not punishment.

Thank you for the opportunity to appear before the committee. I will be pleased to respond to your questions.

"The significant problems we face cannot be
solved at the same level of thinking we were at
when we created them."
Albert Einstein

Testimony
Before the Permanent Subcommittee on Investigations
Committee on Governmental Affairs
United States Senate

Patient Safety: Supporting a Culture of Continuous Quality Improvement in Hospitals and Other Health Care Organizations

Statement of
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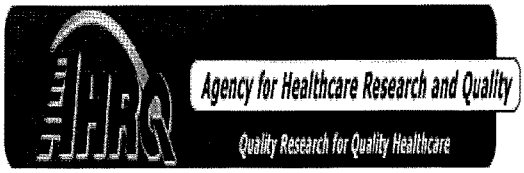

For Release on Delivery
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Good morning. I am very pleased to be here today to discuss the important issue of supporting hospitals and other health care organizations in their efforts to build and sustain a culture of continuous quality and patient safety improvement.

Hospitals and other health care delivery systems provide millions of Americans each year with important, frequently life-saving, care. But, as we all know, medical errors and patient safety issues represent a national problem of epidemic proportions. And as we have seen from recent news headlines, no institution is exempt, and everyone who uses the health care system is at risk.

However, there is good news. Our health care system is committed to improving the quality and safety of the care provided to our Nation's citizens. That commitment has never been stronger as shown by the dedication of the health care organizations like those you have gathered here today.

This issue is a very high priority for HHS Secretary Tommy Thompson and for the Agency for Healthcare Research and Quality. Over the last 3 years, thanks to the vision of the U.S. Congress, AHRQ has dedicated $165 million to patient safety research. AHRQ is now the leading funder of patient safety research in the world.

As a clinician, as well as the head of a federal agency, making sure that patients have safe, high quality health care is a personal priority for me. Like all clinicians, I have had personal experience with patient safety issues in my own practice.

It is important to note that the issue of improving patient safety is not new to the health care system. The landmark 1999 Institute of Medicine report, *To Err is Human*, was preceded by a body of research largely funded by AHRQ.

Also, segments of the health care system began to recognize where improvement was needed and came together to improve patient safety. For example, anesthesiology had an error rate in the 1960s and 70s of 25 to 50 per million patients. After a concerted effort, that rate has been reduced nearly seven-fold, to 5.4 per million.

In the mid-1990s, the American Medical Association launched the National Patient Safety Foundation, an organization committed to improving safety and reducing errors in medicine.

To Err Is Human galvanized fears and served as a further catalyst to efforts to improve safety and reduce errors. The report's estimates that 44,000 to 98,000 people die in hospitals each year due to medical errors shocked our Nation and all of us involved in health care. Media attention was high at the release of the report and continues with each high-profile case that makes news.

With all of this attention before and after the release of the IOM report, it would be easy to assume that we could do something quickly to improve patient safety. Yes, we are making progress and beginning to use what we know works to improve safety. However, we have much more to do. It is imperative that we do what is right and what evidence shows will work. We need to make sure that the cure for medical errors does not make the epidemic worse.

The key message of the IOM report and its sequel, *Crossing the Quality Chasm,* is that "it's the system." Health care professionals are human, and humans are prone to mistakes. We need to make sure that health care professionals work in systems that are designed to prevent mistakes and catch problems before they cause harm. Unfortunately, 3 years after the publication of *To Err is Human*, the message that "it's the system" does not appear to have found much traction.

Yet this is the first step in creating a culture in hospitals and elsewhere in the health care system that focuses on continuous quality improvement. To that end, we need to let go of outdated views on how to deal with errors. We need to shift from "naming, blaming, and shaming," to learning from errors, so they never happen again. This is not easy, but it is the right thing to do.

We can learn from other industries that have done this successfully. All of us involved in health care delivery can learn a lot from Starbucks, which has

very definite systems in place to prevent mistakes. The next time you go in for a latte, notice how many people repeat your order after you place it. Then look at the check marks on your cup made to back up the verbal order. This is teamwork and a well-designed system. And the company has created a culture among its employees that embraces the system.

Obviously, making a latte isn't as complex and challenging as providing patient services in today's health care system. For example, a study found that an intensive care patient might have 178 different tasks performed on him or her by medical personnel in a single day. Each time a task is performed, there is a chance of injury or error.

However, many of the lessons from Starbucks apply: We need to build in redundancy – both within and across professional disciplines. Most importantly, we need much more repetition of instructions – called "read back" in the jargon – for almost all interactions in clinical care. If Starbucks does this for coffee drinks, shouldn't health care providers do if for patients as well?

Another source of lessons on improving safety is the aviation industry. Between 1967 and 1976, the risk of dying in a domestic jet flight was 1 in 2 million. That risk fell to 1 in 8 million by the 1990s.

How did the aviation industry achieve this dramatic reduction? By designing systems that automate and standardize many tasks and controls. The

aviation industry also employs "read back" and other techniques to increase communcation and teamwork.

The aviation industry also has instilled a culture that emphasizes learning over blame. Pilots and other aviation workers are strongly encouraged to report errors and near misses without fear of recrimination.

This is possible because the confidential Aviation Safety Reporting System (ASRS) is not housed in the Federal Aviation Adminstration. Instead, ASRS is a part of NASA, which has no regulatory authority over the industry. ASRS collects and reviews the reports of errors and near misses and issues alerts of different levels based on the seriousness of the situation.

In another example, former Treasury Secretary Paul O'Neill created a culture of improvement and safety at Alcoa in the 1990s. The company reduced its lost work per day rate from 1.87 in 1987 to .42 in 1997, and it is continuing its efforts to improve.

To achieve this success, the company uses an online safety data system to track incidents, analyze their causes, and share solutions and information on how to prevent them from occuring again. To further foster the culture of safety, Alcoa employees at all levels are encouraged not only to report errors and near misses, but also to suggest solutions and improvements.

The lessons from Alcoa are already being put to work in the company's hometown. The Pittsburgh Regional Healthcare Initiative, co-founded by Secretary O'Neill in 1997, is a coalition of approximately 30 area hospitals, major insurers, and corporate and civic leaders who are commited improving health care quality and safety using the principles of continuous quality improvement.

The Veterans Health Administration (VHA) within the Department of Veterans Affairs (VA) provides another excellent example of how re-engineering and a comprehensive effort have improved quality and safety. An article in the May 29 issue of the *New England Journal of Medicine* details the success of the VHA in dramatically improving the care it provides.

In Fiscal Year (FY) 2000, 90 percent of patients in VA health care facilities received appropriate care as measured by scores on 9 of 17 quality indicators that were directly comparable to Medicare and other nationally recognized quality organizations. These included mammography, receiving appropriate heart medications, diabetes testing, and cervical cancer screening. More than 70 percent of patients received appropriate care for 13 of the 17 indicators. VA reports that the current indicators (now a total of 18) are directly comparable to those used by Medicare and other nationally recognized quality organizations.

This is a dramatic improvement resulting largely from a concerted effort in the 1990s to improve the care provided in VA facilities. This effort included the implementation of a systematic approach to the measurement and management of health care as well as development of a systematic approach to accountability for quality. The article in the *New England Journal of Medicine* indicates that after this period of improvement, VA facilities out-performed Medicare fee-for-service care, which has been undergoing improvements of its own.

These organizations represent the leading edge of success, and we need to learn from them. However, we have some basic obstacles to overcome in health care, particularly around reporting of medical errors.

The first obstacle is the perception of the problem of medical errors.

According to a study published in the December 12, 2002, *New England Journal of Medicine*, patients and physicians thought that the published estimates of the numbers of avoidable deaths were much too high. Also, neither group bought the "it's the system" message. In the case of surgical errors, both the public and physicians thought the surgeon should be held responsible, and the public was more likely to cite the institution as well.

A second obstacle is that we need to uproot the deep-seated fear of change within the health care industry. An integral part of this obstacle is that we

need to develop a system that allows people to discuss and report errors without fear of recrimination or being sued.

An AHRQ-sponsored research study has shown that improving communication can improve safety. However, other research funded by AHRQ published in the *Journal of the American Medical Association* in February found open communication about errors still does not happen.

Based on 13 focus groups between April and June 2002, researchers found that patients and doctors largely agreed on telling patients about errors that cause them harm. However, they disagreed about what to disclose about those errors. Patients unanimously wanted an apology; information about the error and how it happened, an explanation of the implications of the error for their health how the problem could be corrected; and assurances that the error would be prevented in the future. Physicians, while wanting to be truthful, were reluctant to provide this basic information to patients because of fears of malpractice lawsuits or damage to their reputations.

Other obstacles to improving patient safety and reducing medical errors include the lack of technology and the need for greater and better evidence about what does and does not work in making the health care system safer.

AHRQ plays a unique role in helping the health care system overcome all of these obstacles and thus build and sustain a culture of quality and safety improvement in hospitals and health care organizations. A key mission of AHRQ is to develop evidence, tools, and systems that help improve patient safety and reduce medical errors

At the direction of Congress, and following recommendations from the Institute of Medicine, AHRQ has successfully built the foundation for a national Patient Safety Initiative from virtually a standing start.

Our 1999 reauthorization legislation added patient safety to the overall mission of the Agency. Specifically, the language stated that:

> *The Director [of AHRQ] shall conduct and support research and build private-public partnerships to -- (1) identify the causes of preventable health care errors and patient injury in health care delivery; (2) develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and (3) disseminate such effective strategies throughout the health care industry.*
> (Public Health Service Act, Sec. 912(c))

AHRQ has funded more than $165 million in research dedicated to improving patient safety since FY 2001. This presents an extensive, user-driven

patient safety research agenda. As with other AHRQ initiatives, we believe that the key to successful implementation of findings from this research is to get input early and often from the users of the research. We also encourage researchers to involve users in their studies, so they can begin using the findings immediately to improve quality.

For instance, we sought input from a broad array of stakeholders and users through a variety of means, including a National Summit on Medical Errors and Patient Safety, which was attended by public and private-sector users and funders of health care research. Held in September 2000 in Washington, DC, the National Summit was a daylong meeting designed to solicit responses from the users of patient safety research about their pressing needs and to highlight specific research questions related to those needs.

We also sought advice from AHRQ's National Advisory Council and the Federal Quality Interagency Coordination Task Force, known as the QuIC. The QuIC includes other HHS agencies, as well as all of the Federal agencies involved in the delivery, purchase, regulation, or study of health care services.

The more than 100 studies and other activities funded under AHRQ's patient safety research initiative fall into four categories:

1. Identifying Threats to Patient Safety: identify medical errors and causes of patient injury associated with the delivery of health care;

2. Identifying and Evaluating Effective Patient Safety Practices: identify, design, test, and evaluate practices that eliminate medical errors and system-related risks and hazards compromising patient safety;

3. Educating, Disseminating, and Implementing to Enhance Patient Safety: disseminate, educate about, and implement patient safety best practices that reduce or prevent actual (or the potential for) patient injury associated with the delivery of health care; and

4. Maintaining Vigilance: monitor and evaluate threats to patient safety.

While much of this research is still ongoing, I would like to give a few examples of our findings and successes to date:

A study cofunded by AHRQ and the National Institute on Aging at the National Institutes of Health found that Medicare patients treated in outpatient settings may suffer as many as 1.9 million drug-related injuries a year because of medical errors or adverse drug reactions not caused by errors. About 180,000 of these injuries are life-threatening or fatal, and more than half are preventable, according to the researchers.

When the researchers analyzed why the preventable adverse drug events occurred, they found that 58 percent involved errors made in the prescribing of

medications, such as ordering the wrong drug or dose, not educating the patient adequately about the medicine, or prescribing a medication for which there was a known interaction with another drug the patient was already taking.

The investigators also found 61 percent of preventable adverse drug events involved mistakes made in monitoring medications, such as inadequate monitoring or a delayed response to symptoms of drug toxicity in the patient. However, the failure of patients to adhere to medication instructions contributed to over 20 percent of the preventable drug-related injuries.

Another AHRQ-funded study found that every year, sponges or medical instruments are left inside more than 1,500 surgical patients, about one or more cases each year for a typical large hospital. This can lead to serious problems ranging from bowel perforation and blood infection to death.

The study reveals for the first time that instruments and sponges associated with surgery are more likely to be left behind in cases involving emergency surgery, obese patients, or unplanned changes in the surgical procedure.

Researchers concluded that a $100 plain x-ray following high-risk categories of operations could prove a cost-effective way of ensuring that no foreign body is left in patients after surgery.

To make it easier for hospitals to encourage a culture of safety, AHRQ developed a Web site modeled on the format of morbidity and mortality (M&M) conferences that are routinely held within individual hospitals across the country. At M&M conferences, clinicians discuss specific cases that raise issues regarding medical errors and safety improvement. However, the findings from these conferences are not routinely shared outside each individual hospital. This is a lost opportunity for learning.

The AHRQ Web M&M site is an online, peer-reviewed patient safety journal and national M&M conference aimed at improving patient safety through analysis of submitted cases. The site http://webmm.ahrq.gov contains five new cases a month, which are submitted anonymously, and then discussed in forums on the site.

The AHRQ Web M&M is already recognized as an important teaching and learning resource on medical errors. It is being used in hospitals and teaching facilities, and there are over 2,000 registered users with the numbers continuing to grow. It fills a badly needed gap in training and education about medical errors and patient safety

AHRQ also supported the development of an evidence report titled, *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*. This report comprises a systematic review of the scientific literature; 79 patient safety "best practices" were identified for review and discussion as to the evidence for their use. This report received a tremendous amount of attention, with several

thousand requests for it over the past 2 years. It represents the first compilation of patient safety practices supported by a review of the related evidence behind them.

To help further the implementation of these patient safety practices by hospitals and others, AHRQ and the Centers for Medicare & Medicaid Services asked the National Quality Forum (NQF) to use the AHRQ evidence report to develop specific recommendations that could be used by other organizations seeking guidance on adoption and implementation of safe practices. The NQF is a not-for-profit membership organization created to develop and implement a national strategy for healthcare quality measurement and reporting.

The NQF used the AHRQ evidence report as a starting point for the consensus development process and supplemented it with information from several other sources. Last month in Los Angeles, AHRQ and the NQF released the consensus report, which recommends 30 practices with good evidence and broad-based support.

In FY 03, AHRQ is poised to begin two exciting new programs under our patient safety initiative.

The first program is the development of a Patient Safety Improvement Corps – a cadre of specially trained patient safety experts who will provide

technical assistance to States, local governments, and health care institutions on improving patient safety using evidence and proven best practices.

For the second program, AHRQ will fund Safe Practices Implementation Challenge Grants. The grants are intended to help hospitals and other health care institutions assess safety risks to patients, devise ways to prevent them, and implement safe practices that show evidence of eliminating or reducing known risks.

AHRQ plays a very unique and important role in helping the health care system improve quality and safety. For example, if the patient safety legislation passes Congress, we will have the information and tools ready and available to help the new Patient Safety Organizations improve safety.

For example, AHRQ has developed a free, Web-based tool that can help hospitals enhance their patient safety performance by quickly detecting potential medical errors in patients who have undergone medical or surgical care. Hospitals use the AHRQ Patient Safety Indicators (PSI) to determine whether the problems detected were caused by potentially preventable medical errors or have some other explanations. The PSIs allow for the detection of 26 types of adverse events, such as complications of anesthesia, blood clots in the legs or lungs following surgery, fracture following surgery, and four types of birth-related injuries.

Although the PSIs were developed primarily for hospitals to use in their quality improvement programs, other kinds of organizations will find the tool useful. For example, hospital associations can show member hospitals how they perform for each indicator when compared with their peer group, the state as a whole, or other comparable states.

Recently, two research articles demonstrated the power of the PSIs. The first, published in the March issue of *Health Affairs*, found that the number of potential safety-related events of most non-obstetric procedures included in the PSIs decreased between 1995 and 2000. The study found that most technical complications, such as postoperative hemorrhage or reopening of a wound, decreased between 1995 and 2000, except for a 7 percent rise in the number of accidental punctures and lacerations. Also during that time, obstetric trauma decreased about 3 percent, foreign bodies left during procedures decreased 7 percent, anesthesia complications decreased 18 percent, and transfusion reactions decreased 40 percent.

The second study was published in the June issue of the journal *Pediatrics*. Use of the PSIs to examine of the types of patient safety problems that children experience in hospitals found that the rates of such problems range from 0.2 (foreign body left during procedure) to 154.0 (birth trauma) problems per 10,000 discharge records. The study also found that those who experienced a patient safety problem in the hospital faced a 2-18 times greater risk of death than children who did not have such a problem.

I would like to thank you again for giving me the opportunity to discuss the very important issue of medical errors, patient safety, and furthering a culture of continuous quality improvement in hospitals and health care organizations.

I would like to reiterate the commitment that Secretary Thompson and the Administration have to creating a culture of improvement and safety in the health care system and providing evidence-based tools and resources to achieve that goal. In particular, I am very pleased that AHRQ is providing the science that is fueling these efforts.

One of the best examples of this commitment is continued support for patient safety research, the patient safety improvement corps, and the challenge grants in our proposed FY 04 budget.

The budget also includes a very exciting new $50 million initiative to spur adoption of information technology by the nation's hospitals. Specifically, this initiative will provide planning and demonstration grants as well as technical assistance to help hospitals and other health care organizations to acquire and improve IT systems that support quality improvement and patient safety. This initiative will include a special focus of $26 million on small and rural hospitals.

Working together, we can improve patient safety, enhance health care quality, and give the American people the best, safest health care system possible. Thank you.

Joint Commission
on Accreditation of Healthcare Organizations

Setting the Standard for Quality in Health Care

TESTIMONY
of
Dennis O'Leary, M.D.
President
Joint Commission on Accreditation of Healthcare Organizations

Before the

Senate Committee on Governmental Affairs

"Patient Safety: Instilling Hospitals with a Culture of Continuous Improvement"

June 11, 2003

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American College of Surgeons
American Dental Association
American Hospital Association
American Medical Association

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I am Dr. Dennis O'Leary, President of the Joint Commission on Accreditation of Healthcare Organizations. I appreciate the opportunity to testify on the critically important matter of how to approach the patient safety issues that continue to plague the delivery of health care services.

The Joint Commission is the nation's preeminent health care standard-setting and accrediting body. Founded in 1951, it is a private sector, not-for-profit entity dedicated to improving the safety and quality of health care provided to the public. Our member organizations are the American College of Surgeons; the American Medical Association; the American Hospital Association; the American College of Physicians; and the American Dental Association. In addition to these organizations, the 29-member Board of Commissioners includes representation from the field of nursing as well as public members whose expertise spans such diverse areas as ethics, public policy, and insurance, and academia.

The Joint Commission accredits approximately 17,000 health care organizations, including a preponderance of the hospitals in this country. Our accreditation programs also evaluate the performance of home care agencies; ambulatory care settings whose services range from primary care to outpatient surgery; behavioral health care programs; nursing homes; hospices; assisted living residencies; clinical laboratories; and managed care plans. Further, the Joint Commission is active internationally and has provided consultation and accreditation services in over 60 countries.

Challenges in Changing the System

I have been asked to comment on what is needed to create a true culture of safety in our health care institutions. We like others, are deeply concerned that the number of serious medical errors remains unacceptably high, despite the focus of significant national attention on patient safety in recent years. In 1996, the Joint Commission made patient safety its foremost priority after a spate of high profile errors were vetted in the media. These errors were a clarion call to all of us involved in quality of care oversight, and these events, plus a number of others which occurred subsequently, eventually spurred the landmark 1999 Institute of Medicine report, "*To Err is Human.*" That report received unprecedented national media coverage and truly put this issue on the map for the public and for policymakers. While clear steps have been taken towards reducing such errors, we as a nation have not achieved the level of success that the IOM report suggested should have been reached by this time.

As part of the Joint Commission's intensified efforts to improve patient safety over the past seven years, we created a Sentinel Event Database that is the world's most complete record of the full spectrum of serious medical errors and their underlying causes. This database, combined with knowledge learned from working with health care organizations to address their patient safety issues, has permitted us to gain a deep understanding of the interplay and complexity of factors that contribute to health care errors and serious adverse events. The solutions, we believe, are equally complex, representing a range of actions - both low and high cost - that must be taken at all levels of the health care system and by all stakeholder groups.

I would like to briefly identify six strategies for tackling medical errors, discuss some of the relevant actions that have already been taken, and present some remaining challenges to reaching widely held safety goals.

Creating Cultures of Safety

First, health care organization leadership must be encouraged to create cultures of safety for their own setting. The associated values and performance expectations must be demonstrated by example and permeate the entire organization. A culture of safety is characterized by an open atmosphere for reporting and addressing errors, and eventually by anticipating and preventing errors through careful monitoring and timely re-design of internal patient care systems. Adopting such a culture is an overarching strategy necessary to the support of all other solutions, and thus the single most important strategic effort to be undertaken. But this is perhaps the most difficult goal to fully achieve. Cultural changes always require significant leadership energy and commitment. In the case of patient safety this is even a more daunting challenge because what is actually being sought is a counter culture to the deep-seated "blame and shame" orientation of American society. For this reason, the success of this effort depends heavily upon other key actions, the most of important of which is the passage of federal "safe harbor" legislation.

The Joint Commission has been on the forefront in proselytizing cultural change as the foundational basis for achieving real error reduction. To this end, the Joint Commission has established and implemented safety standards that strongly encourage leaders of accredited organizations to make patient safety their top priority; to set a constructive tone for dealing with safety concerns that promotes a safe environment for care; and to invest human and other resource investments in systems improvements and in adopting safe practices. Moreover, the Joint Commission has actively promoted the empowerment of patients and their families as active participants in care planning and treatment. Involving patients as valued partners on the patient care team, and providing them essential information about their care are key elements of an important part of an enlightened organization culture.

The culture of an organization emanates from all of its leaders, but is most notably set by its CEO. However, it is difficult to be sanguine about achieving this goal because of the pragmatic realities facing CEOs today. With operation resources already strained in many organization, potential investments in patient safety compete every day against other basic needs such as staff recruitment, maintenance of the physical plant, clinical technology upgrades simply to meet the standard of care and other investments to respond to community needs. Further, investments in patient safety -- while a moral obligation – usually provide financial benefits to payors and purchasers rather than the organization.

Late last year, the Joint Commission, the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, the Department of Defense and the American Hospital Association sponsored a symposium of hospital CEOs to discuss the business case for safety. Those of us who conceived the idea of the symposium believed that if we could demonstrate a quantifiable return on investments (ROI) in patient safety, then health care executives would be more motivated to elevate safety efforts in their assessments of operational priorities. After two days of intense discussion, the conclusion was reached that the business case had not been made, despite clear consensus that the pursuit of patient safety is the right thing to do. Among the many reasons that the business case could not be made is that public payers pay the same reimbursement for unsafe care as they do for safe care. Further, little capital is available to support major patient safety

improvements, such as computerized physician order entry. And finally, internal and external reward systems place little or no value on investments in patient safety and demonstrated reductions in medical errors.

While I will come back to the issue of paying for safety later in the testimony, I would like to point out that creating a culture of safety involves more then external resource commitment. There are many low-cost dimensions to the needed cultural change. These dimensions involve such factors as an open and non-punitive environment for surfacing the existence of errors and risk points within an organization; creating an atmosphere that encourages broad-based involvement in developing safety solutions; information-seeking behavior that looks externally for safe practices to emulate; and a willingness to re-design care processes as a team function. This leads me to my second strategy, which is introducing engineering tools into the health care industry as a way to improve care processes.

Importing Engineering Concepts and Tools

Concepts and tools are critical ingredients to any type of sea change. If we are to truly achieve improvements in patient safety, we must give health care organization leaders, clinicians and patients the information and tools they need to effect such changes. One of the Joint Commission's important contributions in this regard has been to incorporate into its accreditation requirements a "systems approach" to managing risk that is borrowed from engineering and quality control principles that have been successfully applied in manufacturing. Individuals will always make errors and they should be held accountable for their errors. However, adverse events usually occur when internal systems fail to anticipate errors and keep the effects of mistakes from reaching the patients.

The Joint Commission requires accredited health care organizations to engage in both retrospective and prospective risk analyses that assesses weak points in their systems of care. If a serious medical error occurs in an accredited organization, a "root cause analyses" is required. This analysis must fully assess the circumstances and causes of the event and identify all systemic problems that must be fixed in order to prevent a similar event from happening again. The root cause analysis involves a "no-holds-barred" examination of the contributing factors to the adverse event and should include all staff who were involved in the event. There are invariably many more factors underlying to an event than initially meet the eye, and there are almost always underlying "systems" reasons for the failure. Because the root cause analysis is always rich with causal factors, it becomes the basis for future preventative actions that bear both on the event in question and upon other patient dimensions. Actions commonly taken include the re-design of systems of care, staff training, and the incorporation of checks and balances to mitigate risk.

Of equal value is the prospective analysis of high-risk processes in the delivery of care. In its July, 2001 patient safety standards, the Joint Commission has now brought the application of Failure Mode and Effects Analysis (FMEA) to accredited health care organizations. This systems approach to improving care involves the prospective evaluation of processes identified by the organization as being vulnerable to risk, and the re-design of such processes "to build safety in," e.g., through creating redundancies, before an adverse event occurs.

Improving and Investing in Professional Education

While health care professionals can be provided tools to evaluate risk and re-design care, this country is neglecting to concomitantly improve the professional education system to support this new thinking about prevention of errors and adverse events in this complex delivery system. We need to graduate health care professionals who are proficient in "systems thinking," who are comfortable using decision support tools, and who can actively engage in solving patient safety problems. Instead, we educate physicians for too many years and lead them to believe that they should know how to do it all themselves; that they are more important than any other member of the health care team; and that blame belongs to people, not poorly designed systems and processes. This mindset reinforces the "blame and shame" mentality that retards our progress in solving the medical errors issues by focusing on punishing the person most proximal to the error.

By contrast, nurses -- who are on the front line of the most complex health care we deliver every day -- are educated 2.4 years and receive brief periods of post graduate supervision that average 30 days before they assume responsibility for patient care duties. As a result, many nurses leave patient care because they do not receive the types of clinical skills and training necessary to deal with today's high acuity patients and pervasive safety issues. In deed, many cite fear of making a mistake as a seminal reason for leaving the nursing profession. This becomes a vicious cycle, because the record is clear that inadequate numbers of nurses lead to medical errors and diminishes the overall quality of care. Data from the Joint Commission's Sentinel Event Database demonstrate that in 24% of the unanticipated deaths and serious patient injuries, inadequate numbers of nurses is a contributing factor.

Last year, the Joint Commission published two major white papers on the nursing shortage, its causes and solutions. The papers developed with the assistance of a multidisciplinary expert roundtable contained a number of recommendations, one of which urged federal funding of nursing internships of at least one-year in length. In the view of the Joint Commission, this is a de minimus investment in patient safety. Another dire funding need is additional money to supplement the extremely modest dollars allocated to last year's Nurse Reinvestment Act. Appropriations under this Act are essential to the funding of faculty in nursing schools which today must turn away hundreds of qualified nursing applicants. This is an untenable situation in the face of a major and growing nursing shortage.

I would finally suggest that consideration be given to a government commissioned study of the content of professional education as it relates to patient safety. Such a report could create pressure for sufficient reforms of medical and nursing education to permit appropriate allocations of time to systems learning education about the contribution of human factors to patient safety, and intense professional team training.

Improving Information Infrastructure

Information technology can make important contributions to reducing medical errors. For example, technology can provide significant decision support in the processes of patient assessment, treatment and education. It can further make critical patient information available on a timely basis

to enable appropriate patient management; elicit patient care reminders; raise flags about medication dosages, therapeutic uses and interactions; and enable communication among providers. However, the health care industry lags far behind most other industries in the use of information technology. Investment in information systems at the health care organization level has often been problematic because these expensive systems are usually proprietary and therefore unable to accommodate exchange of information between organizations and between organizations and practitioners. However, there have recently been substantive concerted effort recently to make health care information technology more interoperable through achievement of consensus on standards for data interchange and development of systems that can "talk" to one another. I believe that within the next few years, we will witness accelerated progress in this area and that this progress will favorably impact our collective patient safety improvement efforts.

Notwithstanding the forenoted progress, there remain significant impediments to broader use of information technology. They reside in its cost, the implications for health professions training, and to some degree, government leadership. Few health care organizations can afford major investments in electronic health information systems today, or even in computerized order entry for reducing medication- prescribing errors. We are particularly pleased, therefore, that Secretary Thompson has made the attainment of a national health information infrastructure a priority of his Department. However, we believe that this federal government focus must be expanded to encompass support of timely public health data collection and emergency preparedness. Further, the Congress itself must be prepared to make the capital investments necessary to facilitate rapid adoption of appropriate technologies by health care organizations. The information infrastructure gap between what is possible and where this country is must be closed as quickly as possible. Logic would dictate that any such capital investment be tied to organization incentives to encourage rapid pursuit of this goal.

Performance Incentives for Safety Goals

Behavior change is best achieved when there are incentives that reward desired actions. I would like to mention two powerful incentives that can help move the health care industry toward safer care.

The first incentive lies in targeting the expectations of the oversight framework to health care. All providers, organizations and practitioners want to do the right thing, but even when informed and armed with the tools for change, intervening priorities may take precedence. We have found that organizations respond best to what they know is going to be externally measured. For example, the Joint Commission has issued over two-dozen Sentinel Event *Alerts*, which set forth specific safe practices for avoiding high profile errors. However, compliance with the recommendations in these *Alerts* was not being specifically measured during our on-site accreditation surveys. Therefore, the Joint Commission decided to set a small number of discrete National Patient Safety Goals around significant, documented safety problems and incorporate assessment of compliance with attention to these Goals and their associated recommendations into the survey process.

The Joint Commission implemented its first set of National Patient Safety Goals in January 2003. The Goals selected were drawn from the Joint Commission's Sentinel Event Database and were based on the recommendations of an expert panel. The expert panel also identified one – two

specific recommendations for each Goal, which provides the substrate for the onsite compliance assessment. The 2003 goals are:

- Improve the accuracy of patient identification
- Improve the effectiveness of communication among caregivers
- Improve the safety of using high-alert medications
- Eliminate wrong-site, wrong patient, wrong procedure surgery
- Improve the safety of using profusion pumps
- Improve the effectiveness of clinical alarm systems

Individual organization compliance with the National Patient Safety Goals will be made public beginning in 2004. We believe that the Medicare and Medicaid programs should consider adopting the same safety goals for relevant, non-accredited health care organizations.

The second type of incentive involves rewarding behaviors through payment. This is probably the most powerful incentive in the toolbox and therefore one that must be used wisely. As mentioned earlier in this testimony, pubic purchasers pay the same for safe care as they do for unsafe care. To complicate matters, when medical errors cause longer patient stays or lead to more treatment, the providers often receive higher payments. This is not to suggest that any provider injures a patient for money, but rather to point out that there are no payment **dis**incentives for experiencing preventable adverse outcomes, nor are there payment **in**centives for successfully providing safe care. There is now a growing imperative to determine how payment incentives can be aligned among payors, purchasers, provider organizations and practitioners toward the goal of improving the quality and safety of care. This lofty goal is not without challenges, but the need to achieve this goal is now being elevated in policy discussions in Washington and elsewhere. It should be self-evident that patient safety improvement must be part of the "pay for performance" equation.

Passage of Patient Safety legislation

I have left this strategy for last, but it is the one that Congress can act upon most quickly. Since 1997, the Joint Commission has been advocating for patient safety legislation that would provide certain protections to medical error information as a way to encourage its production and the dissemination of lessons learned. Thousands and thousands of errors remain hidden today, and each of those is a lost opportunity for education and change. Federal confidentiality protections for reported adverse events, near misses, and their underlying causes are inextricably linked to the efforts to create a culture of safety inside health care organizations, because they would provide the essential safe harbor that organizations must have in order to surface, freely analyze, and then share medical-error related information within the health care community. Such protective legislation would establish a solid foundation for leveraging the sharing of information and engaging in neutral problem-solving.

Legislation is currently pending in Congress that would help us bring about this cultural change. The House recently passed H.R.663, the "Patient Safety and Quality Improvement Act. In the Senate, S.720 was introduced by a number of Senators as a marker for this year. We are very hopeful that this is the year in which this critical piece of legislation will actually be enacted. We urge you to support legislation that (1) will protect from subpoena the production of error-related information by health care organizations and practitioners, and (2) contains explicit language to

clearly preserve that protection when the information is shared with an accrediting body for purposes of improving patient safety and health care quality.

In conclusion, there are considerable barriers to be overcome if we are to truly change the culture of our complex health care delivery system to fully embrace patient safety and health care quality. The knowledge of what to do differently and how to do it exists and progress is being made. However, more needs to be done by all of us, including the Congress, if we are to succeed.

Thank you for the opportunity to testify here today.

Testimony of David R. Page

President and Chief Executive Officer

Fairview Health Services

Before the

Permanent Subcommittee on Investigations

Committee on Government Affairs

June 11, 2003

Creating a Culture of Continuous Improvement

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Creating a Culture of Continuous Improvement

I. Background

Thank you, Chairman Coleman and members of the Permanent Subcommittee on Investigations, Committee on Government Affairs, for convening this hearing of policy makers and leaders, and for inviting me to share Fairview's story. I'm David Page, president and CEO of Fairview Health Services, an integrated health care delivery system serving Minnesota. I also have the privilege of membership on the National Patient Safety Foundation (NPSF) board of directors and leadership of the NPSF Stand up for Patient Safety Campaign.

A. Fairview Health Services: from primary care in the ambulatory, rural setting to organ transplantation in a quaternary care, academic teaching center

Our mission, improving the health of our communities, has been consistent since the first Fairview hospital was founded nearly 100 years ago. Norwegian Lutheran pastors and members of their congregations responded to the needs of the immigrant community for compassionate, culturally appropriate health care.

B. A broad continuum of care close to home

Fairview has two clear differentiators in our marketplace. Our continuum of care or breadth of services is one of those differentiators. We operate seven geographically dispersed hospitals ranging from an inner city location to suburban locations, to greater Minnesota community locations. We are privileged to conduct most of our activities in Minnesota, a perennial leader in health care innovation. In addition to hospitals, in each of these areas we operate clinics and related services appropriate to the local needs. At many of these sites, Fairview provides home care and hospice services, a full range of rehabilitation services, retail and in-hospital pharmacies, elder care, laboratory services and nursing homes. Based on the depth and expertise of the University of Minnesota Physicians at our largest facility, Fairview-University Medical Center, we offer the most advanced quaternary services, including transplantation for all solid organ systems and many other systems, such as blood and bone marrow. Consequently, within Fairview, we believe we can meet all our patients' needs close to their homes for most primary, specialty care and even complex care. Our vision is to allow a patient to move through this integrated system seamlessly, receiving care at the most convenient, appropriate location.

In practice, for example, the continuum might look something like this. A home care nurse might visit an elderly patient at home and determine that the patient requires hospitalization for uncontrolled diabetes. The patient is admitted to Fairview-University Medical Center where she is stabilized. But because of her condition, she cannot safety return home, so a care coordinator arranges for her to stay in a Fairview long-term care facility on either an assisted or independent basis. Over time, when the patient requires hospice care, she enters a Fairview hospice facility for palliative care. Such seamless movement of patients through our system in response to their care needs is our vision for all Fairview patients. We are pursuing excellence in our clinical care systems and the business systems that support them.

C. In partnership with the University of Minnesota Academic Health Center for excellence in clinical care, research and education
Our second differentiator is our partnership with Minnesota's largest medical school. In 1997, Fairview's system of community hospitals entered into a partnership with the University of Minnesota's Academic Health Center (AHC), purchasing the university's hospital and clinics. The AHC educates and trains health care professionals, while Fairview operates the hospital and clinics that provide a setting for clinical training for future health care professionals, as well for the faculty physicians' clinical group practices. In addition to supplying a platform for leading-edge medical research and education, Fairview provides outstanding clinical care and community service through these and its other facilities, serving a significant percentage of the poorest in our state. Moreover, a large portion of the state's most seriously ill patients receive care at these facilities – whether in our neonatal intensive care unit or through our nationally recognized end-of-life services. Fairview also owns and operates the state's largest children's hospital as part of Fairview-University Medical Center. (See attachments: Fairview Health Services "At a Glance" and "Capacity")

II. Introduction

A. The issue: safety in hospitals lags behind quality and safety in other industries
As we know, America's health care system and Fairview's don't always work smoothly. While science and technology advance daily, the health care delivery system has not kept pace. In *Wall of Silence*, Rosemary Gibson reiterates the Institute of Medicine (IOM) data revealing that an estimated 98,000 people die each year from preventable medical mistakes. The IOM is not alone in this estimate. We, along with many of our peers, acknowledge that the processes at work in the health care system lag behind many other American industries in the quality of the output and the safety of the participants. To be sure, there are many contributing factors – health care is a complex subject. But too often, we accept the results even in the areas where change and improvement should be possible.

Often we point fingers and place blame, rather than evaluating the system that supports, and too frequently fails, the health care provider and our patients. This environment of blame has led to a public loss of trust in our national health care system. Blame also inhibits our ability to get a clear picture of the number and reasons for errors that happen so we can learn from mistakes. As leaders in health care, we have a responsibility and an opportunity to restore trust and to take accountability for the care we deliver – and we have begun that journey.

Thankfully, there is hope that a better future is ahead of us, and there are signs that work is underway to change the picture. Health care leaders in Minnesota are making significant efforts in quality and safety initiatives, with no reluctance to tackle the hard work ahead.

I am not here today to describe all the complexities of health care delivery or all the barriers and misaligned incentives we face. Rather, I am here to describe what we are doing to make health care safer and more efficient. And, to suggest a few leverage points at which we believe governmental action could add value. Over its 100-year history, Fairview has always followed the Hippocratic Oath, "First, do no harm...." Emphasis on safety and process improvement is nothing new to us. But as health care has grown into a complex system, we now require new systems and techniques to help us manage patient safety and produce excellent outcomes. And we need to deliver those results within the resource restraints imposed on us.

B. Health care must learn from other industries
We need your help and the help of other organizations here today to facilitate system improvement and system development. If you remember anything from my visit here today, let it be this: ***To become safer, we in health care must learn from other industries that have confronted and overcome similar safety challenges by creating cultures that continue to set high standards, support open communication and embrace continuous process improvement.***

III. Learning from Industry: the Bold Vision and Focus of Alcoa

A. We need: vision, disclosure, process improvement
To meet this challenge, we in health care must do the following. First, we must embrace a bold vision and focus our efforts on applying high standards and expectations. We have examples, like Paul O'Neil modeled at Alcoa to identify and eliminate employee injuries in the workplace. At Alcoa, O'Neil relentlessly focused daily to reduce accidents to a new industry low. He never accepted the "industry average" for injuries as good enough for his organization.

B. Fairview's efforts: committed to the Institute of Medicine (IOM) six aims of medicine
At Fairview, we're striving for relentless attention to safety – incorporating it into our vision statement:

> ***You will know us for our continuum of healing care, our responsiveness and for setting national standards for clinical excellence, innovation and safety.***

We are committed to the Institute of Medicine's six aims of health care outlined in the executive summary of *Crossing the Quality Chasm*. Health care will be:

- Safe – avoiding injuries to patients from the care that is intended to help them.
- Effective – providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding under use and overuse, respectively).
- Patient-centered – providing care that is respectful of and responsive to individual patient preferences, needs and values and ensuring that patient values guide all clinical decisions.

- Timely – reducing waits and sometimes harmful delays for both those who receive and those who give care.
- Efficient – avoiding waste, including waste of equipment, supplies, ideas and energy.
- Equitable – providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location and socio-economic status.

We believe with the IOM that adhering to these aims of care will result in safer, more reliable health care.

We have also created an executive level position to help drive our safety agenda across the system. Further, we have incorporated safety expectations into the goals of every executive at Fairview to increase our safety accountability.

C. Congress can help

• Congress can help by holding the health care industry accountable for safe and high-quality care though reimbursement based on the quality of outcomes. As stated in a May 27 article in *The Wall Street Journal* called "Medicare Plan Would Give Bonuses for Superior Care":

Medicare is planning an experiment: Reward hospitals that provide superior care....

Medicare traditionally has paid hospitals the same fee for a procedure regardless of the outcome. But now, it is following the lead of private employers and managed-care plans that have begun paying hospitals and doctors more if they can show their patients fared better....

Under the latest pilot project by CMS, hospitals would submit data on patients with eight medical conditions – including stroke, heart attack, hip surgery, pneumonia and heart failure – that are common among Medicare's patients. A hospital might, for instance, report how quickly patients with pneumonia get antibiotics, which increases the likelihood of a speedy recovery. Or it might report what percentage of heart-attack patients get beta blockers at discharge, which help prevent future heart attacks. Those results would likely be posted publicly.

As proposed by CMS, hospitals with top scores on quality would get a small bonus – 1% or 2% -- added to their regular Medicare payments. Under the initial plan, the lowest performers wouldn't be affected, while the top hospitals would get additional funds for all three years of the project.

Fairview supports the provider "report cards." We believe it does give consumers important information and prods providers to change their behavior.

IV. Learning from Industry: the Culture of Open Communication and Anonymous Error Reporting Embraced by the Airline Industry

A. A policy of full disclosure
Second, we must put vision into action through open communication and anonymous error reporting systems. Such systems have transformed the culture of the airline industry, making 2002 the safest year in the air. Such reporting works because the culture supports and demands blameless disclosure. The system encourages anyone with safety concerns to raise issues and stop the process if necessary. Even in the face of the awful crash of the Columbia space shuttle, the aerospace industry focused on learning from that tragedy rather than rushing to blame. We need to develop a similar orientation. I'm pleased that at Fairview we are implementing a policy of full disclosure to patients when an error occurs (see attached), and measuring our culture of safety through surveys so that we can identify and respond to reporting barriers.

B. Minnesota in the forefront
Working together to standardize care processes. As mentioned above, Fairview is not facing this challenge alone. Fairview is active in a Minnesota consortium of ten health care systems—one of few such efforts in the country – called Safest in America (SIA). In a current initiative, SIA has established a community standard for surgical site marking to ensure that surgical incisions are made in the right location on the right patient. Such an effort is just the first in what we envision as a way of life for health care in Minnesota – competitor systems cooperating to enhance the safety of patients.

Embracing Leapfrog. Fairview also is active in a national consortium of health care purchasers and providers known as Leapfrog. The group is working to make hospital safety and quality information available to consumers. As chairman of the Minnesota Hospital Association, I worked with other Minnesota hospital leaders to sign the Leapfrog pledge to report safety efforts annually. I'm pleased to report that all 142 Minnesota hospitals signed the pledge. In the words of Jill Egan, senior vice president and chief operating officer of the Minnesota Hospital Association:

"As a demonstration of its commitment to patient safety, Fairview took a leadership role in bridging the commitments of both the hospital and business community. Participating in a program of the Business Roundtable call Leapfrog, ***Minnesota became the first state in the nation to have 100 percent of its hospitals report their safety efforts for consumers…*** *Fairview was instrumental in helping to develop the conceptual framework for a registry designed to capture data about medical accidents and share learning with other hospitals. The registry has now become a key component in the recently passed Minnesota legislation requiring reporting of adverse medical events."*

Establishing accountability for error reporting. Minnesota has further led the charge on patient safety by recently adopting a law to systematically track such adverse medical events as wrong-site surgery or death/ disability associated with medical errors. The Minnesota Adverse Health Care Event Reporting Law mandates that hospitals disclose to the Department of Health when any of 27 "never" events occur and that this information

is shared with the public. This is part of Minnesota's effort to help identify and solve problems, rather than pointing fingers of blame.

C. Congress can help

- Congress can help encourage a culture of full disclosure by supporting a non-punitive reporting environment.

V: Learning from Industry: the Rigorous Process Improvement Methods of Motorola, 3M and Toyota

In addition to the need for vision and blameless error reporting, health care must create a meaningful process improvement culture and apply rigorous process improvement methods like those used at Toyota, Motorola, 3M and countless others to produce better products at lower cost. While Fairview and most other health care providers have pursued quality and process improvement for years, we realized we needed a new level of measurement capability, system-wide alignment of goals and objectives, a commitment to focus, persistent discipline and some new skills to go along with it.

A. The Concern: lack of metrics and rigorous process improvement

As we observed our own systems, we found in some cases we had difficulties spreading our own best practices from one part of the system to another. We didn't always have common metrics across our system. For a variety of reasons, we lack meaningful measures in some of our processes. Like many of our colleagues battling rising costs and falling reimbursement, we found ourselves rushing from one crisis to the next. We struggled to understand our care and business processes enough to rigorously improve those processes and their interactions for dramatic performance improvement.

To be sure, we have many examples of improvements and performance gains; but, to deliver on the expectations of our patients in the future, we need to achieve quantum level change – faster action, credible measurement of our processes and demonstrable outcomes that patients and payers can evaluate. For Fairview, a challenge from a captain of industry became one element of our epiphany. At a health care conference sponsored by Motorola, Bob Galvin challenged health care providers to use the well-known, rigorous and effective process improvement tools of Six Sigma to drive improvement in the health care industry.

B. Fairview's efforts

Aligning performance improvement with strategic initiatives focused on customer requirements. The Motorola conference inspired us to align Fairview around measurement and rapid process improvement. We developed a document outlining strategic direction, process improvements and performance measures, called a balanced scorecard (see copy attached). Creation of the system scorecard requires that management come together on our areas of focus and prioritize our activities. The system scorecard draws attention to performance measures across six strategic objectives, including clinical excellence. It identifies the high leverage areas in which we believe focused

action can deliver dramatic performance improvement. The balanced scorecard exercise also reminds us that our activities involve a great many processes that require ongoing, balanced attention to sustain high performance.

We created balanced scorecards for each of our seven community care systems and for our system-wide businesses such as the pharmacy and laboratory organizations. In addition, many of our individual departments have created scorecards that link to the Fairview Health Services scorecard. We created stretch goals in our performance measurements to challenge our reliance on current processes. Focused measurement areas, such as diabetes management in the clinical excellence area, permit us to align activities better to achieve goals. While still in evolution, the scorecard has served as a key focal point to align the company around process improvement.

During the past two years, we have undertaken process improvement projects designed to increase the quality of our performance and productivity. This effort helps to ensure that the patient safety agenda remains consistently on the minds of everyone within Fairview.

Our commitment to process improvement also is expressed in management action. With assistance from Motorola, 3M and others who have applied the tools successfully, we have pursued an understanding of the Six Sigma concept and the rigorous process improvement tools available to assist us. Several dozen of our employees, including those in senior management, have trained in process improvement techniques at the Juran Institute within the University of Minnesota's Carlson School of Management. We have spread this expert knowledge at various levels within our own employee base to help spark process improvement projects throughout the company. I am currently involved in the Juran process improvement training, and am working on a project team that focuses on how we handle sterile surgical instruments.

C. Congress can help

Congress can help by encouraging and supporting organizations focused on collaborative process improvement across the industry (e.g., The Institute for Healthcare Improvement, The National Quality Forum and others).

VI. The Quality Challenge

Health care organizations need to focus process improvement efforts on those areas identified as "root causes" of unsafe care. In its 2001 report, *Crossing the Quality Chasm*, the Institute of Medicine underlines several reasons for inadequate quality of care. I'd like to talk briefly today about three of them:

- Chaos and fragmentation within a poorly organized health care industry
- Increase in chronic conditions
- Growing complexity of science and technology

I want to share with you examples of the initiatives Fairview Health Services has undertaken to address these inadequacies and what you can do to help enhance the quality of health care delivery.

A. Challenge One: a disorganized system of care
When the health care system works seamlessly, it can be a wonder to behold. Fairview is comprised of seven regional care systems that operate as a total health care provider system. With a hospital as its hub, each is comprised of primary care and specialty clinics, a full range of rehabilitation services, pharmacy services, home care, hospice care and elder care. When patients move among our care systems seamlessly, they access the care most appropriate to their needs. As one patient summed up her experience, *"My son and I died, but you saved our lives."* At nearly eight months pregnant, her heart started failing. She arrived at one of our community hospitals in labor and gasping for breath. A helicopter transferred her to Fairview-University Medical Center in Minneapolis, where she delivered her son by Caesarean section and underwent heart surgery. For this patient, the system worked spectacularly.

Fairview's efforts
Heparin project. Sometimes the system doesn't work even at the best and most prestigious health care institutions. Paper records get lost or delayed, or patients get the wrong drug or the wrong dose. The media is littered with heart-breaking examples of cases that harden our resolve to make systems work better. For example, we are working to spread across our system the gains of a project at Fairview Southdale Hospital in Edina that successfully reduced reported overdose incidents of heparin, a powerful blood thinner, by 66 percent over four months. Staff achieved these gains by consolidating a heparin order form with a medication documentation record, as well as other administrative changes, thereby simplifying the process and reducing the potential for errors.

Hospitalized patient drug therapy. In another recent process improvement effort, a Fairview Southdale Hospital team created a new practice to ensure that a newly hospitalized patient's current, complete drug therapy is integrated accurately with in-hospital medication. I'm pleased that this team has reduced medication errors in their hospital area by 84 percent. Staff created a new form both to record medication histories and for use by physicians to order home medications. Pharmacy technicians deployed to the surgical admission area record medication histories to gather complete information, instead of relying on surgeons who may not be familiar with specific drug therapy or doses.

Investing in an ambulatory medical record system. Part of our system has access to an ambulatory electronic medical record that puts patient information at the fingertips of caregivers, solving many problems associated with paper records. With electronic medical records, physicians can access patient information from any site in the system or even from home. Information can be updated instantly for real-time data on current test results. Information is accessible from anywhere in the system or from any computer with Internet access through a tool called a portal. In the words of one clinic physician:

"I had seen a patient who had a fairly serious problem. I wanted to be able to get the lab results back to her as soon as possible. I couldn't get the paper test results until the next

day. However, the results were available electronically. I just got on the portal, reviewed the test results, and was able to call her and discuss the results that evening from my home. She was relieved and reassured and surprised that I was able to get her results and call her while I was at home. When my patients are happy and get better care, I love it."

A special physician medication and test-ordering feature also provides automatic alerts for allergy or drug interactions at time of medication ordering. Such knowledge-based ordering allows the physician to change a medication order if needed for better safety and effectiveness.

Advanced access scheduling. Also on the ambulatory side, I'm pleased with a recent series of system changes at several of Fairview's clinics. An effort called same day access scheduling allows patients to see their own doctors on the day of request for better continuity and stability of physician/patient relationships. While we still offer urgent care for same day response to acute problems, same day scheduling allows patients to see their own physicians for more seamless care.

Collaborating on standardization. As mentioned earlier, Fairview is participating in a community effort to fight chaos and fragmentation through a surgical site marking project to establish standardized protocols for marking of surgical site in every hospital in the metro area. Ten local health care systems are participating in the effort, which was two years in development.

Congress can help

Congress can help by supporting funding for ambulatory electronic medical records which will result in better integration of patient data.

The Centers for Medicare and Medicaid Services (CMS), in developing Medicare payment methods, has recognized that certain costs are difficult to accommodate appropriately in developing prospective payment system rates and paid them through various pass through methods.

Such legislation could work like a capital-pass through for Medicare or like the Hill-Burton language, which helped hospitals invest in bricks and mortar. Today we need bytes and memory to help health care providers deliver appropriate, safe care to patients.

While the costs of information systems are covered by hospital inpatient and outpatient prospective rates and are considered in determining the annual update factor, increases related to new technology allowed in update factors usually are offset by assumed increases in productivity or other cost savings. We recommend funding to pay for information technology systems related to clinical process improvement and safety. These funds should be used to pay hospitals that implement systems under cost pass through methods.

B. Challenge Two: rise in chronic illness rates
People are living longer than they did even a generation ago, and health care advances can take some of the credit. But as Americans age in larger numbers, the percentage of the population with such chronic illnesses as diabetes, obesity and heart disease are going up as well. Some 19 percent of the population has chronic health conditions, according to the Centers for Disease Control. Chronic conditions, lasting more than three months, are the leading cause of illness, disability and death, according to IOM's *Crossing the Quality Chasm*. Often, clinicians can deliver the best and most cost-effective treatment in non-hospital settings like clinics or the patient's home. For example, patients with congestive heart failure often have more success managing their conditions with medication and diet at home rather than waiting for a serious episode and going to the emergency room.

Fairview's efforts
I'm pleased with Fairview's efforts over the last three years to create systems to manage patients with diabetes for better overall health and more cost-effective care. This is an important initiative, because diabetes accounts for 25 percent of all Medicare claims. Our data indicate that adults with diabetes are four times healthier in 2003 than in 2000 based on improvement shown on five clinical measures. Staff selected measures most indicative of good clinical management to prevent complications and costly hospitalizations, based on American Diabetes Association recommendations. The clinical indicators included blood pressure levels, blood cholesterol levels and other measures. They created a diabetes registry to help track the measures on all adult patients with diabetes. They also shared results with patients and physicians so that each could make adjustments in compliance or treatment for best results. The percentage of patients meeting all five clinical indicators jumped by a factor of four from 2000 to April 2003.

Congress can help
- Congress can help by reimbursing those health care organizations that show improvements in non-hospital-based treatment of the leading chronic conditions. Fairview supports the new strategy by CMS to improve health care for its 40 million Medicare patients.

C. Challenge three: rapidly expanding complexity of health care science and technology
The Institute of Medicine's *Crossing the Quality Chasm* characterizes health care today as "more to know, more to manage, more to watch, more to do and more people involved in doing it than at any time in the nation's history."

The rapid advances in health care research and related drugs, interventions, devices and knowledge are mind-boggling. From advances in human genome research and its implications, to new robot-aided surgery, few human minds can grasp, understand and remember all of the care alternatives without the aid of even more technology. Yet as

health care systems become more complex, smarter technology can reduce errors and cost.

Fairview's efforts

Investment in an ambulatory electronic medical record. Perhaps one of the most important technology investments a health care organization today can make today is in support of an ambulatory electronic medical record. As I mentioned earlier, the AEMR gives physicians immediate access to full patient information and provides continuity of care for our patients. Our goal is to eliminate handwritten medical records and drug prescriptions, which are a leading source of errors because of such factors as illegible handwriting, transcription errors and misleading abbreviations or symbols. As part of the diabetes project I mentioned, staff is using the AEMR to create standing orders for diabetes patients as well as electronic reminders on patient records to signal the need to update such blood tests as measuring levels of hemoglobin A1c and other important indicators and interventions for diabetes.

Telemedicine. Not only can technology reduce errors, it can also broaden access to specialty health care for parts of Minnesota that might otherwise be underserved. In partnership with the University of Minnesota's Academic Health Center, Fairview can use telemedicine to allow a dermatologist to examine skin lesions or a psychologist to interview and counsel a patient.

Working with vendors to improve equipment. In addition to our technology investment, I am proud of a recent technology process improvement by a team at our Edina hospital. This group eliminated program-related infusion errors on an inventory of intravenous pumps by working with the pump's manufacturer to change a dangerous automated feature. A simple programming mistake using an extra or missing zero could cause a ten-fold over- or under- medication dose. The Fairview group requested that the manufacturer create default amounts and volumes for standard medications. They also created a library of standard doses that the manufacturer has adopted. This project has made our patients safer and saved Fairview money by earning 467 free replacement pumps from the manufacturer.

Congress can help

- Supporting funding for ambulatory electronic medical records, which will result in better integration of patient data.

- Supporting the development of Information Technology (IT) standards to move information within the health care industry and its vendor community. For example, such standards might allow laboratory and electronic medical record systems to share information seamlessly to help ensure consistency in medication ordering and error tracking.

- Supporting the Medication Errors Reduction Act of 2001 would reduce medication errors, and the subsequent deaths and injuries, by improving the

systems of delivering inpatient and skilled nursing care. Specifically, the legislation would:

1. Establish a ten-year, $1 billion grant program for hospitals and skilled nursing facilities to offset the prohibitively high costs of developing and implementing new and emerging patient safety and information technologies, so as to reduce medication errors.

2. Provide grants of up to $750,000 for hospitals and up to $200,000 for nursing facilities, thereby mitigating the cost barriers to the purchase and implementation of new, life-saving technologies. In this way, the efforts of early adopters of new technologies are facilitated and rewarded.

3. Create a 20 percent set-aside in the grant awards for rural providers. Small rural providers are often at a disadvantage for applying for grants because of limited resources. Any money left unused should be made available to non-rural providers.

- Health and Human Services Secretary Tommy Thompson's lead on bar coding is a critical improvement for health care delivery. This effort is expected to improve quality significantly through reduced errors in medications and equipment use. Standardized bar code labeling on all hospital-administered drugs and devices will help ensure achievement of the five rights – right drug, right dose, right time, right patient, right method of administration.

VII. Conclusion

Thank you for your interest in this important issue of patient safety. We will look to Congress for support in helping health care learn from other industries that have confronted and overcome similar safety challenges by creating a culture of continuous process improvements. By addressing chaos and fragmentation, chronic illness and the complexity of science and technology with vision, anonymous reporting and rigorous measurement, health care will achieve the same gains as have other high performing industries. All of our citizens will benefit.

Summary of how Congress can help:

- Holding the health care industry accountable for safe and high-quality care through reimbursement based on the quality of outcomes.

- Encouraging a culture of full disclosure by supporting a non-punitive reporting environment.

- Encouraging and supporting organizations focused on collaborative process improvement across the industry (e.g. The Institute for Healthcare Improvement, The National Quality Forum and others).

- Supporting funding for electronic medical records, which will result in better integration of patient data. This legislation could be like a capital-pass through for Medicare or the Hill-Burton language, which helped hospitals invest in bricks and mortar. Today we need bytes and memory to help health care providers deliver appropriate, safe care to patients.

  The Centers for Medicare and Medicaid Services (CMS), in developing Medicare payment methods, has recognized that certain costs are difficult to accommodate appropriately in developing prospective payment system rates and paid them through various pass through methods.

  While the costs of information systems are covered by hospital inpatient and outpatient prospective rates and are considered in determining the annual update factor, increases related to new technology allowed in update factors are usually offset by assumed increases in productivity or other cost savings. We recommend that funds be provided to pay for the costs of information technology systems related to clinical process improvement and safety. These funds should be used to pay hospitals that implement systems under cost pass through methods.

- Reimbursing those health care organizations that show improvements in non-hospital-based treatment of the leading chronic conditions.

- Supporting the development of Information Technology (IT) standards to move information within the health care industry and its vendor community. For example, such standards might allow laboratory and electronic medical record systems to share information seamlessly to help ensure consistency in medication ordering and error tracking.

- Requiring standardized bar code labeling on all hospital-administered drugs and devices, down to the unit dose.

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Fairview Health Services—Capacity

Fairview Health Services is a community-focused health system providing a complete range of services, from prevention of illness and injury to care for the most complex medical conditions. Services are provided in many settings, including community centers, homes, clinics, hospitals and long-term care centers. Fairview is a not-for-profit organization headquartered in Minneapolis with staff and facilities located throughout Minnesota. The following table summarizes Fairview's 2002 operations:

Total Licensed Beds:	2,240	Occupational Health Resource Centers	2
Inpatient Admissions:	77,658	Institute for Athletic Medicine Locations	5
Total Outpatient Encounters	2,229,531	Hand Center Locations	5
Employees (incl. part-time):	18,400	Counseling Centers	8
Hospitals:	7	Home Care & Hospice Locations	4
Primary Care Clinics:	37	Long Term Care Facilities	3
Retail Pharmacies	29	Adult Day Care Programs	4
Specialty Clinics:	30	Senior Living Facilities	14
Urgent Care Centers	6	Durable Medical Equipment	3

On January 1, 1997, Fairview merged with the University of Minnesota Hospital and Clinics. This merger enabled Fairview's affiliation with the University's Academic Health Center, which includes the University Medical School and other health science schools. This merger gives the state's premier medical research and education programs an opportunity to thrive in an environment that preserves academic integrity while offering patient-centered, high-quality, cost-effective services. Fairview's provider partnerships include Fairview Health Services, Fairview Physician Associates (FPA), Behavioral Healthcare Providers, and the Ebenezer Society, a senior-care organization. In every area of medicine, from heart transplant surgery to cancer treatment, we rank among the nation's most respected teaching institutions. Fairview offers a patient care environment that balances leading-edge technology and treatments with personal concern – quality care delivered by a staff that demonstrates Fairview's values of service, dignity, compassion, and integrity.

Testimony of
Dianne Mandernach, Commissioner
Minnesota Department of Health
Before the United States Senate
Permanent Subcommittee on Investigations
Hearing on
Patient Safety: Instilling Hospital with a Culture of Continuous Improvement

June 11, 2003

Thank you for providing me the opportunity to participate in this very important hearing. I am Dianne Mandernach, the Commissioner of the Minnesota Department of Health.

Today I am pleased to share with you some very exciting steps that the State of Minnesota has recently taken to establish a process for the mandatory reporting of serious adverse events, commonly referred to as "medical errors." These efforts go beyond the mere reporting of the events to include the review of information on the underlying cause of the events, the review of corrective actions taken by the reporting hospital, dissemination of information regarding these events and public reporting by type and location of the event. This law integrates many of the recommendations of the Institute of Medicine (IOM) but more importantly, the law provides for accountability within hospitals and to the public. Before discussing the specifics of our legislation, however, I would like to make a few general comments on the issue of patient safety.

Since the 1999 release of the Institute of Medicine's landmark report on patient safety; To Err is Human, we have been flooded with information on this issue from a variety of sources – the media, professional associations, government agencies, and academia. However, the issue of patient safety has been one of my core values for many years.

As the former CEO of a hospital in northern Minnesota, I was very aware of the need for assuring that systems were in place to promptly and accurately identify both errors and potential errors, often referred to as the "near misses." It was my responsibility to assure that steps were taken to quickly, fairly and objectively review any incident and then to make sure that corrective actions were implemented to minimize the occurrence of similar events. The need for ongoing, continuous quality improvement within every institution is a theme that we have repeatedly heard today. I strongly support the initiatives that are being taken by the Joint Commission regarding the reporting of sentinel events as well as the efforts of the Agency for Healthcare Research and Quality (AHRQ), the Leapfrog Group, the National Patient Safety Foundation and the National Quality Forum (NQF). However as the topic of the hearing suggests – instilling hospitals with a culture of continuous improvement, - we must understand that the efforts taken within the hospital will always be the most important, the most direct and the most timely to truly minimize and prevent the occurrence of medical errors.

As Commissioner of Health, I am ultimately responsible for assuring that the care and services provided in state licensed facilities protect the health and safety of patients. Every media story reporting on the serious consequences of medical errors reinforces this need to assure that there is public accountability and follow-up on these serious events.

The formation of the Minnesota Alliance for Patient Safety (MAPS) was one of Minnesota's key responses to the IOM report. MAPS was jointly established by the Minnesota Department of Health, the Minnesota Hospital Association and the Minnesota Medical Association with the mission to "promote optimum patient safety through collaborative and supportive efforts among all participants of the health care system in Minnesota." MAPS now consists of over 50 health care related organizations. MAPS has become a collaborative forum to discuss the implications of medical errors in the health care system; to provide educational and training programs, and to disseminate the successful efforts undertaken by hospitals to reduce errors. The public/private make-up of MAPS has provided opportunities for frank but open discussion on many of the sensitive issues surrounding this topic – access to information, confidentiality, public reporting, legal liability, and others. Without this collaborative process, passage of our mandatory reporting law would have been much more difficult if not impossible. As chair of the Minnesota Hospital Association, David Page played a pivotal role in convincing other hospitals to actively participate in MAPS and the importance to support the efforts to improve patient safety.

The need for and the development of a mandatory reporting system was one of the more controversial discussion topics undertaken by MAPS. Concerns were raised about the benefits of a mandatory versus voluntary reporting system, the types of events to be reported, the ability to analyze the information to identify trends, the ability to provide appropriate follow-up and recommendations for change and the role of government in this process. A subgroup of MAPS was established to review the provisions of the Minnesota's current reporting law, to discuss elements that would be included in any effective medical error reporting system and to prepare recommendations for changes for the 2003 legislative session. I am very pleased that these efforts lead to the bipartisan sponsorship and passage of our Senate File 1019, the Minnesota Adverse Health Care Events Reporting Act of 2003.

One of the key attributes of this law is the inclusion of the reportable events recommended by the National Quality Forum. This list of 27 "never events" i.e., events that should never occur in a hospital such as wrong site surgery, represented a consensus of many interested parties as to what should be included in any mandatory reporting system. This list provided an effective starting point for a medical error reporting system. It is our understanding that Minnesota's law is the first ever in the nation to specifically incorporate the NQF recommendations. The NQF list was consistent with the criteria established by the IOM that a mandatory reporting system focus on serious adverse events and that the events to be reported be defined as clearly as possible.

However, in order to take steps to provide patient protection, any reporting law must go beyond the mere collection of statistics. Our reporting law mandates that information be reported as to the cause of the error as well as the corrective actions taken by the facility. These crucial elements address our concerns as to internal and external accountability and assure that appropriate actions are taken in the facility to protect patient health and safety. In addition, the law directs the Commissioner to review the information to determine whether trends or system problems are being identified and to also furnish information to all providers to assist in the improvement of their patient safety systems.

While Senate File 1019 made significant changes to the reporting laws in the state, the legislation was discussed, debated and enacted in an environment of consensus. As with every piece of legislation, the fine points of the law were often debated; but there was no serious opposition to the need for the law or its value to the enhancement of patient safety. The collaborative process of

MAPS, and the public/private nature of that organization was an asset during the legislative deliberations on the bill.

The major stumbling block to passage was the fiscal impact of the bill in a legislative session focused on dealing with major budget deficits. A "transition plan" was proposed that would allow for a phased implementation of the law. A key provision was the agreement that the Department would not be required to implement the law until sufficient non-state funds were obtained. Bill proponents, and especially the Minnesota Hospital Association believed that the initial start-up funds of approximately $125, 000 could be obtained from either private sources or through grants. The willingness of the hospitals to secure the necessary funds to implement the transition phase of the bill was strong recognition of the commitment to this process.

The transition phase requires that hospitals report the 27 events to the incident reporting system currently maintained by the Hospital Association and requires that the Department be provided summary data on the numbers and types of reported events. This information will for the first time provide a clear picture of the magnitude of the occurrence of medical errors in the state.

We are aware that many states have established systems for the reporting of medical errors. However, we are proud that our law is based on the 27 "never events" recommended by the NQF. The inclusion of these events, which were based on a consensus process among many stakeholders, will hopefully minimize underreporting or non-reporting of the events. This specific listing will allow for easier trend analysis within the state. The use of this listing greatly contributed to gaining consensus on the mandatory reporting law.

There are some recommendations and suggestions that I would like you to consider in the future.

We would encourage a national system that would focus on the mandatory reporting of these specific events. I realize that this will generate some problems for states with existing reporting systems; however, this is the only way that we can get a national perspective on the true extent of this problem. The collection of clearly identified events across state lines will also assist in the identification of trends, the identification of system problems and will encourage more collaborative responses to improving patient safety.

A part of this recommendation is a request for obtaining funds to support these efforts. We realize that funding is always a concern but if steps can be taken to minimize the extent of medical errors, the price paid for these systems will be money well spent. Funding could be directed at the development of demonstration projects or pilot programs to allow for an analysis of the effectiveness of various state systems. However, we are well past the time for continued discussion and debate and systems need to be put in place as quickly as possible.

We hope that the efforts of AHRQ and other organizations continue to address these concerns and to provide information on both public policy and clinical issues. While mandatory reporting is very important, there needs to be continuing efforts to assure that hospitals and other health care facilities have the resources and tools to continue their efforts in developing effective internal quality improvement systems. The federal government should continue to support research in patient safety.

Finally, we encourage that steps be taken through the Medicare and Medicaid survey and certification programs to address both the internal and external reporting of medical errors. Regulations and regulatory agencies should balance the need for public accountability and safety with the need for internal quality improvement efforts. Consistent expectations for the reporting and monitoring of these events and funding for these activities is a critical component to provide accountability to the public that we represent.

I would be happy to respond to your questions.

United States Senate
Permanent Subcommittee on Investigations
Hearing On
Patient Safety: Instilling Hospitals with a Culture of Continuous Improvement
342 Dirksen Senate Office Building
9:00 a.m.
June 11, 2003

Submitted By

Robert E. Krawisz
Executive Director
National Patient Safety Foundation

Patient Safety: Instilling Hospitals with a Culture of Continuous Improvement

I. Case for Change

In 1999, patient safety came into the national spotlight with the November release of the Patient Safety Report by the Institute of Medicine (IOM) of the National Academy of Sciences. The IOM report revealed that 44,000 to 98,000 deaths occur annually due to health care errors. The IOM recommended a four-point plan to reduce errors by 50% over five years: [1]

- Establish a Center of Patient Safety to create national leadership, research, tools and protocol
- Identify and learn from health care errors through mandatory and voluntary reporting
- Raise standards and expectations for safety improvement through actions of oversight organizations, group purchasers and professional groups. Create a culture shift to make safety a top priority.
- Implement safe practices at the delivery level

The second IOM report was released in February 2001. It concluded that the U.S. healthcare industry has failed resoundingly in its ability to consistently provide safe, high quality care to all Americans. The IOM stated that health care is decades behind other industries in terms of creating safer systems. It is the only industry that doesn't know its defect rate (most likely 3-4 sigma). Today, most hospital executives agree that the industry needs a system for capturing, interpreting and acting upon medical errors data. A new agenda was proposed to build a health system for the 21st century: [2]

- Commit to a national statement of purpose for the health care system as a whole
- Engage the Department of Health and Human Services to: Identify a set of priority conditions (chronic); create an infrastructure to support evidence-based practice; expand the knowledge of the workforce.
- Make the health care system safe, effective, patient-centered, timely, efficient and equitable
- Formulate rules to redesign and improve care
- Align payment incentives to have a stronger focus toward quality
- Create an agency for health care research and quality---15 priority conditions
- Leverage information technology...the Internet, video and satellite teleconferencing to widely disseminate information for supporting clinical decision-making

Prior to the IOM reports, there was trouble. The Harvard Medical Practice Study's 1991 publication on the frequency of adverse events in hospitals revealed that iatrogenic injuries occur in 3.7% of hospitalizations. JAMA reported in 1995 that 2.5% of admissions are iatrogenic.

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[1] Institute of Medicine, *To Err is Human: Building a Safer Health System, 1999.*
[2] Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century*, 2001.

II. Why is Change so Difficult in Healthcare?

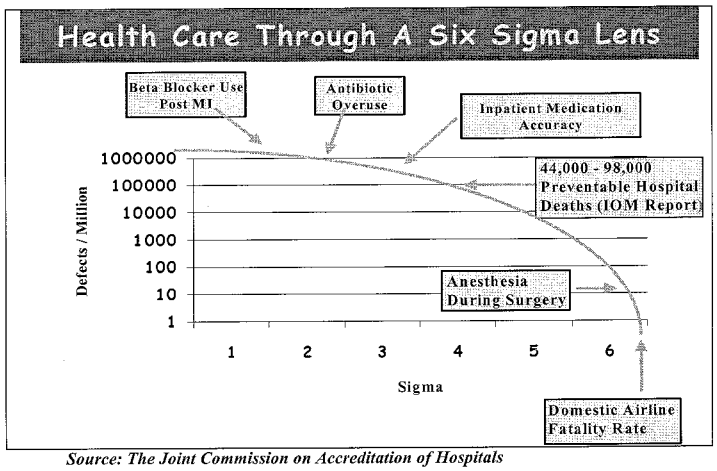
Healthcare is a 1.4 trillion dollar industry which is still based on a pre-industrial revolution craft model—train the clinicians, leave clinical care to them and create parallel administrative/management processes to provide resources for what clinicians do. The legacy of this practice is huge variation in clinical practice, harm to patients, inefficiency, paralyzing misunderstanding and conflict between clinicians and managers.

Regulation and the learning sciences shaped medicine's craft heritage. Regulation of health care started with the Code of Hammurabi in 1750 BC and was influenced by development of the legal system. State Boards added refinements to the regulatory process in the late 1800's and early 1900's. Further enhancements came from hospital accreditation, the opinions of peer review organizations and report cards such as HEDIS and ORYX. Improvements from the learning sciences stemmed from the work of Hippocrates, Nightingale, Codman, and the American College of Surgeons, M&M Conferences and the concept of disease management. The problem with this system is that complex health care processes were unsupported by a carefully designed error-proofing infrastructure. They relied on people checking people during a growing number of "hand-offs".

What happens when processes evolve in a craft-based culture? Highly educated and committed caregivers work within the context of two key factors over which they have no control: the fundamental design of healthcare and the vast complexity of modern healthcare. The processes that evolve contain hazards that can result in fatalities and near misses. Thus, the performance capability of the system ranges from 2-4 sigma (refer to Exhibit I).

Exhibit I

Sigma Level of Health Care Processes



Source: The Joint Commission on Accreditation of Hospitals

During the 20th century, management science was developing and starting to make dramatic quality and safety improvements in other industries. Some say that health care is 50 years behind these industries. The solution is using column three techniques to improve health care.

Quality: 3 Historic Pathways

Regulation	Learning Sciences	Management Science
Hammurabi	Hippocrates	Industrial Technology
Legal System	Nightingale	Tailor: Scientific Management
State Boards	Codman, ACS/Hospital Standardization	Shewart: Statistical Process Control
JCAHO Accreditation	M & M Conferences	Deming, Juran, TQM, Baldrige, ISO
PRO/NCQA	Donabedian, structure, process outcome	Human Factors Engineering
Report Cards (HEDIS< ORYX)	Disease Management	Six Sigma Breakthrough Strategy

III. Patient Safety and Quality

Many definitions exist for both quality and safety. The simple definition of quality is "meeting or exceeding customer expectations". The simple definition of patient safety is "preventing harm to patients in our care". Quality and safety are related. Quality focuses on meeting or exceeding rising customer expectations. Safety is a sub-set of quality. Safety and quality utilize many of the same performance improvement tools. Process changes that improve safety also result in additional quality-related improvements such as faster cycle time, elimination of rework and waste and lower costs. Healthcare quality problems are often classified into three categories:

- Misuse…avoidable complications of appropriate care
- Overuse…services provided when the risk of harm exceed the potential benefits
- Underuse…failure to provide an effective service that would produce a favorable outcome

Misuse is clearly a growing safety problem. In the 2002 Commonwealth Study, more than 20% of adults reported that they or a family member experienced a medical or prescription drug error.

Overuse is a quality problem, but could also be a safety issue. For example: an estimated 40% of hysterectomies are inappropriate or have questionable value and an estimated 21% of all antibiotic prescriptions are written for viral infections.[3]

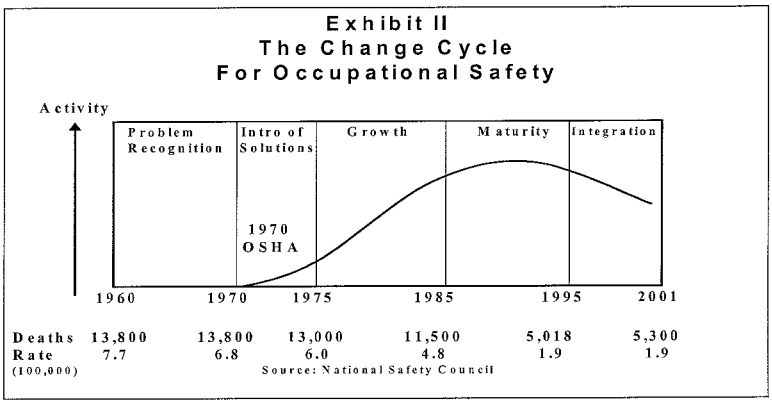
Underuse is also primarily a quality problem, but could be a safety issue as well. An estimated 60% of patients diagnosed with depression receive no medication and studies show that Beta blockers are given to heart attack patients only 25-40% of the time.[4]

[3] St. Joseph's Hospital, West Bend Wisconsin
[4] Ibid

IV. How Long Does it Take to Change an Industry?

A question that is often asked is, how long does it take to change the culture and performance of an industry? Are we making progress in patient safety? We can turn to the transformation of occupational safety and quality in the U.S. for the answer.

The change cycle consists of five stages: problem recognition, the introduction of solutions, growth in prevention activity, maturity and integration. The problem recognition phase usually lasts about ten years as an industry struggles with denial. Once there is a commitment to find solutions, the length of the change cycle depends on the amount of support that is provided and on the strength of the economic business case. It took about 25 years, after the formation of OSHA, to change the culture in occupational safety and secure dramatic performance breakthroughs as outlined in Exhibit II. The quality transformation in the United States was faster with major improvements in place in the mid-1990's following the Baldrige Act of 1987.



The Harvard Medical Practice Study's 1991 publication on the frequency of adverse events in hospitals became the initial focus for discussion in patient safety. In 1996, the decision to create the National Patient Safety Foundation was made during the first Annenberg conference. The final catalyst for change came in 1999 with the release of the first IOM Report, *To Error is Human: Building a Safer Health System.*

We are near the end of the search for solutions phase. In 2001, HHS announced the formation of the Patient Safety Task Force and its $50 million investment to improve patient safety. There are numerous patient safety bills moving through Congress. We are have learned the benefits of full disclosure, identified numerous best practices and adopted management science techniques such as human factors engineering, root cause analysis, FMEA, DOE and Six Sigma. The patient safety movement is gathering steam moving into the growth stage of the change cycle.

V. NPSF's Role in Leading Patient Safety Through the Change Cycle

The National Patient Safety Foundation instills a culture of continuous improvement in hospitals. First, we provide unique opportunities to *network* and identify best practices. The need for action is reflected in the theme of NPSF's 5th Annual Patient Safety Congress: "Lets Get Results" and also in its Integrity and Accountability in Clinical Research Conference.

NPSF creates *awareness* of patient safety issues through its public outreach activities such as National Patient Safety Week which takes place in March, its media relations efforts which generated more than 24 million impressions during the past 12 months and its Web site which receives more than 400,000 visits each month. In addition, NPSF's *Focus* newsletter reaches more than 6000 subscribers and its Listserv continues to grow with more than 2,300 participants. Patients can also demonstrate their support for patient safety by becoming a member of NPSF.

NPSF established the Patient and Family Advisory Council to provide guidance and patient perspective on all of NPSF's activities. In March, we released a National Agenda for Action to Support Patients and Families. It provides a high-level road map for action in four areas: education, culture, research and support services. The first step is to raise awareness on these issues. The second step is to address how these actions should be implemented and funded. The complete agenda is included as Exhibit III.

There are a variety of *educational* opportunities. The Patient Safety Store provides the best single source for securing patient safety videos and publications. The Patient Safety Information Center publishes the most comprehensive list of patient safety publications through Current Awareness and its Bibliography. Training is offered through NPSF's Web based patient safety series for physicians, nurses and patients. In 2003, the National Patient Safety Foundations will launch the Training Institute for Patient Safety, which will offer in-house, and classroom training.

NPSF also *convenes* healthcare leaders to reach consensus on patient safety issues and solutions. Using the Harvard Executive Model, Minnesota hospital CEO's have agreed to collaborate and not compete on patient safety. They served as the catalyst for creating model state legislation on disclosure and reporting and have agreed to deploy numerous best practices. Through NPSF's Stand Up for Patient Safety Program, hospital and system CEO's will establish their own agenda for patient safety. NPSF will assist these organizations in creating action learning projects to test improvement strategies linked to this agenda. Stand Up hospitals also participate in monthly audio conference calls and workshops to secure information from thought leaders on important issues such as building safety into new construction, disclosing medical errors, creating Patient and Family Advisory Councils and dealing with hospital workforce shortages. The Corporate Council program provides an opportunity for suppliers to establish an ongoing dialogue with hospital executives that will lead to patient safety solutions. Under the NPSF umbrella, the Corporate Council will conduct demonstration projects intended to further patient safety and construct components of the associated business case.

VI. Breakthrough Strategies

There are several evidence-based strategies that are starting to produce dramatic quality and patient safety improvements. The challenge is to ***close the gap*** between what is known and what is being practiced in most hospitals. The National Patient Safety Foundation's dissemination strategy plays an important role in closing performance gap.

(A) The Baldrige Healthcare Criteria provides an excellent framework for managing the enterprise and securing performance improvements. Hospitals can set their sights on winning the award or just following the criteria. SSM Healthcare in St. Louis is the first award recipient in healthcare. Results include:

- A 50% reduction in mortality rates in coronary bypass surgery
- Significantly lower readmission rates for congestive heart failure and pneumonia
- A drop in the length of stay of Medicare patients resulting in an annual savings of $5 million
- Significant increases in patient satisfaction and market share during the past three years

(B) A full disclosure policy provides the information essential for identifying problems and developing breakthrough solutions. There are two axioms of disclosure. No one makes an error on purpose and no one admits an error if you punish them for it. NPSF distributed the following statement of principle on disclosure to all hospitals:

When a healthcare injury occurs, the patient and the family or representative is entitled to a prompt explanation of how the injury occurred and its short and long-term effects. When an error contributed to the injury, the patient and family or representative should receive a truthful and compassionate explanation about the error and the remedies available to the patient. They should be informed that the factors involved in the injury will be investigated so that steps can be taken to reduce the likelihood of similar injury to mother patients.

Full disclosure provides data to analyze problems and find solutions, improves patient and family satisfaction and reduces malpractice litigation. SSM healthcare established a "blame free zone" for staff to report errors and near misses. This has led to numerous system improvements. Many other hospitals have also adopted effective disclosure policies.

(C) Another important strategy is engaging patients and families to develop valuable new perspectives. They experience the gaps and fragmentation in the healthcare system. Patients and families keep health care professionals and leaders honest and grounded in reality and they provide timely feedback, new ideas and additional creativity. The result is improved quality and safety and reductions in malpractice allegations.

Patient and Family Advisory Councils were first introduced in children's hospitals and pediatric units in the 1980's. They are typically composed of between 12 and 30 patient and family members who meet regularly to propose and develop programs, policies and services. This concept quickly spread to a variety of hospitals.

Dana-Farber Cancer Institute created its first Patient and Family Advisory Council in 1998. Successes include:

- Patient-faculty programs to help first-year oncology fellows understand the patient experience
- Solutions for reducing infections among neutropenic patients
- Eliminating confusion over provider (residents, interns, nurses and attending physicians) roles and responsibilities
- Changes in architectural plans to build in safety and reduce patient anxiety

The typical breast diagnosis process was built around the needs of practitioners. It asks an anxious woman with possible breast cancer to go from doctor to doctor, place to place and healthcare silo to healthcare silo before see learns whether or not she has cancer. There is a lot of variation in cycle time, which averages 1 to 8 weeks. The Park-Nicollet Health System built a breast diagnosis process around the needs of patients and families. Cycle time was reduced to 2 to 4 hours.

(D) There are numerous process improvement tools that hospitals can use to evaluate processes and identify solutions. Examples include process mapping and analysis software, failure mode and effects analysis (FMEA), root cause analysis, design of experiments and comprehensive six sigma programs. Six sigma has set a new standard for organizations in a variety of industries that are reducing errors to only 3.4 per million opportunities. Froedtert Hospital in Milwaukee utilizes the six sigma methodology extensively to reduce process variation. Successes include improving outcomes with high-risk medication and *reducing* the variability of PCA infusion pumps, cycle times in analyzing lab specimens and patient falls.

(E) The National Quality Forum released 30 evidence-based safe practices in May 2003. Hospitals can secure dramatic improvements in quality and safety by adopting these practices to achieve the following goals:

- Creating a culture of safety
- Matching healthcare needs with service delivery capabilities
- Facilitating information transfer and clear communication
- Adopting safe practices in specific clinical settings or for specific processes of care
- Increasing safe medication use

VII. Barriers to Improving Patient Safety and Quality

A recent NPSF environment scan uncovered ten forces that will inhibit hospitals from management practices designed to improve patient safety and quality. The Delphi methodology was use to rank order these forces by importance.

(A) Hospital Workforce Shortages (Delta mean: 3.78)

Trend: The newest threat to America's health care system is a growing shortage of hospital personnel. Problems persist in recruiting and retention creating safety issues.

Implications: Hospitals across the country are struggling to find qualified staff to serve their communities' needs. Unfilled positions in nursing units and in pharmacies, laboratories and x-ray departments cause delays in care delivery. Emergency departments close to ambulances, surgeries are postponed and inpatient and outpatient capacity is reduced.

Observation: Up to 168,000 hospital positions are unfilled in six job categories (75% of the openings are for nurses). Pharmacists have the highest percent of unfilled positions. The root cause is declining enrollment in health education programs, an aging workforce, competition from other health care employers and compensation issues. [5]

[5] The Lewin Group, *AHA Trend Watch,* June 2001, Vol.3. No.2. p. 2.

(B) The Internet is Leveling the Playing Field for Patients (Delta mean: 3.74)

Trend: A growing number of patients are going online to find treatment alternatives.

Implications: Patient demand for the latest drugs and treatments will increase. Physicians are being forced to share decision-making power with patients. Safety may be compromised as patients start making their own assessments without expert consultation.

Observation: In 1998, more than 17 million people in the U.S. went online to research medical conditions on their treatment.[6]

(C) Need for New Designs in Healthcare (Delta mean: 3.65)

Trend: Unless action is taken, the total cost of poor-quality healthcare could run over $1 trillion by 2011.[7] The modest rate of change demonstrated by improving technologies focuses attention on the need for and potential of new designs for healthcare.

Implications: Healthcare organizations are searching for new solutions, however, funding new designs will be a problem for many providers. Technology promises benefits with huge financial risks.

Observation: Healthcare organizations are abandoning continuous improvement strategies.

(D) Patient Safety Legislation (Delta mean: 3.55)

Trend: The AMA is actively working with the Bush Administration and Congress to introduce federal legislation that provides strong legal and confidentiality protections for information that is voluntarily shared to improve patient safety.[8]

Implications: Strong legal and confidentiality protections will be available for information that is voluntarily shared. This will enable the development of metrics to drive process improvements and measure results.

Observation: Accurate data is needed to measure performance, identify root causes and test improvement solutions.

(E) Technology Promises Benefits with Huge Financial Risks (Delta mean: 3.45)

Trend: Growth and interest continues in IT strategies to streamline services and serve patients in innovative ways. Investment in genomics continues to grow. Organization web sites reach out to patients and providers (such as Allina and Mayo).

Implications: IT requires huge portions of provider capital budgets. The net cost benefit of genomics remains to be determined. Complimentary therapies continue to grow amounting to $13 billion in out of pocket expense for patients.[9]

Observation: The cost benefit of many investments is still unknown.

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[6] Ibid, p. 21.
[7] Ibid, p.18.
[8] AMA Advocacy Report, March 2002.
[9] The Institute for Healthcare Improvement, 2002 Business Plan.

(F) Growing Outpatient Care Increases the Need for Patient Support (Delta mean: 3.44)

Trend: Ambulatory patients in office settings are not receiving the same quality of care as in hospitals.[10]

Implications: If this trend is not fixed, inappropriate and unreasonable regulation may result. In addition, the safety record of outpatient care will remain below acceptable levels.

Observation: There is a lack of appropriate staffing with credentialed providers. There is also a lack of concordance between safety, quality and cost.

(G) Consumers Expect More from Healthcare Providers (Delta mean: 3.40)

Trend: Purchasers are becoming more discriminating in selecting providers. There is significant tension for change to make improvements.

Implications: Dissatisfaction drives litigation. High expectations place pressure on provider profit margins. Weak providers will fail. This environment provides competitive advantages for innovators. Patient safety should improve.

(H) Workforce Stress will Continue in Healthcare (Delta mean: 3.38)

Trend: Labor shortages, low worker morale and staff retention highlight the increasing importance of human resource issues to system and medical group executives. Human resource themes were the top three issues identified by the National Forum participants.[11]

Implications: Labor shortages, low worker morale and high turnover drive poor quality and safety. The aging nursing workforce and faculty raise concerns about the future of nursing.

Observation: Aging baby boomers will create surging demand for healthcare services of all types.

(I) Quality Measures Becoming More Prevalent for Healthcare Purchasers (Delta mean: 3.35)

Trend: Problems of preventable errors and overused, misused and under used tests, treatments and procedures are largely hidden from purchasers and consumers.

Implications: Unless action is taken, the total cost of poor-quality healthcare could run over $1 trillion by 2011.

Observation: Purchasers can play a leadership role in addressing the cost of poor quality care as evidenced by the actions of LeapFrog and the Midwest Business Group on Health.

(J) Medical Liability Issues (Delta mean:3.35)

Trend: Malpractice litigation is growing and settlements are becoming larger.[12]

Implications: The medical liability environment undermines patient safety.

Observation: Malpractice insurance is becoming unaffordable causing physicians to abandon practices.

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[10] NPSF *Collaborative Leadership for Ambulatory Surgery in the Office Setting*, September 2002.
[11] The Institute for Healthcare Improvement, 2002 Business Plan.
[12] AMA Advocacy Report, March 2002.

VIII. Benefits of Improved Performance

In a recent study, the Juran Institute estimates that the cost of poor quality exceeds 30% of all direct health care outlays, consisting primarily of overuse, misuse and waste.[13] With national health expenditures of $1.3 trillion in 2001, the 30 percent figure translates into $390 billion spent each year as a result of poor quality. The advantages of performance improvements include greater patient satisfaction, significant improvements in patient safety and dramatic cost reductions that can be shared with purchasers and consumers.

IX. The Road Ahead for Hospitals

There is a compelling need for all hospitals to close the gap between what is known (best practices) and what is being practiced today. A major lesson learned from occupational safety and quality management is that organizations need a formal program to organize and focus their activities before rapid improvements can take place. The elements of an effective patient safety program include the following:

(A) Secure Management Commitment

Patient safety should be part of a hospital's strategic and business planning process and patient safety improvements should be part of the CEO's compensation. A qualified individual should be designated to manage the patient safety program and adequate resources should be provided.

(B) Create Organization Patient Safety Goals and Objectives

All hospitals need to adopt patient safety goals. This can start with the six Joint Commission goals that were released in January 2003. Additional goals can be added from the lists created by the National Quality Forum, the Leapfrog Group or the National Patient Safety Foundation's Stand Up for Patient Safety Founding and Charter Hospitals. All goals should have measurable objectives to track performance.

(C) Develop an effective Information System

Information management starts by adopting a full disclosure policy and effectively managing patient-specific information. This information should be placed in a database that can be used for analysis and for tracking performance.

(D) Develop an Emergency Response Program (when the unexpected happens)

An emergency response program starts with risk analysis to uncover failure modes and effects. Response plans should be put in place. This includes staff training on disclosure of adverse events to patients and families and the media.

(E) Improve Processes

Process improvements should be continuous. Hospitals can start with the Joint Commission's national patient safety goal requirements and the National Quality Forum's 30 evidence-based safe practices. This effort should be supplemented with the hospital's own process improvement strategy utilizing root cause analysis and other quality tools

[13] Midwest Business Group on Health, Reducing the Costs of Poor-Quality Health Care

(F) Provide Education and Training

In a recent survey of NPSF's Stand Up for Patient Safety hospitals, CEO's indicted that the most important service that they need from outside sources is education. This includes staff training on tools and best practices, Board of Trustee education, leadership activities and patient education.

(G) Utilize Networking Opportunities

Networking is important to identify emerging trends and keep up to date on best practices.

(H) Create and Reinforce Awareness

Constant awareness and reinforcement of hazards and solutions is required to change behavior. Programs include campaigns, such as National Patient Safety Week, along with banners, posters, fact sheets and booklets.

(I) Use Reward and Recognition Programs to Change Behavior

Hospitals can use a variety of reward and recognition activities to change and reinforce positive behavior. These include local celebrations, awards and monetary incentives.

(J) Enforce Compliance

Compliance can be enforced by demonstrating management commitment, utilizing inspections and walk a rounds and through the Joint Commission's accreditation process.

(X) How Can Congress Encourage Improvements?

There are a number of ways that Congress can encourage greater effort at continuous improvement in healthcare. These include the following:

(A) Providing funding to support the National Agenda for Action for Patients and families including development of a Patient and Family Resource Center

(B) Support a central role for the Agency for Healthcare Research and Quality (AHRQ) in coordinating a multifaceted, multi-industry national patient safety initiative. This should include sufficient funding to carry out research and development activities to support and advance public and private patient safety initiatives across the nation

(C) Creating financial incentives for hospitals to support the business case for patient safety

(D) Support patient safety legislation aimed at protecting confidentiality and promoting disclosure such as HR 663, which passed the House by a nearly unanimous vote in March, or S. 720, which currently awaits Senate action.

Exhibit III

The National Patient Safety Foundation

National Agenda for Action:

Patients and Families

in Patient Safety

Nothing About Me, Without Me

Executive Summary

This summary (and complete document) is a report developed by the National Patient Safety Foundation's (NPSF) Patient and Family Advisory Council. The NPSF promotes safer medical care through prevention of medical error and improving the health care system for all patients. NPSF established the Patient and Family Advisory Council (PFAC) to provide guidance and patient perspective on all of NPSF's activities. The following is the PFAC's recommended initial strategy for developing a patient-centered culture of patient safety in healthcare. This document is a call to action to all hospitals, health systems, national and local healthcare organizations to involve patients and families in systems and patient safety programs. The document provides a high-level road map for action in four areas: education, culture, research and support services. This is a first step to raise awareness on these issues. The next step will be to address how these actions should be implemented.

I. Education and Awareness

In the next three years, NPSF will take a leading role by providing a central clearinghouse and interactive resource center for education, training and resources on patient safety and prevention of medical error for patients and professionals.

Actions that need to be taken in individual hospitals and health systems (with leadership from NPSF and through the Stand Up for Patient Safety Campaign) include:

- Establishing interactive, interdisciplinary education programs that bring together patients and professionals by targeting:

  1. The general public, including patients, families, media
     Message topics:
     - Definition and principles of patient safety
     - Frequency of medical error
     - How to safeguard your own care and partner with your providers
     - What to do if you experience a mistake or error

  2. Healthcare organizations and professionals
     Message:
     - Patient/family perspective is important and should be actively integrated into culture of institution.

  3. The behavioral health community, including counselors and social workers
     Message:
     - Experience of medical error differs from other types of trauma — patients and families who experience harm due to a medical error may need specific types of support and advocacy.

II. Building A Culture of Patient and Family-Centered Patient Safety

Meaningful change cannot take place without a fundamental change in the culture of patient safety. The following actions are aimed at building partnerships with patients and families.

In the next three years, NPSF will take a leading role by providing a national forum for sharing and disseminating information to local and state coalitions and initiatives.

Actions that need to be taken by individual hospitals and organizations:

- Teach and encourage effective communication skills for patients, their families and healthcare professionals
- Train and utilize patient representatives for patient safety advocacy in hospitals and health systems
- Implement Patient and Family Advisory Councils in each hospital and healthcare organization
- Incorporate patient and family representation on Boards of Trustees
- Develop patient safety task forces and/or coalitions in each state

III. Research

Suggested areas of internal and external research:

- "Bridging the Gap": Effective methods for building relationships and communication between patients, caregivers, and providers
- Disclosure — Methods and their effects on patients and families
- Short- and long-term effects of integrating patients and families into the healthcare system
- Review of current patient safety information and resources available for patients and families, and their effectiveness
- Post-traumatic stress specific to medical error
- Team relationships (including patients and families)

IV. Support Services

There are three phases of medical error: preventing the error, preventing harm caused by the error, and mitigating the effects of a harmful error.
Support services are needed to address this last category.

In the next three years, NPSF will take the lead in these efforts by providing:
- *A national resource center and information line*
- *A peer resource counseling program to connect patients who have experienced a medical error with trained individuals who have already been through the experience*
- *National training programs*

Individual organizations and local coalitions should provide:
- Support groups
- Disclosure and communications programs

A long-term goal in this area is:
- Emergency line

Conclusion

This National Agenda for Action is by no means exhaustive. It represents a first step in depicting the spectrum of activity needed to address the concerns of patients and families involved with the health care process preceding and following preventable medical error. Through sharing experiences and perspectives with a focus on communication skills and team building, we hope to establish common practices and systems that honor and respect the needs of patients and families. This agenda should serve as a launching pad — not a destination.

Testimony

of

Suzanne Delbanco, Ph.D.

Executive Director

The Leapfrog Group

Before the

United States Senate Permanent Subcommittee on Investigations
Committee on Governmental Affairs

Patient Safety: Instilling Hospitals with a Culture of Continuous Improvement

June 11, 2003

The Leapfrog Group

Good morning. I am Suzanne Delbanco, Executive Director of The Leapfrog Group. Thank you for the opportunity to speak with you today.

The Leapfrog Group was founded by The Business Roundtable (BRT) and works to initiate breakthrough improvements in the safety, quality and overall value of healthcare for Americans. It is a voluntary program aimed at mobilizing employer purchasing power to alert America's health industry that big leaps in patient safety and customer value will be recognized and rewarded.

A 1999 report by the Institute of Medicine (IOM) found that up to 98,000 Americans die every year from preventable medical errors made in hospitals. The report recommended that large purchasers provide more market reinforcement for quality and safety. It is precisely because the scientific literature shows that so many medical errors are preventable that The Leapfrog Group has started its efforts by encouraging employers to take safety "leaps" forward with their employees, retirees and families by rewarding the hospitals that implement significant improvements.

The Leapfrog Group's growing consortium of more than 140 Fortune 500 companies and other large private and public health care purchasers provides health benefits to approximately 33 million Americans in all 50 states; Leapfrog members and their employees spend more than $57 billion on health care annually. Under Leapfrog, employers have agreed to base their purchase of health care on principles encouraging more stringent patient safety and quality improvement measures.

The Mission

The Leapfrog Group's mission is to trigger a giant leap forward in quality, customer service and affordability of health care of all types.

The name Leapfrog signifies the need to make breakthrough improvements and to "leapfrog" the gridlock in the health care system that is keeping us from taking full advantage of the technology and know-how we have today. While we know providers want patients to have the best care possible, they have not been seeing a business case for making the kind of investments required to re-engineer how they provide care to achieve optimal quality and safety gains. Leapfrog chose to focus on the reduction of medical errors to start with because it is a topic that is focused and dramatic enough for purchasers to find common ground, and to engage and activate their enrollees to be concerned about it.

Leapfrog's strategy has two-prongs. On the one hand, it is an organized effort on the part of purchasers to buy right. If purchasers all promote the same safety and quality improvements at the same time we're more likely to see progress – especially if purchasers back up their efforts with incentives that create a business case for providers to implement certain practices. On the other hand, Leapfrog is also about activating and engaging consumers to demand and choose better care. Leapfrog's approach to this is to educate enrollees about how the quality of care can vary and the importance of making informed health care choices.

Initial Leaps in Patient Safety

The Leapfrog Group identified and has since refined three hospital safety measures that are the focus of its health care provider performance comparisons and hospital recognition and reward. Based on independent scientific evidence, the initial set of safety measures includes: computer physician order entry; evidence-based hospital referral; and intensive care unit (ICU) staffing by physicians experienced in critical care medicine.

- **Computer Physician Order Entry (CPOE)** has been shown to reduce serious prescribing errors in hospitals by **more than 50%**.
- **Evidence-Based Hospital Referral (EHR) -** referring patients needing certain complex medical procedures to hospitals offering the best survival odds based on scientifically valid criteria — such as the number of times a hospital performs these procedures each year — can reduce a patient's risk of dying by **more than 30%**.
- **ICU Physician Staffing (IPS)** with physicians who have credentials in critical care medicine has been shown to reduce the risk of patients dying in the ICU by **more than 10%.**

Leapfrog selected these initial "Leaps" because (1) There is overwhelming scientific evidence that these safety leaps will significantly reduce mistakes. (2) Their implementation by the health industry is feasible in the near term. (3) Consumers can readily appreciate their value. (4) Health plans, purchasers or consumers can easily ascertain their presence or absence in selecting among health care providers. These safety leaps are a practical first step in using purchasing power to improve the safety and quality of health care. The Leapfrog Group plans to expand its set of recommendations over the next few years as it identifies other opportunities for breakthrough improvements in the safety, quality and overall value of health care.

Current Progress

In 2001, The Leapfrog Group launched a voluntary, online hospital survey to gauge hospitals' progress toward implementing Leapfrog's three recommended practices. Leapfrog members have sought participation from about 950 urban and suburban hospitals in 18 regions of the country. To date, fifty-nine percent (557) have responded. In addition, more than 250 hospitals outside of the 18 regions have responded to the survey on their own initiative, without a formal request from Leapfrog.

For computerized physician order entry, 5% of responding hospitals currently have instituted the practice. An additional 22 percent say they have specific plans to implement such systems by 2004. This potential four-fold increase is particularly striking considering that this practice is a gold standard for medication error reduction.

Twenty-one percent of responding hospitals currently have specially trained physicians overseeing care in ICUs. Another 15% of responding hospitals indicate plans to enlist intensivists by 2004 – a 75% increase.

Research shows that if urban and suburban hospitals implement these three safety measures, in addition to the nearly 60,000 lives that could be saved and more than a half a million serious medication errors that could be prevented each year, approximately $9.7 billion could be saved annually.

What can Congress do?

While there is much that can be done in the private sector to drive continuous improvement in health care, Congress can facilitate this process in two major ways. First, it can find opportunities to promote the transparency of health care performance information so that individual patients and employers and other health care purchasers can make informed health care decisions. We believe informed decisions will create indirect incentives for improvement in health care. Second, it can find opportunities to encourage demonstrations that work to align financial incentives so that superior providers are rewarded for their efforts, making the economic aspects of health care delivery more conducive to quality improvement.

FDA Consumer magazine
May-June 2003
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The Last Word

Be a Partner in Your Health Care

By Roxanne J. Goeltz

Our health is as much our responsibility as it is our doctors'. It is time to share that responsibility and for the medical profession to encourage and help us in our efforts. We will not be perfect, nor should we expect to be, but we must begin to make our health care journey as safe as it can be.

We need to be a partner in our care, and those of us who have tried are labeled as difficult patients or aggravating family members. Do not accept this label. My friend's mother suffered brain damage because no one wanted to listen to her "overreacting" daughter. No one listened when my friend said, "I cannot wake my mother." She was told that her mother was tired and needed her rest. And in the 36 hours that my friend decided to take a break and leave the hospital, her mother sustained three falls.

This is not a failure of the nurses on duty or the doctors on call. It is a failure in a system that does not provide enough support for those working in it or being cared for by it. A system that has allowed errors to be buried and therefore repeated, instead of learning from them. A system that has not considered how valuable input from the patient and family can be in making it safer.

My brother Mike died three years ago of medical errors after being admitted to a hospital with severe stomach pains. The official cause of death was "blood around the heart," but no one can answer the question of how it got there. Mike's lack of knowledge of specific health problems in our family history and the unwillingness of the medical profession to listen to our requests contributed to his death.

I took one lesson from Mike's death and that is: You don't stay in a hospital alone. I encourage what I call 24/7 care, which is someone in the hospital with you 24 hours a day, 7 days a week. I do not encourage 24/7 to catch a doctor or nurse making an error. I encourage it to help prevent errors by being a partner in your care.

Nine months after Mike died, I had the opportunity to walk the talk.

A tumor was discovered in my chest cavity and I needed surgery to remove it. I set up a network of family and friends and asked them to be partners in my care. They worked with the health care professionals, making my stay as comfortable and safe as possible. They knew the medications I was on and would verify the information when the nurses gave medicines to me. The nurses were happy to answer their questions because we acted as part of the team, not the family police unit checking on them.

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In the hospital I suffered from a blood clot traveling through my heart and into my lungs and was put on Coumadin, a blood thinner. I was scheduled for a second surgery three months later and needed to come off the Coumadin for the surgery. In my appointment with a doctor specializing in blood thinner therapy, we discussed the process of getting me off the drug. I needed to give myself shots and I carefully noted the doctor's instructions.

I went to see a nurse just before the surgery to go over the schedule for my shots, but it was different than what I had written down from my doctor's visit. Did I misunderstand the doctor? I mean, she was the professional and I must have gotten it wrong. The "old" me would have let it go, but after my brother's death, I struggled to become a partner in my care, and this was one of those times to speak up.

She was not happy that I questioned her and began reading the doctor's notes. It was then that I realized how she could have misinterpreted his written instruction. I pointed this out and she offered to check with the doctor to make sure. She called me later and said my understanding was correct.

Remember, this is not about catching someone in an error. It is about being a partner in your care and sharing the responsibility. I wasn't telling her how to do her job, but participating in making sure the care I received was the best and safest possible.

Roxanne J. Goeltz is president of Consumers Advancing Patient Safety and one of the founders of the Patient and Family Advisory Council sponsored by the National Patient Safety Foundation.

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Trial and Error in My Quest to be a Partner in My Healthcare -- A Patient's Story

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Permanent Subcommittee on Investigations
EXHIBIT #1b

Trial and Error in My Quest to be a Partner in My Healthcare -- A Patient's Story

AUTHORS' NOTE:

Presented here is the personal narrative of a cancer patient named Roxanne Goeltz who has become quietly determined -- but very determined -- to be an actual, functioning, decision-making partner in the treatment of her disease, a thymoma that was first discovered in her chest cavity in July 2000. Keep in mind two factors as you read her story. First, Ms. Goeltz's brother (Mike) died in a hospital from what the healthcare literature would call an "unexpected adverse outcome" about six months before her journey into healthcare with her cancer diagnosis. The family suspects medical error in that case, but has not sued. Second, Ms. Goeltz is an air traffic controller by profession and, as such, a seasoned professional player in a complex, dynamic system that is constantly managing the risk of failure.

Ms. Goeltz's experiences are presented with commentary by Martin J. Hatlie, JD, a lawyer who also is the president of Partnership for Patient Safety -- an initiative that works with consumers and healthcare systems to advance the safety and reliability of health care services worldwide.

GOELTZ:

Having looked over notes I've taken in the last two years, I realize the journey I have been on to be a partner in my care is not over and probably never will be. To get where I am now has been a struggle of self-education, since there are no resources readily

available to teach me how to be an effective patient partner. In the healthcare arena of today, the very notion of clinician -patient partnering is only a small seed. Consumers who are trying to be a partner with their healthcare providers are not likely to speak or think in terms of being a partner. What motivated me were my brother's death and the realization we -- the patient and/or family members and friends – have our part to play in increasing our safety in the healthcare system. From that idea grew the belief that I had to be an effective partner with the people treating me.

You can tell if you're dealing with a person like me, because I'm the one asking pointed questions and pushing when I have to for direct and honest answers. I'm also the one doing my own research and bringing in data to back up my concerns. I think you often see patients like me as "difficult" because we may not easily fit into the way your office works or maybe the way you work. The healthcare worker in today's system does not have time to establish the connection that is needed for a meaningful encounter with a partnering patient. Patients like me are not likely to fall in line with the time frame allotted for the appointment. We have learned to understand that your work is time-pressured and driven by economics. However, we can't accept it because to do so would be irresponsible to our families and ourselves. When you establish a "one-way" communication relationship, when you dictate the care you think we need or the circumstances in which we have to fit, when you state your medical opinion and send us out the door, we think you're taking the easy way out. If I'm going to be your partner, yes, I need to be fully informed and I want all the information and advice you have to give. I also need to be heard and to have my thoughts and feelings -- including my fears -- considered. I also want input into the strategy for what my care will be.

HATLIE COMMENTARY:

Recent pronouncements on patient safety from the National Institute of Medicine and others have called for a redesign of the healthcare system to be patient- or family-centered (National Institute of Medicine, 1999 and 2001). Yet too often, an invisible wall separates patients and their clinician that undermines both information exchange and empathic understanding between them. It is at least partially fair to say that this wall was built and is continually reinforced by a legal system that encourages patients and clinicians to become adversaries when something goes wrong. The adversarial system was championed by our forefathers as the best way to see that all factors in an event alleged to cause injury be reasonably brought out and presented to an impartial judge and/or peer jury. As medical malpractice litigation has evolved, however, it's become increasingly angry and sensational. The adversarial process of today more often presents juries with two or more distorted pictures of the facts, as opposed to different perspectives on what really happened. More importantly, it has undermined the free flow of communication and empathy between clinicians and patient that is crucial to producing optimal outcomes.

Ms. Goeltz works professionally in an industry, which respects and relies on the contributions to safety of every team member and culturally strives to keep each person managing risk fully informed. She found herself being treated for cancer in a very different environment, where she wasn't made to feel like a member of the team and where her own sense of responsibility as a patient wasn't always acknowledged.

GOELTZ:

My brother died in September 1999. The first time I visited my clinic after his death was in February of 2000, for stuffiness and earaches that I couldn't shake. It was a very scary experience for me, and I went with my teen-aged son who had similar symptoms. When I think back on it, I wonder if my sickness was a sympathetic reaction to his, motivated by an unconscious decision that I was not going let him go into a system I didn't trust by himself. I also wonder if I was so scared of the doctor, that I needed another reason to get me there.

That visit did nothing to reassure me. There was no real interaction with the doctor. We sat; he listened to our symptoms, prescribed some pills to dry up our congestion, and then sent us on our way. Nothing made me feel like a partner. I took the prescriptions had them filled and started taking them without really paying any attention to what it was we were taking or why.

I went to the clinic again in May, for dizziness and various other rather vague symptoms and remember sitting there, telling myself that I was going to talk to whoever saw me about what happened with my brother, because maybe what I was suffering from was depression. I chickened out, even though the healthcare worker was responsive and seemed interested in me. She listened attentively to the symptoms I gave her, but she also conveyed in her body language and manner that she did not have a lot of time. I did not want to impose, so I gave her a hurried and clipped explanation of how I felt. Why is it that when we go into the healthcare system we have come to feel that it is normal to have to hurry? I think we've learned that from our healthcare workers' example, because

what's normal now is to get hurried, incomplete information from our clinicians. I left with a feeling I can only call resignation and instructions to "give it three more weeks" for my dizziness and other symptoms to go away.

I couldn't wait. Internally I was in shear panic that there was something horribly wrong with me. I'd done some research on the Internet and came up with several possibilities. I had to find someone who would listen, so I called the nurse-line that is available through my insurance. She was patient, listened to my symptoms and suggested that I make an appointment with my doctor to be examined. When I told her my only doctor was a gynecologist, she recommended that I give them a call. When I did so, the person who answered the telephone chastised me. To quote, "Doctor does not see patients for headaches. Call another department." She then ended the call, without any referrals or suggestions about where to find a different doctor. My response was to cry, telling myself that it was obvious why Mike died and feeling very sorry for myself because no one cared. But, after a day of wallowing in self-pity, I realized that I had to take the initiative. It was my health and well being at stake and I had a responsibility to take care of myself.

I went back to the clinic the next day. As I sat in the waiting room, I gave myself a pep talk about how I was going to speak up and talk until I was satisfied that someone heard what I had to say. But I chickened out again! It's amazing to me how I let the system intimidate me into being quiet. The doctor gave me an antibiotic for a slight ear infection and sent me home. I left with my tail between my legs beating myself up for being so weak!

HATLIE COMMENTARY:

Ms. Goeltz would agree that at this stage in her interaction with the healthcare system, she was not being an effective player. A defensive reader could argue with some legitimacy that she had no one to blame but herself -- a sentiment that Ms. Goeltz would agree with as well. But as we dig deeper, a richer lesson can be learned.

What was going on with Ms. Goeltz? Many things, in fact. She had non-specific symptoms that clearly were very worrisome but which she did not have the resources to self-diagnose. She also was grieving for her deceased brother and afraid of healthcare because that's where he died.[1] She also was angry and very confused about who to be angry with -- herself or her healthcare providers.

From a systems point of view, all of these were risk factors contributing to Ms. Goeltz not getting -- or even being able to effectively ask for -- the care she needed. But, while her life circumstances were uniquely hers, many others in the patient population have stories, fears, and communication skill deficits of equal intensity.[2] These individualized risk factors are what make the challenge of achieving safety in healthcare exponentially harder than any other sector of human activity. Establishing reliable service models would be much easier to do if patients were standardized or their roles more contained.

Much has been made about transferring safety lessons learned in the commercial airline industry to healthcare. For healthcare providers, the analogies and extrapolations from airline crew risk management to clinician teams are relatively clear and instructive.

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[1] Mike's treatment did not occur in the same healthcare organization providing Ms. Goeltz's care.

[2] Public opinion polling indicates that more than 40% of the U.S. population believes that they themselves, a family member or a close friend has been the victim of medical error. (National Patient Safety Foundation, October 1997). The collective fear about health system safety was palpable after the release of

Looking at the metaphor from a service recipient's point of view, however, reveals the increased magnitude of the safety challenge in healthcare. Airline passengers are rather fungible in terms of the risk factors they contribute to the safety equation. With the exception of intentional acts of terrorism, passengers have a much smaller role to play in creating risk and, accordingly, much less responsibility in managing risk than patients have.[3]

If our social goal is to effectively manage risk in healthcare, we are called upon as a community to meet this challenge. Looking at Ms. Goeltz's account from a systems perspective, it is notable that she did manage to access the system on several occasions. There were, then, several opportunities for the system to probe further into this patient's non-specific complaints and generate trust. Rather than doing so, it conveyed the impression that the system and the people in it were too busy to care about patients' worries and fears.

GOELTZ:

I was so upset that when I got home I called the clinic again and made an appointment with an internal medicine specialist, asking for the first one who had an opening! The appointment was three weeks out and happened in June 2000. I will never forget this doctor for as long as I live. When I talked to him, I felt like I was stepping off

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the IOM's first report on safety in November 1999. More than 50% of Americans followed that story for over a week, evincing it's strong relevance to people's everyday concerns.

[3] An interesting model, not explored extensively yet as a lesson for the healthcare system, is the measurably successful efforts in this country to change the cultural normalcy of getting behind the wheel of a car while intoxicated. The very public campaign of Mothers Against Drunk Drivers was successful in transforming social understandings as to who is accountable for managing this risk, essentially creating a model of shared responsibility among driver who drink, their friends, those selling alcohol, the press, lawmakers, educators and others. Arguably, in the effort to advance public safety, drunk drivers and patients "who don't do what they are supposed to do" have more in common than patients and airline passengers do.

a steep cliff. He not only caught me, but also in his words and manner encouraged me to keep jumping off each cliff I came to; I believed he would be there to support me. I shared all my symptoms, Mike's story, my fear of being written off as depressed and my worry that depression was masking real physical problems. He listened without rushing me, calmly writing notes. He thought about what I had to say, and encouraged me to say more. I felt like he was pulling out of me the information I so wanted to discuss with someone who had expertise to help me decipher what was going on. We parted that day with a series of tests set up and a plan to look at the possibility of depression if the tests indicated I was sound physically. He asked me if I was in agreement with the route he had mapped out! I left there feeling much better about the healthcare system in general and remember thinking that maybe some of them did care and could be trusted. Although I didn't put it together at that moment, it was the beginning of partnering with my doctor!

One of the tests – a chest x-ray – identified a problem. The doctor had ordered it because I reported being short of breath, a symptom I was initially hesitant to reveal because I thought it was related to the weight I had gained and I was embarrassed! It was the doctor's respect for me and my resulting trust in him that encouraged me to share this vital piece of information. The x-ray came back showing a small shadow by my lungs, which prompted a CT-Scan identifying a mass in my chest.

Ever since Mike died I had preached to friends, family, co-workers -- basically anyone who would listen -- about how our family accepted part of the responsibility for his death. Mike was not aware of his own family medical history, which made him more vulnerable to a bad outcome than he should have been. Because the hospital was an unfamiliar environment, we should have been with him to support him. If we had been

there, perhaps we could have answered questions or spoken up if he was too sick or intimidated to do so, supplying information to his doctors and nurses that might have made a difference. Instead we left him alone; he passed away without anyone knowing it. No one teaches us that mistakes can be made in hospitals -- if anything, we are led to believe the opposite -- but we should have known it and not been complacent. We also should have done our part in ensuring his safety.

I learned from my brother's death the importance of having someone with you 24 hours a day, 7 days a week while you are in the hospital. Based on my own experience, I also knew or should have known that it's also important to have someone accompany a patient to significant appointments as well. Once again, however, I didn't follow my own advice, and was alone when I learned of my test results. I ran from the doctor's office after being told I had the mass, wishing someone had been with me for the news yet simultaneously determined that I wasn't going to tell anyone. I would handle this by myself! I soon realized that would not be possible and asked God to give me the strength and dignity to deal with this part of my life.

My next appointment was with the cardio-thoracic surgeon, during which I thought he was to do a biopsy of the mass to determine if it was cancer. I went to this appointment with a small infantry of supporters: my husband, son, stepson and best friend. My husband went with me into the exam room. The first impression made by the surgeon was one of a gentle confidence, and our communication was an extraordinary example of what it means to be partners.

I was anxious to know whether the mass was cancer, and really wanted the biopsy that I was expecting done. He disagreed. But, rather than discounting my wishes or

telling me what to do, he fully explained his rationale. The location and size of the mass next to my vital organs required it to be removed in his opinion, whether or not it was cancer. He advised that doing a biopsy and a subsequent surgery would put me through an unnecessary procedure, but he left it up to me to decide what I wanted to do. In that one episode of communication, I knew he was a person who respected and was listening to me. I felt I could share all my feelings and concerns with him, and I did. I made the decision to follow his advice before our appointment was over, and said "Let's take it out, I am ready. I have not eaten since before midnight, so let's do it now!"

He laughed and told me that things do not happen that quickly. He was going on vacation for two weeks and we could schedule it after that. I shook my head and told him I had a personal reason for wanting to have it happen this week; my son was in town from school and I wanted him to be here. He acknowledged that personal reason and suggested that one of his colleagues could do the surgery. I shook my head again, looked him in the eye and said, "No, I have just shared my most personal feelings and fears with you. I trust and want you to do the surgery." He looked at me for a few seconds. I felt just as confident as he seemed to be. Then he smiled and invited me to go with him to see his scheduler. I had surgery two days later, before he went on vacation!

While I was satisfied with myself for how I dealt with this surgeon, I must say that it only happened because he allowed it to happen. He partnered with me at the level I wanted and was capable of handling. He also invited me to call him if I had further concerns. I did so, the night before surgery as I was experiencing very cold feet. He responded to my page quickly, listed to my being nervous and was very reassuring. I

relaxed and thanked him, confident that the decision he helped me reach was the right one for me.

HATLIE COMMENTARY:

As Ms. Goeltz's story eloquently expresses, respect is an attitude. It's communicated and received in several ways, through words, tone of voice, body language and responsiveness. Patients seeking medical attention are -- virtually by definition -- sick, injured or, at least, worried. As such, they are intrinsically vulnerable and often react irrationally. Ms. Goeltz, like many patients, knew she should be doing things differently but controlled by fear she behaved in ways that made no sense even to her. When an intimidated patient can manage to communicate despite his/her fear or embarrassment, a truly existential moment in the relationship between healer and patient is created. If the doctor or nurse responds in a manner that acknowledges the dignity of the patient despite their dependency, as well as their role as ultimate decision-maker about what will be done to them, a much more functional relationship is created. If the "healer" responds with an attitude that is dismissive, that opportunity for a rich partnership relationship is squandered, and cynicism or anger eventually takes its place.

Goeltz's surgeon not only responded to her concerns respectfully, but in her view made the partnership "happen" by giving her the permission she needed to express her fears and embarrassing thoughts. As a group, surgeons are not renowned for their people skills, but from Goeltz's perspective the communication was direct and clear. Her surgeon gave her information and medical advice in language that she could understand and made it clear that the decision about treatment was hers to make. He then listened for

her decision and responded to it. He did not underestimate her ability to deal with the information he provided. That interchange is what led her to trust and feel empowered and, in a very real way, responsible for her own treatment decisions. Her surgeon should bottle the formula and sell it. He'd make a fortune.

For nearly thirteen years, I was the American Medical Association's strategist on tort reform. During that tenure, time and again I heard physicians lament the deterioration of the trusting relationship between patient and physician, more often than not blamed on the interference of the tort system. True, the tort system does position patients and clinicians as potential adversaries and I agree that this is a disservice to both. The economics of reimbursement are perhaps an even more powerful disincentive to the establishment of a functional healer-patient relationship because of the pressure created for" efficient" use of time.

But the fact remains that clinicians continue to have the opportunity day-to-day, encounter-by-encounter, to establish trusting relationships with their patients. I believe that patients who feel like partners in their own treatment are also more likely to join with their healthcare providers in advocating for reimbursement reform and legal policies that support a strong physician-patient relationship. Conversely, clinicians who convey the message that they are too busy to listen or too distant to care about their patients' fears diminish the goodwill their patients historically have had toward their healers.

GOELTZ:

The first day after the surgery to remove the mass in my chest cavity, I suffered a pulmonary embolism. I had not been up or out of my bed for 32 hours after my surgery,

in part because the nurses on my unit were clearly overworked. I had to urinate, and finally a nurse had time to help me. As I sat up at the edge of my bed, I became short of breath. But I had to pee! So, I did not say anything and the nurse helped me to the bathroom. As I sat in the bathroom, I tried to concentrate on the task at hand but the breathing problems worsened. Telling the nurse that I could not breathe is the last thing I remember before realizing I was back in bed with my nurse putting an oxygen mask on me. As the nurse left to summon a doctor, I could see through my mask my 24/7 team member mouthing words of encouragement, "Stay calm, breathe slowly." I was really glad she was there.

Several people tried to convince me to "blame the nurse" for my embolism -- especially other nurses! -- but I don't think the fault is hers. She was the only nurse on duty that morning. She was covering two wings of patients and every time she would get ready to help me she was called away to something more urgent. The system failed her and me. I also heard later that the surgeon had blamed himself. How ridiculous. I know embolisms are a risk of surgery and are not always preventable.

In the hospital, now recovering from both chest surgery and an embolism, the oncologist assigned to me saw me for the first time. By that time I must have had some kind of reputation, because he greeted me by saying "I was elected to come talk to you". He then told me I had a malignant thymoma. Unfortunately for me, he caught me in a gap of my 24/7 coverage and I was alone.[4] When I heard the word malignant, I shut out

[4]. Going into this surgery I had organized among my friends and family five days of continuous "24/7" presence of someone in my room. The goal of this team is to ensure that someone is always there, asking the kinds of question I ask when I can't because I'm sleeping, or drugged or groggy. My hospital stay was longer than anticipated because of the pulmonary embolism, and the oncologist visited me on day six after the 24/7 coverage I organized was over.

everything that came after it and began crying. The oncologist was impatient and asked what I was crying about. I told him I was upset because he had just told me I had cancer. He said he had not. What ensued could only be described as an argument. Shortly into it, the oncologist threw up his hands, said he would have someone else talk to me in the morning, and walked out.

I still can't believe he handled me so poorly. Essentially we were arguing over a technicality. My tumor was considered a malignant thymoma because of its location near vital organs (heart and lungs) but the cells making up the tumor did not appear as cancer cells. I wanted to hear I did not have cancer, but even more than that I wanted the truth. I accepted the oncologist's explanation, but didn't really know if I should trust him because we had not established an interactive rapport, as I had with my other doctors. After my discharge from the hospital and during my first visit with my cardio-thoracic surgeon he made a statement that added to my confusion about the oncologists explanation. "Now Roxanne, you know you have cancer," he told me. I believed him and was attempting to deal emotionally with that diagnosis, yet the statement by the oncologist that I didn't have cancer was something I desperately wanted to be the truth. It was a confusing situation at best, and it took over a year to sort out my feelings and the facts. In the end, the oncologist turned out to be the one who was technically wrong. My stage III thymoma had two "fingers" that had penetrated the sac that contained the tumor and penetrated my phrenic nerve. Technically, cancer is any type of cell that is able to infiltrate other cells or organs in your body. The fact that my rampant thymus cells had infiltrated my phrenic nerve made it cancer.

The difficult interchange between the oncologist and myself raises another argument for the importance of a 24/7 team. Cancer patients are going to be emotional, especially as they are wrestling with a new diagnosis. If the clinician can't deal with that, a good option is to talk to a supportive person who can then work with the patient in a supportive way to give them the information they need. I did want the truth and found other ways to get it when we were unable to respectfully communicate with each other.

HATLIE COMMENTARY:

Seasoned systems people understand how successful teams function. What do they do when confronted with a system that isn't effectively including the patient as a member of the team? Goeltz's solution was to organize an alternate team of her own that she could rely on to support and protect her in an environment she had the expertise to recognize was not very patient-centered. Her attitude toward the post-surgical nurse also reflects an understanding of a basic safety principle: blaming individuals for bad outcomes frequently masks underlying systems deficiencies that set workers like that nurse up to fail. As an air traffic controller, Goeltz works in an environment where teams share accountability and support one another when a bad outcome occurs. Individuals who blame each other or take complete responsibility themselves for a bad outcome sound wrong to her. It's everybody's job to manage risk.

GOELTZ:

In November 2000 I faced a second surgery for suspected ovarian cancer. I had cysts that appeared to be growing. Given that I had rampantly growing cells in my

thymus, both my gynecologist and I were worried this could be serious. In consultation with my doctor, I decided to have an elective hysterectomy, which was done three months after the removal of my thymoma. Fortunately, tests showed it was not cancer.

The gynecologist reminded me of my cardio thoracic surgeon. She was very willing to give me all the information I requested and encouraged my active participation during appointments and in setting up the surgery, which was for suspected ovarian cancer. I wish I could say the same about all the people that worked with and around her. I know it is necessary for doctors to manage their time well and to keep from being overwhelmed with calls from patients. We both must rely on nurses and office personnel to be part of the treatment team. But my family has experienced office staff making statements about treatment issues that exceed their expertise, and we've experienced them editing information we think is important so that the doctor doesn't hear it. I am highly sensitive about this because it was a factor in my brother's death. My family has a history of aneurysms, which we shared with a nurse, who made the judgment that it wasn't relevant to what was going on with Mike. He died and I wonder to this day if he would have had a chance if that information we gave the nurse had been passed effectively to his doctors.

To determine if my radiation treatment needed to be interrupted or if we could wait until its completion before doing surgery, my oncologist ordered a CA-125 blood test. She explained if the levels were high, ovarian cancer was very likely and we would want to do surgery right away. When I got home I got up on the Internet and got all the particulars. Although my doctor had said the results were to take a couple of days, when I called about them the nurse could not find any results, and she told me that it could take

up to two weeks or longer. I waited instead of pushing back. I think I was tired of bucking the system at that moment and emotionally overwhelmed that I could be facing more cancer. I think the nurse was also overwhelmed when I called and said what she did basically to get me off the telephone. When I called two weeks later, the nurse said the same thing: she could not find the results. Clearly something about the process was wrong, and I was determined to do whatever had to be done to figure out what was going on. I began telling her what I knew, that I had the test taken at the hospital with my other labs for radiation treatment and coumadin monitoring. This prompted her to realize she needed to look in a different computer, because test taken in the hospital are on a different computer system than those done at the clinic. In fact the test results were probably available the first time I called. The nurse knew about the second computer system, and she had access to it. She just hadn't stopped to consider that they might be there.

Nothing bad happened to me as a result of this mix-up, since my CA-125 test results showed in the normal range. But, if it had not, two weeks would have been lost in dealing with ovarian cancer. The doctor was going to terminate my radiation to get me into surgery if the levels had been high, so I really believe those weeks would have been important if I had had cancer.

The healthcare system could have done two things to prevent this kind of thing from falling between the cracks. First, nurses can be trained to be more directly factual about what they do or do not know. During that first phone call, the nurse told me what she did either because she didn't know how long blood tests take or because she didn't have time to deal with me. Second, at the time the sample was taken from me, I could

have been given more specific instructions about where to call or what to say about where the test was taken when I did call. Something as simple as "Your doctor will need to refer to the hospital computer to get these results" would have done it. Either of these steps would have given the nurse and I the opportunity to problem solve during the first conversation, instead of two weeks later.

What did I learn from this experience? It is that one cannot count on everyone in the healthcare system being trained well enough to ask the right questions or thorough enough to find answers. I was able to help my gynecologist's nurse do her job better, but I had to take the initiative. I suspect she didn't see me as a partner at all in achieving the goal of keeping me healthy. As I now advise everyone I talk to, if you're going to be a partner in your healthcare decisions you have to drive the conversation until you get your questions answered. If you do not get an answer you are happy with, keep asking and pushing to get what you need to be informed.

HATLIE COMMENTARY:

Goeltz the air traffic controller knows a dangerous system when she sees or smells one. Although the mix-up she describes may have been "small" and no bad outcome was produced, systems people realize that these small failures too often combine with other small failures to cascade into full-blown disasters. Systems people are also trained to know that the most reliable teams are those that try hard to share information fully and accurately. Hurried conversations or statements asserted as fact -- when the speaker doesn't really know all the facts -- undermine effective team communication.

They are a sign of unreliable system/team performance. And they lead to things like airplane accidents and patient injuries.

GOELTZ;

After my surgeries and radiation treatments I had two follow-up appointments with the oncologist I'd clashed with earlier. I wanted to work with him and hoped that if we met under less stressful circumstances we could communicate. I brought information to our appointments I'd gathered through my own research to help establish my follow-up care plan. I truly believe I gave him a chance to work with me, but after two appointments I knew I had to trade him in. He would not discuss the studies I brought with me or address any of my concerns, pooh-poohing them as unimportant. His treatment plan was vague and he relayed it to me in a condescending manner. I had no say in what kind of protocol would be used for follow-up monitoring and care.

I wasn't interested in another confrontation with him, so I went to my primary care doctor and told her I wanted to see a different oncologist. Her back was turned to me when I said this, and I remember noticing her visibly tense up. I continued, saying I needed someone who was willing to consider my input and respond to my concerns. She listened and she agreed, giving me a referral and an appointment slip to see a new oncologist.

However, changing doctors was easier said than done. When I took the appointment slip to the front desk, the scheduler tried to set me up with my original oncologist. I calmly but firmly said no. She wouldn't accept my answer initially, and strongly advised me that doctors did not like it when other doctors saw their patients. I

informed the scheduler it was a decision made with my primary care doctor and suggested she talk to her if she needed an explanation but that I wanted the referral I had been given. And by being firm and calm, she then became very helpful in setting up the appointment.

I went into that first appointment with the new oncologist with the conviction that I was going to lay out at the beginning how I wanted our relationship to be, then see if he was willing and able to be that kind of doctor for me. He was! He acknowledged my concerns and reviewed with me the data I had brought in on thymoma. Admitting he had only seen one other thymoma years ago in an elderly woman, he said he was willing to learn with me. Since there was not an established protocol for follow-up treatment on thymoma's we came up with one together with which we were both comfortable.

During a second appointment with him six months later we went over the results of the CT scan done in early November 2001. This was the fourth scan I had done since my surgery, and they all appeared to show a soft tissue mass in my chest that could have been several things. The possibilities ranged from scar tissue following my first surgery, to a shift in the position of my internal tissue following the first surgery, to re-growth of the thymoma. While we were in agreement that the best thing to do was continue to watch, I noticed that each time a new scan was taken it was only compared with the one taken immediately before it. Although there was variation from scan to scan that could have been indications of tumor growth, the results were still inconclusive. I also learned that each interpretation of a scan was somewhat subjective, given that my position in the scanner or small movements that I might make in the process could account for the variation from scan to scan. For these reasons, I asked whether it would make sense to

compare the most recent exam with the earliest, taken in October 2000. My doctor agreed and said he would request it and let me know the results.

I didn't hear from him, but waited from early November through the holidays before becoming a pest. When I left a phone message with his office the first week of January 2002, it was not returned. I called again the next week, and got a response saying that the results between the July 2001 and November 2001 were such and such. This was not the comparison the oncologist and I had agreed upon doing, so I called back leaving another message to this effect. They acknowledged the misunderstanding and did the comparison. When the oncologist finally got the results, he called and explained them to my husband because I was not available. He then mailed the written report to me with a note to call him if I had any questions. The comparison of scans did show more definitively that there had been no real change in the mass in the year preceding November 2001. From a patient's point of view, this was much more reassuring than being told after each scan that it was unclear whether there was new growth and we'd just keep watching.

I appreciate the way my current oncologist is working with me and considering my suggestions. I don't think my original oncologist would have been as forthcoming. He wouldn't have explained things, probably rationalizing that he knew best and that there is no reason to worry the patient about things we won't understand. I have outgrown that kind of doctor and I am educating others to outgrow them as well. The safety of their healthcare depends on it.

HATLIE COMMENTARY:

While the little mix-ups in the exchange of messages about the CT scan comparisons are troubling, what's notable is how patient and providers worked together to recover from these system failures. Mistakes do happen in complex, dynamic, time-stressed environments and the ability to recover before an injury occurs is a huge part of effective risk management. Goeltz's pestering has actually become a part of the safety net. She and her 24/7 teams track what is supposed to happen according to the treatment plan, and she communicates with the system when it doesn't. The goal is not to nail the system or people who work within it or to build a record for a lawsuit; it's too help that system perform better by becoming part of it.

CONCLUDING SUMMARY:

Hatlie:

A fearful stranger to the healthcare sector when she became a frequent user two years ago, Goeltz clearly is now a sophisticated and creative partner. She is fully engaged in decision-making and holds the decisions made as her own. Physicians often worry that their patients don't fully consent to the treatment given them, because they don't fully understand the risks. This is often a factor in malpractice litigation. Goeltz's healers don't have that worry.

When it comes to the complicated process of treatment, Goeltz doesn't take for granted that the system will operate optimally, and holds herself accountable for doing what she can to deliver good outcomes for herself and her loved ones. She knows her active participation keeps the system safer. She challenges those she meets who want to

discount her role and refuses to be treated by those who can't meet and adapt to those challenges. She has a lot to teach us all.

Goeltz:

The circumstances of my brother's death are what taught me the crucial importance of active participation in my own healthcare. The best tribute I can pay to him is to continue trying to show consumers and those in healthcare how they can partner with each other to truly improve safety.

To those healthcare workers who are willing to work with me, and put up with my challenging them from time to time, please accept my deepest gratitude. I would not be as healthy as I am today without you and maybe I wouldn't even be alive. I know your jobs aren't easy and you have earned my greatest respect.

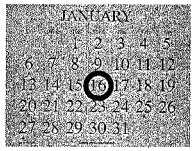
REFERENCES:

1. National Institute of Medicine, Committee on Quality Care in America. (1999). *To Err is Human: Building a Safer Health System.* Washington, DC: Institute of Medicine.
2. National Institute of Medicine, Committee on Quality Care in America (2001). *Crossing the Quality Chasm: A New Health System for the 21st Century.* Washington DC: National Academy Press
3. Louis Harris & Associates (1997). Public Opinion Study on Patient Safety Issues. Chicago, IL: National Patient Safety Foundation at the AMA.
4. Wilson N and Hatlie M. Advancing patient safety: a framework for accountability and practical action, Journal of Healthcare Quality 2001.

Permanent Subcommittee on Investigations
EXHIBIT #2

Ensuring Correct Surgery in the Veterans Health Administration

Days to hours before surgery



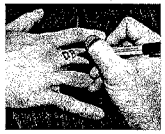
☑ Step 1: Consent Form

The consent form must include:

- patient's full name
- procedure site
- name of procedure
- reason for procedure

☑ Step 2: Mark Site

The operative site must be marked by a physician or other privileged provider who is a member of the operating team



☞ **Do NOT mark non-operative sites**

Just before entering OR

☑ Step 3: Patient Identification

OR staff shall ask the patient to state (NOT confirm):

- their full name
- full SSN or date of birth
- site for the procedure

☞ Check responses against the marked site, ID band, consent form and other documents

Immediately prior to surgery

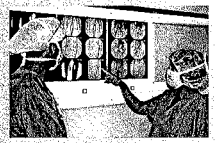
☑ Step 4: "Time Out"

Within the OR when the patient is present and prior to beginning procedure, OR staff must verbally confirm through a "time out":

- presence of the correct patient
- marking of the correct site
- procedure to be performed
- availability of the correct implant

☑ Step 5: Imaging Data

If imaging data is used to confirm the surgical site, two or more members of the OR team must confirm the images are correct and properly labeled



For more information see the Veteran's Health Administration Directive and your Patient Safety Manager _____

Produced by the Department of Veterans Affairs National Center for Patient Safety
(*www.patientsafety.gov* **or** *vaww.ncps.med.va.gov*)

October 25, 2002

FAIRVIEW
Fairview Health Services

Fairview Health Services
At a glance

Fairview has a tradition of service and partnership with community and local organizations to improve health care. Through its continuum of care model, Fairview Health Services provides access to services for families from birth through all of life's stages to senior care and hospice services. Partnered with the University of Minnesota and its Academic Health Center, Fairview offers access to leading-edge research, medical treatment and medical education.

The values of Fairview Health Services

- Dignity
- Integrity
- Service
- Compassion

The Mission of Fairview Health Services
Fairview's mission is to improve the health of the communities we serve. We commit our skills and resources to the benefit of the whole person by providing the finest in health care, while addressing the physical, emotional and spiritual needs of individuals and their families. We further pledge to support the research and education efforts of our partner, the University of Minnesota, and its tradition of excellence.

Fairview Health Services offers a continuum of care
Fairview operates through seven geographic care systems in Minnesota. Each care system, with a hospital at its core, includes primary-care clinics, specialty clinics, pharmacies, senior services, rehabilitation services, home care and hospice services. In addition, Fairview provides access to a full continuum of care and leading-edge medical research through our partnership with the University of Minnesota. Our seven care systems are:

- Fairview Southwest Metro Care System, Fairview Southdale Hospital, Edina (1965)
- Fairview Minnesota Valley Care System, Fairview Ridges Hospital, Burnsville (1984)
- Fairview Central Metro Care System, Fairview-University Medical Center, Minneapolis (1997) (original Fairview facilities 1908,1914)
- Fairview Northland Care System, Fairview Northland Hospital, Princeton (1986)
- Fairview Lakes Care System, Fairview Lakes Regional Medical Center, Wyoming (1994)
- Fairview Range Care System, Fairview University Medical Center – Mesabi, Hibbing (1997)
- Fairview Red Wing Care System, Fairview Red Wing Medical Center, Red Wing (1997)

Employees: approximately 18,000 employees in seven care systems, system businesses and corporate offices

Fairview Corporate Offices
2450 Riverside Avenue, Minneapolis, MN 55454
Phone: 612.672.6300 Fax: 612.672.6303
Web site: www.fairview.org

Affiliations (medical accreditations)
Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
Minnesota Hospital Association (MHA)
American Hospital Association (AHA)
Safest In America
Minnesota Alliance for Patient Safety

Permanent Subcommittee on Investigations
EXHIBIT #3a

DAVID R. PAGE
President and Chief Executive Officer
Fairview Health Services

Mr. Page received a Bachelor's Degree in Economics from Davidson College (Davidson, NC) in 1962 and a Master's Degree in Hospital Administration from Duke University (Durham, NC) in 1964. Mr. Page was named President and CEO of Fairview Health Services in July 1998. Prior to joining Fairview, he served as the Chief Operating Officer of the Memorial Hermann Healthcare System (Houston, Texas) and President and Chief Executive Officer of Memorial Hermann Hospital System from 1997 to June 1998. He was President and Chief Executive Officer from 1993 until the merger of Hermann Hospital and Memorial Healthcare System in November 1997.

Mr. Page served in the U.S. Army Medical Services Corps from 1965-1968 and achieved Captain's rank. After leaving the Army, he held various administrative and executive jobs at hospitals in Kansas City, MO, Asheville, NC and New Orleans, LA, where he was Executive Vice President and Hospital Director of Ochsner Foundation Hospital from 1981-1993.

Mr. Page is an American College of Health Care Executive Fellow and his current appointments include: the American College of Healthcare Executive Groups and Women's Healthcare Executive Networks Committee, external board member on the following boards: American Excess Insurance, College of St. Catherine, Health Education and Research Foundation, Inc., KARE Eleven Who Care, Minnesota Business Partnership and Minnesota Hospital Association (formerly Minnesota Hospital and Healthcare Partnership) (Board Chair – 2002 through June 2003).

In January 2003, Mr. Page received the Minnesota Hospital Association's Stephen Rogness Distinguished Service Award. In 1997, he was awarded the American College of Healthcare Executives Regent's Award for Senior Healthcare Executives. In addition, Mr. Page has served as a guest lecturer at the LSU School of Nursing and Adjunct Professor of Management at the University of North Carolina-Asheville for Health Care Administration. He has also served as guest lecturer at Bethel College, St. Paul.

Permanent Subcommittee on Investigations
EXHIBIT #3b

System Policy
Code:S:RI-2003

Entity: Fairview Health Services
Manual: Policy and Procedure

Category:	**Patient Rights and Organizational Ethics**
Subject:	Communication/Disclosure Policy
Purpose:	To clarify the philosophy and approach to patient communication by providing policy guidelines for communicating unanticipated outcomes and medical accidents.
Definitions:	**Outcome:** The result of the performance (or nonperformance) of a function(s) or process(es). **Unanticipated Outcomes:** A result that differs significantly[1] from what was anticipated to be the result of a treatment or procedure. Note: An unanticipated outcome is associated with the performance of a treatment or procedure and may be negative or positive. It may or may not be associated with an error. **Medical Accident:** An unintended event in the system of care with actual or potential negative consequences to the patient. Medical accidents can result from defect, failure and error within the system of care. **Near Medical Accident:** An event that would have constituted a medical accident but which was intercepted at the point of patient care services before it actually reached the patient.
Philosophy:	Open and ongoing communication with patients about their care and the outcomes of such care is critical so those patients can be full partners in their health care. Patients have the right to receive accurate, timely and easily understood information so that they can make informed decisions about their care. Health care institutions and providers have an obligation to inform patients about all outcomes of all care, including unanticipated outcomes. Institutions and providers have a legal and ethical duty to disclose medical accidents when there are clinical consequences[2] resulting from the medical accidents or

[1] For example, JCAHO refers to a significant medication error as "unintended, undesirable, and unexpected effects of prescribed medications or of medication errors that require discontinuing a medication or modifying the dose; require initial or prolonged hospitalization; result in disability; require treatment with a prescribed medication; result in cognitive deterioration or impairment; are life threatening; result in death; or result in congenital abnormalities.
[2] These consequences result in any temporary or permanent change in the patient's current condition and/or results in a change of treatment plan.

Permanent Subcommittee on Investigations
EXHIBIT #3c

	when a reasonable person[3] would want to know, regardless of whether any negative clinical consequences resulted from the medical accident.
Policy:	Patients or the appropriate guardian or representative will be provided relevant, easy to understand information about all outcomes of care in a timely manner. Patients will receive a truthful and compassionate explanation when: • Outcome of care varies significantly from what was anticipated; or • A medical accident has occurred resulting in clear clinical consequences; or • A medical accident has occurred that has the potential to result in clinical consequences; or • A medical accident has occurred and unanticipated outcomes have occurred, but there is not a definitive causal relationship between the accident and the outcome. In this case, the accident will be disclosed immediately, facts will be disclosed as they are known, and if/when a causal relationship is identified that information will be disclosed as soon as possible; or • A medical accident has occurred that has not resulted in clinical consequences, but a reasonable person would want information about the accident because it might assist them in planning future care; or • A near medical accident has occurred that has reached the patient's awareness. When a medical accident has occurred, open dialogue of the resolution available to the patient will occur. Patients or the appropriate guardian or representative will receive information on the steps taken to eliminate or minimize the clinical consequences of the medical accident. There will also be open dialogue of non-clinical resolutions available to the patient, if such remedies are appropriate.
External Ref:	American Society for Healthcare Risk Management 'Perspectives on Disclosure of Unanticipated Outcome Information.' National Patient Safety Foundation Statement of Principle JCAHO Patient Safety Standards, Effective July 1, 2001
Internal Ref:	Fairview Policy S:PI-2000 Organizational Response to a Sentinel Event
Source:	Fairview Health Services - VP Patient Safety
Approved by:	Fairview Health Services Policy Committee
Date Effective:	December 30, 2002
Date Revised:	-
Date Reviewed:	

[3] The reasonable person standard is an ethical/legal standard that calls for the disclosure of information to patients based on what a hypothetical reasonable person would want to know.

Entity Procedure
Code:E:RI-2003 pr

Entity: **(Insert Entity Name)**
Manual: **Policy and Procedure**

Category:	**Patient Rights and Organizational Ethics**
Subject:	Communication/Disclosure Procedure
Purpose:	To clarify procedural guidelines for communicating unanticipated outcomes and medical accidents.
Definitions:	**Outcome:** The result of the performance (or nonperformance) of a function(s) or process(es). **Unanticipated Outcomes:** A result that differs significantly[1] from what was anticipated to be the result of a treatment or procedure. Note: An unanticipated outcome is associated with the performance of a treatment or procedure and may be negative or positive. It may or may not be associated with an error. **Medical Accident:** An unintended event in the system of care with actual or potential negative consequences to the patient. Medical accidents can result from defect, failure and error within the system of care. **Near Medical Accident:** An event that would have constituted a medical accident but which was intercepted at the point of patient care services before it actually reached the patient.
Philosophy:	The circumstances surrounding anticipated or unanticipated outcomes vary. Therefore, the approach taken to communicate any given outcome will vary. The following procedural guidelines provide a general approach to guide clinicians and administrators in their approach to such communications.
Procedure:	**Procedure for disclosure of outcomes** 1. The treating practitioner or his/her designee[2] should explain the outcomes of all care to the patient, or appropriate guardian or

[1] For example, JCAHO refers to a significant medication error as "unintended, undesirable, and unexpected effects of prescribed medications or of medication errors that require discontinuing a medication or modifying the dose; require initial or prolonged hospitalization; result in disability; require treatment with a prescribed medication; result in cognitive deterioration or impairment; are life threatening; result in death; or result in congenital abnormalities.
[2] Treating practitioner: The responsible licensed independent practitioner caring for the patient. This is usually the patient's physician, but may be a nurse, nurse practitioner, pharmacist, physician assistant, therapist or other licensed care provider. If the treating practitioner is unable or unwilling to explain the outcomes, a practitioner designated by administration will provide such explanation. In instances where

representative, whether the outcomes are anticipated or differ significantly from the anticipated outcomes.

2. If the treating practitioner is unable or unwilling to explain the outcomes, a practitioner designated by clinical leadership, management or administration will provide such explanation.
3. The content of the communication with the patient will be documented in the patient record, if one exists and can be accessed.
4. When a medical accident occurs, the process outlined below will guide the treating practitioner.
5. Fairview should provide necessary tools when special types of communication are needed. Persons with limited English proficiency, individuals with a dramatically different cultural framework for health care services, persons with language, auditory or visual challenges and those with diminished or cognitive impairment fall into this category.
6. Fairview will protect the privacy of patient identifiable information. When it is deemed appropriate for family members to participate in discussion about outcomes, the patient's permission will be obtained. When a patient is deemed to be unable to understand information about his or her outcomes, or when the patient is an unemancipated minor, a legal or otherwise appropriate surrogate decision-maker will be informed.

Procedure for disclosure of medical accidents

Patients or the appropriate guardian or representative has the right to a prompt and truthful conversation when a medical accident has occurred.

1. To assure continuity and appropriate perspective in discussion, the disclosure of information and subsequent discussions with the patient or his/her guardian or representative should be handled by the treating practitioner or his/her designee. In most cases, the practitioner caring for the patient is the preferred communicator in the disclosure of unanticipated outcomes.
2. Administrative personnel and clinical leaders should be consulted prior to discussing such outcomes with the patient for the purposes of mentoring the individual on appropriate, humanistic ways to broach the discussion, reviewing what should be discussed, and the initiation of the organization's support, risk management and performance improvement functions as may be required. If the actual or potential consequences of the accident are negligible, this is not necessary.
3. A second individual (e.g. clinical leader, manager or supervisor, patient representative, risk manager or administrator) should be present during the initial conversation with the patient or the appropriate guardian or representative to assist with documentation of the conversation and to provide continuity of communication from all members of the care team. If the actual or potential consequences of

there is negligible harm to the patient, another individual may be designated by the treating practitioner as the primary person to communicate the event.

	the accident are negligible, this is not necessary. 4. Facts should be reviewed and shared with the patient or appropriate guardian or representative without unnecessary delay. 5. In rare instances where disclosure of a medical accident will have a harmful effect on the patient's well being, disclosure may be withheld until such a time that the benefits of disclosure are greater than the harm. Prior to making this decision the treating practitioner will request that another practitioner review the case in order to verify the risk:benefit to the patient. The treating practitioner will also consult with the accountable administrator. The decision to withhold disclosure and rationale for doing so will be documented in the patient chart. 6. For discussions anticipated to be complex or difficult, patients or appropriate guardian or representative should be given the option of having another person with them as support during the discussion. 7. During initial and follow-up discussion the following subjects may be discussed, although discussion of each subject on the list is not required nor is discussion limited to these topics: a. The organization and its staff regret and apologize that a medical accident has occurred. If an individual treating practitioner is responsible for the accident, that person should also apologize. b. The nature of the medical accident. What happened. c. The time, place, and circumstances of the medical accident. d. The proximate cause of the medical accident, if known. e. The known, definite consequences of the medical accident for the patient and potential consequences. f. Actions taken to eliminate or minimize the consequences of the medical accident. g. Who will manage ongoing care of the patient. h. Planned investigation or review of the medical accident. i. Who else has been informed of the medical accident (in the hospital, review organizations, etc.) and the facility's confidentiality policy. j. Actions taken to identify systems issues that may have contributed to the medical accident and to prevent the same or similar medical accident from re-occurring. k. Who will manage ongoing communication with the patient or appropriate guardian or representative. l. The names and phone numbers of individuals in the hospital to whom the patient or appropriate guardian or representative may address complaints or concerns about the process around the medical accident. m. The names and phone numbers of agencies to which the patient or appropriate guardian or representative could communicate about the medical accident (e.g. Department of Health, Board of Nursing, Board of Medical Pratice).

	n. How to obtain support and counseling regarding the medical accident and its consequences both within the hospital and from outside. o. If appropriate, the organization's approach to compensating patients for harm. The treating practitioner should consult with a risk management specialist for assistance with this topic. 8. The facts and pertinent points of the conversation with the patient and or family will be recorded in the medical record, if one exists and can be accessed, by the treating practitioner or his/her designee. 9. Appropriate communication will be made within the health care organization consistent with organizational policy and practices (e.g. risk management, public relations).
External Ref:	American Society for Healthcare Risk Management 'Perspectives on Disclosure of Unanticipated Outcome Information.' National Patient Safety Foundation Statement of Principle JCAHO Patient Safety Standards, Effective July 1, 2001
Internal Ref:	'airview Policy S:PI-2000)rganizational Response to a Sentinel Event 'airview Policy S:RI-2003P :ommunication / Disclosure Policy
Source:	FHS VP Patient Safety / (Entity Safety Officer)
Approved by:	
Date Effective:	
Date Revised:	
Date Reviewed:	

Red: changes for 2003 scorecard

Fairview Performance Excellence System-wide Scorecard

Scorecard Date: Approved April 2002
2003 Draft Revision: 1/06/03

Strategic Direction

LONG TERM DIRECTION
Ongoing/Reviewed Annually

VALUES
Dignity Integrity
Service Compassion

MISSION
Fairview's mission is to improve the health of the communities we serve. We commit our skills and resources to the benefit of the whole person by providing the finest in health care, while addressing the physical, emotional and spiritual needs of individuals and their families. We further pledge to support the research and education efforts of our partner, the University of Minnesota, and its tradition of excellence.

CUSTOMERS
Patients (primary), Employers, Payers, Government

VISION
You know us for our continuum of healing care, our responsiveness and for setting national standards for clinical excellence, innovation and safety.

STRATEGIC OBJECTIVES

1. **Customer Service and Responsiveness**
   Fairview demonstrates service responsiveness so we are the most accessible and highly recommended health care system in the nation.
2. **Clinical Excellence**
   Fairview provides the highest level of excellent, safe, and reliable care in the nation.
3. **Employee Engagement**
   Fairview employees are the most highly engaged, committed and customer responsive people in the nation.
4. **Engaged Physicians**
   Fairview physicians are fully engaged in Fairview to provide excellent clinical services that are safe, affordable,reliable, easy to use and responsive to our customers.
5. **Growth, Integration and Performance of Fairview Through Our Care Systems**
   Fairview will grow to sustain our mission and will effectively coordinate care through integrated care systems that deliver the most affordable, safe, reliable, accessible and easiest to use services.
6. **Financial and Operational Performance**
   Fairview demonstrates the financial capability to sustain our mission, provide the most affordable care and invest in our people, our services, and our communities.

CURRENT CYCLE INITIATIVES
One Year (2003-2004)

- **Embed process improvement in the Fairview culture**
- **Patient Safety** – reduce incidents of harm to patients by engaging clinicians in standardization of processes and process improvements in:Medication errors, Surgical site marking process
- **Work force** – Advance our nursing unit work force redesign, nursing leadership development, and process improvement strategies in partnership with clinicians and employees to achieve targeted results
- **Leverage technology to better meet the demands of our customers and support our workforce**
  - Rely upon clinical leadership and standardization of clinical care to enhance use of technology
  - Invest in technologies that can achieve dynamic breakthrough results
- **Develop and implement a Senior Care Plan that improves care delivery, market positioning, and financial viability of Senior/Chronic Care patients.**
- **Develop and implement staged plans for emerging growth markets to improve access, engage physicians and improve market share (NW-Maple Grove, SW-Chanhassen, East Metro)**
- **Develop and implement the plan to be the children's health services leader in Minnesota**
  - **Best in primary and secondary care in MN Valley**
  - **Central Metro (F-UMC) plan including services and facility plan.**
- **Leverage and optimize the Fairview-University relationship**
  - Cardiology services
  - Improve innovation rate – clinical trials *(more specific)*
  - Develop and gain approval for an F-UMC long-term strategic facilities/campus plan
- **Achieve JCAHO Accreditation with Commendation**

Processes

PROCESSES (90 day)

- **CLINICAL AND PATIENT CARE PROCESSES**
  - Accountable physician process
  - Diabetes care
  - Pneumonia care
  - Medication error reduction of harm
  - Surgical site marking process
  - Employed providers care management improvement processes
  - Engineered standards for nursing units: work redesign
- **LEADERSHIP**
  - **Governance**
  - **Education processes**
  - **Role Clarification**
  - **Nursing Leadership Development**
- **STRATEGIC PLANNING**
  - Process improvement portfolio inventory, hopper/selection process, education and training processes
- **CUSTOMER AND MARKET**
- **INFO AND ANALYSIS**
  - Charge master process
- **LEVERAGING AUTOMATION**
  - PACS, EPIC, FCIS
  - Revenue Cycle
  - Supply Chain
- **ENGAGED EMPLOYEES**
  - Recruitment process
  - Retention process
  - Temporary agency utilization
- **PROCESS MANAGEMENT**
  - Staffing to demand
  - order fulfillment process
  - Patient throughput
  - Revenue cycle

Performance Measurement

RESULTS 3-5 Years (2007)

CUSTOMER SERVICE AND RESPONSIVENESS

- **Share of market**
  - Net revenue leader in Minnesota
  - Service line, acute and ambulatory market share
- **Customer satisfaction**
  - Customer recommended top box 90th percentile

CLINICAL EXCELLENCE

- **High leverage processes**
  - **Patient touch time** - customers satisfied top box 90th percentile
  - **Accountable physician** - 100% staff knowledge of accountable physician
  - **Care system specific process improvements** – % care systems to breakthrough goal
- **Clinical conditions**
  Common diagnoses
  - **Diabetes** - % patents meeting five criteria for diabetes care.
  - **Pneumonia** - breakthrough improvements
  - **Diagnoses identified by care system** – % of care systems to breakthrough goal
- **Safety**
  - **Medication error** – breakthrough improvement
- **Innovation rate**
  - 10x increase in number of active AHC accounts for clinical trials
  - 10x increase in awards and recognition

EMPLOYEE ENGAGEMENT

- **Employee engagement** - 100% workgroups grand mean in top quartile on Viewpoint employee survey

ENGAGED PHYSICIANS

- **Physician satisfaction** – Index satisfaction of 80%
- **Activity level** - 100% care systems at breakthrough goal

FINANCIAL AND OPERATIONAL PERFORMANCE

- **Return on net assets (RONA) 18%**
- **Economic value added (positive economic value added)**
- **Operating margin 6%**

Permanent Subcommittee on Investigations
EXHIBIT #3d

Minnesota Department of Health Profile

Commissioner Dianne Mandernach

Dianne Mandernach (MAN-duhr-knock) was appointed Minnesota Commissioner of Health by Governor Tim Pawlenty on February 3, 2003.

Commissioner Mandernach is responsible for directing the Minnesota Department of Health. MDH is the state's lead public health agency, responsible for protecting, maintaining and improving the health of all Minnesotans. The department operates programs in disease prevention and control, health promotion, community public health, environmental health, maternal and child health, bioterrorism, emergency preparedness, health care policy, and regulation of health care providers.

The department employs approximately 1,300 staff in the Twin Cities area and in seven offices in Greater Minnesota.

Professional Background

Prior to being appointed commissioner, Ms. Mandernach served for nine years as the CEO of Mercy Hospital and Health Care Center in Moose Lake, Minn. She began at the hospital as an admitting clerk in 1987, followed by positions as director of Human Resources and associate administrator, before becoming the CEO.

Prior to working at the hospital, Mandernach spent 11 years teaching science, math and English to junior high school students. She also served on the Board of Directors of the Minnesota Hospital and Healthcare Partnership, and is a member of the American College of Healthcare Executives.

Educational Background

Commissioner Mandernach attended the College of St. Theresa and received a Bachelor of Arts from the University of Minnesota, St. Paul. She also received Nursing Home Administration certification at the University of Minnesota's Long Term Care Center and has achieved the Fellow Level of the American College of Health Care Executives.

Community Service

Commissioner Mandernach has been a resident of Sturgeon Lake, Minn., for 25 years. She has been active in her community, having served on a variety of boards and service organizations, including:

- Arrowhead Area Agency on Aging Advisory Council
- Carlton County School-to-Work Board
- Moose Lake Corrections Liaison Board
- Moose Lake Chamber of Commerce
- Moose Lake Kiwanis
- Moose Lake Coalition Executive Board
- Moose Lake School Board

Commissioner Mandernach is married and has four children.

MDH

Commissioner's Office
85 E. Seventh Place, Suite 400
P.O. Box 64882
St. Paul, MN 55164-0882
(651) 215-1300
www.health.state.mn.us

Permanent Subcommittee on Investigations
EXHIBIT #4a

Background Information

Minnesota MDH of Health 6/10/03

Adverse Health Care Events Reporting Act of 2003

Background

In 1999, the Institute of Medicine released its report regarding the prevalence of medical errors in hospitals. This report generated considerable discussion regarding the reporting of adverse events, the best types of reporting systems, the need for educational efforts to provide information regarding the types of reported events, and methods that could be undertaken by hospitals to minimize or prevent these errors.

In response to this report, the Minnesota Department of Health (MDH) worked with the Minnesota Hospital Association and the Minnesota Medical Association to establish the Minnesota Alliance for Patient Safety (MAPS). In addition to the three founding members, MAPS now consists of many health care related organizations. MAPS serves as a forum to discuss the implications of medical errors in the health care system; to provide educational forums for discussing the issue and for disseminating successful efforts undertaken by hospitals to reduce errors; and, to look at changes that need to take place to further minimize the occurrence of these events.

MAPS discussed the development of a medical error reporting system in the state that would:

- Accurately track the number of errors;
- Provide information regarding the types of errors; and
- Provide information that could be used to establish best practices or to provide recommendations to reduce the extent of errors within a system.

Currently, health care providers are required to report incidents of abuse and neglect under the provisions of the Vulnerable Adult Abuse Reporting Act (VAA), Minn. Stat. 626.557. While the VAA could provide some reporting capability, MAPS raised legitimate policy concerns about the appropriateness of this law as a true medical error reporting system. Concerns were identified about the specificity as to the types of reportable events, the ability to analyze the information to identify trends, and the ability to inform providers as to steps to minimize errors.

A subgroup of MAPS was established to review the provisions of the VAA and discuss elements required in an effective medical error reporting system as a proposal for the 2003 legislative session. Key discussions focused on a list recommended by the National Quality Forum (NQF.) This list identified 27 "never events" i.e., events that should never occur in a hospital such as wrong site surgery. The 27 adverse events are in six major categories: Surgical Events, Product or Device Events, Patient Protection Events, Care Management Events, Environmental Events, and Criminal Events. The list provides an effective starting point for a medical error reporting system in Minnesota.

Legislative Proposal

On May 27, 2003 Governor Tim Pawlenty signed into law the "Minnesota Adverse Reporting Act of 2003." Minnesota is the first state to incorporate the 27 adverse events developed by NQF into state law. The law requires the Commissioner to:

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Permanent Subcommittee on Investigations
EXHIBIT #4b

Adverse Health Care Events Reporting Act of 2003– page 2

- develop a reporting system for adverse events and the corrective action taken by the facility;
- review the information to determine whether trends or system problems were being identified and to provide information to providers that can lead to improvements in their systems and in the quality care;
- take sanctions against hospitals that did not make reports; and,
- monitor discussions on the issues of medical error reporting.

Changes were also made in the law to make necessary conforming amendments to the peer review reporting law, Minn. Stat. 145.64.

Budget Implications

One of the major stumbling blocks was the fiscal impact for full implementation of the law. In addition to the development of the reporting system, there were also costs associated with the MDH review of serious events, the need for investigations and determination as to any violations of federal hospital regulations and the costs associated with analysis of the data and development of recommendations

Transition Plan

A "transition plan" was proposed that would allow for the start-up process. The MDH is not required under this new law to take action until sufficient non-state funds were obtained. The transition phase requires:

- hospitals to report the 27 events to the reporting system currently maintained by the Hospital Association;
- aggregate data provided to the MDH to establish the extent of the reportable events;
- evaluation of the 27 adverse events included in the law and further clarification of those events, if necessary;
- legislative reports; and
- full implementation in July 2004 if sufficient non-state funds could be obtained.

The requirements to report under the VAA would still continue during the transition phase; however, the findings of the MDH are limited to determinations of whether regulatory provisions were violated. The MDH is not required to make determinations as to whether neglect or abuse had occurred.

The MDH recognizes the transition plan as an effective start to the development of a medical error reporting system. It will, for the first time, provide a much better reporting process for hospitals. This was a creative process to at least begin the development of an effective medical error reporting system.

To see the complete language of the bill, please link to: http://www.revisor.leg.state.mn.us/cgi-bin/getbill.pl?session=ls83&version=latest&number=SF1019&session_number=0&session_year=2003

A Call to Action:

Roles and Responsibilities for Assuring Patient Safety

Minnesota Alliance for Patient Safety (MAPS)

Permanent Subcommittee on Investigations
EXHIBIT #4c

A Call to Action:

Roles and Responsibilities for Assuring Patient Safety

Introduction

Patient safety has become a major priority for health care organizations. Studies have shown that medical errors lead to at least 44,000 deaths per year[1]. With the publication of the Institute of Medicine report, "To Err is Human: Building a Safer Health System" released November 1999, the mandate to improve patient safety has gained significant momentum and emphasis. Minnesota's commitment to safety and quality was reflected by Minnesota's 4th place ranking in the nation for providing quality care to Medicare patients.[2] The Minnesota Alliance for Patient Safety (MAPS) was created to promote optimum patient safety through collaborative and supportive efforts among all participants of the health care system in Minnesota.

This document is a resource that originated from three years of work during the Harvard Executive Session on Patient Safety. The Best Practice Subcommittee of MAPS has modified this document in the belief that it could be a helpful resource for Minnesota health care leaders as they tackle the issue of patient safety. Specifically, the Subcommittee recommends that this document be used as a template by leaders in each health care organization as they develop their own plan of action related to patient safety. This document focuses on the roles and responsibilities of leaders throughout the organization and, thus, underscores the key message that patient safety is everyone's business.

Since most of the research that has been done on patient safety examines what occurs within acute health care organizations, this document relates primarily to the issues related to patient safety found within these types of organization. However, the Best Practice Subcommittee believes that the principles included in this document can be modified to apply to all health care organizations. Furthermore, the membership of MAPS is very broad, including more than health care delivery organizations. We believe that all organizations have a role to play in improving the safety of care delivery and, thus, we hope that these other organizations will also find benefit in this document.

1.Kohn LT, Corrigan JM, Donaldson MS. Eds. "To Err is Human: Building a Safer Health System." Washington DC: National Academy Press, 1999.
2 Stratis Health study, published in the Journal of American Medical Association October 4, 2000.

An Urgent Problem

- Medical errors and accidents take an enormous toll causing patient injuries and deaths among patients in US hospitals. Medical accidents increase costs by $1.3 billion. The cost of outpatient-related medication errors is estimated to exceed $70 billion. Medical accident is a public health catastrophe
- Patient safety is an ethical imperative for health care providers individually and collectively. Safety is the essential attribute of quality care.
- There is substantial evidence that medical accidents are a product of risks and latent failures in processes and systems in which care is delivered and received.
- Human beings are fallible, and therefore depend on the teams, processes, and systems within which they function..
- Despite the prevalence and burden of medical accidents, most health care executives, clinicians, and consumers are not sufficiently aware of the extent of the problem. This is attributable to several factors including systematic underreporting, the myth of perfect performance, fear of punishment, and acceptance of inadequate systems, and lack of understanding about how to improve the situation.
- We must forge a coalition on behalf of patient safety. The coalition should include health care executives, consumer groups, direct care staff, medical and surgical specialty societies, hospital associations, purchasers of health care, and drug and device manufacturers.

The Challenge

Patient safety presents a set of difficult challenges for health care leaders.

- How do we design and operate processes and systems that protect against error or failure ever harming a patient?
- How do we gain the cooperation of autonomous professionals? How can we create an infrastructure for improvement?
- How do we create an environment in which reporting error is the standard and failure to report is the risk?
- How do we deal with the negative publicity and vulnerability to legal liability associated with open discussions about mistakes, errors, and accidents?
- How do we help patients, families, and clinicians deal with errors, failures, and accidents that result in patient harm?

We believe these represent some key issues about patient safety. The intent of this document is to clarify roles and responsibilities related to patient safety as leaders tackle these issues.

Executive Leadership (including the Board of Trustees)

1. Health care executive leadership must embrace patient safety as a key strategic priority, employing lessons learned from effective executive leadership within and outside of the health care industry.
2. Although the moral imperative to do no harm is sufficient to drive patient safety efforts, this work makes good business sense as well. It builds consumer confidence and perhaps market share. CEOs should direct their financial officers to examine the financial impact of medical error and accidents in their organizations.
3. Because most medical accidents and error involve problematic processes rather than the incompetence or malice of individual workers, improvement strategies that punish clinicians are misguided. In fact, responsibility for patient safety rests squarely on the shoulders of executives and managers who design and oversee the delivery of care.
4. Making organizational change requires leaders' time and attention. Patient safety work must become a critical part of the agenda and reviewed regularly with the senior management team.
5. The work of the executive is to communicate the objective in multiple channels and reinforce it consistently. Improving patient safety is a long-term investment, and the executive must bear personal responsibility for creating a culture of patient safety.
6. Health care organizations must remain accountable to their patients and to the community by disclosing errors that result in harm, providing fair compensation for injuries and introducing measures to prevent recurrence.
7. Health care executives should hold themselves accountable for patient safety in the same way they are accountable for financial performance, market share, and consumer satisfaction.
8. Import new knowledge and expertise and focus to advance patient safety.

All Management (from the Board to Line/Staff Management)

1. Measuring performance in patient safety is challenging. Since underreporting occurs, data about error, failure, and near-misses are incomplete. Creating a non-punitive reporting system is essential. Sharing information about errors in a non-judgmental way with frontline workers will build collaboration and shared purpose. Increasing the frequency of measurement can accelerate the pace of change.
2. While recognizing that health care is a distinct environment, we can learn much about medical error, accident, and patient safety from safety-minded industries such as aviation, aerospace, manufacturing, and nuclear power. Health care leaders must stay informed about the occurrence and causes of medical accidents through a variety of mechanisms, e.g. personally investigating cases, consulting with human factors experts, reading about safety in other industries.
3. Health care leaders should implement patient safety "best practices" identified by reliable health care organizations. They should evaluate the patient safety initiatives in their organizations and report the results.
4. A safety culture involves the alignment of organizational objectives and rewards. Ingredients of a safety culture include free and open communication, interdisciplinary work teams, flexible hierarchy, frontline engagement, blameless reporting, and recruitment and training with patient safety in mind. Senior leadership must establish such a culture

All Health Care Providers

1. Error prevention is the job of every health professional and of everyone who works in a health care organization. Careful recruitment of individuals who value safety, orientation and ongoing training are as essential in health care organizations as in other high-reliability organizations.
2. Health care organizations should embrace the tools of rapid cycle improvement and continuous system redesign from resources.
3. All health care providers should contribute to a culture of safety in health care.
4. Gross negligence and unethical behavior are barriers to patient safety and can not be shielded. Professional misconduct is a grave threat to patient safety and should be dealt with accordingly.

Governing Entities (Federal/ State Governments, Regulators, Accreditors, etc.)

1. Information on medical accidents must be able to be shared so learning can occur learn from these situations and prevent future harm. Fear of discovery and punishment of clinicians' accidents drives information underground and decreases organizational learning. Legal discovery must be structured to allow for this exchange of information.
2. Accreditation and regulatory organizations, including State and Federal governments, should recognize the need to balance the role of public accountability while supporting an environment conducive for institutions to learn and improve from error. "Searching for the bad apple" is misguided and counterproductive except in cases of gross professional negligence or ethical breach. Regulations and guidelines should encourage multi-causal analysis and facilitate blameless reporting, balancing the need for public accountability and safety with the need for improvement.
3. The federal government should play a more active role in patient safety, requiring pharmaceutical and device industries to complete and disclose human factors testing of naming, packaging, and labeling of medications and post-market surveillance of adverse events.
4. Government should support research in patient safety, modeling this effort on aviation safety and the role of the NASA-Ames Research Laboratory. Research is needed in the management, implementation, and spread of efforts to improve patient safety.

Patients and their Families — Partnership with Providers/Accountability/Involvement

1. To reduce the likelihood that patients will become the victim of a medical accident, patient and family partnerships are essential. Information, education, and opportunities for patients and families to be active participants in care can be facilitated by:
   - Asking questions of all care providers.
   - Alerting the physician to allergies, discuss the patient's diet, and mention any medications or dietary supplements they take.
   - Asking the doctor for copies of their medical records, and bringing them along whenever they see another physician.
   - Before taking any medications, asking what they are, what they're for and what they can expect from them.
   - Asking the doctor to rewrite a prescription if it is not clear and legible.

2. Additionally, if facing surgery or another serious procedure, patients and families should:
   - Research the condition and treatment options.
   - Consider getting a second opinion.
   - Have someone accompany them to pre-surgery sessions to help ask questions, take notes and understand what to expect before and after surgery.
   - Have someone accompany them to the hospital to serve as advocate and help make sure wishes are carried out.

3. Once a patient is admitted to a health care facility (e.g. hospital, nursing home), they should be able to expect leadership to encourage the following principles:
   - "Nothing about me without me". This policy embraces practices and tools to involve the patient and family in decision-making and participation in the care process to the extent they are willing and able.
   - "If it looks wrong, it is wrong." This is a policy that not only legitimizes, but also requires anyone who perceives a risk to safety to stop the process, including the patient and family.
   - Disclosure and truth telling. This policy provides guidance in working with patient and families in the face of an error or medical accident. Elements of disclosure include:
     - A prompt and compassionate explanation of what is understood about what happened and the probable effects
     - Assurance that a full analysis will take place to reduce the likelihood of a similar event happening to another patient
     - What changes are being made based on the analysis
     - An apology and acknowledgement of accountability.

Conclusion

Patient care safety is the responsibility of everyone within a health care organization, as well as others in the health care industry, e.g., faculty, researchers, providers, consumers, community leaders, regulators, and purchasers. This document provides a template for beginning the dialogue about and clarifying the roles played by leaders in this process.

Thanks

The Minnesota Alliance for Patient Safety would like to thank Julie Morath at Children's Hospitals and Clinics, for contributing the Patient Safety Manifesto, which was a fundamental resource for this document. The Manifesto originated out of the Harvard Executive Session on Patient Safety. The MAPS Best Practice Subcommittee modified the manifesto in the belief that it could be a helpful resource for Minnesota health care leaders as they tackle the issue of patient safety. This final version was approved by the MAPS Steering Committee Nov. 14, 2001.

The Following Operating Guidelines were approved by the MAPS Steering Committee March 21, 2001. Recommended revisions for review are in bold p.4.

MAPS: Minnesota Alliance for Patient Safety

OPERATING GUIDELINES:

BACKGROUND:

MAPS Mission:

To promote optimum patient safety through collaborative and supportive efforts among all participants of the health care system in Minnesota.

MAPS Goals:

1) Improve patient safety.
2) Improve the culture for patient safety.
3) Mobilize community resources for patient safety.
4) Develop and implement educational processes for patient safety

Structure:

MAPS was launched as a new organization in November 1999 by three convening founders working together as a public-private partnership:
- Minnesota Hospital and Healthcare Partnership (MHHP)
- Minnesota Department of Health
- Minnesota Medical Association (MMA)

MAPS will operate as an unincorporated coalition according to operating guidelines agreed to by the members.

At the time of its launch, there were 36 organizations that provided original consent to list themselves as a MAP organization, and were then identified as initial members. (See Attachment)

PRINCIPLES:

MAPS Membership Principles:

- The goal of MAPS is to be as inclusive as possible in its membership in order to support its mission of collaboration and support across Minnesota.
- MAPS membership is focused on key organizations (rather than individuals).
- MAPS members should be comprised of individuals from organizations who are directly involved in the delivery of health care, or who directly impact the care of patients in Minnesota (e.g. purchasers, policy makers, researchers, care delivery, payers)
- National organizations desiring MAPS membership should have a specific leadership structure in Minnesota, or be able to identify and isolate their Minnesota membership to be able to target MAPS initiatives.

Recommendations:

- *MAPS membership should be reviewed.*
- *The three founders and initial members should work to define which organizations are critical for representation on the Steering Committee so that the best representation across stakeholders and across the state is possible. Attempt to include all stakeholders working towards the MAPS mission.*
- *Each MAPS member should specify a designated contact for their organization.*
- *At the appropriate time, MAPS should further involve the public in the organization and its work.*

MAPS Leadership Principles:

MAPS will be governed by three important structural bodies in order to make substantial change, share leadership, engage a broad stakeholder group and drive action:
- Executive Committee
- Steering Committee
- Subcommittee and Task Force structure.

EXECUTIVE COMMITTEE

- General oversight of MAPS will be provided by the executive leaders of the three founding organizations: MHHP, MN Dept. of Health, MMA.
- These three leaders will form the MAPS Executive Committee.
- The Executive Committee will appoint one of their staff members to perform the duties of a Treasurer for MAPS.

- The Executive Committee will appoint one of their staff members to perform the duties of a Secretary for MAPS.

Purpose and Role of the MAPS Executive Committee:

- Provide vision and mission for the MAPS coalition.
- Provide focus and direction regarding coalition goals and objectives.
- Provide guidance regarding operating processes and structure both long and short-term.
- Provide resources from their organizations to assist with the operations and administration of the MAPS coalition.
- Manage financial resources provided to the MAPS coalition.
- Act as ambassadors of MAPS in all appropriate activities.

STEERING COMMITTEE

- Oversight for establishing priorities and accomplishing the goals and objectives of MAPS will be provided by an executive-level leadership group representing the key member organizations who directly impact health care and who are instrumental in improving patient safety across Minnesota. This leadership group will form the MAPS Steering Committee and will be limited to approximately 50 participants in order to keep meetings and interactions manageable.
- Each MAPS member should have one individual from their organization serving on the MAPS Steering Committee. Guests from MAPS members are welcome, space permitted.
- MAPS Executive Committee members should also be members of the MAPS Steering Committee.
- MAPS Subcommittee Chairs should also be members of the MAPS Steering Committee. In some cases this would allow for an organization to have more than one individual on the steering committee with voting rights.

Purpose and Role of the MAPS Steering Committee:

- Set an agenda for the both the short and long-term work of MAPS according to the vision and mission of the coalition.
- Establish specific goals and objectives for areas of focus and key opportunities.
- Establish working structure and identify participants to accomplish key goals and objectives through Subcommittees and Task Forces.
- Prioritize the programs and projects among Subcommittees and Task Forces according to available resources and overall direction.
- Determine systems of measurement to evaluate effectiveness of MAPS work.

SUBCOMMITTEE AND TASK FORCES

- Specific initiatives, work direction, and projects should be led and managed through a designated subcommittee or task force structure.

- The MAPS Executive Committee and Steering Committees should create and support these subcommittees and task forces.
- Subcommittee and task force chairpersons are appointed by the MAPS Executive Committee or Steering Committee, and endorsed by both committees.
- Subcommittee and task force participants may or may not be members of MAPS.

Purpose and Role of MAPS Subcommittees and Task Forces:

- Develop action plans to accomplish key MAPS goals and objectives.
- Determine and secure resources needed to accomplish plans.
- Determine and implement measures of effectiveness for plans.
- Engage and involve experts from across the state and nation as team members.

MAPS Operating Principles:

MAPS Executive Committee:

The MAPS Executive Committee will meet when necessary in order to provide focus, resources, and future direction for MAPS and patient safety in Minnesota. As the organization is still evolving and direction is being formed, these meetings will be closed to the public. Members of the public may attend by special invitation by the Executive Committee. Meeting minutes are not required.

MAPS Steering Committee:

The MAPS Steering Committee will meet 4 times per year, or more if necessary. MAPS Steering Committee meetings will be led on a rotation basis, by the Executive Committee members. Members of the public may attend Steering Committee meetings by special invitation. MAPS Steering Committee participants may be called upon for input, guidance or decision making via other means as well. MAPS will operate by striving for consensus. If consensus is not apparent and the Executive Committee member(s) and/or Steering Committee participants feel a formal decision is needed, the meeting chair may determine if a vote is needed. If a vote is required, each MAPS member organization will have one vote each in making decisions. Formal decisions will be reached using an appropriate voting mechanism (voice, hand, or written ballot) as selected by the Executive Committee member(s) and will require a majority vote for approval. Steering Committee members who are unable to attend meetings or participate in key activities may designate an alternate from their organization to attend and/or participate. Minutes of Steering Committee meetings will be created and distributed to MAPS members as well as posted on the MAPS website. Meeting minutes will document agenda items, key decisions, and important actions.

MAPS Subcommittees and Task Forces: MAPS will operate with four standing committees:
- Communication and Education
- Best Practice
- Best Practice Technology Subgroup
- Data Privacy, Management, Measurement

At this time, MAPS has two shorter-term task forces with assignments:
- Annenberg III task force to develop local focus around May 2001 conference
- Operating Guidelines task force to develop guidelines for MAPS

MAPS subcommittees and task forces will meet when necessary, as called by the appropriate chairperson or leader. Meeting times and agendas should be disseminated to MAPS Steering Committee members and posted on the MAPS website. Meeting minutes are not required. Recommendations from subcommittees or task forces should be reviewed and approved by the MAPS Steering Committee prior to action.

EXPECTIONS OF MAPS MEMBERS

- MAPS members are expected to have an active representative who attends MAPS meetings; provides input on key initiatives, positions, or issues; shares pertinent information with other members; and represents MAPS activities as appropriate.

- MAPS members may be asked to support the work of MAPS financially, in principle, and through in-kind support. Each member should determine for themselves the best way they are able to support MAPS.

- MAPS will seek to work on issues and priorities that are of common interest and importance to all MAPS members. MAPS leadership expects that there will be differing opinions and positions among MAPS members on certain issues and will seek to understand those differing opinions so that all members are well-informed and can benefit from these learnings.

- MAPS will serve as a clearinghouse to gather and disseminate patient safety information relevant and pertinent to Minnesota. Members will be asked to contribute information about their work and activities for sharing among other MAPS members.

- MAPS will serve as a leadership forum to encourage dialog and discussion among members about issues that affect patient safety and possible solutions. Members will be asked to openly and candidly share their learning and experiences about patient safety for further leadership development.

- MAPS will serve as a network of organizations and individuals who are interested in the improvement of patient safety in Minnesota and who work together to achieve that goal. Members will be asked to participate with and meet with other key organizations or individuals when appropriate to share best practices, facilitate learning and develop common approaches to common problems.

RESOURCES AND SUPPORT

As MAPS exists today, and until further organizational goals and structure are determined, the three founding organizations will provide the majority of the staff and administrative resources to keep MAPS functioning. This support would include:

- meeting space and meeting support
- administrative support
- any other support deemed necessary

MAPS members will be asked to make a financial and/or in-kind contribution to support the operations and programs of MAPS each year. The suggested amount of the financial contribution will be the decision of the MAPS Executive Committee, and will be based on historic and planned operating expenses, as well as expected expenses associated with program goals and activities.

Recommendations:

- *The Task Force recommends that those organizations MAPS seeks as members should be asked to make a voluntary contribution of $500 for the calendar year 2001 to support the operations and programs of MAPS for the current year.*

- *The Task Force recommends that each Subcommittee submit programs and projects they intend to implement in 2001 that require funding so that a 2001 budget can be prepared.*

MAPS Guidelines for Receipt of Resources and Support
These guidelines apply to MAPS receipt of in-cash resources and support from any MAPS member or non-MAPS member organization. These guidelines are intended to assure that MAPS engages only in activities that are consistent with MAPS mission, do not create inappropriate conflicts of interest, maintains MAPS's credibility in the community, and assures that Supporters are clear that in-kind and cash support will not influence the mission, outcome, or activities of MAPS.

Prior to accepting any support beyond $500 from a MAPS member or non-MAPS member organization the MAPS Executive Committee shall assure that:
acceptance of support offered will further MAPS mission, values, and purposes; the supporting organization has provided the support without imposing specific restrictions as to MAPS's use of the support, or, if specific restrictions have been suggested, these restrictions have been determined by MAPS Executive Committee to be appropriate and acceptable.

If the supporting organization wishes to identify MAPS as the recipient of support, otherwise use MAPS's name or, if any data, products or publications may be prepared in conjunction with or as a result of the support, MAPS has established appropriate controls over the use of MAPS's name and appropriate restrictions on the ownership, distribution, and use of any data, products, or publications. If MAPS is expected to recognize the supporter, MAPS has assured that the means for providing such recognition have been clearly set forth, that such recognition is not intended (nor will be perceived as) an endorsement of the supporter or its products, and that such recognition is consistent with MAPS's mission and interests.

MAPS LEGISLATION REVIEW (approved January 2001)

1. Participation in the Minnesota Alliance for Patient Safety Coalition allows organizations to receive current legislative and administrative information that impacts patient safety practices.

2. Upon receipt of policy proposals, MAPS staff will e-mail an alert to Coalition members identifying the legislative or administrative proposal.

3. Coalition members are asked to review and analyze the proposal by comparing the MAPS Mission Statement and sub-committee principles to the legislative language.

4. Feedback to MAPS staff will be organized for presentation to the large group, should the need arise to develop a specific positionSpecial thanks to the task force who helped develop and prepare this document:

FINAL DRAFT : February 2001 MAPS Operating Guidelines Task Force: Dawn McGinley, NPSF, Chair; Members: Marie Dotseth, MN DoH; Jill Egan; MHHP: Shireen Gandhi-Kozel; MHHP: Lorrie Holmgren, MMA; Tania Krueger, MHHP; Amanda Sarata, MN DoH; MaryAnn Stump, Blue Cross.

-Approved by MAPS Steering Committee March 21, 2001
-Revised by MAPS Planning Committee June 11, 2001-collated MAPS Legislative Review to Operating Guidelines, revised voting structure

DRAFT

Minnesota Alliance for Patient Safety
Strategic Direction for MAPS
Working Draft April 2002

A. Background

MAPS was launched as a new organization in November 2000 by three convening founders working together as a public-private partnership:

- Minnesota Hospital and Healthcare Partnership (MHHP)
- Minnesota Department of Health
- Minnesota Medical Association (MMA)

B. Mission

To promote optimum patient safety through collaborative and supportive efforts among all participants of the health care system in Minnesota.

MAPS will achieve this mission through convening and actively engaging key patient safety stakeholders across the state to collectively advance the state of patient safety in Minnesota.

C. Goals

1. Improve patient safety in Minnesota
2. Improve the culture for patient safety at Minnesota health care organizations
3. Mobilize community resources to improve patient safety
4. Develop and implement educational processes for patient safety

MAPS will achieve these goals by:

- Working on issues and priorities that are of common interest and importance to all Minnesotans and therefore by the individuals and organizations that serve them.
- Serve as a clearinghouse to gather and disseminate patient safety information relevant and pertinent to Minnesota.
- Serve as a leadership forum to encourage dialog and discussion among members about issues that affect patient safety and possible solutions.
- Identifying and coordinating specific projects that will have significant impact on patient safety

D. Objectives and Strategies 2001-2002

Committee Charge	Committee Goals/Objectives	Strategies	Target Date
Steering Committee To promote optimum patient safety through collaborative and supportive efforts among all participants of the health care system in Minnesota.	a. Be an effective convener and facilitator to collaboratively engage all key patient safety stakeholders across Minnesota.	a. Provide leadership forums for patient safety stakeholders across health care organizations to collectively dialogue and create solutions to improve patient safety. • Hold 4-6 meetings from January to January.	a. December 2002.
	b. Promote the Spring 2001 Annenberg conference among health care providers and organizations throughout Minnesota and create visibility for MAPS by formally introducing MAPS initiatives and generate further Minnesota activities to promote patient safety.	b. Activities to promote MAPS at the Annenberg Conference: • Include a welcome letter from MAPS in the conference materials. • Host a MAPS reception for conference participants from Minnesota. • Set up a MAPS booth in the exhibitors' area.	b. Goals met May 2001
Communication and Education Subcommittee: Establish MAPS as the number one source for patient safety information in Minnesota	a. Instill confidence in consumers to actively participant in health care decisions.	a MAPS is developing a patient educational brochure to engage consumers.	a. June 2002
	b. Achieve a community wide understanding of patient safety issues.	b. Partner with MMIC and NPSF to disseminate a video on communicating disclosure to patients and families.	b. June 2002
	c. Increase access to patient safety information	c. Enhance MAPS Web site.	c. Completed March 2002
	d. Facilitate a culture change from one of retroactive blame to proactive learning.	d. Partner with MMIC and NPSF to disseminate a video on communicating disclosure to patients and families..	d. June 2002

Data Privacy, Measurement, and Management Subcommittee To identify, review, and develop recommendations on data measurement, data reporting and data privacy issues related to patient safety in Minnesota.	a. Develop recommendations on a data measurement strategy for patient safety in Minnesota. b. Develop recommendations on a data reporting strategy for patient safety in Minnesota. c. Develop recommendations to address data privacy and peer review issues related to the measurement and reporting of patient safety information in Minnesota.	a. Develop data reporting principles and measurement guidelines. b. Develop standardized working definitions related to patient safety. b. Data measurement/safety indicators will be developed. c. tbd	a. June 2002 b.Draft (Jan) June 2002 c. tbd
Best Practice Subcommittee Serving organizations to successfully identify and advance effective patient safety efforts.	a. **Identify what works to improve patient safety and why.** b. **Disseminate information about effective safe practices.** c. **Evaluate the impact of MAPS best practice dissemination efforts.**	a. Championing a 'Patients as Partners' campaign to engage consumers to be active and informed partners. b. Disseminate tool kits as a component of the 'Patients as Partners' campaign. c. tbd	a.December 2002 b.December 2002 c. tbd

Best Practice Subcommittee-Technolgy Project Improve patient safety and decrease medical error through the use of technology that is proven to be effective.	a. Collect recommendations regarding technology from the multitude of national and local organizations that are actively working to improve patient safety.	a. Identify principles for procurement and use of technology as it relates to patient safety.	a. Completed March 2002
	b. Develop a patient safety template from the recommendations that are evidence based which would have the most impact on reducing medical error.	b. Identify and disseminate resources around run-away pumps, technology around teams, bar coding, and computer order entry systems.	b. tbd
	c. Customize this template for long term care settings, hospitals, ambulatory clinics and retail pharmacies – or any other identified entity, including rural facilities.	c. tbd	c.tbd

E. Organizational Structure (from MAPS operating principles approved March 21, 2001):

The MAPS Executive Committee's purpose and role is to:

- Provide vision and mission for MAPS coalition.
- Provide focus and direction regarding coalition mission, goals and objectives.
- Provide guidance regarding operating processes and structure both long and short term.
- Provide resources from their organizations to assist with the operations and administration of the MAPS coalition.
- Manage financial resources provided to the MAPS coalition.
- Act as ambassadors of MAPS in all appropriate activities.

The MAPS Steering Committee's purpose and role is to:

- Set an agenda for both the short and long term work of MAPS according to the vision and mission of the coalition.
- Establish specific goals and objectives for areas of focus and key opportunities.
- Establish working structure and identify participants to accomplish key goals and objectives through Subcommittees and Task Forces.
- Prioritize the programs and projects among Subcommittees and Task Forces according to available resources and overall direction.
- Determine systems of measurement to evaluate effectiveness of MAPS work.

The MAPS Subcommittees and Task Force's purpose and role is to:

- Develop action plans to accomplish key MAPS goals and objectives
- Determine and secure resources needed to accomplish plans.
- Determine and implement measures of effectiveness for plans.
- Engage and involve experts from across the state and nation as team members.

Unique Role of MAPS

MAPS will promote the highest level of broad-based patient safety efforts for the Minnesotans they serve through the collaborative efforts of all stakeholders.

It is recognized that many other specific patient safety initiatives are underway locally and nationally as well as specific hospital programs. MAPS will attempt to coordinate and collaborate with these efforts and offer its' unique features, such as the benefits of a public-private partnership and its broad-based membership and expertise, in order to facilitate patient safety efforts throughout Minnesota.

Minnesota Specific Coalitions

Initiative	*Structure/ focus*	*Specific Projects*
Minnesota Alliance for Patient Safety	MAPS is Co-Chaired by MHHP, MDH and MMA. This coalition convenes over 50 key patient safety stakeholders from across the state including peer review organizations, regulators, professional associations, healthcare systems, professional insurance companies, health plans, purchasers, patient representation associations, and academics. MAPS focuses on broad-based patient safety activities that will improve the culture and advance safety within MAPS organizations including dissemination of patient safety resources.	• Developed Brochure '*Redefining the Culture for Patient Safety' Available at www.mhhp.com* • Patient safety education session for the 2001 legislators • Statewide collaboration to address safety culture barriers within each MAPS organization • Sharing of safety activities across MAPS participating organizations • Developed network for quick-response to legislative issues • Assisted the national planning committee for the Annenberg III patient safety conference • Disseminated '*A Call to Action: Roles and Responsibilities for Assuring Patient Safety' Available at www.mnpatientsafety.org*
Stratis Health, HCFA, Institute for Healthcare Improvement, and Rice Memorial Collaborative	HCFA and The Institute for Healthcare Improvement spearheaded a patient safety collaborative in Minnesota with assistance from Stratis Health, Mn's QIO and Rice Memorial Hospital in Wilmar, Mn. The Minnesota-based community laboratory was chosen to study quality initiatives in high-risk areas. Rice Memorial studied safety in the emergency department.	• Rice Memorial performed a study on noise levels in the ER with assist from an outside industry, which concurred with other industry studies that noise level above 60 decibels creates an environment conducive to human error based on interference with analytical abilities, ability to hear verbal orders, and problem solve.

(cont) Stratis Health, HCFA, Institute for Healthcare Improvement, and Rice Memorial Collaborative	Rice Memorial Hospital identified 3 specific safety issues within the Emergency Department to study. Their aim was to reduce medication errors by 25%, reduce incidence of missed pulmonary embolism diagnosis by 25%, and study and reduce noise levels by 25% in the Emergency Room.	• The use of a D-dimer upon ER visit increased the diagnosis of pulmonary embolisms. • This study has also reduced medication errors through reorganizing and storage of medicines improving standardized templates for high-risk medications, decrease in verbal orders, and use of allergy bands.
Safest in America	This group consists of 9 Twin City hospital system CEO's, COO's and CMO's. It is an operations group that identifies topics for collaboration. The topics will be process improvement activity and standardization of frontline practices.	Initial collaboration for standardization of practices will include: • Safe medication practices • Correct site surgery policies and procedures • Developing capability for ready exchange of best practice information around patient safety.
MHHP Patient Safety Committee	This committee convenes key rural and urban patient safety staff from MHHP facilities statewide. The committee develops and revises patient safety policies to advise and advance MHHP member facilities. Policy areas may include reporting, reporting, legislative issues, and patient safety policies such as response to unexpected outcomes.	• Developed safety tool kits for leadership, management, and staff. • Developed standardized beliefs for reporting systems • Developed "*Communicating Outcomes to Patients*." This is a model policy that provides suggested language and processes to use when communicating unanticipated outcomes with patients and their families. It is available at www.mhhp.com.
MMA Patient Safety Committee	This committee will convene key patient safety members from MMA to provide a physician-specific forum to coordinate patient safety initiatives across specialties.	First meeting was held June 14, 2001
MDH Interagency Task Force on Patient Safety	MDH is considering convening a task force that will convene Minnesota state agencies to collaboratively address patient safety across departments and ensure patient safety is a priority across all departments.	Education seminar sponsored by AHRQ and MDH being held July24th to learn more about this opportunity

Research Collaborative	This research collaborative will address patient safety across health care settings. The group is facilitated by Carlson School of Management and represented by Minnesota health care organizations.	The focus will be researching new questions within patient safety, such as the effectiveness of teams and work place culture.
Minnesota Executive Session on Patient Safety	The National Patient Safety Foundation and Harvard University co-sponsor The Minnesota Executive Session on Patient Safety. This is an executive forum, formatted after the 1999 Harvard Executive Session on Patient Safety. The goal of the Executive Session is to maximize leadership action to create a threshold change into the Minnesota health care system.	The Minnesota Executive Session on Patient Safety has met 3 times over the past 1 1/2 years. The goal is to meet 1-3 more times to provide a forum in which hospital executives and trustees dialogue about patient safety issues and successful strategies that are specific to the leadership level.

State Coalitions

Massachusetts
The Massachusetts Hospital Association established the Massachusetts Coalition for the Prevention of Medical Error (MCPME) in 1997. This group is a public-private partnership much like MAPS is. MCPME released a set of 12 best practice guidelines for preventing medication errors as well as a consumer's guide to the prevention of medication errors. The formal set of recommendations on medication error was sent out by the Commissioner of Health in a letter to all hospitals in the state. They are now in the process of measuring implementation of these recommendations and will report findings publicly.

Other projects include 'Safety First Alert' periodic publications, consumer brochure on their role with safe medication use. They have workgroups looking at developing best practices for wrong site surgery and anesthesia and are in the process of developing best practices for restraint and seclusion, which will be published summer 2001. The coalition advisory committee is advocating for a Betsy Lehman Center for Patient Safety and Medical Error Reduction(SB 526).

Illinois
The governor of Illinois established the Governor's Task Force on Patient Safety last year (November, 2000). This group was charged with looking at issues related to medical errors in Illinois and to make recommendations for improvement of health service delivery systems specific to eight areas: staffing levels, performance of specified activities by licensed staff only, reporting systems, assuring qualifications and competence of staff for specified units within hospitals, coordination/information sharing between state agencies, clearinghouse for best practices, reporting of repeat offenders to the Department of Professional Regulation, and drug and alcohol impaired health care providers. The Task Force recently released its recommendations.

Utah
The Utah Hospital Association and the Utah Medical Association recently formed the Utah Hospital Patient Safety Task Force that is looking at reducing errors in hospital care. The group recently approved two proposed administrative rules (proposed by the Department of Health) on patient safety related matters. One rule establishes a mandatory but confidential sentinel events reporting system; the second requires facilities to set up patient safety programs. This group is still new, but is different from MAPS in its hospital focus.

Iowa
Iowa has established a patient safety coalition that is still in the very early stages of development. This coalition is a partnership between the state government and the University, particularly the School of Public Health. Based on the tie to academia, this coalition may focus primarily on research.

State Coalitions (cont)

Florida
In Florida, the Commission on Excellence in Health Care was established pursuant to Chapter 2000-367, Florida Laws in 2000. This organization has various members, including the Board of Medicine, the Secretary of Health, the Florida Medical Association, the Board of Nursing, the Florida Nurses Association, the Florida Hospital Association, etc. This group was charged with writing a report outlining a statewide strategy on improving the health care delivery system through meaningful reporting standards, data collection and review, and quality measurement. Although this group is looking at issues involving general quality problems, the report addresses medical error and patient safety dominantly, and all the recommendations are applicable to patient safety.

Wisconsin
Coalition includes health care organizations similar to MAPS, in addition to Wisconsin Manufacturer's Union, Teacher's Union, and ASHP state Representative. Project that focused on medication errors resulted in the publication and endorsement of 10 medication error recommendations. The core coalition organizations fund a state center for patient safety-with potential for future state funding. They are also exploring changing the payment system to reward for quality.

Michigan
Coalition is on a 'fast track' with specific initiatives led by individual coalition members. Members include BCBSM, GM, Ford, Chrysler, unions, and education groups. They have received over $500,000 in grants. 4 initiatives include: Addressing medication errors community-wide; Connecting providers to BCBS's dry risk analysis system; task force to recommend ICU physician staffing; and a committee to collect data on nurse staffing.

Pennsylvania
Coalition is very similar to MAPS. They are in the process of surveying hospitals to develop a compendium of 'best practices.' They have recently published a brochure on culture which describes staff role to create a safe culture.

Suggested Measurements for MAPS

Each objective can be evaluated by both process measures and short and long term outcome measures based on the proposed strategies. When the strategies are accomplished, they should form the basis for measuring the success of the overall MAPS mission and subcommittee charge based on the pre-determined measurements. These measurements should be developed at the committee level. Examples include:

- Process measures (e.g. number of meetings, increased participants, number of publications, etc.)
- short-term outcome measures (e.g. development of operational web site, catalogue for web site, a thorough list of pertinent literature, establishment of a web-based interactive clearinghouse of best practices, data policy and plan for public reporting)
- long-term measures of the impact of the project overall. These would include some process and outcome measures of improvements in patient safety in Minnesota hospitals.

© Minnesota Alliance for Patient Safety. Please contact Tania Krueger, MAPS coordinator at (651) 641-1121 for information.

Minnesota Alliance for Patient Safety Participation List
June 2003

*** MAPS Contributors ***

- **3M**
- **Allina Hospitals and Clinics**
- **Association for Professionals in Infection Control and Epidemiology-Minnesota**
- **Blue Cross and Blue Shield of Minnesota**
- **Buyers Health Care Action Group**
- **Children's Hospitals and Clinics**
- **Fairview Health Services**
- **Healthcare Education and Research Foundation**
- **HealthPartners**
- **Medical Alley**
- **Midwest Medical Insurance Company**
- **Minnesota Association of Nurse Anesthetists**
- **Minnesota Board of Nursing**
- **Minnesota Board of Pharmacy**
- **Minnesota Council of Health Plans**
- **Minnesota Dental Association**
- **Minnesota Department of Health**
- **Minnesota Hospital Association**
- **Minnesota Medical Association**
- **Minnesota Medical Group Management Association**
- **Minnesota Nurses Association**
- **Minnesota Pharmacists Association**
- **Minnesota Society of Health System Pharmacists**
- **North Memorial Medical Center**
- **Park Nicollet Health Services**
- **Pharmaceutical Research Manufacturers of America**
- **Preferred One**
- **StratisHealth**
- **UCare Minnesota**
- **United Healthcare**
- **University of Minnesota, Carlson School of Management**
- **University of Minnesota, Medical School**

Additional MAPS Participants

- **Academic Health Center, University of Minnesota**
- **American Academy of Neurology**
- **Institute for Clinical Systems Improvement**
- **Joint Commission on Accreditation of Healthcare Organizations**
- **Katharine J. Densford International Center for Nursing Leadership – University of Minnesota**
- **Medica**
- **Minnesota Association of Patient Representatives**
- **Minnesota Center for Health Care Ethics**
- **Minnesota Department of Employee Relations**
- **Minnesota Department of Human Services**
- **Minnesota Health and Housing Alliance**
- **Minnesota Optometric Association**
- **Minnesota Organization of Leaders in Nursing**
- **Minnesota Safety Council**
- **Minnesota Society for Healthcare Risk Management**
- **Minnesota Wholesale Druggist Association**
- **National Patient Safety Foundation**
- **Ramsey Medical Society**
- **Wisconsin Physician Service/Medicare part B**

Minnesota Department of Health

News Release

June 6, 2003

Contact information

Gov. Pawlenty signs legislation creating new system for reporting adverse events in hospitals

Minnesota is the first state to fully adopt National Quality Forum standards for mandatory reporting of medical errors

June 6, 2003 — For the first time ever, Minnesotans will begin to have information about how well hospitals are doing at preventing 27 "never" events — medical errors and other adverse events that should never occur — thanks to a new law authored by State Senator Steve Kelley (D-Hopkins) and State Representative Lynda Boudreau (R-Faribault) and signed by Governor Tim Pawlenty on May 27, 2003. Examples of incidents that will now be systematically tracked include wrong-site surgery, retention of a foreign object in a patient after surgery and death or serious disability associated with medication error.

"No one finds these errors acceptable, whether they are patients, nurses, doctors, hospital managers or policy makers," Minnesota Commissioner of Health Dianne Mandernach said. "But we have to do more than point fingers. We have to identify problems and solve them so that we prevent them from occurring again."

Minnesota is the first state to fully adopt the standards established by the National Quality Forum (NQF) for reporting medical errors. NQF established the reporting standards in response to a 1999 report by the Institute of Medicine, which documented the prevalence of medical errors in hospitals. The new Minnesota Adverse Health Care Events Reporting Law mandates that hospitals disclose to the Minnesota Department of Health when any of these 27 events occur and that this information is shared with the public.

"This legislation provides a way for people in Minnesota to know whether we're making progress on the issues of safety that have everyone's attention," said David K. Wessner, Park Nicollet Health Services president and CEO and chair-elect of the Minnesota Hospital Association (MHA). "We've never had a way to measure this before. If you can't measure something, you can't improve it. This legislation gives us a way to consistently measure, report and be accountable for the events that we all agree should never happen," Wessner said.

The legislation (Senate File 1019 and House File 1001) earned broad support from legislators. The bills also had the support of the Minnesota Nurses Association and the Minnesota Medical Association.

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Some states have forms of mandatory reporting — some required by law and others by administrative action. The standards of measurement are not consistent, however, and in some states, the reporting standards could change over time. Minnesota, however, is the first state to adopt all of the NQF's 27 adverse events by legislative action. NQF hopes Minnesota's new law will lead to establishment of a national standard with consistent language and standards of measurement. This would enable the federal government and states to accurately compare data and benefit from shared information.

"Minnesota's decision-makers have demonstrated national leadership in improving patient safety," said NQF President and CEO Kenneth W. Kizer, MD, MPH. "Focusing on the National Quality Forum's list of 27 serious reportable events — identified through national consensus of a broad range of stakeholders — will lead to improvements in health care delivery and safer care for Minnesotans. We commend Minnesota for being the first state to adopt this systematic and standardized approach, and we hope other states will follow Minnesota's lead," Kizer said.

The law will begin to go into effect by the fall, after funds are raised to pay for MDH to begin initial implementation. During a two-year transition period, all Minnesota hospitals will begin reporting data to MHA, which will turn over aggregate data to MDH. MDH will then share data about the number and type of reported events with the Legislature and the public. When the law is fully implemented, the commissioner will publish public annual reports describing reported adverse events by facility.

-30-

For more information, contact:

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MHA media contacts:
Shireen Gandhi-Kozel or John Manning
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KEY: ~~stricken~~ = old language to be removed
underscored = new language to be added

NOTE: If you cannot see any difference in the key above, you **need to** change the display of stricken and/or underscored language.

Authors and Status ■ List versions

S.F No. 1019, 3rd Engrossment: 83rd Legislative Session (2003-2004) Posted on May 9, 2003

A bill for an act

relating to health; establishing a reporting system for adverse health care events; amending Minnesota Statutes 2002, section 145.64, subdivision 1; proposing coding for new law in Minnesota Statutes, chapter 144.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. [144.706] [CITATION.]

Sections 144.706 to 144.7069 may be cited as the Minnesota Adverse Health Care Events Reporting Act of 2003.

Sec. 2. [144.7063] [DEFINITIONS.]

Subdivision 1. [SCOPE.] Unless the context clearly indicates otherwise, for the purposes of sections 144.706 to 144.7069, the terms defined in this section have the meanings given them.

Subd. 2. [COMMISSIONER.] "Commissioner" means the commissioner of health.

Subd. 3. [FACILITY.] "Facility" means a hospital licensed under sections 144.50 to 144.58.

Subd. 4. [SERIOUS DISABILITY.] "Serious disability" means (1) a physical or mental impairment that substantially limits one or more of the major life activities of an individual, (2) a loss of bodily function, if the impairment or loss lasts more than seven days or is still present at the time of discharge from an inpatient health care facility, or (3) loss of a body part.

Subd. 5. [SURGERY.] "Surgery" means the treatment of disease, injury, or deformity by manual or operative methods. Surgery includes endoscopies and other invasive procedures.

Sec. 3. [144.7065] [FACILITY REQUIREMENTS TO REPORT, ANALYZE, AND CORRECT.]

Subdivision 1. [REPORTS OF ADVERSE HEALTH CARE EVENTS REQUIRED.] Each facility shall report to the commissioner the occurrence of any of the adverse health care events described in subdivisions 2 to 7 as soon as is reasonably and practically possible, but no later than 15 working days after discovery of the event. The report shall be filed in a format specified by the commissioner and shall identify the facility but shall not include any identifying information for any of the health care professionals, facility employees, or patients involved. The commissioner may consult with experts and organizations familiar with patient safety when developing the format for reporting and

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in further defining events in order to be consistent with industry standards.

Subd. 2. [SURGICAL EVENTS.] Events reportable under this subdivision are:

(1) surgery performed on a wrong body part that is not consistent with the documented informed consent for that patient. Reportable events under this clause do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent;

(2) surgery performed on the wrong patient;

(3) the wrong surgical procedure performed on a patient that is not consistent with the documented informed consent for that patient. Reportable events under this clause do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent;

(4) retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained; and

(5) death during or immediately after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

Subd. 3. [PRODUCT OR DEVICE EVENTS.] Events reportable under this subdivision are:

(1) patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the facility when the contamination is the result of generally detectable contaminants in drugs, devices, or biologics regardless of the source of the contamination or the product;

(2) patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Device includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators; and

(3) patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

Subd. 4. [PATIENT PROTECTION EVENTS.] Events reportable under this subdivision are:

(1) an infant discharged to the wrong person;

(2) patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have decision-making capacity; and

(3) patient suicide or attempted suicide resulting in serious disability while being cared for in a facility due to patient actions after admission to the facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the facility.

Subd. 5. [CARE MANAGEMENT EVENTS.] Events reportable under this subdivision are:

(1) patient death or serious disability associated with a medication error, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong

4.5 route of administration, excluding reasonable differences in
4.6 clinical judgment on drug selection and dose;
4.7 (2) patient death or serious disability associated with a
4.8 hemolytic reaction due to the administration of ABO-incompatible
4.9 blood or blood products;
4.10 (3) maternal death or serious disability associated with
4.11 labor or delivery in a low-risk pregnancy while being cared for
4.12 in a facility, including events that occur within 42 days
4.13 postdelivery and excluding deaths from pulmonary or amniotic
4.14 fluid embolism, acute fatty liver of pregnancy, or
4.15 cardiomyopathy;
4.16 (4) patient death or serious disability directly related to
4.17 hypoglycemia, the onset of which occurs while the patient is
4.18 being cared for in a facility;
4.19 (5) death or serious disability, including kernicterus,
4.20 associated with failure to identify and treat hyperbilirubinemia
4.21 in neonates during the first 28 days of life.
4.22 "Hyperbilirubinemia" means bilirubin levels greater than 30
4.23 milligrams per deciliter;
4.24 (6) stage 3 or 4 ulcers acquired after admission to a
4.25 facility, excluding progression from stage 2 to stage 3 if stage
4.26 2 was recognized upon admission; and
4.27 (7) patient death or serious disability due to spinal
4.28 manipulative therapy.
4.29 Subd. 6. [ENVIRONMENTAL EVENTS.] Events reportable under
4.30 this subdivision are:
4.31 (1) patient death or serious disability associated with an
4.32 electric shock while being cared for in a facility, excluding
4.33 events involving planned treatments such as electric
4.34 countershock;
4.35 (2) any incident in which a line designated for oxygen or
4.36 other gas to be delivered to a patient contains the wrong gas or
5.1 is contaminated by toxic substances;
5.2 (3) patient death or serious disability associated with a
5.3 burn incurred from any source while being cared for in a
5.4 facility;
5.5 (4) patient death associated with a fall while being cared
5.6 for in a facility; and
5.7 (5) patient death or serious disability associated with the
5.8 use of restraints or bedrails while being cared for in a
5.9 facility.
5.10 Subd. 7. [CRIMINAL EVENTS.] Events reportable under this
5.11 subdivision are:
5.12 (1) any instance of care ordered by or provided by someone
5.13 impersonating a physician, nurse, pharmacist, or other licensed
5.14 health care provider;
5.15 (2) abduction of a patient of any age;
5.16 (3) sexual assault on a patient within or on the grounds of
5.17 a facility; and
5.18 (4) death or significant injury of a patient or staff
5.19 member resulting from a physical assault that occurs within or
5.20 on the grounds of a facility.
5.21 Subd. 8. [ROOT CAUSE ANALYSIS; CORRECTIVE ACTION
5.22 PLAN.] Following the occurrence of an adverse health care event,
5.23 the facility must conduct a root cause analysis of the event.
5.24 Following the analysis, the facility must: (1) implement a
5.25 corrective action plan to implement the findings of the analysis
5.26 or (2) report to the commissioner any reasons for not taking
5.27 corrective action. If the root cause analysis and the
5.28 implementation of a corrective action plan are complete at the

5.29 time an event must be reported, the findings of the analysis and
5.30 the corrective action plan must be included in the report of the
5.31 event. The findings of the root cause analysis and a copy of
5.32 the corrective action plan must otherwise be filed with the
5.33 commissioner within 60 days of the event.
5.34 Subd. 9. [ELECTRONIC REPORTING.] The commissioner must
5.35 design the reporting system so that a facility may file by
5.36 electronic means the reports required under this section. The
6.1 commissioner shall encourage a facility to use the electronic
6.2 filing option when that option is feasible for the facility.
6.3 Subd. 10. [RELATION TO OTHER LAW.] (a) Adverse health
6.4 events described in subdivisions 2 to 6 do not constitute
6.5 "maltreatment" or "a physical injury that is not reasonably
6.6 explained" under section 626.557 and are excluded from the
6.7 reporting requirements of section 626.557, provided the facility
6.8 makes a determination within 24 hours of the discovery of the
6.9 event that this section is applicable and the facility files the
6.10 reports required under this section in a timely fashion.
6.11 (b) A facility that has determined that an event described
6.12 in subdivisions 2 to 6 has occurred must inform persons who are
6.13 mandated reporters under section 626.5572, subdivision 16, of
6.14 that determination. A mandated reporter otherwise required to
6.15 report under section 626.557, subdivision 3, paragraph (e), is
6.16 relieved of the duty to report an event that the facility
6.17 determines under paragraph (a) to be reportable under
6.18 subdivisions 2 to 6.
6.19 (c) The protections and immunities applicable to voluntary
6.20 reports under section 626.557 are not affected by this section.
6.21 (d) Notwithstanding section 626.557, a lead agency under
6.22 section 626.5572, subdivision 13, is not required to conduct an
6.23 investigation of an event described in subdivisions 2 to 6.
6.24 Sec. 4. [144.7067] [COMMISSIONER DUTIES AND
6.25 RESPONSIBILITIES.]
6.26 Subdivision 1. [ESTABLISHMENT OF REPORTING SYSTEM.] (a)
6.27 The commissioner shall establish an adverse health event
6.28 reporting system designed to facilitate quality improvement in
6.29 the health care system. The reporting system shall not be
6.30 designed to punish errors by health care practitioners or health
6.31 care facility employees.
6.32 (b) The reporting system shall consist of:
6.33 (1) mandatory reporting by facilities of 27 adverse health
6.34 care events;
6.35 (2) mandatory completion of a root cause analysis and a
6.36 corrective action plan by the facility and reporting of the
7.1 findings of the analysis and the plan to the commissioner or
7.2 reporting of reasons for not taking corrective action;
7.3 (3) analysis of reported information by the commissioner to
7.4 determine patterns of systemic failure in the health care system
7.5 and successful methods to correct these failures;
7.6 (4) sanctions against facilities for failure to comply with
7.7 reporting system requirements; and
7.8 (5) communication from the commissioner to facilities,
7.9 health care purchasers, and the public to maximize the use of
7.10 the reporting system to improve health care quality.
7.11 (c) The commissioner is not authorized to select from or
7.12 between competing alternate acceptable medical practices.
7.13 Subd. 2. [DUTY TO ANALYZE REPORTS; COMMUNICATE
7.14 FINDINGS.] The commissioner shall:
7.15 (1) analyze adverse event reports, corrective action plans,
7.16 and findings of the root cause analyses to determine patterns of

7.17 systemic failure in the health care system and successful
7.18 methods to correct these failures;
7.19 (2) communicate to individual facilities the commissioner's
7.20 conclusions, if any, regarding an adverse event reported by the
7.21 facility;
7.22 (3) communicate with relevant health care facilities any
7.23 recommendations for corrective action resulting from the
7.24 commissioner's analysis of submissions from facilities; and
7.25 (4) publish an annual report:
7.26 (i) describing, by institution, adverse events reported;
7.27 (ii) outlining, in aggregate, corrective action plans and
7.28 the findings of root cause analyses; and
7.29 (iii) making recommendations for modifications of state
7.30 health care operations.
7.31 Subd. 3. [SANCTIONS.] (a) The commissioner shall take
7.32 steps necessary to determine if adverse event reports, the
7.33 findings of the root cause analyses, and corrective action plans
7.34 are filed in a timely manner. The commissioner may sanction a
7.35 facility for:
7.36 (1) failure to file a timely adverse event report under
8.1 section 144.7065, subdivision 1; or
8.2 (2) failure to conduct a root cause analysis, to implement
8.3 a corrective action plan, or to provide the findings of a root
8.4 cause analysis or corrective action plan in a timely fashion
8.5 under section 144.7065, subdivision 8.
8.6 (b) If a facility fails to develop and implement a
8.7 corrective action plan or report to the commissioner why
8.8 corrective action is not needed, the commissioner may suspend,
8.9 revoke, fail to renew, or place conditions on the license under
8.10 which the facility operates.
8.11 Sec. 5. [144.7069] [INTERSTATE COORDINATION; REPORTS.]
8.12 The commissioner shall report the definitions and the list
8.13 of reportable events adopted in this act to the National Quality
8.14 Forum and, working in coordination with the National Quality
8.15 Forum, to the other states. The commissioner shall monitor
8.16 discussions by the National Quality Forum of amendments to the
8.17 forum's list of reportable events and shall report to the
8.18 legislature whenever the list is modified. The commissioner
8.19 shall also monitor implementation efforts in other states to
8.20 establish a list of reportable events and shall make
8.21 recommendations to the legislature as necessary for
8.22 modifications in the Minnesota list or in the other components
8.23 of the Minnesota reporting system to keep the system as nearly
8.24 uniform as possible with similar systems in other states.
8.25 Sec. 6. Minnesota Statutes 2002, section 145.64,
8.26 subdivision 1, is amended to read:
8.27 Subdivision 1. [DATA AND INFORMATION.] (a) Except as
8.28 provided in subdivision 4, data and information acquired by a
8.29 review organization, in the exercise of its duties and
8.30 functions, or by an individual or other entity acting at the
8.31 direction of a review organization, shall be held in confidence,
8.32 shall not be disclosed to anyone except to the extent necessary
8.33 to carry out one or more of the purposes of the review
8.34 organization, and shall not be subject to subpoena or
8.35 discovery. No person described in section 145.63 shall disclose
8.36 what transpired at a meeting of a review organization except to
9.1 the extent necessary to carry out one or more of the purposes of
9.2 a review organization. The proceedings and records of a review
9.3 organization shall not be subject to discovery or introduction
9.4 into evidence in any civil action against a professional arising

9.5 out of the matter or matters which are the subject of
9.6 consideration by the review organization. Information,
9.7 documents or records otherwise available from original sources
9.8 shall not be immune from discovery or use in any civil action
9.9 merely because they were presented during proceedings of a
9.10 review organization, nor shall any person who testified before a
9.11 review organization or who is a member of it be prevented from
9.12 testifying as to matters within the person's knowledge, but a
9.13 witness cannot be asked about the witness' testimony before a
9.14 review organization or opinions formed by the witness as a
9.15 result of its hearings. For purposes of this subdivision,
9.16 records of a review organization include Internet-based data
9.17 derived from data shared for the purposes of the standardized
9.18 incident reporting system described in section 145.61,
9.19 subdivision 5, clause (q), and reports submitted electronically
9.20 in compliance with sections 144.706 to 144.7069.
9.21 (b) Notwithstanding paragraph (a), a review organization
9.22 may release nonpatient-identified aggregate trend data on
9.23 medical error and iatrogenic injury and a facility may file the
9.24 reports, analyses, and plans required by sections 144.706 to
9.25 144.7069 without violating this section or being subjected to a
9.26 penalty under section 145.66 and without compromising the
9.27 protections provided under sections 145.61 to 145.67 to the
9.28 reporter of such information; to the review organization, its
9.29 sponsoring organizations, and members; and to the underlying
9.30 data and reports.
9.31 (c) The confidentiality protection and protection from
9.32 discovery or introduction into evidence provided in this
9.33 subdivision shall also apply to the governing body of the review
9.34 organization and shall not be waived as a result of referral of
9.35 a matter from the review organization to the governing body or
9.36 consideration by the governing body of decisions,
10.1 recommendations, or documentation of the review organization.
10.2 (d) The governing body of a hospital, health maintenance
10.3 organization, or community integrated service network, that is
10.4 owned or operated by a governmental entity, may close a meeting
10.5 to discuss decisions, recommendations, deliberations, or
10.6 documentation of the review organization. A meeting may not be
10.7 closed except by a majority vote of the governing body in a
10.8 public meeting. The closed meeting must be tape recorded and
10.9 the tape must be retained by the governing body for five years.
10.10 Sec. 7. [ADVERSE HEALTH CARE EVENTS REPORTING SYSTEM
10.11 TRANSITION PERIOD.]
10.12 (a) Effective July 1, 2003, limited implementation of the
10.13 Adverse Health Care Events Reporting Act shall begin, provided
10.14 the commissioner of health has secured sufficient nonstate funds
10.15 for this purpose. During this period, the commissioner must:
10.16 (1) solicit additional nonstate funds to support full
10.17 implementation of the system;
10.18 (2) work with organizations and experts familiar with
10.19 patient safety to review reporting categories in Minnesota
10.20 Statutes, section 144.7065, make necessary clarifications, and
10.21 develop educational materials; and
10.22 (3) monitor activities of the National Quality Forum and
10.23 other patient safety organizations, other states, and the
10.24 federal government in the area of patient safety.
10.25 (b) Effective July 1, 2003, facilities defined in Minnesota
10.26 Statutes, section 144.7063, subdivision 3, shall report any
10.27 adverse health care events, as defined in Minnesota Statutes,
10.28 section 144.7065, to the incident reporting system maintained by

10.29 the Minnesota Hospital Association. The association shall
10.30 provide a summary report to the commissioner that identifies the
10.31 types of events by category. The association shall consult with
10.32 the commissioner regarding the data to be reported to the
10.33 commissioner, storage of data received by the association but
10.34 not reported to the commissioner, and eventual retrieval by the
10.35 commissioner of stored data.
10.36 (c) The commissioner shall report to the legislature by
11.1 January 15 of 2004 and 2005, with a list of the number of
11.2 reported events by type and recommendations, if any, for
11.3 reporting system modifications, including additional categories
11.4 of events that should be reported.
11.5 (d) From July 1, 2003, until full implementation of the
11.6 reporting system, the commissioner of health shall not make a
11.7 final disposition as defined in Minnesota Statutes, section
11.8 626.5572, subdivision 8, for investigations conducted in
11.9 licensed hospitals under the provisions of Minnesota Statutes,
11.10 section 626.557. The commissioner's findings in these cases
11.11 shall identify noncompliance with federal certification or state
11.12 licensure rules or laws.
11.13 (e) Effective July 1, 2004, the reporting system shall be
11.14 fully implemented, provided (1) the commissioner has secured
11.15 sufficient funds from nonstate sources to operate the system
11.16 during fiscal year 2005, and (2) the commissioner has notified
11.17 facilities by April 1, 2004, of their duty to report.
11.18 (f) Effective July 1, 2005, the reporting system shall be
11.19 operated with state appropriations.

Statement For The Record

of the

Alliance of Specialty Medicine

to the

Senate Permanent Investigations Subcommittee of the Governmental Affairs Committee

regarding

Patient Safety: Instilling Hospitals with Culture of Continuous Improvement

June 11, 2003

Mr. Chairman, members of the subcommittee, the Alliance of Specialty Medicine, a coalition of 12 medical organizations representing over 160,000 specialty care physicians in the United States, appreciates this opportunity to submit for the hearing record our comments on patient safety.

The Alliance of Specialty Medicine believes that physicians, other health care providers, and patients working together can design safety processes into the nation's health care system.

Specialist physicians strive to provide the best medical care to their patients. As in all other professions, however, errors can occur in the delivery of that care. Creating a health care environment that encourages the development of safety systems and eliminates the culture of blame is essential for improving patient safety.

As part of our commitment to safety and quality in the nation's healthcare system, Alliance member organizations have already implemented a number of safety programs. Below is a brief list of some of those patient safety accomplishments:

The **Society of Thoracic Surgeons'** risk-stratified National Cardiac Surgical Database is the largest voluntary clinical database in medicine with over 2.1 million patient records harvested since its inception in 1989. While individual data is held confidential – to encourage reporting – every participating hospital and surgeon can readily compare its outcomes, risk-stratified, against the outcomes of other facilities or surgeons, encouraging faster adoption of best practices. Use of

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this data has contributed to the 40 percent reduction in mortality from bypass surgery in the last ten years.

The **American Academy of Orthopaedic Surgeons** launched the "Sign Your Site" initiative, an education program that urges surgeons of all surgical specialties to mark the operative site, in consultation with the patient, as part of their pre-surgery routine. AAOS supports the "Sign Your Site" initiative as a required protocol for every hospital seeking certification by the Joint Commission on Accreditation of Healthcare Organizations.

Over the past 20 years, the **American College of Cardiology** has collaborated with the American Heart Association, the Society for Coronary Angiography and Intervention, and other cardiovascular organizations to provide guidance in the diagnosis and management of various cardiovascular conditions and to establish protocols for patient care that is consistent and based on timely clinical evidence.

The **American Society for Clinical Pathology** hosted a "Consensus Conference on Second Opinions in Diagnostic Anatomic Pathology: Who, What and When." The conference, which was open to the public, convened with pathology experts of various disciplines, surgical representation, and a patient advocate. The conferees worked to reach a consensus on what specimens should be reviewed under second opinions, whose opinion prevails upon a second review, when a second opinion should occur, and to develop general guidelines for second opinions in diagnostic anatomic pathology. Second opinions are a key aspect in the assurance of patient safety for tissue and cytology based diagnoses.

The **American College of Emergency Physicians** assigned a task force to define appropriate data elements that should be collected to further patient safety, and have already developed clinical policies that incorporate safe care for the patient.

The **American Academy of Dermatology Association** has developed 49 guidelines of care for medical and surgical dermatologic services, ranging from acne to psoriasis to office-based medicine. New guidelines of care are appropriately developed and updated.

The **American Urological Association** initiated a Documented Outcomes Collection System (DOCS) as a way in which outcomes data could be used to analyze significant trends and outcomes in the treatment of kidney stones.

National Association of Spine Specialists has a web site page dedicated for spine care patients who seek information on preventing injury and on common spine conditions.

Transfusion medicine laboratory professionals have a long tradition for error detection and prevention systems by following standard operating procedures and conducting audits. Blood administration-related accidents and errors -- which occur outside the confines of blood bank/transfusion service laboratory -- represent a significant cause of transfusion morbidity and mortality. To address this issue, the **American Society for Clinical Pathology** joined with the American Organization of Nurse Executives in a Patient Safety Transfusion Medicine Project Team to identify seven essential components of the blood transfusion process. The joint project team developed flow charts and standard operating procedure checklists to assist hospital

personnel in assessing the status of their own processes and procedures and take necessary actions to close gaps that may compromise blood transfusion safety.

The **American Urological Association** is part of an ongoing effort to create model federal and state guidelines to ensure optimum patient safety in the office and ambulatory surgical settings. In addition, the AUA strongly supports patient education efforts as the first line of patient safety and publishes a series of patient education brochures and treatment guidelines as well as offers a patient oriented website regarding the treatment of urological diseases.

The **American Academy of Orthopaedic Surgeons** conducted a series of closed-claim professional liability insurance studies, through on-site retrospective review of the records of insurance companies across the country, in order to assist orthopaedic surgeons in providing optimum patient care. Several orthopaedic diagnoses and procedures have been reviewed that have resulted in the publication of two books and numerous articles that have identified trends in unexpected outcomes and medical errors. From these studies, appropriate treatment protocols and operating methods have been established or clarified leading to promotion of patient safety and appropriate surgical practice.

The **American College of Emergency Physicians** developed curriculum for teaching emergency physician residents about patient safety.

The **American College of Cardiology** operates the National Cardiovascular Data Registry - the only national cardiovascular data repository for cardiac catheterization laboratory measures of care that enables physicians and facilities to compare their practice patterns and outcomes with those of national and peer groups. Participants use this data for improving patient care at their facilities and supporting local quality improvement programs.

The **American College of Radiology** established its own Patient Safety Task Force that represents all segments of radiology, including residents, radiologic technologists, radiological nurses, and a National Electronics Manufacturers Association representative. The purpose of the Task Force was to study the issues of patient safety as they relate to radiology and radiation oncology. The Task Force's mission now has been incorporated into the Commission on Quality and Safety.

The **American Academy of Dermatology Association** has produced a number of comprehensive manuals designed to assist dermatologists with compliance with a number of federal statutes covering quality and safety issues.

National Association of Spine Specialists designed a "Sign, Mark & X-ray" program to prevent wrong-site spinal surgery, including a health care provider checklist for safety. NASS has also created Clinical Guidelines for Multidisciplinary Spine Care Specialists that represent a complete guideline from primary care to chronic, multidisciplinary treatment that includes specific time frames for treatment, and definitions of end points for treatment and treatment success or failure.

The Agency for Healthcare Research and Quality funded research and analysis of data in the existing **Society of Thoracic Surgeons'** risk-stratified data base on outcomes in Coronary Artery Bypass and Graft Surgery. This 2001 AHRQ-funded analysis demonstrated that wider adoption of two practices - pre-operative use of beta blockers and, in older patients, use of the Internal

Mammary Artery for at least one bypass (use of the IMA was already accepted as state of the art for younger patients) would significantly improve outcomes - that is, that adoption of these practices would save lives.

Further Improvements
Improvements in healthcare quality require the cooperation and participation of many individuals. Voluntary sharing of information promotes and is often a prerequisite to such improvements at all levels of our complex, interconnected health care delivery system. The sharing of patient safety data may enable qualified researchers to identify specific techniques and processes of care to improve outcomes. To encourage such information exchange, appropriate legal protections should be granted to health care providers that disclose medical errors.

The optimal patient safety reporting system would:

- Foster a non-punitive environment for reporting adverse outcomes, including adequate legal protections for the providers who supply information to medical error databases, patient safety committees and organizations,

- Establish and enforce guidelines to protect the confidentiality of patients, healthcare professionals, and healthcare organizations,

- Analyze reported data to identify the factors contributing to adverse events in order to minimize future risk, and

- Share patient safety information, to the extent possible, among healthcare organizations and healthcare reporting systems.

The Alliance of Specialty Medicine is committed to safety and quality in the nation's healthcare system. The above-mentioned principles would help contribute to an appropriate patient safety reporting system.

Thank you for your consideration of our comments. The Alliance of Specialty Medicine, whose mission is to improve access to quality medical care for all Americans through the unified voice of specialty physicians promoting sound federal policy, stands ready to assist you on this and other important health care policy issues facing our nation.

Statement for the Record

of the

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

to the

Permanent Subcommittee on Investigations
Governmental Affairs Committee
United States Senate

June 11, 2003

Patient Safety: Instilling Hospitals With a Culture of Continuous Improvement

The American College of Obstetricians and Gynecologists (ACOG), an organization representing 46,000 physicians, commends the Committee for its attention to legislation to improve patient safety. As partners in women's health care, we strongly support legislation that works to eliminate health care errors and ensure quality care for every woman. Patient safety is a critical component of ACOG's efforts to reform our nation's health care system.

Although the focus of today's hearing is to improve hospital safety measures, ACOG recognizes that all health care providers must make patient safety a top priority. The College has long encouraged physicians and other health care professionals to participate in a voluntary, non-punitive system to report and evaluate errors and share their experiences with others. We support the principles that provided the foundation for the Institute of Medicine's 1999 report entitled, *To Err is Human,* which noted that systems must be improved. It is imperative that we work together to transform the health care system from a culture of blame to a culture of safety, focused on information sharing to prevent adverse outcomes.

ACOG urges Congress to focus on the adoption of preventable measures rather than punitive ones to reduce the incidence of adverse events. We support House-passed legislation, HR 663,

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the Patient Safety Act of 2003, which addresses patient safety and the reporting of medical errors and near misses. We also support S.720, the Patient Safety and Quality Improvement Act, introduced by Senator James Jeffords and co-sponsored by Senators Bill Frist, MD, Judd Gregg, and John Breaux. Critical provisions contained in both the House and Senate bills ensure that information submitted by physicians, hospitals and health care providers to patient safety organizations (PSOs) remains confidential. Enabling physicians to confidentially report information that can then be comprehensively analyzed will improve systems and ensure that errors are corrected.

It is essential that any legislation enacted create a non-punitive environment that ensures confidentiality protections for patients, health care professionals, and health care organizations submitting data to PSOs. There must also be the opportunity to share information among health care organizations and to foster confidential collaboration with other health care reporting systems. Most important, legislation must ensure federal legal protection for information submitted to patient safety reporting systems. Rather than seeking to blame physicians and other health care providers, it is critically important to support meaningful system change that will ensure future adverse events and near misses are avoided altogether. Such protections should extend to any data, report, memorandum, analysis, statement or other communication developed for the purposes of the system.

In addition to supporting current legislation, ACOG remains committed to educating its Fellows on patient safety. One of the College's most successful patient safety programs is the Voluntary Review of Quality Care (VRQC) program, established in 1986. The mission of the VRQC program is to provide peer review consultations to departments of obstetrics and gynecology, assess the quality of care provided, and suggest possible alternative actions for improvement. At the request of hospitals, this program makes available three or more board-certified, practicing obstetrician-gynecologists to evaluate the hospital's clinical performance in obstetrics and gynecology. In addition, a nurse and other specialty physicians may assist in the evaluation. The program offers comprehensive, department-wide reviews that focus on all practitioners with obstetric-gynecologic privileges and focused reviews of an individual physician's quality of care. It is a good example of positive collaboration between physicians and hospitals.

During the site visit, the reviewers use various quality improvement techniques, including an evaluation based on the College's policies and publications. Based on findings revealed from hospital data, medical record review, and interviews of key hospital staff, the review team provides a confidential comprehensive final report for the hospital containing specific recommendations. These reports are valuable tools in promoting constructive changes and helping to identify potential areas for improvement of quality of care provided. Typically, the report contains recommendations on how to improve the system, adopt new programs, and address the hospital's particular concerns.

Programs like the VRQC serve as the foundation to our efforts to ensure quality care. This successful program, however, is only one of the many tools we offer our physicians.

For three decades, the College has published documents to inform and assist physicians who participate in peer review and quality improvement activities. Our 2000 volume, *Quality*

Improvement in Women's Health Care, is intended to serve as a primer for obstetricians and gynecologists starting or managing quality improvement programs within their hospitals. In addition, ACOG publishes patient safety articles that appear in *ACOG's Clinical Review* and *ACOG Today* on various topics including, medication errors, surgical errors, laboratory test result tracking, regulatory changes, and cultural changes necessary to improve patient safety. Because we believe that our role as a medical specialty society is to serve as a catalyst for improvement, we continue to reach out to our physicians through postgraduate continuing medical education courses as well.

We thank the Subcommittee for their attention to this important issue, and appreciate the opportunity to present our concerns for the Subcommittee's consideration. The College looks forward to working with you as we push for a meaningful solution to ensure greater patient safety in the delivery of quality health care for every woman.

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ATTACHMENT A
Patient Safety Coalition[1]
General Principles for Patient Safety Reporting Systems

1. **Creating an Environment for Safety.** *There should be a nonpunitive culture for reporting healthcare errors that focuses on preventing and correcting systems failures and not on individual or organization culpability.*

- Healthcare professionals and organizations should foster a positive atmosphere that encourages the submission of healthcare error reports to public or private oversight organizations, accrediting bodies, an official compendial body, or other generally recognized patient safety reporting systems. The existence of a reporting system does not relieve healthcare professionals and organizations of their responsibility to maintain professionally recognized standards of care.

2. **Data Analysis.** *Information submitted to reporting systems must be comprehensively analyzed to identify actions that would minimize the risk that reported events recur.*

- Systems within organizations should be scrutinized to identify weaknesses and processes that make healthcare errors possible or likely to occur, and to identify actions to prevent future errors. Effective procedures and/or protocols developed through reporting systems should be compiled and widely disseminated to all healthcare professionals and organizations.

3. **Confidentiality.** *Confidentiality protections for patients, healthcare professionals, and healthcare organizations are essential to the ability of any reporting system to learn about errors and effect their reduction.*

- Reporting systems should protect the identity of individual patients and abide by all relevant confidentiality laws and regulations. The identities of healthcare professionals and organizations involved in errors should not be disclosed outside a reporting system without consent.

4. **Information Sharing.** *Reporting systems should facilitate the sharing of patient safety information among healthcare organizations and foster confidential collaboration with other healthcare reporting systems.*

- Sharing information is fundamental to a reporting system's ability to achieve widespread improvements in patient safety and to instill a confidence in the public that safety issues are being addressed. Sharing of error-related information is subject to the confidentiality principle.

[1] ACOG is a member of the Patient Safety Coalition, a group of healthcare professionals and organizations, which developed five basic principles to inform policymakers about the essential elements of an effective reporting system.

- The causes of errors and their solutions must be widely shared so that all healthcare organizations can learn from the experiences of others.

- In some circumstances, it will be desirable to share reports of errors among reporting systems, and with other appropriate quality improvement entities, in order to accomplish root cause analyses, to construct action plans, and to engage in other efforts to enhance patient safety.

5. **Legal Status of Reporting System Information.** *The absence of federal protection for information submitted to patient safety reporting systems discourages the use of such systems, which reduces the opportunity to identify trends and implement corrective measures. Information developed in connection with reporting systems should be privileged for purposes of federal and state judicial proceedings in civil matters, and for purposes of federal and state administrative proceedings, including with respect to discovery, subpoenas, testimony, or any other form of disclosure.*

   (a) Scope. The privilege for the information prepared for a reporting system should extend to any data, report, memorandum, analysis, statement, or other communication developed for the purposes of the system. This privilege should not interfere with the disclosure of information that is otherwise available, including the right of individuals to access their own medical records.

   (b) No Waiver. The submission of healthcare error information to a reporting system, or the sharing of information by healthcare organizations or reporting systems with third parties in accordance with these principles, should not be construed as waiving this privilege or any other privilege under federal or state law that exists with respect to the information.

   (c) Freedom of Information Act. Healthcare error information received by and from reporting systems should be exempt from the Freedom of Information Act and other similar state laws. Such an exemption is necessary to preserve the privilege discussed in this principle.

   (d) Impact on State Law. A federal law is necessary to assure protection of information submitted to national reporting systems, but the federal protection should not preempt state evidentiary laws that provide greater protection than federal law. Providing such information to reporting systems should not constitute a waiver of any state law privilege.