

PATIENT SAFETY AND QUALITY INITIATIVES

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED NINTH CONGRESS
FIRST SESSION

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PATIENT SAFETY AND QUALITY INITIATIVES

THURSDAY, JUNE 9, 2005

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:06 p.m., in room 2322, Rayburn House Office Building, Hon. Nathan Deal (chairman) presiding.

Members present: Representatives Deal, Shimkus, Myrick, Burgess, Barton (ex officio), Waxman, Capps, and Baldwin.

Staff present: Nandan Kenkeremath, counsel; Brandon Clark, health policy coordinator; Eugenia Edwards, legislative clerk; Puwee Kempf, minority professional staff member; Bridgett Taylor, minority professional staff member; and Voncille Hines, minority research assistant.

Mr. DEAL. I will call the meeting to order and I will recognize myself first for an opening statement. First of all, I am pleased to tell you we have two panels today of distinguished individuals to talk to us on the general issue of patient safety. We look forward to hearing their testimony.

The purpose of today's hearing is to focus on public and private sector initiatives to reduce the number of medical errors to improve patient outcomes and to improve overall quality.

In 1999, the Institute of Medicine released a report on the problem of medical errors and their impact on health in America. In this report, they estimated that at least 44,000 Americans die each year as a result of medical errors and that this number may be as high as 98,000.

If these numbers are accurate—and they rank medical errors as the fifth overall leading cause of death—and I think all of us understand that this is just unacceptable. There is no question that we should be doing more to protect patients from unnecessary medical errors. This hearing can serve as a springboard for moving forward on finding a solution to this pervasive problem.

A broad list of agencies and stakeholders are working on efforts to improve patient safety and reduce the number of medical errors. Many of these groups are represented here today.

I applaud your efforts and look forward to continuing to work with you in the future. I firmly believe that we have the necessary technological resources and understanding of the problem to be able to reduce the number of deaths caused by medical error by at least half in the next 5 years. I am committed to achieving this

goal and I ask each of the members of this committee to join me in that event.

As an important first step, I want to work with my colleagues on both sides of the aisle and in both houses of Congress to pass a bipartisan patient safety bill before the August recess. That is my goal.

Again, I welcome our witnesses, and I thank them for their participation. I now recognize Mrs. Capps for her opening statement—are you going to defer to Mr. Waxman? Go ahead.

Mr. WAXMAN. No, go ahead.

Mrs. CAPPS. Thank you, Mr. Deal. I commend you for your goal before recess of legislation. Addressing patient safety is a broad and intricate issue that could be the subject of a dozen hearings and addressed by at least as many separate witnesses and initiatives. I want to thank the witnesses today for taking the time to be with us.

I am going to focus on the national shortage of nurses in my opening remarks, and I hope that we will be able to discuss this topic, because it has a direct effect on patient safety. Several reports have concluded what many health care professionals have known for years, that there is a direct link between the number of registered nurses and the quality of care provided in our Nation's hospitals.

A study in the New England Journal of Medicine in May of 2002 linked higher levels of nursing care to better patient care and outcomes in hospitals. Another study in 2002 by the Joint Commission on the Accreditation of Health Care Organizations, JCAHO, found that nearly one-quarter of all unanticipated events that result in death, injury or permanent loss of function are caused by inadequate nurse staffing levels.

Research published in October 23, 2002, Journal of the American Medical Association, concluded that a patient's overall risk of death rose roughly 7 percent for each additional patient above four on a nurse's workload.

Health Affairs article in 2004, based on research funded by the Agency for Healthcare Research and Quality and the Robert Wood Johnson Foundation, linked the prevalence of nursing shifts longer than 12 hours to increased risk of medical errors.

It should not take us this many studies to understand that overworked, overstressed medical professionals make more mistakes.

There are a number of steps that we can and need to address—that we need to take to address this part of the problem. In the 107th Congress, this committee took the lead in addressing the nursing shortage by passing the Nurse Reinvestment Act. But funding for nurse education programs is a paltry \$150 million, while we spend billions on training our physicians. I am not saying we shouldn't spend this money on training our physicians, I am just making the contrast.

In 1974, during the last serious nursing shortage, Congress appropriated \$153 million for nurse education programs. In today's dollars, that would be worth \$592 million, approximately four times what we are spending now.

But new funding alone will not solve this problem. We must also make significant changes to the nursing workplace. Proper staffing

levels allow nurses the time they need to make patient assessments, complete nursing tasks, respond to health care emergencies and provide the level of care that their patients deserve.

The Robert Wood Johnson Foundation is taking a lead on this issue by funding a program called Transforming Care at the Bedside, which has assisted hospitals to redesign themselves to provide more effective, less stressful care. This is the kind of effort we need to encourage and enhance.

We also need to make sure nurses are not overworked by the practice of mandatory overtime and requiring adequate staffing levels for patients. The Safe Nursing and Patient Care Act of 2005, H.R. 791, would deal with the issue of mandatory overtime.

I have introduced the Quality of Nursing Care Act, H.R. 1372, to direct hospitals to work with their nursing staff and develop staffing level standards that will be enforced by Medicare. These bills, among other approaches and along with other efforts to transform the health care workplace, would have a real impact on patient safety. If this committee wants to adequately address patient safety, we have to take up bills like this and look seriously at the nursing shortage.

I yield back the balance of my time and thank you for the extra time.

Mr. DEAL. I thank the gentlelady.

Dr. Burgess, do you have an opening statement?

Mr. BURGESS. Thank you, Mr. Chairman. Yes, I will make a brief statement. Of course, I want to thank you for calling the hearing today. Having practiced medicine for over 20 years, I think I can say without being too immodest that patients in the United States are treated to the highest quality of medical care than anywhere else in the world.

But that doesn't mean that improvements aren't necessary or aren't achievable. I believe that there are many elements that hold back medicine in the United States from making that next leap in quality. Setting quality benchmarks and dissemination methods for best practices are important elements of any legislation developed by this committee. Creating portals for patients to access this data will be critical as well.

I will just have to tell you too, on a side note, I was a practicing physician in 1999 when the Institute of Medicine came out with that book, "To Err Is Human." I read through their data development. I was astounded that anything that was put together that sloppily, for want of a better word, ever found its way into print.

We take two studies, one from a hospital in one part of the country in 1984, another from another part of the country in 1992. Get a data set from each one, and, in fact, the error rate went down between 1984 and 1992—but you never hear about that—and then we extrapolate that to the whole country, come up with a number, 44,000. Just to be sure we have got it right we double it and then add 10 percent. When you figure it out for yourself.

But that doesn't mean that the problem isn't real, because it is. We all know it is. We can argue about the number, but if one patient is injured, that is too many. One dollar that is spent correcting a medical error is a dollar that is not spent buying a child vaccine or providing someone prenatal care.

It is in fact a major contributing factor to the litigious environment that doctors have been forced to work under, the fear of being sued. Because of the fear of being sued some doctor errors never come to light and are not adequately reviewed by peers in medicine.

Because of this, best practices can at times be hard to come by, because doctors feel disinclined to draw a target on themselves if they provide care in minor variance of those best practices.

To fully address patient safety in this country, we also need to look at the legal environment that suppresses, suppresses self-reporting and stanches quality peer review.

I am pleased that we are joined with our witnesses today and I would be especially interested in hearing from all of you, but Dr. Griffen about the work that is being done by the thoracic surgeons to improve the quality of thoracic care.

I yield back the remainder of my time.

Mr. DEAL. Thank you, Mr. Burgess.

Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman, for holding this hearing. I want to associate myself with your opening comments. There is nothing partisan about the issue of trying to stop medical errors. Those of us who want to see if we can give attention to this issue and some focus on it should try to work together to see if there is some legislative proposal that would try to avoid the errors before they take place.

So much of our time is often taken up in Congress about how to put limits on pain and suffering and how to have lawsuits in one court jurisdiction or another, State court, Federal or however. If we could avoid these errors, that should be our goal.

I think the Institute of Medicine did us a real service in their report. They pointed out the errors, so many of which could have been prevented. I would hope that we could look at some of their recommendations, and I am looking forward to hearing from the testimony of our witnesses today.

One group that I didn't see on the list are representatives from the nurses. Because I have a constituent in Los Angeles, a man by the name of Dan Sandell, who has done a lot of work developing medical technologies and devices and simple procedures based on extensive conversations with nurses and hearing from them about some things that would just make it less likely—or some of the errors that we hear about taking place.

I think we have to be mindful that it is not so easy to develop standards, developing and measuring quality standards is pretty complicated, but also very important. Here we have a very critical issue. Not only do we need to know what we are measuring, but to be sure we are measuring the right things. We have to be sure the information is available to the public and available in a way that allows people to make informed judgments about the quality of care being provided.

I understand hospitals internally keep records and keep track of medical errors of one sort or another. We might try to see whether we can incorporate some of their information into a broader data base that would be helpful without causing intrusion into the privacy of hospital internal procedures.

We don't want people in the medical professions to fear telling us about medical errors. We want to work in a way that will give assurances to everybody that we all want to work together to accomplish the same goal, and that is to try to prevent medical errors.

I think fear of litigation is one way that medical errors are often prevented, because medical professionals want to be sure they take all the steps necessary so they won't be questioned later. In doing so, they probably do a much better job and the patients are better served.

These are all factors that go into this whole mix. I would look forward to the testimony, because this will be useful to us in figuring out what is best to do. Thank you.

Mr. DEAL. Mr. Shimkus, do you wish to make an opening statement?

Mr. SHIMKUS. Just briefly, Mr. Chairman. I want to welcome our witness. Illinois just passed, and the Governor has not yet signed—

Mr. WAXMAN. Is your mike on?

Mr. SHIMKUS. I am attempting to.

Mr. DEAL. An electrical error.

Mr. SHIMKUS. I may try. I will be the chairman. No, I won't.

Illinois just passed medical liability reform. It had other provisions in there too that I think, when we addressed consensus, that I have worked with the chairman on, does talk about the tort issue and caps. But it also—there is some insurance issues, and there is also some safety concerns and technology addressing issues that I think are all part of it.

For those of us who have been ravaged by the medical liability issue, we also understand that we have got to do a better job using technology to help us in patient records, in addressing medicine and tracking that.

I, fortunately or unfortunately, have just come out of a major medical procedure. The good hospitals have, you know, computers, not only in the operation rooms, but they have them in your recovery rooms.

Others are slower to do that, because there is a cost incurred. I think we will do well if as we address how to start talking about errors and reforms that being able to have good data that is—that people can plan on and count on would be helpful. So I hope that we will also look at that as we move forward in our hearings.

I thank our guest and I look forward to her testimony. I yield back, Mr. Chairman.

Mr. DEAL. Thank you. Ms. Baldwin.

Ms. Baldwin. Thank you, Mr. Chairman. I also want to thank our witnesses who will join us this afternoon. I am glad to have this opportunity, Mr. Chairman, to explore the topic of patient safety. To me, the issue of medical errors is in many ways similar to the issue of the uninsured. Everyone recognizes the problem, and we agree that even one instance is one too many. Yet Congress remains stuck and has not passed legislation to address the problem. I am hopeful, Mr. Chairman, that today's discussion will open a new dialog and move us toward a constructive way of reducing the number of medical errors. Maybe we can have a similar hearing on

the uninsured at a later point in time to move that issue forward, too.

Regarding medical errors, I am interested in exploring ways that we can use health care information technology, IT, to address this issue. Part of why I find health care IT to be so promising is that effective use of IT systems could potentially reduce medical errors in multiple ways.

For example, IT systems can prevent medical errors from ever occurring. IT systems can provide built-in safeguards to double-check for adverse drug reactions prior to a prescription even being written. IT systems can prevent medical errors through information gathering and sharing.

With a national health care IT system, we can potentially have access to incredible amounts of information for research purposes. Think of how much sooner we might have been able to know about Vioxx and its negative side effects if information had been collected through an IT system.

I don't want to focus on IT to the exclusion of our human resources in medicine. Clearly, there is more that we can and must do to support them in their mission to care for our health. Certainly, the doctor's Hippocratic oath says first to do no harm, and there are additional things we can do in that regard.

I look forward to hearing our witnesses' views on health care IT and the ways in which we can help our practitioners, and again thank the witnesses for joining us today and yield back.

Mr. DEAL. Thank you. I might add to you and Mr. Shimkus both, we are looking at the possibility of holding a hearing on the issue of information technology, because it definitely has a relationship.

Yes, Mrs. Capps.

Mrs. CAPPS. Thank you. I would like to ask unanimous consent to submit Mr. Dingell's statement for the record.

Mr. DEAL. Without objection.

Mr. WAXMAN. For all members?

Mr. DEAL. Yes, we will extend that to any member who wishes to do so.

[Additional statement submitted for the record follows:]

PREPARED STATEMENT OF HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Thank you, Mr. Chairman, for holding this hearing on the important topic of patient safety and quality.

Thousands of Americans die needlessly every year as a result medical errors. The great shame in that statistic is that many of these errors were ultimately preventable. These deaths also highlight the failure of our health systems to address the problem of patient safety and medical errors.

The challenge we face is how to design and pay for health systems that substantially reduce the risk of medical errors. There is no one single answer, or silver bullet, that will miraculously solve the problem. Nor do I believe the answer is (as is too often the case here in Washington) to simply throw more money at the problem. First, we should do no harm. Second, we need to consider how to come up with smarter, more efficient ways to keep patients safe.

Since the 1999 release of the groundbreaking Institute of Medicine study on medical errors, hospitals, doctors and health plans have all worked to develop innovative initiatives to reduce medical errors. The witnesses today will describe some of the boldest of these new initiatives.

These initiatives reflect three core issues that need to be addressed if we are to ever substantially reduce medical errors. These issues include: 1) the need to better

educate providers, 2) improving systems to detect and address medical errors, and 3) promoting greater accountability.

The Committee has already done important work to address some of these needs. We worked closely with Mr. Dingell and his staff to draft a bipartisan patient safety bill to promote the development of patient safety organizations and encourage providers to use these organizations to identify and eliminate medical errors. I intend to do everything I can to resolve the outstanding issues we have with the Senate, so we can pass this bill and send it to the President for his signature soon.

I also look forward to hearing from the witnesses today about the lessons we can learn from their initiatives. There is likely much more than could be done beyond the modest goals we set out in our patient safety legislation. I believe we owe it to patients, their families, and the American taxpayers to better prevent the needless loss of lives and taxpayer dollars due to preventable medical errors.

Thank you again Mr. Chairman for holding this hearing.

Mr. DEAL. We are pleased to have as our first panel Dr. Carolyn Clancy, who is the Director of the Agency for Healthcare Research and Quality. Dr. Clancy, thank you for being with us today. It is your floor.

STATEMENT OF CAROLYN M. CLANCY, DIRECTOR, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Ms. CLANCY. Thank you, Chairman Deal, distinguished members of the subcommittee. Thank you for inviting me to this important hearing on initiatives to improve patient care and safety in America. I would ask that my written statement be entered in the record.

Improving patient safety is a high priority for President Bush and Secretary Leavitt and an important statutory responsibility for the Agency for Healthcare Research and Quality. Your timing in calling this hearing couldn't have been more perfect, for you have chosen the week of AHRQ's first joint meeting of patient safety and information technology grantees. They are over at the Convention Center now. That meeting is open to the public, so the potential for discourse and learning has been great, our grantees from each other and the public and the public from our grantees.

There is great excitement about our successes to date, but we also recognize that we have a lot more work to do to achieve the goal of a safe, high quality health care system. Our grantees are committed and dedicated to this goal, and they are very pleased to have your support for their efforts.

The Institute of Medicine report "To Err Is Human" is a critical turning point in the awareness of the issue of patient safety. It changed the way the public sees the health care community and the way the health care community sees itself. It reminded us that safety and quality in health care were no longer something to be taken for granted, nor did the current state have to be accepted, whether good or bad, as the best that could be done. We can measure how we are doing and improve, and the tools to do that job should be developed.

It essentially changed the conversation in two essential ways. First, it suggested that a fundamental change was needed in how the health care system should react when an error occurs. It suggested that we shelve the traditional name, blame and shame response in favor of openness and an opportunity of learning from mistakes.

Second, the Institute of Medicine also reminded us that health care is a highly collaborative enterprise. As my predecessor John Eisenberg used to say, patient safety is a team sport. Providing high quality, safe health care requires ongoing communication, collaboration and teamwork.

In many ways, your subcommittee led the charge on improving patient safety in the Nation before the Institute of Medicine report was published in November 1999. Earlier that summer, the subcommittee included a mandate to address medical errors in the bill reauthorizing the agency. Appropriations followed a year later, and direction from the Senate Appropriations Committee, for AHRQ to lead a national effort to combat medical errors and improve patient safety. As a result of your mandate, AHRQ has made improving patient safety and reducing medical errors a top priority.

Since fiscal year 2001 we have funded over 225 patient safety and related health information technology projects. These projects fall into four broad approaches. One is identifying medical errors and other threats to patient safety so we can understand why they occur.

The second is advancing our knowledge and practices that will effectively reduce or eliminate the occurrence of medical errors or minimize the risk of patient harm.

A third is developing, assembling and widely disseminating information on how to implement patient safety best practices.

Fourth is enabling providers to continually monitor and evaluate threats to patient safety and the progress they are making.

In the spirit of patient safety as a team sport, I would like to note that our colleagues at the FDA, CMS and the Centers for Disease Control and Prevention are also supporting efforts to improve patient safety. My written statement has more detail on our and the other agencies' activities.

I would like to make several brief observations from our work that I hope will prove useful as you think about the issues related to improving patient safety and reducing medical errors.

First, this culture of patient safety that the Institute of Medicine and others have recognized is critical on two levels. Health care professionals need to feel safe to acknowledge errors or near misses within the institutions in which they practice.

Second, as a culture of safety develops within an individual institution, it is important to recognize that the number of reported errors is likely to rise as previously hidden errors are disclosed.

For this reason, an initial increase in the number of reported errors is actually a sign of success, not failure. What we would expect to see is that the overall volume would increase, but ultimately the severity of those mistakes would decrease.

Third, while an increasing number of hospitals are developing the capacity to analyze the causes of medical errors, we need to recognize that the ability to conduct these analyses is uneven, both in terms of experience and skill level.

Fourth, knowing the right thing to do to improve the quality and safety of patient care is only the first step. To increase the pace of improvement, the emphasis on implementation research—that is step-by-step guidance on implementation, and tools to facilitate the

use of effective interventions—is critical. AHRQ has already begun to shift its emphasis within our existing resources in this direction.

Fifth, there is a significant amount of information on how to improve the safety of hospital care, but the evidence base is less robust for other settings of care.

Finally, as a nonregulatory agency, I believe that AHRQ can make effective use of voluntary collaboratives that bring together health care organizations at different stages of development in the application of health care interventions. By providing an opportunity to learn from the experience of organizations on the cutting edge, we can eliminate the inherent delays that occur while each institution reinvents the wheel and learns the same lessons on their own.

In fact, yesterday I announced that AHRQ had just awarded over \$8 million in funding for 15 projects that are designed to help clinicians, facilities and patients implement evidence-based patient safety practices. These grants, called Partnerships in Implementing Patient Safety, will use existing knowledge in partnerships to improve the safety of patient care. Over half the projects focus on reducing medication errors, an area known to be in need of patient safety solutions. Many of the projects will apply interventions to improve health care communications, also a well-known source of errors.

Mr. Chairman, thank you for the opportunity to present these remarks, and I would be delighted to answer any questions. Let me also say that the administration remains supportive of passing patient safety legislation, has looked to this subcommittee as an essential partner and encourages error reporting without fear of litigation and looks forward to continuing to work with you.

[The prepared statement of Carolyn M. Clancy follows:]

PREPARED STATEMENT OF CAROLYN M. CLANCY, DIRECTOR, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Chairman Deal, Congressman Brown, distinguished Subcommittee members, thank you for inviting me to this important hearing on initiatives to improve the safety of patient care in America. Patient safety is a high priority for President Bush and Secretary Leavitt; it is a statutory responsibility for my agency, the Agency for Healthcare Research and Quality (AHRQ); and it is a key area of emphasis for agencies across the Department of Health and Human Services and other Federal Departments. The Administration remains supportive of passing patient safety legislation that protects and encourages error reporting without fear of litigation and looks forward to continuing to work with the Committee on this important issue.

CONGRESSIONAL DIRECTION

It is now more than 5½ years since the Institute of Medicine (IOM) elevated national awareness of the issue of patient safety with its landmark report, *To Err Is Human*. Since then, the issue of patient safety has become almost inescapable. Nearly every week, newspaper articles, reports on the radio and television, and articles in the medical literature keep issues of patient safety in the national spotlight.

The IOM report was a critical turning point. It changed the way the public sees the health care community, and the way the health care community sees itself. It essentially “changed the conversation” in two essential ways. It made us realize that when medical care goes badly, the traditional response of “name, blame, and shame” not only does little to improve safety for the next patient, it may actually put the next patient at greater risk by encouraging mistakes to be hidden. The IOM also reminded us that safe, high quality care requires a team effort; patient-centered

care requires tremendous ongoing communication and collaboration, requiring adjustment in our ongoing trend to greater specialization.

It is worth noting that congressional action to promote patient safety actually preceded the November 1999 release of the IOM report. During the summer of 1999, Mr. Chairman, your Subcommittee included a mandate to address medical errors in the bill reauthorizing and renaming my agency. Appropriations followed a year later, with a directive from the Senate Appropriations Committee for AHRQ to lead a national effort to combat medical errors and improve patient safety.

Mr. Chairman, this hearing is especially well-timed. It coincides with the annual patient safety conference AHRQ hosts for the researchers we fund, health professionals and the public. These annual conferences are designed to assess progress and accomplishments, promote better coordination and foster mutual learning. Because we made a significant number of health information technology awards last year, many of which were related to patient safety, we expanded this conference to include a dual focus on patient safety and health information technology. We focused on patient safety on Monday and Tuesday, had a general plenary session on Wednesday that was keynoted by Secretary Leavitt, and today and tomorrow will highlight health information technology.

DEPARTMENT-WIDE COMMITMENT

I will address how AHRQ has responded to congressional direction in a moment. It is important to note at the outset that the response to the challenge of improving patient safety is shared Department-wide. For example, MedWatch, the Food and Drug Administration's (FDA's) Safety Information and Adverse Event Reporting Program, provides important and timely clinical information about safety issues involving medical products, including prescription and over-the-counter drugs, biologics, devices, and dietary supplements. FDA has issued a final rule requiring the bar coding of most drugs to promote electronic prescribing and to reduce the number of medical errors that occur in hospitals and health care settings. FDA's MedSun program of 2-way communication between FDA and health care facilities is improving the identification, understanding, and sharing of information about medical device problems. It is currently being used to pilot tissue surveillance. In addition, FDA is working on an integrated reporting system to allow reporters to submit an adverse event report about any FDA-regulated product through a single gateway and website. FDA is also working on human factors engineering to make medical devices more user-friendly and to eliminate device errors that cause harm.

The Centers for Medicare & Medicaid Services (CMS), in collaboration with the Centers for Disease Control and Prevention (CDC), AHRQ, and many private sector partners, has launched a major patient safety initiative, the Surgical Care Improvement Project, to eliminate surgical complications, such as post-operative pneumonia and surgical site infections. This work builds on the National Surgical Improvement Project begun in the Department of Veterans Affairs (VA), tested in civilian hospitals through support from AHRQ, and now being implemented nationwide through Medicare's Quality Improvement Organizations (QIOs).

The CDC maintains a sentinel network of hospitals, the National Nosocomial Infection Surveillance (NNIS) System, and has launched a Campaign to Prevent Antimicrobial Resistance in Health Care. Monitoring infections, antimicrobial resistance, disease-specific screening and preventive healthcare practices, and other health events is a proven prevention strategy. In addition, CDC funds Prevention EpiCenters (academic medical centers) to conduct research to prevent healthcare-associated infections and improve patient safety.

AHRQ RESPONSE

Since FY 2001 AHRQ has funded over 225 patient safety and related health information technology projects. These projects fall into four broad approaches:

- Identify medical errors and other threats to patient safety and understand why they occur;
- Advance our knowledge of practices that will effectively reduce or eliminate the occurrence of medical errors and minimize the risk of patient harm;
- Develop, assemble, and widely disseminate information on how to implement patient safety best-practices; and
- Enable providers to continually monitor and evaluate threats to patient safety and the progress they are making.

Our projects address a broad array of issues linked to preventing risks to patient safety: advancing the effective use of health information technology, an issue of particularly high importance to President Bush and Secretary Leavitt; medication safety; communication issues within the health care team and availability of patient

support; error prone clinical practices; problems that arise because of an institution's internal culture or organization; provider fatigue; unique safety issues in intensive care units, issues related to education and training; and reporting of adverse events or near misses.

ADVANCING PATIENT SAFETY

Increasingly, our projects have emphasized the development of skills to undertake patient safety improvement, development of practical tools to facilitate the use of what is now known, and working in voluntary partnership with public and private sector groups to actually implement that knowledge. I will briefly describe projects in these three areas.

Developing Skills to Implement Patient Safety Initiatives

AHRQ has created a Patient Safety Improvement Corps, a training program that brings together teams of state officials and private sector providers to learn and work together and undertake joint patient safety initiatives. The VA has partnered with us in carrying out the training sessions. Thirty-three states and the District of Columbia, 13 of which are represented on this Subcommittee, have participated in the first two years of the program. In recruiting for the third class we are giving preference to applications from States that have not participated.

Some teams have been successful in developing projects involving a large number of providers. For example, the Georgia team involved 28 hospitals and health systems across the state to develop and adopt strategies to ensure that the correct site has been verified before a surgical procedure is begun on a patient.

Another initiative, with the Department of Defense (DoD), is built on the recognition that teamwork is a critical aspect of patient safety. Poor team coordination is a major cause of preventable patient harm. The DoD and AHRQ have developed a public domain curriculum for training health care professionals to improve teamwork. This curriculum has been extensively field-tested and will be made available to all health care institutions nationally in the fall of 2005. AHRQ and DoD will be working with CMS and the QIOs to set up a national training program in teamwork using the new curriculum. The curriculum will also be available on the AHRQ PSNet (<http://psnet.ahrq.gov/>).

It is important to increase the skill level for analyzing patient safety threats at the hospital level. The most common approach in hospitals is known as Morbidity and Mortality, or M&M, conferences to assess what went wrong in cases where a patient was harmed. We have built upon that approach with a popular web site, known as the AHRQ Web M&M (<http://www.webmm.ahrq.gov/>) in which new cases are shared, along with expert commentaries on how to think through such cases, identify problem areas and potential solutions. Each month a "spotlight" case is presented, accompanied by an educational slide set that health professionals can download and use as an educational tool in their own institutions. More than 10,000 health care professionals are now ongoing registered users of Web M&M, and 28,000 visited the site in a recent month. This approach is bringing lessons learned about patient injury and medical error outside the confines of individual hospitals, and the users include nurses, pharmacists, physician assistants and other allied health professionals in addition to physicians.

Communication with patients is another important skill, especially when an error has occurred. One of our grantees, the Partnership for Health and Accountability, comprised of the Georgia Hospital Association (GHA) and Emory University, has developed a video, *Discussing Unanticipated Outcomes and Disclosing Medical Errors*, to assist providers on effective approaches for disclosing medical errors. The videotape was evaluated and refined and distributed to all GHA members. Over two dozen workshops were held throughout Georgia, to discuss the content of the video and to distribute a questionnaire to ascertain hospital disclosure practices. Distribution of the video is available at no cost through the PHA website (<http://www.gha.org/pha/>).

Developing Tools to Improve Patient Safety

In response to requests by state hospital associations, state data organizations and others, AHRQ developed a set of indicators that any hospital can run against its hospital discharge data set to evaluate how it is doing in terms of safety and quality. —The AHRQ Patient Safety Indicators are being used by a variety of hospitals and other organizations to screen for suspiciously high rates of potentially preventable complications from surgery and medical care, such as complications of anesthesia or postoperative infection.

Because the AHRQ indicators can allow for comparisons between hospitals, they are being used by a variety of organizations for public reporting and private and

public sector pay-for-performance initiatives and demonstrations, in addition to internal hospital quality improvement. Many State and regional hospital associations, including the Georgia Hospital Association and the Dallas-Fort Worth Hospital Council, have integrated the AHRQ indicators into their quality improvement programs. —A number of Blue Cross plans are using these indicators to align financial incentives with achievement of specific performance objectives, and some of the indicators are being used by CMS as part of their pay-for-performance demonstration.

Public and private sector organizations, such as Premier, Inc., have recognized the importance of measuring organizational conditions that can lead to adverse events and patient harm. To assist in that effort, AHRQ developed and recently released, in collaboration with DoD and Premier, another tool, known as the Hospital Survey on Patient Safety Culture. This public domain tool is being rapidly adopted across the country. For example, Catholic Health Partners has 70 hospitals in their system. They are using the survey and have received so far about 3,000 responses. DoD anticipates using it in all of its facilities world-wide and AHRQ has made it available on our patient safety website PSNet.

Voluntary Partnerships to Improve Patient Safety

The largest initiative, developed by the Institute for Health Improvement and co-sponsored by AHRQ, CMS, and CDC, is the 100,000 Lives Campaign. This campaign has enlisted more than 2,200 hospitals to commit to implement changes in care that have been proven to prevent avoidable deaths. The initiative is starting with six interventions: deployment of Rapid Response Teams, delivery of evidence-based care for acute myocardial infarction, prevention of adverse drug events, prevention of central line infections, prevention of surgical site infections, and prevention of ventilator-associated pneumonia. The goal is to save 100,000 lives annually that would otherwise have been lost without these changes in the delivery of care. In addition to saving lives, the benefits of preventing complications are significant. For example, patients on ventilators are very susceptible to pneumonia because it is easy for bacteria to get into the lungs. If they develop pneumonia, they are likely to spend an extra week in the hospital, and the extra cost of care can easily reach \$40,000.

An AHRQ grantee at Johns Hopkins University is paving the way for success of the 100,000 Lives Campaign by working to prevent deaths resulting ventilator associated pneumonia and blood stream infections related to central lines. The Hopkins team is now working with 127 Intensive Care Units (ICUs) in Michigan, 30 in New Jersey, 45 in Maryland, and recently expanded into Rhode Island. Michigan's experience suggests the significance of what can be accomplished. An Associated Press story last week noted that Michigan hospital officials estimated that they had saved 77 patients' lives: 73 from pneumonia and 4 from blood infections. In addition, a small number of ICUs have actually gone as long as 9 months without one of these two complications. This project has developed implementation tool kits to assist other hospitals in putting these safety improvements into practice.

Building upon our research investment over the last 5 years, this week AHRQ awarded over \$8 million in funding for 15 projects that are designed to help clinicians, facilities, and patients implement evidence-based patient safety practices. These grants, Partnerships in Implementing Patient Safety, will use existing knowledge to improve the safety of patient care. They are projects that will have both an immediate and a long-term impact. Over half the projects focus on reducing medication errors, an area known to be in need of patient safety solutions. Many of the projects will apply interventions to improve health care team communications, also a well-known source of errors.

There are two key elements to these projects. First, the interventions are generalizable; they will work in a wide array of other settings of care. Second, like the Johns Hopkins grant described previously above, these projects will develop implementation toolkits that will share lessons learned on how to best implement patient safety practices, identify the barriers they are likely to face as well as ways to work through them. The implementation toolkits will be available on PSNet.

CONCLUDING OBSERVATIONS

Mr. Chairman, we have made significant progress since the Congress and the IOM highlighted the importance of patient safety. But we are still a long way from the lofty goals reflected in the IOM report. So there is more to be done. I am reminded of the final slide of the Patient Safety Improvement Corps team from Georgia, during a presentation reviewing their experience, which said: "Patient safety is a never-ending process."

I would like to conclude with several brief observations from our work that I hope will prove useful.

First, a culture of safety is critical on two levels. Health care professionals need to feel safe to honestly acknowledge errors or “near misses” within the institutions in which they practice. Institutions also need to feel safe to seek help in identifying and resolving organizational and system-based threats to patient safety without retribution.

Second, as a culture of safety develops within an individual institution, it is important to recognize that the number of “reported” errors is likely to rise as previously hidden errors are disclosed. For this reason, an initial rise in the number of reported errors is a sign of success, not failure.

Third, while an increasing number of hospitals are developing the capacity to analyze the causes of medical errors, we need to recognize that the ability to conduct these analyses is uneven, both in terms of experience and skill level. One of our state Patient Safety Improvement Corps teams determined that, after excluding a large hospital with a pro-active patient safety program, most hospitals in their state completed only four root cause analyses per year. State teams that focused on the skills needed to undertake such analyses found that the need for better skill development was significant. Moreover, few institutions have any experience with other pro-active risk assessment methods. Moving to a system in which hospitals routinely undertake analyses of the causes of errors will require significant skill development and technical assistance.

Fourth, knowing the right thing to do to improve the quality or safety of patient care is only the first step. To increase the pace of improvement, the emphasis on implementation research, step-by-step guidance on implementation, and tools to facilitate the use of effective interventions is critical. AHRQ has already begun shifting its emphasis within our existing resources in this direction.

Fifth, there is a significant amount of information on how to improve the safety of hospital care, but the evidence base is less robust for other settings of care.

Finally, as a non-regulatory agency, I believe that AHRQ can make effective use of voluntary collaboratives that bring together health care organizations at different stages of development in the application of effective health care interventions. Collaboratives provide a natural setting for shared learning which accelerates the pace of improvement and innovation. By providing an opportunity to learn from the experience of organizations on the cutting edge, we can eliminate the inherent delays that occur while each institution reinvents the wheel. This approach also enables AHRQ to better focus its technical assistance and short-term implementation research.

Mr. Chairman, that concludes my prepared remarks. I would be delighted to answer any questions.

Mr. DEAL. Thank you. We will begin the questioning process, and I will start it off.

Would you tell us what intervention methods or measures you have chosen for the 100K Lives Campaign and how those intervention methods would work, if you could?

Ms. CLANCY. The 100,000 Lives Campaign is actually led by another group called the Institute for Healthcare Improvement that is based in Boston, Massachusetts. But they have many, many partners, of which AHRQ is one, as is the Centers for Medicare and Medicaid Services and the Centers for Disease Control.

As I understand it, the rationale for the areas chosen were to focus on areas where there was a significant amount of momentum, where there was a good evidence base about what to do to address the problem. For example, ventilator-associated pneumonia. This is an area where we supported a very large demonstration project, with the expectation that that project team would team up with others, and indeed they have. They have teamed up with many, many others that they didn’t plan to because there is a great deal of interest in it.

It was also done because there was some way that they could calculate how many lives they might save over an 18-month period. Hence the 100K lives. I am told by Don Berwick, who couldn’t be

here today, that about 2,300 of the Nation's hospitals have signed up to be part of that campaign.

Mr. DEAL. You are making grants and supervising and overseeing those awards. What is the plan to try to consolidate and learn from all of these experiences that are gained, a so-called best practices or suggested methodologies? Is that going to be the responsibility of your agency to do?

Ms. CLANCY. We regard that as an essential part of our responsibility. For example, the concept of a culture within a health care institution sounds nice. But the question is, what does that really mean? So the past year we actually developed a survey tool that hospitals can actually use.

So a hospital leader who says that he or she is committed to having a culture of safety within that institution can actually use this survey to find out if that is the experience within his or her institution. So if I as a leader am committed to a culture of safety, but indeed some of my employees are fearful for making note of when there are errors—and this is to make a culture of safety, you really need to do that. So that would be one example.

A number of our reporting demonstrations have partnered with others. Another part of the 100K Lives Campaign focuses on errors in medications that are made at the time that someone is discharged from the hospital. It sounds almost self-evident. But it turns out that a lot of patients have a group of medications that they take. They are admitted to the hospital. Sometimes those change. They go home with a new set.

Oftentimes there is insufficient checking to make sure that the patient knows how to reconcile the new set of medications with what they are taking at home. The consequences can be fairly disastrous. Sometimes people are effectively taking 2 or 3 kinds of the same medication or taking medications that have adverse interactions and so forth. And that has been part of the 100K Lives Campaign. But many States have stepped up to join and be part of that.

In your State, in Georgia, there has been a very nice Voluntary Hospital Reporting Initiative, which has been very successful. We are also training a group of individuals called the Patient Safety Improvement Corps. These are individuals from across the country—and we were actually inspired to do this by States, who said to us, you know, we have a lot of data. What we don't have are people to analyze that. Periodically you see this in the newspaper where some incident was reported but the health department or no one else actually had the time or capacity to do that.

So these individuals are nominated by their States and hospitals and come and attend a program for about 3 weeks of intensive learning. The rest is done back at their home institution to try to understand why errors occur, what strategies can be put in place to prevent them and so forth.

So those are just a few examples, and I think you are getting the sense. I could probably keep on going but I will stop here.

Mr. DEAL. Thank you very much.

Mrs. Capps.

Mrs. CAPPS. Thank you, Mr. Chairman, and Dr. Clancy, thank you for your testimony. I have been impressed with the work that

your agency has done on medication errors and the lessons that you have drawn from health care providers. Can you tell me what kind of research your agency is currently conducting regarding the relationship between the nursing workforce and patient safety?

Ms. CLANCY. Yes. Interestingly, one of the first publications looking at the relationship between what some people refer to as nursing sensitive outcomes—that is to say patient outcomes that you would expect to be influenced by nurses directly and nurse staffing—was done by someone who was a visiting scholar at the agency. That was about 7 or 8 years ago. Since then, we have funded some of the research that you cited in your opening remarks.

An important part of our initial patient safety portfolio has been a group of projects that we call working conditions. Now, these projects look at such issues as nurse staffing, nurse perceptions of how often they are called or mandated to work overtime. They have also looked at resident work hours. One of the new projects that we are funding, that we just announced, is actually going to test ways to make sure that residents can work for work hours. It turns out that the nurse staffing is both about how many nurses there are, which is obviously an issue of great urgency, but also how those nurses are organized. That is the research that is still ongoing.

Mrs. CAPPS. Some of the results have been published?

Ms. CLANCY. Yes.

Mrs. CAPPS. Are there more then that we can expect to see?

Ms. CLANCY. Yes.

Mrs. CAPPS. And a timeframe for that.

Ms. CLANCY. I could follow up on that for you with details.

Mrs. CAPPS. Thank you very much. I am including this in your—I guess you could say culture of safety. I was interested to how you responded to Chairman Deal on some of these topics. You talk about developing this culture of safety in health care facilities. For the most part, I have heard medical error reporting as being one of those issues. It is certainly a very important one. I am wondering if the culture of safety—you are designing projects also to look at medical professionals, the way that they safely deal with patient loads in terms of their own numbers, as a part of this fostering of the culture of safety?

Ms. CLANCY. Some of our projects deal very specifically with that. One of the projects includes a national survey of nurses to see their perceptions about work and what are people hearing in terms of what they have to say about patient load and so forth and how does that affect their perception that they are at higher risk of providing unsafe care and so forth.

Mrs. CAPPS. Okay. How about making sure that the same medical professionals are sufficiently well rested on the job, the number of hours that they have been working, their ability to be cogent and really attentive to patients' needs? Do you consider this—you could lump it all into mandatory overtime but you could also talk about shift length and other times?

Ms. CLANCY. The area where we have the greatest amount of information actually relates to medical interns and residents. But I think that the findings are likely to be generalizable. I think many of you may be aware that, unlike when I was training, the interns

and residents are now limited to 80 hours a week of working. Some people believe that actually it matters how that 80 hours is divided up.

So there were two studies published this past year in the New England Journal. One looked at the rate of medication, serious medical errors made by medical interns in an ICU at Brigham and Women's Hospital in Boston. Those interns who worked a 30-hour shift had significantly higher rate of serious medical errors than those who worked a shorter shift.

In addition to that they looked at car accidents incurred by those interns on their way home after a long shift. It turns out they were twice as likely to be involved in a serious motor vehicle accident. The same grantee is now following up working with that institution to design ways to make sure that they eliminate those longer shifts, and the Accreditation Council on Graduate Medical Education that regulates how the hours for interns and residents is actually taking this issue up this summer.

Mrs. CAPPS. I would submit that, yes, you can extrapolate on the basis of interns. I would commend you because not until these kinds of studies were done did people actually begin to realize the great risk that they were providing both for the intern but also certainly for the patient. I am convinced that until specific research is done on the population that we are very concerned about—

Ms. CLANCY. I would agree.

Mrs. CAPPS. So we really need to, and I would urge you to take that on. I am sure you are concerned about it as well.

I wonder, just finally, if you would talk a little bit more about skill development, for a better analysis, which hospital—you mentioned that. But I am wondering which hospital personnel you anticipate needing this training and what kind of skill development you think is needed among medical professionals like doctors and nurses to make this work.

Ms. CLANCY. Well, I think there are two parts of it. Most hospitals now have someone who is designated as the lead patient safety officer who works with quality professional officers and others across the organization. Some hospitals have the capacity to have more people with that kind of expertise than others. So that was actually the focus of our Patient Safety Improvement Corps. We are doing this jointly with the VA because I think they have been acknowledged leaders in the field of developing some of these techniques.

The other part of skill development, which I think is more of a research area, is actually building on the techniques that we currently have to create others that may be more specific and useful for certain circumstances.

Mrs. CAPPS. I am going over my time, but I do look forward to continuing to be in touch with you and thank you for the work that you doing.

Mr. DEAL. Thank you. Dr. Burgess.

Mr. BURGESS. Thank you, Mr. Chairman. Well, let us continue on Mrs. Capps' line with the resident work hours, something I have some familiarity with, having trained at Parkland Hospital back in the 1970's when resident work hours were thought to be not long enough.

Are you working with the Council on Resident Education to be certain there is exposure to an adequate amount of clinical material? If you cut residents down to a maximum of 80 hours a week—and we probably worked a little more than that back in the 1970's—should an internship now be 14 months or 16 months or 18 months instead of 12 months? Should other parts of the training program be similarly extended?

Ms. CLANCY. We have not gotten into whether the length of time for training should be expanded, but I know that is very much on the minds of leaders in medical education. The specific issue they will be taking up this summer as a result of the work we funded is within 80 hours a week.

Do they need to make recommendations or guidelines about how that 80 hours is allocated? For example, could 72 of it—which you probably did quite often at Parkland in the 1970's—can you work 72 hours in a row or not? Right now I believe that the current rules allow people to work up to 36 hours.

Having seen the results of this study, I think they feel compelled to go back and do that. One of the other areas that was inspired by the Institute of Medicine report is to actually include some training about systems and team practices. So, for example, one of the modules that they have developed focuses on why can't we get thrombolytic treatment to patients who are coming into the emergency room with a heart attack.

It has to be done in a very timely fashion. That is an exercise that people go through. It is not because no one knows to actually administer the treatment. The issue is how do you make the decisions in a fast enough fashion that you can get the medication from the pharmacy and the cardiologist who is on call comes in, and so on and so forth. So that is now a part of residency training. I expect that we will continue to be in touch with them.

Mr. BURGESS. Let me move on to the issue of information technology. We hear a lot about that up here. I will have to tell you, I worry that your information technology may be like hyperbaric oxygen. It may be the last refuge of the uninformed. I remember when we got—well, there has been some significant breakthroughs in technology since I started in medicine. The pulse oximeter was one of those that I think saved a tremendous number of lives. The fetal monitor has arguably saved a great number of lives.

But I still remember the morning that Dr. Pritchard, my old residency chairman, walked into the room, and there were eight or nine of us huddled around the monitor, no one paying any attention to the patient and her baby at the bedside. That was a lesson that will probably stay with me the rest of my life. We had a good few good laughs over that afterward, as you might imagine.

But the IT part is only as good as the people who put the data in and then the people who analyze the data. If we just simply throw a bunch of IT or IT dollars at that time problem, I can see the opportunity for some spectacular failures in that avenue.

Ms. CLANCY. I couldn't agree with you more. Our grantees generally tend to agree that using information technology to improve the safety and quality of health care is one part technology and two parts work processes and getting people to collaborate and be very clear about what they are doing. Simply installing computers with

a magic wand everywhere is not going to address these problems if it is not linked with a work flow and doesn't actually enhance what physicians, nurses and other health care professionals do in terms of patient care. All of the grants that we are making in this area are focused explicitly with evaluating applications of health information technology to see their impact on safety and quality, including when they don't work as intended.

Mr. BURGESS. Just from my own experience with a trial of e-prescribing, it adds 1 to 2 minutes per patient encounter, if you do it accurately, which was the whole idea, I think, of e-prescribing, that we will be more accurate. But in a typical doctor office where you see 35 or 45 patients or more, and almost all of those patients walk out with a prescription of some sort, we are adding an hour, conservatively, to that practitioner's day. Do we have a plan in place for compensating that practitioner for that hour?

Ms. CLANCY. Well, that would specifically be within the jurisdiction of the Congress and CMS and other payers. We do have a couple of trials ongoing right now examining the use of electronic prescribing to reduce medication errors.

We are finding out a lot about the limitations of the current existing technologies. We think it is very important to feed that back to the vendors and others who develop them, because if you add time to a physician's day the likelihood that they are going to use that technology as often as intended seems to me to diminish.

Mr. BURGESS. It does diminish rather strikingly in my experience.

My time is up, Mr. Chairman. I would just ask, would there be the possibility of submitting written questions as well?

Mr. DEAL. Yes.

Mr. BURGESS. All right. Thank you.

Mr. DEAL. We will do that. Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman.

Dr. Clancy, thank you very much for your testimony. All of us want to work very closely with you. The idea of patient safety and quality initiatives are important, and the work that you are doing has shown many different ways to lessen medical errors, some big and some small. I would hope that you would continue to dedicate significant time and resources toward such initiatives.

My concern is that since 2004 much Federal funding for patient safety research has been diverted to health information technology. Although information technology is an important component of improving quality of care, other research actions and implementations are also necessary. Could you tell us what portion of your budget is going to health information technology and how much is going to other patient safety initiatives?

Ms. CLANCY. This year we are investing a total of \$84 million in patient safety, including those projects that are labeled patient safety and those that are labeled health information technology. It turns out the break isn't quite as clean as you think. But \$50 million this year is focused explicitly on evaluating selected applications of health information technology for their impact on quality and safety.

This may sound a little bit more verbose than I would like, but the point is that many of the people who have been the early

adapters making investments in IT, quality and safety is on the list but it is not actually one of the top two reasons they are making those investments. So we think there is a lot to learn and a lot of good lessons to share about how to make sure these applications work well for the clinicians using them and have the desired impact on safety and quality.

Mr. WAXMAN. Do you think that more resources are necessary to implement and continue patient safety initiatives, including health information technology improvements? Can you talk about what else we need to be doing to attain a safer health care system in terms of patient safety?

Ms. CLANCY. I think that we need to continue on both fronts, both on the smart, if you will, use of health information technology as well as all of the system supports around that. This includes identifying and testing better ways for evaluating what happens when a medical error does take place, continuing to learn from how to report errors in a way that is meaningful, rather than simply making long lists of mistakes or errors that occurred, so that people can learn from them and prevent them in the future. We need to learn a lot about how we can standardize safe practices.

I know you will hear a lot more about that from Dennis O'Leary a little bit later this afternoon.

Mr. WAXMAN. How about the intersection between health information technology and the patient safety?

Ms. CLANCY. It is huge. In fact, I would say of that portfolio there is probably a good quarter of the projects that I would not know, even though I could probably tell what year they were funded, which portfolio they actually came out of. So from the outset of patient safety we funded a group of projects that looked at specific applications of information technology. All of the IT investments we are making now are focused. All of the grantees have to evaluate the impact on patient safety and quality.

Mr. WAXMAN. Do you have some kind of systematic way of getting information from the people on the front lines? I generally think of operating room nurses and general care nurses. They must have a wealth of information. How do you make sure you get the benefit of their experience?

Ms. CLANCY. To some extent this survey tool that I mentioned a little bit earlier on culture of safety, one of the series of questions in there, the items in there actually examine whether or not people who are working on the front lines in hospitals have the opportunity to bring their concerns forward. Are they heard or are they actually punished or told to stop doing that? But we think advice from people on the front lines is critically important. They are an important component of all of the meetings that we have. We think it is very important to hear from consumers or recipients of care, also.

Mr. WAXMAN. Do you recommend structures for hospitals so that the hospital and administration has a way to continually get information on what is being done and it is in fact being done?

Ms. CLANCY. I wouldn't make a specific recommendation for any hospital. What I think is that we have seen that those leaders who are committed to safety and quality and have boards of trustees

who are very interested in this topic tend to keep it on the front burner. I don't know if you had something more specific in mind.

Mr. WAXMAN. I am just wondering if there are systems approach in a hospital—all hospitals I would think would want to have decent patient care to try to avoid errors, but is there some kind of systematic approach that hospitals have in place, not that they all have to be uniform, but is there something they could be doing to get the information and figuring out what advances there are in patient safety and how to avoid medical errors?

Ms. CLANCY. We are making all of the tools from our research available to hospitals as rapidly as we can. I think the response to the 100K Lives Campaign, about 2,300 of the Nation's hospitals having volunteered to participate—they are not getting paid—this is just part of what they are doing—is a strong reflection of how interested hospitals are, which I think is a good sign.

Mr. WAXMAN. Thank you. Thank you, Mr. Chairman.

Mr. DEAL. Mr. Shimkus.

Mr. SHIMKUS. I have great respect for Dr. Burgess, but he cut me to the quick when he said the debate on information technology was the last refuge of the uninformed, because in my discussions with—not just on patient safety, but with driving down cost, I kind of concur. I think we are going to reap great benefits. I have seen a couple of doctors' handwritings, Dr. Burgess.

Mr. BURGESS. What is your point?

Mr. SHIMKUS. Type those babies in. They may be easier to read. I just think the great institutions around our country are doing it themselves, are putting money into information technology so that they can follow the file. Instead of going to the bedside and pulling out the chart and going through paper on paper, they can readily access it. I think you are making a strong investment in that, and I would encourage you to continue to do so.

I want to address—talk to me about the issue—again, I am from southern Illinois. We have a medical crisis, medical liability. 160 doctors have left in a two-county area. The State legislature has just passed reforms that we think are going to be very, very helpful, if the Governor signs it.

One thing that is driving patient safety issues is this whole—a small percentage of bad doctors who practice, cause problems and then cross State lines and cause problems and cross State lines and cause problems. It is a minority. It is a vast minority.

So that brings up the debate of a list per State or nationally. I would like to hear your comments on how do we track the issue of bad doctors who are causing great cost and escalation in this whole debate?

Ms. CLANCY. I think there is a fair amount of information that would suggest that not all doctors who are sued have actually provided poor or negligent care. In fact the studies that Dr. Burgess referenced as contributing greatly to the Institute of Medicine report are looking at to what extent are malpractice suits attributable to poor care. The overlap is smaller than you think. Many of the victims of poor care don't sue, and many people who sue have not received negligent care. So that is one problem.

From our recent research we know that when patients are injured they really want three things. One is they want an apology.

They want an explanation. They would like some assurance that the institution and others involved are going to do something to prevent it from happening again. The doctors agree with them. But they are terrified. They are terrified that if they surface, errors or near misses, that they will be punished.

That is something people figure out right away. So I think that in many, many areas, many specialties, liability is a huge barrier to our making progress on patient safety.

Mr. SHIMKUS. But you didn't address the question on a bona fide listing of—you know, I concur. I have been living this medical liability crisis ever since I have been a public official in my State. So I know that those—both issues of people suing, not suing who are harmed and those who aren't harmed suing. But the issue is, what if you do have a poorlytrained bad doctor who practices, harms someone, then moves across the State line? I mean, we know the cases, we know that they are doing it. How do we address that issue?

Ms. CLANCY. Yes. I would like to defer that to the general counsel for the Department, if that is okay with you. We can get back with a response.

Mr. SHIMKUS. I would love it. Thank you. The last thing, what is the patient's role on patient safety?

Ms. CLANCY. It is interesting there have been a number of surveys of the public that show between 30 and 40 percent say that they or a family member have been injured or believe they have been injured as a result of a medical error. The proportion of doctors is about the same.

Both doctors and members of the public think that patients have an important role to play. Based on that, based on the best information that we could develop, we actually launched a campaign with the American Medical Association and American Hospital Association, about five steps that individuals could take to make sure that they get the safest health care possible.

This is not about telling patients it is your fault that an error is committed, but simply alerting them to opportunities. One is to ask questions if you don't know what is happening. Another is to make sure that you get the results of any lab tests. The third is to make sure that you understand that you always have all the medications that you take with you. The fourth is to, if necessary, bring someone in with you. I can send you a copy of the five steps. It has been very, very popular.

We are also working closely with a couple of consumer advocacy organizations, usually led by people who themselves have had a family member who has been the victim of a medical error. They want very, very much to work with others in health care to make positive changes.

Mr. SHIMKUS. Mr. Chairman, I will end on this. I like that idea of asking questions. A lot of us, we love our doctors and we trust them. Seeking second opinions, when there is a question, would probably be very, very helpful. So I think that is also an important role.

Thank you, Mr. Chairman.

Mr. DEAL. Thank you. Ms. Baldwin.

Ms. BALDWIN. Thank you, Mr. Chairman. I am going to follow along the lines that Mr. Shimkus was just asking about in terms of patients' role in all of this. I think that public reporting of errors and quality data is important if we are to empower patients.

Would AHRQ support the public reporting of things like infection rates at hospitals and process measurements such as has every person with a heart attack received an aspirin and a beta blocker within the appropriate amount of time? These are the types of measures that the National Quality Forum develops through the consensus building process.

I think public reporting of these types of measures helps prompt entities to improve by allowing the public to choose quality providers. In my home State of Wisconsin, we have a system that does this. It is called QualityCounts, which provides health care consumers with various hospital performance measurements. QualityCounts seems to have been very effective in informing consumers. So I am wondering if this is something that you are supporting and trying to further?

Ms. CLANCY. Yes, we work very closely with the Quality Forum as well as the Joint Commission of the American Hospital Association and so forth. In fact, I think, as all of you were aware, almost all of the Nation's hospitals right now are reporting publicly on 10 clinical measures of quality, starting in 2005. Our role in that has actually been to develop a consumer survey called HCAHPS, which will assess the patient's perspectives on their care in the hospital. That should be up and running later this year.

I was literally at a meeting with some other colleagues from the Hospital Association, the Joint Commission and other organizations before coming here, trying to think about what are the next measures that need to be added to those 10, because I think it is very, very important that people have good information.

A critical issue with respect to infections and some other dimensions of errors or bad outcomes that we don't necessarily want, is making sure that we know what we are counting is fair. So, for example, right now it is often difficult to know whether higher infection rate means worse care, more infections in a hospital or more attention being paid to counting infections. We are still struggling with that. That did not make it through the National Quality Forum endorsement process. But we are still struggling to find out how to make it easier to do that because obviously a lot of information that is important to consumers.

Ms. BALDWIN. Great. One of the things that I am curious about is making sure that any new Federal involvement in patient safety and quality improvement is synchronized with our efforts in this area. As I understand it, currently the most significant Federal investment in patient safety and quality is the Medicare Quality Improvement Organization Program, QIO. Again in Wisconsin our QIO is called MetaStar. In my experience they have done really great work in our State, playing a central role in Wisconsin's patient safety initiative since it was first created.

So in light of the work that QIOs are doing, what assurances can you offer us that any additional resources for AHRQ's effort in patient safety and quality are not duplicative or lacking in coordina-

tion with the substantial investment of Medicare and programs in the same area?

Ms. CLANCY. We worked actually very closely with the QIO program and consider them pretty vital partners. For example, this year in the eighth scope of work, one of their priorities will be focusing on helping small physician practices adopt health information technology. Many of those practices don't have—well, they are certainly not going to have their own IT staff, for example, or a host of computer guys. We are looking to partner with them whenever possible, to make sure that we were as focused on alignment and coordination as we could be. We actually have a joint employee with CMS that makes sure that our activities with the QIOs and other aspects of quality improvement are aligned as close as possible.

Ms. BALDWIN. Great. Thank you.

Mr. DEAL. Thank you.

Ms. Myrick.

Mrs. MYRICK. Thank you. I appreciate the fact that you are here today to share with us. I am delighted to hear that there is more going on in the area of when we talk about patient safety and errors in the area of cleanliness relative to staph infection, because it is so hard for me to understand in this day and age when we have got something that is so simple that can be solved, like washing your hands, and people in the medical field are not doing it.

In our area, I know that, you know, it seems like every third or fourth person that comes out of the hospital says they have a staph infection. I mean, we have experienced it too. It is very frustrating. I know some hospitals have been very successful in their programs, and I just hope that that stays a major part of what you all are doing relative to the quality improvements, and so forth, with the hospitals that you are going to be working with.

Then the other thing I wanted to say was I know, just again from working with them at home, the anesthesiologists, when you are talking about different specialty groups in safety, started back in the 1980's in trying to really improve their error rate, because it was like 1 in 10,000 back then. It is now 1 in 200,000, which is a huge improvement. But they did it through training and increased technology and other means.

Are other specialties taking this on, as far as you know? I mean, are other people actively really looking at their own areas, not just the hospital but specialties?

Ms. CLANCY. Yes, what the anesthesiologists did I think was groundbreaking for the field of medicine. They took some lessons from aviation and other industries so that any time an anesthesiologist walked into an operating room, all the cylinders of gas and things like that, all the different technology and equipment they used always worked the same way. So that tragic errors wouldn't be made because someone didn't mention to you that in this OR we turn it the other way.

So that I think was really terrific. Interestingly in Wisconsin, the Department of Anesthesiology at the medical school has actually expanded on that work to now focus on quality of care in the operating room, which is the anesthesiologist, it is the surgical nurses, it is the surgeons and so forth.

Mrs. MYRICK. Good.

Ms. CLANCY. What they have done I think is incredibly encouraging. Of great interest a few years ago we reached out to the American Board of Internal Medicine. The boards are those entities that provide certification for physicians in different specialties. Right now, all of the medical boards, medical and surgical boards are doing two things. One is that they are requiring that all physicians be periodically recertified. So you don't just take a test once and then you are done. They are referring to this as maintenance of certification, but they are all making efforts to link maintenance of certification with your efforts to improve safety and quality wherever it is that you practice.

Mrs. MYRICK. Very good.

Ms. CLANCY. So it isn't just that you read a lot and take a test, but it is actually linked to the application and the work that you are already doing in trying to improve patient safety and quality.

Mrs. MYRICK. Well, I appreciate very much what you are doing. Thanks.

Ms. CLANCY. Thank you.

Mrs. MYRICK. I yield back.

Mr. DEAL. Thank you. Well, Dr. Clancy, thank you so very much. That is been very helpful and informative. There probably will be some written questions submitted and we would appreciate your response to you. Thank you for being with us today.

I would ask our second panel if they would please come to the table. Let me introduce our second panel.

First of all, Dr. Dennis O'Leary is President of the Joint Commission on Accreditation of Healthcare Organizations; Dr. F. Dean Griffen, who is representing the American College of Surgeons; Dr. William A. Bornstein, who is representing the Medical Association of Georgia and Emory Healthcare System; Ms. Jane Loewenson, who is the Director of Health Policy for the National Partnership for Women & Families.

Gentlemen and gentlelady, we are happy to have you with us.

Dr. O'Leary, I will start with you.

STATEMENTS OF DENNIS O'LEARY, PRESIDENT, JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS; F. DEAN GRIFFEN, AMERICAN COLLEGE OF SURGEONS; WILLIAM A. BORNSTEIN, MEDICAL ASSOCIATION OF GEORGIA; AND JANE LOEWENSON, DIRECTOR, HEALTH POLICY, NATIONAL PARTNERSHIP FOR WOMEN AND FAMILIES

Mr. O'LEARY. Thank you, sir. I am Dr. Dennis O'Leary, President of the Commission on Accreditation of Healthcare Organizations. As the Nation's principal health care accrediting body, the Joint Commission has long been dedicated to improving the safety and quality of care provided to the public.

In recent years the Joint Commission has worked intensely on public awareness and safety issues and to promulgate a range of workable and necessary solutions. The Joint Commission's successful efforts in this regard have been recognized in articles recently published in Health Affairs, and the Journal of the American Medical Association.

Today I would like to highlight some of the initiatives in which the Joint Commission is engaged and to suggest some areas of merit for their exploration.

The most compelling need is for provider organizations to adopt broad-based systems approaches to managing and actually reaching patients. More to the point, we need organization environments where safety is always in mind and in which identified errors are viewed as opportunities for improvement, in which apology, honesty and transparency characterized the relationship of patients who have been harmed with error and which there is constant vigilance for emerging risks. With this framework in mind, the Joint Commission has created a substantial portfolio of patient safety initiatives.

Taken together, they constitute a road map for improving patient safety. Let me highlight some of these efforts.

First, the Joint Commission earlier this year launched a new International Center For Patient Safety. The center will initially focus on the identification, gathering, analysis, and dissemination of patient safety solutions both in this country and abroad, and upon the creation of cultures of safety and health care organizations. The center will obtain input and guidance through an international steering committee of patient safety experts and five global regional advisory councils.

In addition, the center will shortly convene this country's 10 principal patient safety organizations to explore opportunities to collaborate in promulgating patient safety solutions. This domestic collaboration will set the stage for creation of a worldwide network of patient safety leadership organizations. Indeed, the World Health Organization last year launched a World Alliance For Patient Safety, and the Joint Commission is soon expected to be designated as a WHO international collaborating center for patient safety solutions as a part of this initiative.

A second critical effort involves the annual setting of national patient safety goals and associated requirements. The purpose of the national patient safety goals is to focus the attention of accredited organizations on obvious, straightforward, inexpensive patient safety solutions. Compliance with the specific requirements is evaluated during each onsite accreditation survey and the organization's performance with respect to each national patient safety goal is publicly reported.

Third, this past winter the Joint Commission joined with the centers for Medicare and Medicaid services to partner with the Institute For Health Care Improvement in a national campaign to save 100,000 lives by June 2006. This initiative is enlisting thousands of hospitals across the country in a commitment to implement specific evidence-based patient care interventions to prevent avoidable deaths. This campaign is viewed by the growing number of partners and participants as an outstanding opportunity to realize some of the Institute of Medicine's major goals through a concerted effort.

The last set of issues I would like to mention is framed in the Joint Commission's recently released policy report, *Strategies for Improving the Medical Liability System and Preventing Patient Injury*. This particular initiative was spurred by the chilling effect

that the current system has on reporting adverse events in health care by the high, exorbitantly high cost of defensive medicine and by the fundamental lack of fairness of the current system in compensating injured patients. The Joint Commission believes that the debate over medical liability reform must be broadened to encompass the patient safety issues that fuel litigation at the front end.

Of the almost two dozen recommendations in the report, two are especially relevant to the hearing today. First, more should be done to encourage appropriate adherence to clinical guidelines and other desired performance. Adherence to clinical guidelines is known to be an effective way in which to improve quality, reduce variation in care, and improve financial performance. Adherence to the guidelines can also have a substantial role in reducing legal risk. One way to promote greater use of clinical guidelines and accepted patient safety solutions is to pursue strategies that provide incentives for their use.

Second, we need to encourage clear and honest communication between practitioners and patients when an adverse event occurs. Specifically, patients and their families need a prompt explanation of what happened, a commitment that an investigation will be done to understand what went wrong, assurance that steps will be taken to make it unlikely that such an event will happen again, and, most importantly, an apology.

The Joint Commission's accreditation standards require the disclosure of unanticipated outcomes to patients and their families when they occur. However, a recent study confirms that half of hospitals are reluctant to comply with this standard for fear of liability suits.

In a very real sense, the health care industry is a victim of the rapid and continuing advances and its capabilities and sophistication. Much progress has been made in improving patient safety since the IOM issued its report *To Err Is Human*, but we may actually be falling further behind as new drugs, procedures, and technologies are introduced every day. Each of these has inherent safety risks that have not been identified, and they are usually introduced into care delivery systems where patient safety and systems thinkings are not constantly top of mind. The knowledge of what to do differently and how to do it exists, but we are far closer to the beginning of the journey than we are at the end. We as a society must ramp up our efforts if we are to successfully bridge the chasm between the current state of health care and what is truly safe, high quality care.

[The prepared statement of Dennis O'Leary follows:]

PREPARED STATEMENT OF DENNIS O'LEARY, PRESIDENT, JOINT COMMISSION ON
ACCREDITATION OF HEALTHCARE ORGANIZATIONS

I am Dr. Dennis O'Leary, President of the Joint Commission on Accreditation of Healthcare Organizations. I appreciate the opportunity to testify on new patient safety and quality initiatives that are currently underway in this country and, in some instances, around the world.

Founded in 1951, the Joint Commission 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, insurance, and academia.

The Joint Commission currently accredits over 15,000 organizations in the United States. These include hospitals (both general acute care and specialty), critical access hospitals, laboratories, health care networks (including integrated delivery systems, HMOs and PPOs), ambulatory care, office-based surgery, assisted living, behavioral health care, home care, hospice, and long term care organizations. About one-third of accredited organizations are hospitals, comprising the 80% of hospitals that contain 96% of U.S. hospital beds.

Accreditation is voluntary for all types of accredited organizations. However, both federal and state government regulatory bodies recognize many of the Joint Commission's accreditation programs and rely upon its accreditation findings and decisions for Medicare and licensure purposes. Furthermore, the Joint Commission standards are widely utilized by private sector organizations even where accreditation is not the objective. The Joint Commission also has a large international presence working with major leadership organizations such as the World Health Organization and the World Bank; accrediting individual hospitals in multiple countries; and providing consultation to foreign governments that are seeking to create similar accrediting bodies.

This country has been engaged in a highly visible national dialogue on patient safety for over five years. For an even longer time, the Joint Commission has been working diligently on a number of fronts both to raise professional and public awareness of safety issues and to identify and promulgate a range of workable and necessary solutions. We believe that some notable progress has been made, and the Joint Commission's successful efforts in this regard have been recognized in recent articles by Robert Wachter in *Health Affairs* and by Lucian Leape and Don Berwick in the *Journal of the American Medical Association*. In point of fact, there has been a remarkable change in how leaders in health care organizations talk and think about patient safety issues and how they approach medical errors when they occur. Moreover, there is broad support across the health care industry and among policymakers for creation of blame-free environments that foster increased reporting of patient safety events. Nonetheless, we have a long way to go to reach our shared goals. This is because the root causes of medical errors and quality problems are numerous, complex, and hard-wired into the way we deliver health care. We therefore need a multifaceted, multi-stakeholder approach to ensuring that high quality, safe care is provided on a consistent and predictable basis in this country.

Today, I would like to highlight some of the initiatives in which the Joint Commission is engaged in its continuing efforts to improve care, and to also suggest some areas that merit further exploration.

The Joint Commission's efforts to improve patient safety are based upon a fundamental recognition of the need for provider organizations and practitioners to adopt a "systems approach" to managing risk and keeping inevitable human error from reaching patients. The systems approach idea is borrowed from engineering and quality control principles which have been successfully applied in manufacturing and other industries to mitigate the effects of human error. The growing awareness of practices used in other high risk endeavors (e.g., in the nuclear power and airline industries) to create safety, makes clear that a name, blame, and shame approach to safety will fail, and that the end goal must be the design of safe systems—systems that are designed to anticipate human error and prevent the occurrence of adverse events.

This approach to safety—"systems thinking"—requires tools such as retrospective root cause(s) analysis when adverse events occur and prospective failure mode and effects analyses to identify and eliminate risks in identified vulnerable processes before actual adverse events can occur. This approach also requires a learning environment in which errors and preventable harms are identified (rather than hidden) so that they can become learning experiences for the organization.

Also required is an organizational environment that is safety-focused; that is, one in which safety is always top of one's mind; in which reporting of errors and unsafe conditions is rewarded, not punished; in which apology, honesty, and transparency characterize the relationship with patients who have been harmed through error; and in which there is constant vigilance for emerging risks. This type of organization environment—often called a "culture of safety"—only develops when the organization's administrative and clinical leaders collaboratively and intentionally create it.

TOOLS FOR CHANGE

With this framework in mind, the Joint Commission has created a substantial portfolio of initiatives, practical tools, and solutions for patient safety over the past decade. Taken together, they constitute a roadmap for organizations that are seeking ways to improve their performance and enhance patient safety. Concepts and tools are critical ingredients for 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, tools and potential solution they need to effect such changes.

The patient safety initiatives that I would like to highlight today are: 1) our new International Center for Patient Safety, 2) new accreditation standards, 3) the Sentinel Event Policy and Alerts, 4) the National Patient Safety Goals and Universal Protocol, 5) the Speak-Up Campaign, 6) the Patient Safety Event Taxonomy, 7) the 100 Thousand Lives Campaign, and 8) selected recommendations from our initiative to link potential improvements in the medical liability system to the prevention of patient injury.

International Center for Patient Safety (ICPS)

In March of this year, the Joint Commission launched a new International Center for Patient Safety (ICPS). The Center will initially focus on the identification, gathering, analysis, and dissemination of patient safety solutions, both in this country and abroad, and upon the creation of organization cultures of safety which embrace continuous attention to safety-focused, systems improvement efforts. These are seen as the most significant near-term opportunities for achieving major advancements in patient safety. The center will also serve as a focal point for research and related efforts to develop additional patient safety-related solutions. The center will obtain input, feedback and guidance through an international steering committee of patient safety experts, five global regional advisory councils, and strategic domestic and international.

The Patient Safety Center recently launched a new Web site which will serve as a central repository of resources and information related to all aspects of patient safety. Its content is relevant to patients, provider organizations, purchasers, physicians, nurses, and other practitioners. Health care organizations and health professionals will, for example, be able to use the Center's Web site to find information on the most frequent types of identified sentinel events and their root causes and resources for understanding and meeting the Joint Commission's National Patient Safety Goals. Patients and their families, as well as purchasers, will be able to use the Center's Web site to obtain quality-related performance information on health care organizations, become familiar with public education campaigns on patient safety such as the Joint Commission's Speak Up Campaign, and become knowledgeable about public policy issues that impact patient safety. Online discussion groups will provide an interactive forum for international dialogue on critical patient safety issues and topics.

The Center's Web site will also become the focus of the Center's efforts to create a worldwide collaborative network of patient safety leadership organizations. The international context is particularly significant, because patient safety is a universal problem. In fact, the World Health Organization launched its own World Alliance for Patient Safety in October 2004, and the Joint Commission and Joint Commission International are now involved in several of the Alliance's major initiatives. These include the lead role for creation of an International Patient Safety Events Taxonomy and designation as the WHO International Collaborating Center for Patient Safety Solutions, to coordinate the work of the Alliance's Solutions Initiative. A WHO collaborating center is a national institution designated by the Director-General of the World Health Organization to participate in an international collaborative network that carries out activities in support of WHO's mandate to promote international health.

The World Alliance for Patient Safety has been charged to conduct six initiatives over the next two years:

- Global Patient Safety Challenge—to focus on the reduction of health care-associated infections through the promotion of hand washing and other preventive efforts.
- Patients for Patient Safety—to identify and create a network of patient and consumer groups interested in identifying and promoting constructive patient safety solutions.
- International Patient Safety Events Taxonomy—to utilize the Joint Commission's Patient Safety Events Taxonomy to create a high level international umbrella

taxonomy that accommodates taxonomies already in existence in other countries.

- Research for Patient Safety—to undertake prevalence studies of adverse events in selected developed and developing countries and to pursue other patient safety research initiatives.
- Solutions for Patient Safety—to identify, gather, evaluate and disseminate patient safety solutions that are tailored to the needs of developing and developed countries.
- Reporting for Learning—to identify best practice guidelines for reporting systems that facilitate learning from adverse events and analyses of their underlying causes.
- The Joint Commission's International Center for Patient Safety will shortly convene the principal patient safety leadership organizations in the United States to explore opportunities to collaborate in coordinating the identification and dissemination of patient safety solutions and in pursuing other opportunities to improve patient safety. Those organizations that have agreed to participate are the Agency for Healthcare Research and Quality, United States Pharmacopeia, VA National Center for Patient Safety, ECRI, Institute for Healthcare Improvement, Institute for Safe Medication Practices, the Leapfrog Group, the National Patient Safety Foundation and the National Quality Forum.

Patient Safety Related Standards

One of the key elements in the Joint Commission's commitment to patient safety is the development, updating, and deployment of state-of-the-art patient safety standards. Over half of Joint Commission standards are directly related to safety—addressing such issues as medication use, infection control, surgery and anesthesia, blood transfusion, restraint and seclusion, staffing and staff competence, fire safety, medical equipment maintenance, emergency management, and security, among other areas.

In recent years, new and revised standards now require the internal definition, reporting and in-depth analysis of serious adverse events; internal systems improvements based on these analyses; the implementation of comprehensive virtual patient safety programs that actively engage organization leaders; the prevention of accidental harm through the prospective analysis and redesign of vulnerable patient systems (e.g. the ordering, preparation and dispensing of medications); and transparency in the communication of outcomes of care—whether good or bad—from the organization (usually through the responsible physician) to the patient. The Joint Commission has also taken steps to ratchet up the performance expectations respecting medication management and infection control and has introduced patient flow standards to mitigate the impacts of emergency department overcrowding on patient safety. Under development are major standards revisions that will substantially increase the stringency of current processes for credentialing physicians and licensed, independent practitioners and assessing their competency in the performance of various clinical procedures. These enhanced expectations anticipate increasing greater use of performance data as part of both the privileging and performance monitoring process.

Sentinel Event Policy

In 1995, the Joint Commission developed and implemented a Sentinel Event Policy that encourages the *voluntary* reporting of serious adverse events and requires the performance of root cause analyses that meet pre-determined criteria for thoroughness and credibility. Soon thereafter, the Joint Commission began to characterize and organize the reported events and their underlying causes for all identified occurrences (whether self-reported or otherwise), into a learning database. The resulting Sentinel Event Database is now this country's most complete record of the full spectrum of serious medical errors and their underlying causes. This database, combined with knowledge gained from working with health care organizations on a daily basis to address their patient safety problems, has given us a deep understanding of the interplay and complexity of factors that contribute to serious adverse events. It has also helped us craft solutions to some common safety issues. The solutions represent a range of actions—both low and high cost—that can be taken at various levels of the health care system and in which different stakeholder groups can participate.

The Sentinel Event Policy and its resultant database have proven their value. However, we would have many more reports and a more robust understanding of root causes of error if there were federal protection for reporting adverse events and near-misses. This Subcommittee has previously shown strong leadership in this

area, and we hope it will continue to work toward passage of such safe harbor legislation this year.

Sentinel Event Alerts

For the past seven years, patient safety solutions from the Sentinel Event Database have been disseminated in the periodic publication, *Sentinel Event Alert*. Since its creation, over 30 issues of *Sentinel Event Alert* have raised awareness in the health care community and the federal government about the occurrences of adverse events and the ways in which these events can be prevented. By distributing *Sentinel Event Alert*, the Joint Commission encourages organizations to implement the suggestions found with the publication to prevent errors and enhance patient safety. The most recent topics covered in *Sentinel Event Alerts* have been patient controlled analgesia by proxy and anesthesia awareness.

National Patient Safety Goals

Based upon the data from the Sentinel Event Database and other patient safety databases, and the advice of a national panel of patient safety experts, the Joint Commission now annually establishes and issues a set of National Patient Safety Goals and associated Requirements. The purpose of the Joint Commission's National Patient Safety Goals is to focus attention on obvious, relatively straight-forward, inexpensive patient safety solutions that all accredited organizations are expected to adopt. The goal-related requirements are specifically surveyed during the onsite accreditation survey, and the organization's performance with respect to each National Patient Safety Goal is reported in an organization-specific Quality Report on the Joint Commission's public website (www.qualitycheck.org). This public disclosure is not of errors or adverse events, but, rather, of whether the organization is performing the specific safe practices described in the Requirements.

Last month, the Joint Commission Board affirmed its required "do not use" list of abbreviations. The list was originally created in 2004 by the Joint Commission as part of a National Patient Safety Goal which mandates identification of a list of abbreviations, acronyms and symbols that are not to be used throughout the organization. Participants at a 2004 Summit convened to address this issue supported the "do not use" list. During the ensuing four-week comment period, the Joint Commission received 5,227 responses that included 15,485 comments. More than 80 percent of the respondents supported maintenance of the "do not use" abbreviation list.

Universal Protocol

In 2003, the Joint Commission's Board of Commissioners approved a separate Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery as a supplement to the National Patient Safety Goals. The Universal Protocol was created to staunch the continuing occurrence of a specific type of adverse type that should simply never occur. The Universal Protocol became effective July 1, 2004 for all accredited hospitals, ambulatory care and office-based surgery facilities. The Universal Protocol drew upon, and expanded and integrated, a series of previous requirements under the Joint Commission's 2003 and 2004 National Patient Safety Goals and is applicable to all operative and other invasive procedures. The principal components of the Universal Protocol include: 1) the pre-operative verification process; 2) marking of the operative site; and 3) taking a "time out" immediately before starting the procedure. The protocol has been endorsed by nearly 50 professional associations and societies.

Speak-Up Campaign

Several years ago, the Joint Commission, together with the Centers for Medicare and Medicaid Services, launched a national program to urge patients to take an active role in preventing adverse events in health care by becoming involved and informed participants on the health care team. The program utilizes various media to reach patients and consumers, including incorporation into selected purchaser employee benefits strategies, and has been embraced by a number of provider organizations and practitioners. The original *Speak Up* initiative was subsequently expanded to *Help Prevent Errors in Your Care for Surgical Patients*. This campaign provided tips to help patients prepare for surgery and assure their involvement in making certain that the correct procedure is performed at the correct body site. The two campaigns launched in 2004 included *Preparing to be a Living Organ Donor* which urges individuals to think through the risks and realities of becoming a living organ donor, and *Three Things You Can Do To Prevent Infection* which highlights a series of easy to steps anyone can take to avoid contagious respiratory diseases like the common cold, strep throat, and influenza. This year, the Joint Commission launched *Things You Can Do To Prevent Medication Mistakes*. This provides important tips for preventing medication mistakes and outlines key questions that the pa-

tient may want to pose to the doctor, pharmacist, nurse or other caregiver. Additional patient safety topics—such as discharge planning and pain management—stroke will be addressed in the future.

Standardized Patient Safety Events Taxonomy

It is no small irony that the progressively expanding national discussions on patient safety over the past several years are not based on a common language. For example, there are no agreed upon definitions of “medical error” or “adverse event,” making it extremely difficult, if not impossible, to aggregate safety data across various types of reporting programs. This critical missing element has hindered our collective ability to collect patient safety data in a consistent fashion, analyze process failures, mine data (e.g., trends, pattern analysis), and disseminate new knowledge about patient safety. In response to this challenge, the Joint Commission has created the framework for a comprehensive Patient Safety Event Taxonomy. This taxonomy is currently in the final stages of the National Quality Forum’s consensus development process. Having a standardized taxonomy will facilitate the management of patient safety data and the development of patient safety reporting systems. It should eventually have broad potential utility for consumers, provider organizations, health care practitioners, purchasers, researchers and other audiences.

As noted previously, this taxonomy is being used as the starting point for a WHO-led project to create an international Patient Safety Events Taxonomy. The development of a common international framework for classifying, measuring, and reporting adverse events and near misses is one of the principal technical components of the WHO’s global strategy to improve health care delivery systems, product safety (devices, drugs, biologics, and vaccines) and the safety of services (medical decision-making, diagnosis, and laboratory analysis). The intent is to create a scalable, portable framework that can be used to classify patient safety incidents reported through different systems in different countries with varying levels of technology.

100,000 Lives Campaign

Much of what the Joint Commission does and achieves is realized through partnerships with other health care leadership organizations. This past winter, the Joint Commission announced that it was joining with the Centers for Medicare and Medicaid Services to partner with the Institute for Healthcare Improvement in the national campaign to save 100,000 lives by June 2006. The campaign aims to enlist thousands of hospitals across the country in a commitment to implement changes to prevent avoidable deaths. The 100,000 lives campaign is viewed by the growing number of partners and participants as an outstanding opportunity to realize some of the Institute of Medicine’s major goals through a concentrated effort. Hospitals that choose to participate in the campaign will specifically commit to implement one or more of the following six quality improvement changes:

- Deploy Rapid Response Teams at the first sign of patient decline
- Deliver reliable, evidence-based care for Acute Myocardial Infarction to prevent deaths from heart attack
- Prevent adverse drug events by implementing medication reconciliation
- Prevent central line infections by implementing a series of interdependent, scientifically grounded steps called the “Central Line Bundle”
- Prevent surgical site infections by reliably delivering the correct perioperative antibiotics at the proper time
- Prevent ventilator-associated pneumonia by implementing a series of interdependent, scientifically grounded steps called the “Ventilator Bundle”

Strategies for Improving the Medical Liability System and Preventing Patient Injury

Through its Public Policy Initiatives, the Joint Commission periodically tackles tough patient safety and health care quality issues that would benefit from an independent voice. This year, the Joint Commission released a public policy report called “Strategies for Improving the Medical Liability System and Preventing Patient Injury.” The initiative was spurred by the chilling effect that the current system has on identifying and reporting adverse events in health care; by large jury awards; the exorbitantly high cost of defensive medicine; and by the fundamental lack of fairness of the current system in compensating injured patients. The Joint Commission wanted to broaden the debate over liability reform to encompass the patient safety issues that fuel litigation at the front end.

To address this issue, the Joint Commission convened a roundtable of experts in law, medicine, health care policy and related research, as well as patient safety advocates to frame the issues and create recommendations for action. The basic finding of the Roundtable was that there is a fundamental dissonance between the medical liability system and patient safety. Patient safety depends upon the trans-

parency of information on which to base improvement, while medical liability drives information underground and out of reach to those who could most benefit from it. Of the more than a dozen recommendations from the recently issued report, several are relevant to this hearing today.

1) *Encourage appropriate adherence to clinical guidelines and performance recognitions.* Adherence to clinical guidelines has long been touted as an effective way in which to improve quality, reduce variation in care, and improve financial performance. However, there is also a significant relationship between medical liability and clinical guidelines. A new study has shown that adherence to guidelines can have a substantial role in reducing legal risk. One way to promote greater use of clinical guidelines and consensus approaches to patient safety solutions is to pursue strategies that provide incentives to focus on improvements in patient safety and health care quality.

Pay for performance programs, for example, hold great promise for transforming the health care system to achieve the Institute of Medicine's six aims (safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity.) Indeed, only small, symbolic rewards may be needed to achieve desired behavior changes. Also on this point, pay for performance opens a larger opportunity to reform. Reimbursement systems today usually fail to recognize, let alone compensate for necessary investments by provider organizations and practitioners in patient safety.

2) *Encourage communication between practitioners and patients when an adverse event occurs.* One of the basic principles of patient safety is to communicate with and listen to patients. Several elements are fundamental to any disclosure effort when an adverse event occurs. These include a prompt explanation of what is understood about what happened and its probable effects; assurance that an analysis will take place to understand what went wrong; follow-up based on the analysis to make it unlikely that such an event will happen again; and an apology. The Joint Commission's accreditation standards require the disclosure of sentinel events and other unanticipated outcomes of care to patients and to their family members when they occur. A recent study nonetheless confirms that half of hospitals are reluctant to comply with this standard for fear of liability suits. But there is growing consensus that this openness has the potential to heal, rather than harm relationships between practitioners and patients.

3) *National Practitioner Data Bank.* One of the ways through which health care organizations seek to assess competencies of their physicians and other practitioners with clinical privileges is to query available data sources about disciplinary actions or medical liability judgments and settlements. However, such information is impossible to obtain from any one source. We need a centralized repository, or a network of linked sources, to make such information available. The Department of Health and Human Services, through the Health Resources and Services Administration, operates the National Practitioner Data Bank (NPDB) to permit hospitals and licensing boards to track physician performance issues. However, since its inception, the reliability, validity, and completeness of the NPDB's information have been questioned. A 2000 GAO report pointed out the need for reform of the NPDB. We believe that pursuit of these reforms is long overdue. The only reliable alternative is to create an alternative resource to house this information in the private sector.

CONCLUDING REMARKS

In conclusion, there remains much work to be done to truly change the culture of our complex health care delivery system to fully embrace patient safety and health care quality. The health care industry is a victim of its rapid success in the explosion of biomedical science, sophisticated technologies, and trained personnel who have highly specialized knowledge. Much progress has been made in improving patient safety since the IOM issued its report, *To Err Is Human*, but we may actually be falling further behind as new drugs, procedures and technologies are introduced every day. Each of these have inherent safety risks that have not been identified, and they will, for the most part, be introduced into care delivery settings where patient safety and systems thinking ("to keep the error from reaching the patient") are not constantly top of mind. In addition, the absence of electronic information exchange capabilities to provide decision support makes it virtually impossible for practitioners to maintain a current clinical knowledge base.

The knowledge of what to do differently and how to do it exists but we are we are far closer to the beginning of the journey than we are to the end. We as a society must ramp up our efforts if we are to successfully bridge the chasm between the current state of health care and what is truly safe, high quality care.

Mr. DEAL. Thank you. Dr. Griffin.

STATEMENT OF F. DEAN GRIFFEN

Mr. GRIFFIN. Thank you. My name is Dean Griffin, and I am a practicing general surgeon in private practice in Shreveport, Louisiana. I am pleased to be here today representing the American College of Surgeons and its 67,000 fellows and their patients. The College commends the subcommittee for undertaking this important hearing. We are pleased to have this opportunity to present testimony detailing some of the surgical programs that have been developed to improve surgical patient safety and quality of care.

While the American College of Surgeons has had a long history of involvement in patient safety and quality efforts, I would like to focus today on those things that are currently rather new.

The National Surgical Quality Improvement Program is the first nationally validated, risk adjusted, outcome based program that has been demonstrated to measure and improve the quality of surgical care. The program was initially developed by the Department of Veterans Affairs in the early 1990's. In the VA system, this group had impressive results with a 27 percent decline in post-operative mortality, a 45 percent drop in postoperative morbidity, a reduction in average postoperative length of stay from 9 to 4 days, and an increased patient satisfaction level.

In 2001, the College developed its own NISQIP, which expanded the program to the private sector through a grant from the Agency of Health Care Research and Quality. The program employs a prospective, peer controlled, validated data base to qualified 30-day risk adjusted surgical outcomes, allowing valid comparisons of outcomes among the hospitals now in the program. Medical centers and their surgical staffs are able to use the data to make informed decisions about their continuous quality improvement efforts.

Of particular interest to hospitals is the generation of a risk adjusted observed to expected outcome ratio from each center which could be compared to other participating centers on a blinded basis. Statistical analysis of the preoperative data identifies risk factors, and further analysis calculates the expected outcome for each hospital's patient population. So far, the College has expanded the NISQIP program to over 30 hospitals, and applications are under development for dozens of others who want to be involved.

In 2002, the Institute of Medicine named the NISQIP the best in the Nation for measuring and reporting surgical quality outcomes.

The College is one of 10 organizations on the Surgical Care Improvement Project Steering Committee. SCIP is a national partnership of organizations dedicated to improving the safety of surgical care by reducing postoperative complications. This summer, the SCIP partnership will launch a multi-year national effort to reduce surgical complications by 25 percent by 2010. SCIP quality improvement efforts are focused on reducing perioperative complications in the area where the instance and costs of complications is significant.

Recently, the College has developed a Bariatric Surgery Center Accreditation Program to foster high quality care for patients undergoing bariatric surgery for morbid obesity by setting, monitoring, and reporting appropriate standards. Because the number of surgeons and hospitals providing bariatric surgery has grown so

quickly, the College decided recently to place high priority on establishing this new accreditation program.

The ACS has recently issued a patient safety manual titled *Surgical Patient Safety: Essential Information for Surgeons in Today's Environment*. This publication provides information and guidance for surgeons and others involved in surgical patient safety. It describes a variety of practical resources and provides a broad overview of key issues, such as the scientific basis of surgical patient safety. Issues such as decision support, electronic prescribing, and area detection, analysis, and reporting are all analyzed. Legal challenges for surgeons participating in patient safety activities are also reviewed. Broad error prevention methods and strategies for preventing wrong-site surgery and for safe blood transfusions and handling are also included.

The College last year initiated an extensive analysis of closed general surgery malpractice claims in order to generate data that will help guide its patient safety educational efforts and perhaps maybe some research and standard setting as well.

The College is a sponsor of the National Time Out Day, which highlights the JCAHO universal protocol and other initiatives that have been developed to reduce medical and surgical errors. The surgical time out is an opportunity before a surgical procedure begins for all members of the operating team to review the case for the patient's benefit.

In conclusion, the College is proud of its many important innovations and quality improvement and patient safety, and it has plans for sponsoring additional programs. We welcome initiatives by Congress that would create an environment that will facilitate the developments of these private sector innovations and initiatives that hold such promise for improving the quality and safety of surgical patient care.

Thank you, Mr. Chairman, for allowing me to testify on behalf of our fellows and their patients, and thanks to all of the members of the subcommittee for their ongoing efforts to help us help our patients.

[The prepared statement of F. Dean Griffen follows:]

PREPARED STATEMENT OF F. DEAN GRIFFEN, CHAIR, PATIENT SAFETY AND PROFESSIONAL LIABILITY COMMITTEE, AMERICAN COLLEGE OF SURGEONS

"The American College of Surgeons is dedicated to improving the care of the surgical patient and to safeguarding standards of care in an optimal and ethical practice environment."

This mission statement of the American College of Surgeons can be found in the lobby of its building in Chicago. But this is not just a statement; elevating the standards and safety of surgical patient care are goals that the College has been putting into action since its founding in 1913.

My name is Dean Griffen, MD, FACS, and I am a general surgeon in private practice from Shreveport, Louisiana. I am pleased to be here today representing the American College of Surgeons and its 67,000 members. The College commends the House Energy and Commerce Subcommittee on Health for undertaking this important hearing. We are pleased to have this opportunity to present testimony detailing some of the surgical programs that have been developed to improve surgical patient safety and quality of care.

Patient safety and quality improvement depend on a composite of factors within the broad scope of the American health care system. In surgery, safety relies on the presence of competent and trained surgeons, on a "safe" institution, and on systems of good practices with which the surgical care is rendered.

ACS HISTORY OF INVOLVEMENT IN QUALITY IMPROVEMENT INITIATIVES

In 1918, the College initiated a Hospital Standardization Program in an effort to ensure a safe environment and effective system of care for surgical patients and others who are hospitalized. That program ultimately led to the establishment of what is known today as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). This commitment continues through the participation of three College JCAHO commissioners, as well as through other programs and initiatives conducted by College committees and programs.

In 1922, the College established the multidisciplinary Commission on Cancer to set standards for high-quality cancer care. Today, the commission is comprised of more than 100 individuals representing more than 39 national professional organizations. Among other initiatives, the Commission on Cancer has established cancer program standards and conducted the accreditation of nearly 1,500 hospital cancer programs. It also provides clinical oversight for standard-setting activities and for the development and dissemination of patient care guidelines; and it coordinates national cancer site-specific studies on pattern of care and patient management outcomes through the annual collection, analysis, and dissemination of data for all cancer sites.

Shortly thereafter, the Committee on Fractures was formed, later to evolve into the Committee on Trauma, which develops the standards that most states employ to designate trauma centers. The trauma program also includes a National Trauma Data Bank that facilitates studies and the development of treatment guidelines for optimal care of injured patients.

While the American College of Surgeons has had a long history of involvement in patient safety and quality efforts, I would like to focus my testimony on some of our most recent initiatives, including:

- National Surgical Quality Improvement Program (NSQIP)
- Surgical Care Improvement Project (SCIP)
- ACS Bariatric Surgery Center Network Accreditation Program
- Committee on Emerging Surgical Technology and Education (CESTE)
- Surgical patient safety manual
- Closed claims analysis project
- National Surgical Time Out Day
- Various patient safety guidelines and principles

NATIONAL SURGICAL QUALITY IMPROVEMENT PROGRAM

The National Surgical Quality Improvement Program (NSQIP) is the first nationally validated, risk-adjusted, outcomes-based program that has been demonstrated to measure and improve the quality of surgical care. The program was initially developed by the Department of Veteran's Affairs (VA) in the early 1990s, as an outgrowth of the National VA Surgical Risk Study. In the VA system, NSQIP had impressive results, with a 27 percent decline in post-operative mortality, a 45 percent drop in post-operative morbidity, a reduction in average post-operative length of stay from 9 to 4 days, and increased patient satisfaction. In 2001, the College developed its own NSQIP, which expanded the program to the private sector through a grant from the Agency for Healthcare Research and Quality.

The program employs a prospective, peer-controlled, validated database to quantify 30-day risk-adjusted surgical outcomes, allowing valid comparison of outcomes among the hospitals now in the program. Medical centers and their surgical staffs are able to use the data to make informed decisions about their continuous quality improvement efforts. The program involves the following key components:

- Data Collection
- Data Monitoring
- Validation Report Generation
- Data Analysis

Of particular interest to hospitals is the generation of a risk-adjusted, observed-to-expected outcome ratio for each center, which can be compared to other participating centers on a blind basis. Statistical analysis of the pre-operative data identifies risk factors and further analysis calculates the expected outcome for each hospital's patient population.

The NSQIP program involves a number of mechanisms to provide feedback to the participating hospitals and to the program as a whole. These mechanisms include annual data audits, site visits, and the sharing of best practices. This structured and careful feedback by program staff ensures the consistent reporting of data across sites and the rapid dissemination of information about successful surgical practices and about the environments that produce the highest quality of care.

So far, the College has expanded the NSQIP program to over 30 hospitals, including Partners HealthCare hospitals (the Harvard Medical School system), and applications are under development from dozens of others who want to be involved. In 2002, the Institute of Medicine named the NSQIP “the best in the nation” for measuring and reporting surgical quality and outcomes.

SURGICAL CARE IMPROVEMENT PROJECT

The College is one of the 10 organizations on the Surgical Care Improvement Project (SCIP) steering committee. SCIP is a national partnership of organizations dedicated to improving the safety of surgical care by reducing post-operative complications. Its steering committee reflects the range of public and private organizations that must work together to reduce surgical complications, and includes groups representing surgeons, anesthesiologists, perioperative nurses, pharmacists, infection control professionals, hospital executives, and others who are working to improve surgical patient care.

The program was initiated in 2003 by the Centers for Medicare and Medicaid Services and the Centers for Disease Control and Prevention. This summer, the SCIP partnership will launch a multi-year national effort to reduce surgical complications 25 percent by 2010.

SCIP quality improvement efforts are focused on reducing perioperative complications in the following four areas, where the incidence and cost of complications are significant:

- Surgical site infections
- Adverse cardiac events
- Venous thromboembolism
- Postoperative pneumonia

SCIP stresses that surgical care can be improved significantly through better adherence to evidence-based recommendations and by giving more attention to designing systems of care with thorough safeguards. Other evidence-based programs such as NSQIP, the National Nosocomial Infections Surveillance (NNIS) system, and the Medicare quality improvement organizations, have demonstrated this time and again. The College is proud to play a leadership role in the development of the SCIP performance measures, and our organization will continue to play a significant role in further developing SCIP initiatives.

ACS BARIATRIC SURGERY CENTER NETWORK ACCREDITATION PROGRAM

Recently, the College has developed a Bariatric Surgery Center Network (BSCN) Accreditation Program to foster high-quality care for patients undergoing bariatric surgery for morbid obesity. The program describes the necessary physical resources, human resources, clinical standards, surgeon credentialing standards, data reporting standards, and verification/approvals processes required for designation as a “bariatric surgery center.”

Severe obesity has reached epidemic proportions and because weight-reduction surgery provides an effective treatment for the condition—and because the number of surgeons and hospitals providing this care has grown so quickly—the College decided recently to place high priority on establishing this new accreditation program. The College contracts with hospitals and outpatient facilities that agree to implement its facility and other resource standards by reporting outcomes data on all their bariatric surgery patients, by submitting to site visits, and by completing annual status reports. By reviewing existing studies and consulting with experts in the field, the College has developed standards, defined necessary resources, organized the means to collect data, and organized the processes for conducting site visits to accredit hospitals and outpatient facilities in order to improve patient safety within this accredited network.

COMMITTEE ON EMERGING SURGICAL TECHNOLOGY AND EDUCATION

Indeed, this whole area of disseminating new surgical technology into the broader world of surgical practice is one of great concern to the College generally. The College established its Committee on Emerging Surgical Technology and Education to study the implications of new technology and to suggest best methods of developing policies that will accelerate education in this area and so protect surgical patient welfare.

Through the work of this committee, the College has approved a process by which its Fellows can be verified for the use of emerging surgical technologies. It also has created a voluntary verification process for surgeons performing ultrasound to ensure that these surgeons are, in fact, qualified and that their facilities and equip-

ment are appropriate for medical application and that they meet and maintain quality standards.

SURGICAL PATIENT SAFETY: ESSENTIAL INFORMATION FOR SURGEONS IN TODAY'S ENVIRONMENT

ACS has recently issued a patient safety manual titled *Surgical Patient Safety: Essential Information for Surgeons in Today's Environment*. This publication provides information and guidance for surgeons and others involved in surgical patient safety. It describes a variety of practical resources and provides a broad overview of key issues, such as the scientific basis of surgical patient safety.

Specifically, this manual analyzes the human factors, systems analyses, and processes affecting surgical patient safety. Issues such as decision-support, electronic prescribing, and error detection, analysis, and reporting are analyzed. Legal challenges for surgeon participation in patient safety activities are also reviewed. Broad error prevention methods such as the use of surgical simulation, educational interventions, and quality improvement initiatives are covered. In addition, the manual provides strategies for preventing wrong-site surgery and for safe blood transfusion and handling.

CLOSED CLAIMS ANALYSIS PROJECT

The College last year initiated an extensive analysis of closed general surgery malpractice claims in order to generate data that will help guide its patient safety educational efforts—and perhaps some research and standard setting efforts, as well. The Patient Safety and Professional Liability Committee, which I chair, is in the process of completing this pilot project to determine if we can replicate the success realized by the American Society of Anesthesiologists. The anesthesiology program, which has been in place for about 20 years, has led to engineering and practice changes that have had remarkable impact on reducing surgical patient injury and improving the quality of care.

The program promises to help us better identify and prioritize patient safety concerns. It will also allow the College to report to its members on the most common events leading to the most severe injuries, and help the surgical community develop the processes that will help correct these problems and avoid preventable maloccurrences.

NATIONAL SURGICAL TIME OUT DAY

The College is a sponsor of the National Time Out Day, which highlights the JCAHO universal protocol and other initiatives that have been developed to reduce medical and surgical errors. All JCAHO accredited hospitals, ambulatory surgical centers, and office-based surgery facilities were required to adopt the universal protocol starting July 1, 2004. And, beginning last year, a coalition of physicians, hospitals, nurses, and other health providers partnered in a yearly coordinated effort to reduce medical errors in the future.

The surgical “timeout” is an opportunity before a surgical procedure begins for all members of the operating room team to review the case of the patient before them. Not only does the timeout provide an opportunity to identify inconsistencies and so prevent errors in the operating room, but by improving overall communication it helps empower all members of the team to continue the dialogue during the operation if things do not seem to be going according to plan.

VARIOUS PATIENT SAFETY GUIDELINES AND PRINCIPLES

Over the past few years, there has been a noticeable increase in the number of invasive procedures being performed in the office setting. Recognizing that these settings are largely unregulated and very few have sought accreditation, the College called on the American Medical Association to work with it in convening a work group of relevant specialty societies and state medical associations to develop a set of principles for optimal office-based surgery.

In addition, the College, like others, has set forth guidelines for correct patient, correct site, and correct procedure surgery. In these guidelines, the College urges the surgical team to conduct a detailed final verification process on each of these crucial areas, and it calls for confirmation of the consent form by the patient or the patient's designated representative. If a patient is scheduled for multiple procedures performed by different surgeons, all the items on the checklist are to be verified for each planned procedure. If any verification process fails to identify the correct site, the process must be immediately halted until verification is completely accurate.

This coming weekend, the College's Board of Regents will be reviewing the draft of a new statement on "Prevention of Retained Foreign Bodies After Surgery." These proposed guidelines provide for consistent application and adherence to standardized counting procedures and the use of X-ray, radiofrequency, and bar coded items during surgery.

CONCLUSION

The College is proud of its many important innovations in quality improvement and patient safety, and it has plans for sponsoring additional programs. For example, we currently are conducting a pilot test of a hand-held case log system that surgeons in practice can use to record and report their operative experience. This system could, in turn, provide a quality benchmarking tool and help surgeons engage in practice-based learning and quality improvement. We also are considering the development of new network accreditation programs according to the model set by our bariatric center program. We welcome initiatives by Congress that would create an environment that would facilitate, rather than hinder, the development of these private sector innovations and initiatives that hold such promise for improving the quality and safety of surgical patient care.

Thank you Mr. Chairman and Mr. Brown for allowing me to testify on behalf of our Fellows, and thanks to all the Members of the Subcommittee for their ongoing efforts to promote patient safety and quality.

Mr. DEAL. Thank you. Dr. Bornstein.

STATEMENT OF WILLIAM A. BORNSTEIN

Mr. BORNSTEIN. Thank you. On behalf of the physician members of the Medical Association of Georgia, I want to thank Chairman Deal for your initiative in calling this hearing today to discuss the important issue of patient safety and quality initiatives. I am particularly grateful to have the opportunity to present testimony on the innovative work in this area by physicians on the State level.

1999, as others have pointed out, represents a tipping point for patient safety and quality in the United States. That was the year the IOM published its seminal report *To Err Is Human*. Interestingly, although the IOM report had a galvanizing effect on the health care provider community, as Dr. Burgess has pointed out, the bulk of the data contained is really quite old.

I would argue that the powerful influence of the IOM report was partly a result of its clear, incisive message, but equally a result of superb timing. After several decades of extraordinary advances in therapeutic and diagnostic technology, health care providers in 1999 were developing a growing sense that improvements in the quality and safety of the delivery of this care were lagging behind. Thus, the powerful message of the IOM report fell on receptive ears.

Not coincidentally, 1999 is also the year I became Chief Quality Officer at Emory Crawford Long Hospital in Atlanta. This was a new role for us at Emory and a relatively new role in the country. In the 6 years since then, my responsibility has grown to encompass Emory Health Care System. Emory Health Care is the clinical arm of Emory's Woodruff Health Sciences Center and is the largest, most comprehensive health care system in Georgia. Emory's Woodruff Health Sciences Center is one of the Nation's leading academic medical centers, and my full-time job is improving the quality and safety of care in the Emory system.

In the 6 years since the IOM report, the physicians of Georgia have accomplished a great deal to improve the quality and safety of the care we deliver. I would like to share with you some of those accomplishments as well as some of the challenges we face.

In 2001, the Medical Association of Georgia, MAG, formed the MAG Institute for Excellence in Medicine. I have the privilege of serving on the board of directors of the MAG Institute, whose mission is to improve patient safety and clinical outcomes. The MAG Institute is focusing on educational activities and applied studies to assess the effectiveness of care in the outpatient setting. For example, we are working to improve the detection and treatment of diseases such as colorectal cancer, asthma, and kidney disease.

Perhaps the most exciting aspect of the work that is being done by the MAG Institute is the application of information technology to patient safety and improved clinical care. The MAG Institute is currently partnering with Blue Cross/Blue Shield of Georgia in a study to determine whether the use of hand-held computers to access important clinical data at the bedside will improve patient outcomes. We are also very excited about the variety of projects that are designed to help Georgia physicians adopt and use health information technology to provide safer and more effective care.

At Emory Health Care, a major focus has been on enhancing our culture of safety. We agree with the IOM that the highest levels of quality and safety can only be achieved through systemic approaches in addition to individual efforts. This is a paradigm shift for physicians as we were trained that quality and health care resulted from individuals striving for solo perfection. When errors occurred, they were reviewed as individual failures, resulting in a culture of blame and shame. Physicians were felt to be a special breed that could and should aspire to error-free performance even under adverse circumstances such as sleep deprivation.

Today, we are changing this paradigm at Emory in a number of ways. We now survey our employees, nurses, technicians, everyone, on the culture of safety issues, and in fact helped develop the culture of safety survey tool that AHRQ is now promulgating. We and others have started weekly senior executive patient safety rounds to talk to the staff and ask them what can we do to improve the safety for our patients and to enhance the culture of safety. We have made a total commitment to disclosing errors to our patients and did so before the Joint Commission requirement, and to apologizing for their occurrence.

I would like to point out that the new tort reform law recently enacted in Georgia prohibits such apologies from being introduced as evidence in a medical malpractice case. This is extremely important. A critical aspect of a culture of safety is the encouragement and indeed rewarding of reports of errors and near misses. The blame and shame approach has the inevitable effect of discouraging such reporting.

A corollary of this insight is that reported error rates are an extreme underestimation of true error rates. Benchmarking therefore has the unintended consequence of reducing reporting. Therefore, virtually all patient safety experts, including myself, oppose such error rate benchmarking, whether it is between units within a hospital or between hospitals. What we do need is to be able to report and analyze individual occurrences and to share lessons learned under a protected and nonpunitive umbrella.

Let me turn to what we believe is the absolutely critical role of information technology. The extraordinary increases in the com-

plexity of clinical care of the past two decades reflect remarkable advances. This is a wonderful thing, but managing that complexity is difficult. The dramatic increase in clinical complexity has been further compounded by a parallel increase in administrative complexity. I am referring here to such things as complex billing codes, various documentation requirements, and managed care formularies that vary from plan to plan and moment to moment based on the best available deal of the moment. Administrative errors at best create the need for rework and, at worst, elicit a visit from the Office of the Inspector General. It is no wonder that physicians often seem preoccupied during patient visits as our heads spin trying to manage this complexity.

The simple truth is that this level of complexity cannot be optimally managed without the support of information technology. These health care IT systems are extremely complex and expensive. Like any therapy, these systems carry risks along with their benefits, and it is no surprise to us that recent studies are showing that, if implemented incorrectly or suboptimally, they can cause more harm than good.

At Emory we are spending \$50 million over 10 years on our system, and have made it one of our top organizational priorities. Successful implementation of such systems requires expertise in addition to money. As mentioned earlier, the MAG Institute has recognized this need and has several innovative projects under way to help Georgia physicians incorporate information technology into their practices. These initiatives enable folks like us at Emory who have the resources to be a little ahead of the curve to work with our colleagues across the State to help them work through these hurdles.

However, most health care in Georgia and the rest of the United States is delivered by practitioners in solo or small group practices. At Emory, the investment of money and expert resources we are making in our electronic medical records system is a severe strain and competes with important other investments and needed diagnostic and therapeutic equipment. Physicians in small group practices will not be able to afford such investments without help.

The achievement of optimal quality and safety is also critically dependent on the ability of these systems to share information. This in turn requires the development of data standards. In order to protect physician investment in these systems, it is very important that these standards be developed as rapidly as possible. To this end, we applaud the goals and early efforts of the National Health Care IT Initiative under the leadership of Dr. David Brailer and the announcement this week by Secretary Leavitt of the creation of the American Health Information Community, which Secretary Leavitt himself is planning to chair.

Through the efforts like those I have described, we have made substantial progress in the 6 or so years since the publication of the IOM report *To Err Is Human*. We still have a long way to go. In the meantime, despite our understanding that the system approaches that are in progress are essential for optimal quality and safety, our doctors and nurses are continuing to do what they need to do and what they have been doing all along, working heroically to deliver the best quality and safety with the tools they have.

With the remarkable progress of the last several decades, we are in what could be a golden age of health care. All the Institute of Medicine reports now have on their frontispiece a quote from Goethe that begins: Knowing is not enough; we must apply. Physicians need financial and administrative support from Congress to succeed in implementing the systems to apply the remarkable knowledge base that we have accumulated. I believe that with efforts like those I have described and with your help and support we can deliver on this promise of a golden age of health care in this country.

Again, I would like to thank Chairman Deal and the members of the committee for the opportunity to share these thoughts with you, and I would be happy to answer any questions at the conclusion.

[The prepared statement of William A. Bornstein follows:]

PREPARED STATEMENT OF WILLIAM A. BORNSTEIN, MEDICAL ASSOCIATION OF
GEORGIA

On behalf of the physician members of the Medical Association of Georgia (MAG), I want to thank Chairman Deal for his initiative in calling this hearing today to discuss the important issues of "Patient Safety and Quality Initiatives." I am particularly grateful to have the opportunity to present testimony on the innovative work in this area by physicians on the state level.

1999 represents a tipping point for patient safety and quality in the U.S. That was the year the IOM published its seminal report "To Err is Human." Interestingly, although the IOM report had a galvanizing effect on the health care provider community, the bulk of the data it contained were really quite old. I would argue that the powerful influence of the IOM report was partly a result of its clear and incisive message but equally a result of superb timing. After several decades of extraordinary advances in therapeutic and diagnostic technology including remarkable imaging and image guided interventional technology, pharmaceuticals, fiberoptics, genomics and proteomics, health care providers were in 1999 developing a growing sense that improvements in the quality and safety of the delivery of care were lagging behind. Thus, the powerful message of the IOM report fell on receptive ears. The evidence for this is that when the IOM report was released, despite some debate about the numbers, there was remarkably little disagreement about the message itself.

Not coincidentally, 1999 is also the year I became Chief Quality Officer, a new role, for Emory Crawford Long Hospital in Atlanta. In the six years since then, my responsibility has grown to encompass the Emory Healthcare system. Emory Healthcare is the clinical arm of the Woodruff Health Sciences Center and provides patient care to millions of Georgians each year. As the largest, most comprehensive health care system in Georgia, Emory Healthcare includes The Emory Clinic, Emory Children's Center, Emory University Hospital, Emory Crawford Long Hospital, Wesley Woods Center of Emory University, the jointly owned Emory-Adventist Hospital, and EHCA, LLC, a limited liability company created in collaboration with HCA-The Healthcare Company. Emory Healthcare has 9,000 employees, \$1.2 billion in net patient service revenue, and 1,184 licensed patient beds. In addition to Emory's own primary and multispecialty health care centers located throughout metro Atlanta, the Emory Healthcare Affiliate Network comprises 45 hospitals representing 65 communities and more than 6,000 physicians throughout Georgia, Alabama, North Carolina, and South Carolina. Emory Healthcare also is an owner of 1st Medical Network, Georgia's largest PPO network of physicians and hospitals, serving more than 700,000 lives. It is designed to serve as a delivery system for HMOs, PPOs, insurers, and others with a managed care network of hospitals and physicians in the state. The Woodruff Health Sciences Center is a top-ranked research institution with an annual budget is \$1.85 billion. We have over 1,752 full time faculty, plus 1,391 adjunct or volunteer faculty and collaborative scientists, and close to 3,500 students and medical residents in training.

In the six years since the IOM report the physicians of Georgia have accomplished a lot to improve the quality and safety of the care we deliver to our patients. I would like to share with you today some of those accomplishments. I would also like to share my thoughts about challenges and threats to progress.

In 2001, the Medical Association of Georgia, Georgia's largest physician organization, formed a separate 501 (c) 3 organization, the MAG Institute for Excellence in

Medicine. I have the privilege of serving on the Board of Directors of the MAG Institute. The mission of the MAG Institute is to improve patient safety and improve clinical outcomes for the patients of Georgia physicians. The MAG Institute is focusing on educational activities as well as sponsoring applied studies to assess the effectiveness of practices and processes in the outpatient setting, primarily in physician's offices. For example, we are working in areas such improving the detection and treatment of diseases such as colorectal cancer, asthma and kidney disease. Perhaps the most exciting aspect of the work that is being done by the MAG Institute is the application of information technology to patient safety and improved clinical care. The MAG Institute is currently partnering with Blue Cross Blue Shield of Georgia in a study to determine whether the use of handheld computers to access important clinical data at the bedside will improve patient outcomes. We are also very excited about the variety of projects that are designed to help Georgia physicians adopt and use health information technology to provide safe and more effective care. We are pleased to be working with the Georgia Medical Care Foundation (GMCf), the Medicare Quality Improvement Organization (QIO) on a series of initiatives sponsored by the Centers for Medicare and Medicaid Services. MAG and GMCf together will work with physicians to promote the adoption of health information technology (HIT) to improve the quality and efficiency of care—with a focus on e-prescribing, registries and deployment of full electronic health record systems. This project will help physicians select HIT products, reorganize their workflow and care processes to effectively use HIT, and undertake quality improvement projects to realize the benefits of HIT.

MAG also participated with the Georgia Hospital Association and other statewide organizations to form the Partnership for Health and Accountability (PHA) in 2000. Whereas, the MAG Institute has focused on patient safety in the outpatient setting, the PHA has focused its efforts on the hospital or inpatient setting, which was the primary focus of the IOM report. Through the PHA, hospitals confidentially and with peer review protection share lessons learned from adverse events, outcome and process data and best practices.

At Emory Healthcare, we have been taking a multi-pronged approach to improving quality and safety. A major focus has been on enhancing our "culture of safety." Fundamentally, this means a culture that emphasizes a systemic rather than an individual approach to quality and safety. This represents a major paradigm shift in health care. Traditionally, most of us were trained that quality in health care resulted from individuals striving for solo perfection. When errors occurred, they were viewed as individual failures, resulting in a culture of "blame and shame." Health care workers were felt to be a special breed that could and should aspire to error-free performance, even under adverse circumstances such as sleep deprivation. We thought ourselves exempt from the "laws" of human performance. This may have been a reasonable approach decades ago when the complexity of health care was orders or magnitude less. However, it has not been reasonable for at least the past 20 years. One of the major accomplishments of the IOM report "To Err is Human" was to send that message loud and clear.

A critical aspect of a culture of safety is the encouragement and indeed, rewarding of reports of errors and near misses. The blame and shame approach had the inevitable effect of discouraging such reporting. A corollary of this insight is that reported error rates are an extreme underestimation of true error rates. Benchmarking on error rates therefore has the unintended consequence of reducing reporting. Therefore, virtually all patient safety experts, including myself, oppose such benchmarking whether it is between units within a hospital or between hospitals. This in no way disputes the public's right to know. Rather it is a statement that outside of research settings, reported error rates do not convey meaningful comparative information, that public reporting of such rates has negative impacts on safety, and that for now, we need to focus on increasing internal reporting of each occurrence so that we can analyze and learn from each such event. When we are successful at creating such a culture of safety, one of the signs of success is a paradoxical increase in error rates due to an increase in self-reporting. I should emphasize that I am talking here about error rates. I do favor reporting of individual occurrences under a protected and non-punitive umbrella so that lessons learned can be shared. This has worked well for aviation. In Georgia, the Partnership for Health and Accountability has created a peer review protected mechanism for reporting and mutual learning throughout the state. I also support the reporting of quality process measures such as the Joint Commission National Quality Measures.

There are many ways we are working on creating a culture of safety at Emory. We have begun surveying our employees on culture of safety issues and in fact helped develop the culture of safety survey tool that AHRQ is now promulgating. PHA is facilitating such surveying for all hospitals in the state. We and others have

started weekly senior executive patient safety rounds to ask our staff about what we can do to improve the safety for our patients and to enhance the culture of safety. We have made a total commitment to disclosing errors to our patients and apologizing for their occurrence. It should be noted that the new tort reform law recently enacted in Georgia prohibits such apologies from being introduced as evidence in a medical malpractice case; this is extremely important. At Emory we have a national expert on medical error disclosure, Dr. John Banja. Dr. Banja is working with both the MAG Institute for Excellence in Medicine and PHA to teach physicians and other health care providers in Georgia how to improve their skills in such empathic communications.

As we are succeeding at creating a culture in which our staff reports more errors and near misses, we are committed to analyzing each error, learning from each error and sharing what we learn through peer protected channels both internally and with other providers in Georgia. These activities are critically dependent upon the continuation of peer protected reporting options.

We also learn through these activities where to focus our quality and safety improvement efforts. Over the past several years, Emory Healthcare has won patient safety and quality awards from PHA for our "Medication Error Prevention Initiative," our "Correct Site Surgery Initiative," and our "Skinsational Program" to reduce pressure ulcers.

Let me turn to what we believe to be the absolutely critical role of information technology. The extraordinary increase in the complexity of clinical care over the past two decades reflects the remarkable advances that I have previously cited. This is a good thing but managing that complexity has created challenges. The dramatic increase in clinical complexity has been compounded by a parallel increase in administrative complexity. I am referring here to such things as complex billing codes, various documentation requirements, and managed care formularies that vary from plan to plan and moment to moment based on best available deal on a particular drug. Administrative errors at best create the need for rework and at worst elicit a visit from the OIG. It is no wonder that physicians often seem preoccupied during patient visits as their heads spin trying to manage this complexity. The simple truth is that this level of complexity cannot be managed without supporting information technology any more than flights in and out of Atlanta's airport could be. Like any therapy, this technology will have some adverse effects, much as looking at instruments rather than out the window may have occasional undesired effects in aviation. Recent reports, like the one from the University of Pennsylvania which appeared earlier this year and highlighted new errors caused by such systems, raise appropriate cautions. However, it is very clear that done right, these systems will improve safety and quality. These systems are becoming the most important tools in our quality and safety improvement toolboxes. They are, however, just that—tools. We must learn from one another as we go along about how to start right and how to continuously refine these tools to continuously improve quality and safety. These systems must also be able to share information between one another. To both these ends, I applaud the goals and early progress of the National Healthcare IT initiative under Dr. Brailer's able leadership and the announcement this week by Secretary Leavitt of the creation of the American Health Information Community, which he will personally chair.

These systems are extremely complex and expensive. At Emory we are spending around 50 million dollars over 10 years on our system and have made it one of our top organizational priorities. We have project leaders who are highly sophisticated and dedicated to this project. We are doing this to improve the quality and safety of the care we deliver. However, most care in the state of Georgia, and throughout the United States, is delivered by physicians in solo or small group practices. How are they going to make this transition and how are they going to do so safely? Clearly, funding support is crucial. Even at an organization of Emory's size, our 50 million dollar investment in this technology is a severe strain and competes with other crucial capital investments in the latest diagnostic and therapeutic equipment. Expertise is also a critical success factor. As mentioned earlier the MAG Institute has recognized this need and has several innovative projects under way to help Georgia physicians incorporate information technology into their practices. These initiatives enable folks like us at Emory who have the resources to be a little ahead of the curve to work with our colleagues in the state to help them work through these hurdles.

When I look back to when I was in medical school and residency 30 or so years ago, I am amazed at how much better we can care for our patients now than then. We health care providers should be ecstatic about the progress, yet by and large we are a stressed out and often unhappy bunch. I think that's because we are keeping our patients safe through heroic individual efforts that can't be sustained. We des-

perately need these systemic approaches such as electronic medical records and others including those I've mentioned in order to be able to truly appreciate and deliver on what could be viewed as the beginning of a golden age of health care. As part of the "tipping point" phenomenon that is underway, that realization is bubbling to the surface of consciousness for the great majority of providers.

The other thing I realize looking back to when I started my medical training is that I thought then that knowledge was both necessary and sufficient to deliver outstanding patient care. I thought that if I could just learn everything about what needs to be done, it would get done. What we have learned from the IOM reports and the other emerging literature on these topics is that knowledge is, in fact, not enough; we have to learn how to more reliably apply this knowledge. Indeed, each IOM report now has on its frontispiece a quote from Goethe that begins, "Knowledge is not enough; we must apply." Through efforts like those I've described, we are intensely focusing on increasing the reliability and safety of the application of our knowledge. I believe that with such efforts and with your help and support, we can achieve what will truly be a golden age of health care in this country.

However, as with any great opportunity, there are challenges and risks that must be overcome. As I have mentioned these efforts are expensive and labor intensive. We need to find ways to fund and incentivize them and we must do so quickly. Meaningful measurement of quality and especially safety is challenging and still fairly primitive. Electronic medical record systems will help us collect and report better data. In the meantime, we need to be able to report individual errors in a protected non-punitive environment so that we can share lessons learned. Benchmarking of error rates must be avoided. The latter would undermine our efforts to enhance reporting and the culture of safety and would not help anyone identify which health care providers are safer. Finally, we must strive for a more rational approach to health care financing that deals with coverage for all Americans and that rewards health rather than disease.

Again, I want to thank Chairman Deal and the members of the committee for the opportunity to share these thoughts with you and I will be happy to answer any questions you may have.

Mr. DEAL. Thank you. Ms. Loewenson.

STATEMENT OF JANE LOEWENSON

Ms. LOEWENSON. Good afternoon, Chairman Deal, Representative Baldwin, and Representative Burgess. My name is Jane Loewenson, and I am the Director of Health Policy for the National Partnership for Women and Families. Thank you for the opportunity to testify before you today.

The National Partnership is a nonprofit, nonpartisan advocacy organization that has fought for economic, employment, and health security for women and families for more than 30 years. We are committed to improving the quality of our health care system because health care is central to the vitality and economic security of women and their families. The responsibility to make health care decisions often falls to women, yet there is very little meaningful information to help them with such important decisions as choosing a doctor or a hospital.

Consumers are left to hope that they receive optimal care in a health care system where there are reports that as many as 98,000 people die of preventable medical errors in hospitals. And, according to a recent RAND study, the likelihood of getting the right care at the right time is about 50/50.

The Institute of Medicine has called for both a national and mandatory reporting system for serious medical errors and a voluntary system for more minor errors or near misses. The National Partnership strongly supports those recommendations. Though it is only part of the equation, we also strongly supported passage of patient safety legislation during the last Congress that would create only a voluntary reporting system. We believe this could be an im-

portant step forward. However, it should address several key issues that I have laid out fully in my written testimony. They include the need for a clear definition of patient safety information, protection of existing and future reporting requirements, and a rigorous certification process. The legislation also should not preclude information, where appropriate, from use in criminal proceedings.

We appreciate all the work this committee has done on patient safety legislation, and are pleased that the bill will be moving forward this summer.

Now let me turn to the primary focus of my testimony today, the critical need for the public reporting of comparative information on how well physicians, hospitals, and other providers are delivering care. Right now, it is easier to get information about stocks and cars than doctors and hospitals. At the National Partnership, we believe it is not only possible but imperative to evaluate and publicly report providers' performance on standardized quality measures that will enable people to have meaningful information to guide their health care decisions.

There are multiple efforts to measure and report quality and safety information in both the private and public sector. One of the oldest public reporting efforts is in New York State. Since 1989, the New York State Department of Health has published annual data on risk adjusted mortality following coronary artery bypass graft for each hospital and surgeon. Between 1989 and 1992, mortality from bypass surgery fell 41 percent statewide in New York. By 1992, New York had the lowest risk adjusted mortality rate of any State in the Nation for bypass surgery and the most rapid rate of decline in any State with below average mortality.

A second example of public reporting is Minnesota's adverse health event reporting law that was passed during the 2003 legislation session. The law mandated hospitals to report the occurrence of any of the 27 "never events" endorsed by the National Quality Forum. The purpose of the law is to learn from serious medical errors so that harm to patients can be prevented. Examples of "never events" include: Retention of a foreign object in a patient after surgery; wrong-site surgery; and acquisition of a very serious pressure ulcer or bed sore after admission.

Hospitals are required to report information on the event along with their determination of why the event happened and what they are doing to prevent the event from happening again. The fact that health care providers in Minnesota's hospitals are now reporting serious errors and identifying ways to prevent harm is a major step forward. From the examples I have described as well as others, we have learned that quality can be measured, that what gets measured gets improved, and what gets measured and publicly reported gets improved even more.

The National Partnership co-leads and provides the organizational home for the Consumer-Purchaser Disclosure Project. The Disclosure Project is a coalition of large employers, business coalitions, consumer organizations, and labor unions that have united around a common goal of making our health care system more transparent by championing performance measures to the National Quality Forum consensus based endorsement process, encouraging the implementation and public reporting of NQF endorsed meas-

ures, and encouraging the development of new standardized quality measures to create a more complete and meaningful picture of the quality of care.

Going forward, the National Partnership welcomes the opportunity to provide you with further information on our activities and perspective as you consider the issues of patient safety and quality improvement. We appreciate the subcommittee's interest in these issues, and thank you for the opportunity to testify this afternoon.

[The prepared statement of Jane Loewenson follows:]

PREPARED STATEMENT OF JANE LOEWENSON, DIRECTOR OF HEALTH POLICY,
NATIONAL PARTNERSHIP FOR WOMEN & FAMILIES

Good afternoon, Chairman Deal, Ranking Member Brown, and other members of the Committee. My name is Jane Loewenson, and I am the Director of Health Policy for the National Partnership for Women & Families. Thank you for the opportunity to testify before you today on patient safety and health care quality. I appreciate the opportunity to share the National Partnership's views.

The National Partnership for Women & Families is a non-profit, nonpartisan advocacy organization that has long fought for economic, employment and health security for all women and families. The Partnership has more than 30 years of experience promoting fairness in the workplace, policies that help women and men meet the competing demands of work and family, and access to quality health care.

Over the past six years, the news about the quality of our health care system has been grim. The Institute of Medicine's (IOM) reports, *To Err is Human* and *Crossing the Quality Chasm*, document the wide gap between the health care that Americans are getting and what health care could and should be. In fact, more people die in hospitals from preventable medical errors than from breast cancer and AIDS combined. The IOM reports also document pervasive misuse, under-use and overuse of treatments and diagnostic tests. A recent study by the RAND Corporation found that an American's likelihood of getting the right care at the right time was about 50/50, no better than the toss of a coin. The evidence is clear: medical errors and poor quality take an enormous toll on our health and our lives.

The National Partnership is committed to improving the quality of our health care system, because health care is central to the vitality and economic security of women and their families. The responsibility to make health care decisions for their families often falls to women. Yet there is very little meaningful information to help with such important decisions as choosing a doctor or hospital. No tool exists that provides a complete picture of the quality and safety of the care delivered by providers. Consumers are left to hope that they receive optimal care in a health care system that fails patients far too often.

At the National Partnership for Women & Families, we believe that a critical strategy for reducing medical errors and improving the quality of our health care system is to enable Americans to select hospitals, physicians, and other providers on the basis of publicly reported, standardized performance information.

My testimony today touches briefly on the patient safety legislation that was under consideration during the last Congress. However, it will primarily focus on the critical need for greater transparency in our health care system.

PATIENT SAFETY LEGISLATION IN THE 108TH CONGRESS

In response to the finding that as many as 98,000 people die of preventable medical errors in hospitals, the Institute of Medicine called for a both a national mandatory reporting system for serious medical errors, and a voluntary system for more minor errors or near misses. The National Partnership strongly supports those recommendations.

While creating a mandatory reporting system for medical errors is a key goal for the National Partnership, we also strongly supported passage of patient safety legislation during the last Congress that would create patient safety organizations to collect and analyze voluntary, confidential reports of medical mistakes. Creating such a mechanism would be an important step forward, although only part of the equation. To make a voluntary system as effective as possible and to avoid undermining other efforts to improve health care quality, we believe that patient safety legislation should address several key issues.

The legislation should provide a clear definition of patient safety information. A certain level of confidentiality and protection from legal discovery is needed to encourage the voluntary reporting of medical errors and near misses. This protection,

however, should not shield information from a patient that they otherwise would have access to, nor should it preclude information, where appropriate, from use in criminal proceedings. Legislation should also protect federal, state, and local reporting requirements, such as those for public health.

Public reporting is a powerful incentive for quality improvement, and patient safety legislation should not undermine it. The confidential reporting of information to patient safety organizations should not hide from public view information that otherwise would be subject to public reporting. It should preserve the reporting of performance information that increasingly has been required by purchasers, states and accrediting organizations.

An effective voluntary reporting system also depends on having qualified independent organizations to collect and analyze the data reported by providers. We believe the legislation should include a rigorous certification process for patient safety organizations, evaluation of the qualifications and operations of these organizations including the ability to maintain the privacy of patient records, and clear requirements for what they should do with the data they collect. The process for certifying patient safety organizations should protect against conflicts of interest.

The National Partnership appreciates all the work this committee has done on patient safety legislation and hopes that a bill moves forward during this session of the Congress.

PERFORMANCE MEASUREMENT AND PUBLIC REPORTING

Now let me turn to the primary focus of my testimony today: the critical need for the public reporting of comparative information on how well physicians, hospitals, and other providers are delivering care. We support the IOM definition of quality as care that is safe, timely, effective, efficient, equitable, and patient-centered, and agree that these elements should be measured.

Right now, it is easier to get information about the performance of a company's stock than the performance of a doctor. And consumers have more information about the safety record of a car than the safety record of a hospital. It is our view that this reality must change. People should have access to objective, comparable information that allows them to choose the best surgeon for their bypass surgery, the safest hospital for giving birth, the physician who will do the best job of keeping their diabetes under control, or the pediatrician who will best treat their child's asthma so that they can avoid trips to the emergency room.

At the National Partnership, we believe it is not only possible, but imperative, to evaluate and publicly report providers' performance on standardized quality measures. This will enable people to have meaningful information to guide their health care decisions. Not only do we believe people have a right to this information, there is strong evidence that measurement drives quality improvement and that quality improves even more dramatically when information is publicly reported.

There are multiple efforts to measure and report quality and safety information in both the private and public sector. I will describe three concrete examples:

1. *New York*

One of the oldest public reporting efforts is in New York State. Since 1989, the New York State Department of Health has published annual data on risk-adjusted mortality following coronary artery bypass graft (CABG) for each hospital and surgeon. Between 1989 and 1992, mortality from bypass surgery fell 41 percent statewide in New York. By 1992, New York had the lowest risk-adjusted mortality rate of any state in the nation for bypass surgery and the most rapid rate of decline in any state with below-average mortality. This example clearly demonstrates the relationship between public reporting and better health outcomes.

2. *Wisconsin*

A second example of the impact of public reporting and performance measurement is Wisconsin's *QualityCounts* Report. This report, released in the fall of 2001, reported 24 hospitals' performance across five categories: surgery, non-surgery, hip/knee surgery, cardiac care, and maternity care. *QualityCounts* was the first public report on hospital quality issued in this region and it generated substantial interest. Of the 24 hospitals, eight performed poorly in obstetrics and three had poor scores in cardiac care.

An evaluation of the *QualityCounts* experience, published in *Health Affairs* in 2003, found that public reporting of performance led to greater quality improvement activities. The evaluation compared the hospitals that had their performance publicly reported with those that received a private report of their performance and those that received no report. The study found clearly demonstrates that hospitals

that publicly reporting their performance undertook the greatest number of quality improvement activities.

3. Minnesota

Minnesota's Adverse Health Event Reporting Law was passed during the 2003 legislative session, and mandated hospitals to report the occurrence of any of the 27 "never events" endorsed by the National Quality Forum (NQF). The purpose of the law is to learn from serious medical errors, so that harm to patients can be prevented. Examples of "never events" include:

- Retention of a foreign object in a patient after surgery;
- Wrong-site surgery; and
- Acquisition of a very serious pressure ulcer (or bed sore) after admission.

Minnesota is the first state to fully implement the "never event" reporting. Hospitals are required to report information on the event, along with their determination of why the event happened and what they are doing to prevent the event from happening again. This past January, the Minnesota Department of Health reported that, over the course of 15 months, there were 99 incidences of "never events" and named the hospitals in which they occurred. Findings from the report include:

- 31 patients had foreign objects left in them after surgery;
- 24 patients acquired a serious pressure ulcer (or bed sore) after admission;
- 13 patients had surgery on the wrong part of their body.

Some examples of corrective action plans that hospitals have submitted include: 1) purchasing surgical sponges and other materials that are easier to track and count; 2) marking the surgical site prior to surgery; and 3) setting up physicians orders to make sure patients at risk for bed sores are re-positioned on a regular basis. The fact that health care providers in Minnesota's hospitals are reporting serious errors and identifying ways to prevent harm to patients is a major step forward in patient safety.

From the examples I have described, as well as others, we have learned that:

- Quality can be measured;
- What gets measured gets improved; and
- What gets measured and publicly reported gets improved even more.

The National Partnership recognizes that measurement and public reporting are powerful mechanisms to address the safety and quality crisis in the health care system. We have embraced a vision of a transparent health care market, one in which standardized, comparative information on provider performance is available to the public. To advance this vision, the National Partnership has forged a groundbreaking collaborative—the Consumer-Purchaser Disclosure Project. The National Partnership co-leads and provides the organizational home for this effort. The Disclosure Project is a coalition of large employers, business coalitions, and consumer organizations and labor unions that have united around a common goal of making our health care system more transparent by:

1. Championing performance measures that reflect consumer and purchaser needs through the National Quality Forum's (NQF) consensus-based endorsement process;
2. Encouraging the implementation and public reporting of NQF-endorsed measures by public and private purchasers, accreditation bodies, health plans, and other key stakeholders; and
3. Encouraging the development of new standardized quality measures such as infection or complication rates, or patient experience with providers, so that consumers and purchasers have a more complete and meaningful picture of the quality of care.

Through our work on the Disclosure Project, we recognized the need for additional consumer engagement around the issues of patient safety and quality improvement. Consumers are the ultimate stakeholder in health care, yet their voices can be lost among the multitude of other interests in a complex health care system. In response, the National Partnership recently launched a major initiative, with support from the Robert Wood Johnson Foundation, to engage consumer advocates at the local, state, and national level in these issues.

Going forward, the National Partnership welcomes the opportunity to provide you with further information on our activities and perspective as you consider the issues of patient safety and quality improvement. We appreciate the Subcommittee's interest in these issues and thank you for the opportunity to testify this afternoon.

Mr. DEAL. Thank you. We will now begin the questioning. Dr. Bornstein, are you aware of any medical schools that are actually

teaching classes on patient safety? And, if so, how do they approach the subject?

Mr. BORNSTEIN. Yes, sir. There are a number of efforts under way to begin to incorporate this kind of information into the curriculum both at the medical student level and also at the level of interns and residents. And fundamentally it is about training and systems thinking, ideally it involves participation in actual projects to improve safety and quality. We actually think that a lot of this training should occur at the level of interns and residents, and we have applied at Emory for grants to do this kind of training. Nothing is simple in health care, as the members of the committee know better than anyone, and part of the unintended consequence of some of the workweek restrictions relate to how much time is available for this critically important training. But we think that is very important for the future of safety of health care.

Mr. DEAL. Ms. Loewenson, some people have argued that simply making the public aware of serious events that have occurred during their treatment doesn't really improve the quality of care overall. How would you respond to that?

Ms. LOEWENSON. Well, I guess I would point to the examples in my testimony and others as well. In the New York experience where the mortality rates were published, mortality following bypass surgery actually went down. In Minnesota, in the Minnesota example, the serious events are not only being reported but corrective action plans are as well.

Mr. DEAL. Dr. O'Leary, I think one of the two suggestions that you had was to encourage clear communications between the doctor and the patient. And Dr. Bornstein has alluded to the fact that in my State of Georgia, our State of Georgia, that our legislature included in its medical liability reform package the provision for simply saying I am sorry and not having that being allowed into evidence in a trial proceeding. Is that something that you are seeing take place at the State level in other places as well?

Mr. O'LEARY. There are actually, to our knowledge, only a handful of States that have done that so far. But this is one of the recommendations in our public policy white paper, that that be done. It is a relatively simple but very important step I think to encourage real apologies. I think we all understand that, even without the medical liability specter, apology is a hard thing to do and we need to do everything we can to encourage that.

Mr. DEAL. I certainly hope, if this committee revisits the issue of another medical liability reform bill, that we will take into consideration perhaps the addition of that particular provision. I think it has some real therapeutic value in the overall scheme of things.

I have been impressed with your testimony. I appreciate the fact that all of you have taken the time to be with us. As you know, we are just piercing the veil on many of these issues, and they certainly do interrelate to the IT issue that we have all alluded to and trying to make sure that whatever we accumulate by way of information is useful information that is going to achieve a goal, that of protecting patients in the future, and that we can learn from that. So as each of you look at this issue on an ongoing basis, we will appreciate your continued funneling to us of information or

thoughts or ideas because we are hopeful that we will have some legislation that will be forthcoming before our recess.

I would add, however, I do not view that whatever we will do as the end of the course on that subject matter, because I think it would be impossible for us to formulate in any particular piece of legislation everything that perhaps is going to have to be addressed down the line. We probably will have to at some point in the future consider such things as building in to reimbursement formulas money for the development of the IT systems that will be necessary and making sure that those do talk to each other so that information is not just collected and put in a box somewhere or in a computer disk and doesn't go any further and is not of any use.

So it is a challenge that I think our committee faces, and your testimonies here today have been very helpful and we appreciate that very much.

Our ranks have dwindled. Ms. Baldwin.

Ms. BALDWIN. Thank you, Mr. Chairman. First I have more of a comment than a question for Ms. Loewenson. I was happy to see in your written testimony that you also referenced Wisconsin's QualityCounts report as an example of the impact of public reporting and performance measurement. And as I mentioned earlier, one of the important features of Quality Counts is that the results are a part of the public domain. And I just wanted to emphasize that part of your testimony, that this data could be collected and used certainly for internal quality improvement purposes. But including it in the public domain really enhances the power of the data collected and the power of patients to make wise decisions about their health care.

Dr. Bornstein, I was pleased to see and hear in your testimony the emphasis you placed on health care information technology, and I certainly believe it is a powerful and very important tool in reducing medical errors, and it was interesting to hear about your work with physicians in Georgia to promote the adoption of health care information. The doctors that I speak to at home are very excited about information technology, and the promise it holds, but they also frequently mention their concerns. You raised several of them in your testimony: The barriers that are keeping them from adopting health care IT, including the cost of the system obviously, the ongoing need for software and technology support services, the fact that we are not yet at a point where we have national interoperability standards. And you can certainly understand why a doctor especially in a small practice might hesitate before investing very significant sums of money into an IT system when the system could become obsolete in the future if they—you know, as the national processes continue.

I guess I would like to hear if you are hearing similar feedback in Georgia, and what specifically you are helping these doctors, especially in the small practice settings, maybe one doctor or a small number, to overcome these barriers.

Mr. BORNSTEIN. Thank you for that question. Those are all very important points. First, on the matter of cost. As you were speaking, and I think you captured it exactly right and not only for cost. Doctors, many doctors are enthusiastic about the promise, fearful about the price they are going to have to pay both in terms of dol-

lars but also in terms of change and how they deliver care and the learning curve that is involved. I think, you know, part of what we can do is organizations like Emory that partly are funded to help develop these things through grants from AHRQ and others, we need to be able to share that information. And the Institute, the MAG Institute is a vehicle for doing that.

So one of the things that we are looking to do at the Institute is create some sessions where physicians of Georgia can come together, meet with us and other experts from within the State and from around the country to hear tips about how to make this easier, how to make it work better, how to be able to incorporate it into their practice.

Ms. BALDWIN. Just a quick followup, and I don't know if you have had further chance to study the initiative that you were talking about, the initiative that Secretary Leavitt announced this week, the four grant programs. Do you remember the time line of that, when we can actually expect results out of those various?

Mr. BORNSTEIN. No. I am sorry. I would love to know the time line myself.

Ms. BALDWIN. Maybe we can hold further hearings on information technology and electronic medical records so we can get further detail on that. Thank you for your time.

Mr. BORNSTEIN. I think it was Secretary Leavitt who made the comment that what we don't want to get into a situation where it is sort of last vendor standing becomes the vendor of choice. You know, with our \$50 million investment, you know, we are taking some risk in that regard.

Ms. BALDWIN. Thank you.

Mr. DEAL. We are pleased to have the chairman of the full committee here, Mr. Barton. I would recognize you at this time.

Chairman BARTON. Mr. Chairman, I don't have any questions. I have missed the hearing, basically. I just came to show support and to thank our panelists for attending. This is an important issue and, as you pointed out, something that we hope possibly to legislate on later in the year.

Mr. DEAL. We appreciate your coming. Dr. Burgess for questions.

Mr. BURGESS. Thank you, Mr. Chairman. Dr. O'Leary, on the back page of your printed testimony you talk, have a paragraph here talking about the National Practitioner Data Bank, which I think is what Mr. Shimkus was asking about during the earlier round. Would you share your thoughts with us on what you think the shortcomings of what the National Practitioner Data Bank are and how that might be improved to improve the environment and patient safety?

Mr. O'LEARY. Well, the Practitioner Data Bank, as you are all aware, is probably 15 years or so old. It has probably never met its full expectations, and I think those are probably best articulated in the 2000 GAO report on the subject. For instance, there has been an ongoing problem about underreporting of disciplinary actions, you know, the 30-day rule, and if it is not 30 days it doesn't count. But there has really been very little texture in there so that the data bank tends to be weighted toward information on settlements and actual judgments, probably more heavily on settlements. And yet in the data bank it turns out, of all of the settlements,

fewer than 10 percent have any—put any information about whether a standard of care was violated. This starts to be relatively unhelpful information. What is I think most troubling to us is that nothing has been done about the recommendations in that GAO report. It is 5 years later now, and we feel very strongly that this, if it were properly designed and utilized, could be a helpful resource because, amongst other things, it crosses State lines. But it is falling well short of that now. And if HIRS and HHS are not going to fix it, maybe we need to be looking at other alternatives, which might, for example, even include a network of data bases. I mean, I think we have to be thinking creatively as to how we meet this need which is not being met right now.

Mr. BURGESS. You mean like a network of State boards of medical examiners?

Mr. O'LEARY. It could be that, yes.

Mr. BURGESS. Very well. Thank you. Dr. Griffin, you talk about your effort in compiling the data base and the 15-year effort that you put forth, and I really appreciate all the hard work that the American College of Surgeons has put into that. Now, we are likely to copy you to some extent and may in fact even be providing somewhere along the line some effort at relief of liability for people who are willing to set up those same types of programs. Do you think it would be fair to do a look-back and incorporate already standing programs such as yours in any future endeavor that we undertake?

Mr. GRIFFIN. Yes.

Mr. BURGESS. I just wanted to get that on the record.

Mr. GRIFFIN. Interestingly, the Thoracic Society has been very influential in taking the bull by the horns. In the absence of the wonderful protections that you all have written into your drafts of current legislations that has been proposed as the Patient Safety Improvement Act, there is other examples of this. The cardiology groups up in New England have tackled their problems in the same way. And just like Ms. Loewenson says, if you measure something, it gets better. And they have shown that, as have the thoracic surgeons. And so measurement is so critical. And that is what we are trying to achieve in a very dense milieu of frustration. Measurement of outcomes gives something concrete that can be used by hospitals and by patients to see where they are, if they are outliers in there. In other words, if their observed versus expected outcomes fall below one, they have got a problem that patients will find out about for sure, because the hospital that has an outcome above one is going to advertise in the paper and then therefore—and through this process we are going to be able to help those below one improve.

Reporting of errors is so critical. And if we can get that data base with error reporting, then we can not only help the good hospitals advertise and get the patients, we can also then help the lesser hospitals improve to keep the patient base spread out. One doctor who is the best one can't see everybody, and so everybody needs to perform well.

Mr. BURGESS. I couldn't agree more. Thank you.

Mr. Chairman, I will just point out, too, you talked about getting the IT systems to the point where they can talk to each other and there be complete interconnectability between the IT systems. And,

unfortunately, with the HIPPA legislation that you all passed before I got here that may be a detriment.

And, finally, Ms. Loewenson let me ask you. One thing I have been impressed with in Congress is that science moves a lot faster than legislation. How do you propose that mere performance measures will keep up with science?

Ms. LOEWENSON. Well, we think that they should, No. 1. But we support measurements being endorsed through the National Quality Forum and having all of the relevant players involved in the consensus building as to whether it is an appropriate scientifically based measurement, and then I think that we need to revisit them on a regular basis.

Mr. BURGESS. And how regular? What is regular? Is that yearly, is it quarterly?

Ms. LOEWENSON. I guess it would depend on the situation and what it was. Maybe certain things would have to be revisited more quickly than others.

Mr. BURGESS. I just have been impressed with my visits to the NIH. The types of things that they are working are lightyears ahead of where anyone is in the actual practice of medicine today. And you are right, we are going to have to keep up. But we have got to make certain that our performance indicators don't hinder us delivering the best science and the best medicine.

Thank you, Mr. Chairman. My time is up. I yield back.

Mr. DEAL. I thank the gentleman, and once again, I thank the panel members. Your testimony has been very useful. It has been distributed to those members who weren't present at the hearing today and it is a part of this record and certainly is something that we will be reviewing as we go forward. Thank you again for your attendance.

[Whereupon, at 3:50 p.m., the subcommittee was adjourned.]

