MEDICAL ERRORS: IMPROVING QUALITY OF CARE AND CONSUMER INFORMATION

JOINT HEARING

BEFORE THE

SUBCOMMITTEES ON
HEALTH AND ENVIRONMENT

AND

OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON COMMERCE

AND THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON VETERANS' AFFAIRS
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MEDICAL ERRORS, IMPROVING QUALITY OF CARE AND CONSUMER INFORMATION

WEDNESDAY, FEBRUARY 9, 2000

HOUSE OF REPRESENTATIVES, COMMITTEE ON COMMERCE, SUBCOMMITTEE ON HEALTH AND ENVIRONMENT AND SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS, JOINT WITH THE COMMITTEE ON VETERANS' AFFAIRS SUBCOMMITTEE ON HEALTH,

Washington, DC.

The subcommittees met, pursuant to notice, at 10:30 a.m., in room 2123, Rayburn House Office Building, Hon. Michael Bilirakis (chairman of the Subcommittee on Health and Environment) presiding.

Members present from Subcommittee on Health and Environment: Representatives Bilirakis, Stearns, Greenwood, Burr, Whitfield, Ganske, Norwood, Bryant, Bliley (ex officio), Green, Strickland, Barrett, and Towns.

Members present from Subcommittee on Oversight and Investigations: Representatives Cox, Burr, Whitfield, Ganske, Bryant, Bliley, Green, and Strickland.

Members present from Subcommittee on Health: Representatives Stearns, Gutierrez, Smith, Bilirakis, Moran, Snyder, and Rodriguez.

Also present, Committee on Veterans' Affairs: Representatives Evans and Udall.

Staff present: Jason Lee, majority counsel; Chuck Clapton, majority counsel; Ralph Ibson, majority counsel; Kristi Gillis, legislative clerk; Bridgett Taylor, minority professional staff; John Ford, minority professional staff; Karen Folk, minority professional staff; Susan Eddgerton, staff director; and Sandra McClellan, professional staff.

Mr. BILIRAKIS. I want to welcome aand thank all of our witnesses and the members for taking the time to join us today for this very important hearing. As chairman of this subcommittee, I have conducted many hearings with other subcommittees and committees. I believe, frankly, in the joint hearing because you spend a lot less time since multiple committees don't have to go over material repeatedly. Today, however, marks my first joint hearing with the Veterans' Affairs Subcommittee on Health, on which I serve as vice chairman. And I want to extend a special welcome to my VA committee colleagues and particularly to the chairman of the subcommittee, Mr. Cliff Stearns, my fellow Floridian.

Together we will examine the issue of medical errors in our Nation's healthcare system. A recent report by the Institute of Medi-

cine entitled "To Err is Human, Building a Safer Health System", takes a serious look at the prevalence and causes of medical mistakes. During my tenure as a member of this subcommittee, we have constantly focused on ways in which the quality of health care can be improved.

As chairman, I have appreciated the support of the subcommittee's ranking member, Mr. Sherrod Brown, of Ohio, and I regret and I know we all regret that he is unable to join us today. You, I am sure, all realize he had a pretty serious accident up in Ohio and I talked to his chief of staff yesterday and I understand he got out of the hospital the day before and is mending but it will take a while to do so.

Last year the subcommittee approved H.R. 2506, the Health Research and Quality Act of 1999. This bi-partisan legislation was enacted into law to reauthorize and rename the Agency for Healthcare Quality and Research. I introduced this measure, joined by Mr. Brown, to refocus the agency's mission and promote research to improve the safety and quality of healthcare. America's healthcare system provides high quality affordable healthcare coverage to millions of Americans each day, but we must always continue to closely monitor the system and strive to make it better.

Today's hearing is not intended to cause public alarm but rather to focus needed attention on real problems within our healthcare system. Like many people, I was deeply disturbed by the Institute of Medicine's recent report. It cites estimates that at least 44,000 and possibly as many as 98,000 deaths each year are the result of medical errors. This makes medical errors roughly the eighth leading cause, and I have even seen some figures which put medical errors as the fifth leading cause, of death in the United States. We can and should work together to reduce these startling figures.

As a senior member of the Veterans' Affairs Committee, I have had the opportunity to review detailed information about ongoing efforts to reduce medical errors within the VA system. The VA operates an integrated national healthcare system providing a full range of services to eligible veterans through some 170 hospitals, more than 600 clinics and some 130 nursing homes. In 1997 a local newspaper in my congressional district ran a series of stories about healthcare services at the Department of Veterans' Affairs.

These articles recounted mistakes resulting in the deaths of 23 Florida veterans. The newspaper also reported that another 23 deaths occurred at other VA facilities across the country since 1993. These deaths were caused by unusual or avoidable circumstances. In response I urged VA Committee Chairman Bob Stump to investigate this matter. The Health Subcommittee, which is chaired by our colleague, as I indicated, Cliff Stearns, conducted two hearings on the quality of care and patient safety at VA medical facilities during the last Congress.

I was pleased to work with Subcommittee Chairman Stearns on these hearings and I want to commend his leadership on this very serious issue. Since those hearings, the VA has undertaken numerous initiatives to improve patient safety within its healthcare system. Many of the steps taken by the VA were also recommended in the IOM report. Our witnesses from the Department of Vet-

erans' Affairs will provide valuable insight on their experiences in addressing these concerns.

In June 1997, the VA ordered its hospitals to report medical errors, which are logged into its National Patient Safety Registry. Last year the VA's Office of the Medical Inspector used this data to report that veterans hospitals around the country committed about 3,000 medical errors leading to approximately 700 deaths between June 1997 and December 1998, a year and a half.

While these numbers are disturbing and must be examined, the VA should be recognized for its efforts to create a data base of adverse events which can be used to identify and correct system errors. In addition to the National Patient Safety Registry, the VA established a national center for patient safety to lead the department's patient safety effort. The VA also created several patient safety centers of inquiry to develop practical solutions to the patient safety challenges.

And one of those inquiry centers is located at the VA Medical Center in Tampa, Florida, and I would like to take this opportunity to welcome Dr. Audrey Nelson, Director of the Patient Safety Center of Inquiry at the James Haley VA Medical Center in Tampa. This center is focused on preventing patient falls and promoting safe wheelchair mobility. All of our witnesses today will help us better understand the problem of medical errors, the Institute of Medicine report and its recommendations and related concerns, and we will also highlight successful private and public sector initiatives.

As we consider these issues, our shared goal must be to reduce the number of medical errors and to improve protections for the patients in our Nation's healthcare system. And I now yield to Mr. Green, who is sitting in for Mr. Brown as the ranking member of this subcommittee. Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman. I am pleased that we are beginning to address the issue of medical errors in a non-partisan and collaborative way. Members of the three subcommittees will hear witnesses representing a host of government, quasi government, and private organizations that will be giving serious thought to the issues before us.

Mr. Chairman, a coordinated hearing is so important because of our joint referral and joint jurisdiction issues, and not only we as Members of Congress and committees have to work together but also our staffs need to know each other so we can work together for efficiency. While the question how to address medical errors is as old as medicine itself as we know first do no harm, there are still many questions to answer and many issues to think through.

The complex nature of our medical system and the practice of medicine being an art as much as a science a solution does not come easily. I am pleased that the Institute of Medicine report has rekindled the interest in the matter but I hope the rush of publicity does not push us to act irrationally. We should have thorough analysis and assessment of the problems and potential solutions before we act hopefully in a very bi-partisan manner.

There are some activities that are going on today to reduce and prevent the incidence of errors in various settings with varying degrees of success. We should explore how we can buildupon these

ideas and we should examine new approaches to developing safe systems and insuring patient safety and also explore what Congress can do to foster these as well. I know other members here share that sentiment and it is great to have my good colleague from Chicago next to me.

Lois Capps, who unfortunately is unable to join us today because of the death of her daughter, asked that I share a short statement with you. Due to a death in her family, Ms. Capps cannot be here today. A former nurse, Ms. Capps has indicated her concern to me about the IOM report and the medical errors problem particularly as they pertain to nurses and patient safety. She has told me that her main concern is that we approach this problem not by blaming the healthcare professionals who make individual errors but rather that we address the systems that often fail our healthcare professionals and ultimately our patients.

Ms. Capps is working closely with me on the medical errors issue and I look forward to her return to the committee so that we can continue this important work. I look forward to working with Ms. Capps and the other members of the three subcommittees who are here today on the topic so that we can develop a comprehensive effective solution to a problem that has been plaguing our medical system for quite some time.

Mr. Chairman, I would like to ask unanimous consent for our colleague, Sherrod Brown, who again because of his auto accident, as you mentioned, could not be here and have it placed into the record. I yield back the time.

Mr. BILIRAKIS. I thank the gentleman. The Chair recognizes the chairman of the full Commerce Committee, Mr. Bliley.

Chairman BLILEY. Chairman Bilirakis, I want to thank you, Chairman Upton for calling this hearing today, and I also would like to extend a special welcome to Chairman Stearns and the other members of the VA Health Subcommittee. Mr. Chairman, recent Institute of Medicine estimates that the prevalence of medical errors have highlighted an important concern that we all share. According to the IOM report of hospitals alone almost 100,000 people die each year due to medical errors.

If nursing homes, ambulatory care centers, home health services and doctor offices were included estimates of the number of unnecessary deaths would be much higher. It is important that we see today's hearing as part of the committee's larger efforts to insure patient safety. Through the remainder of this session of Congress, the committee will continue to focus attention on improving the quality of care that patients receive.

Included in this effort will be a hearing tomorrow before the Oversight and Investigation Subcommittee examining the reuse of medical devices. In addition, next month the committee will examine how consumers could benefit from information about their healthcare providers and specifically how the information in the national practitioner data bank may be made available to empower consumers choice in the healthcare marketplace.

Today's hearing will examine many of the complex issues relating to the goal of reducing medical errors including Federal versus State controlled, liability concerns, under reporting of adverse events and consumers access to information about medical errors.

An important aim of this hearing is to identify ways to prevent medical errors before they occur. The witnesses before us today bring valuable perspectives on the issues and problems identified in the IOM report.

Their testimony will reflect the diversity of concerns and issues about reporting of adverse events and ultimately reducing the rate of medical errors. Stopping unnecessary deaths from medical errors should be after all our primary goal. I look forward to hearing testimony from today's three panels of witnesses on how this can be done, and I thank you for yielding me the time.

Mr. BILIRAKIS. I thank you, Mr. Chairman. The Chair now recognizes Mr. Gutierrez of Chicago, who is ranking member on the Veterans Hospitals and Healthcare Subcommittee.

Mr. GUTIERREZ. Thank you, Mr. Chairman. I am pleased that the Commerce and Veterans' Affairs committees are holding this joint hearing today to examine the issue of medical errors in the healthcare delivery system. I believe that improving healthcare safety is a bi-partisan issue that strongly deserves our attention. And I thank the witnesses for taking the time to be here today. I have had the opportunity to preview some of the witness testimony and I am troubled by some of the findings.

Some of the studies cited by the witnesses claim that medical errors lead to the deaths of between 44,000 and 98,000 patients per year in healthcare settings ranging from hospitals to nursing homes. One report states that between 3 and 4 percent of hospital patients are harmed by the care that is supposed to help them. According to the report, 7 percent of all hospitalized patients are exposed to a serious medication error that either harms them or could have harmed them.

This data suggests that we have a serious health crisis on our hands. However, the reports state that the majority of medical errors do not result from individual carelessness but rather can be attributed to equipment, communication designs and procedures. This is important to know because this information tells us that we must take steps to improve patient safety. We must make serious efforts to create a culture of safety where the reporting of errors is encouraged and those who do so will not be punished for revealing problems.

I commend the Office of the Medical Inspector at the Department of Veterans' Affairs for its recent report entitled VA Patient Safety Event Registry. This document recorded and analyzed medical errors and other adverse events that occurred throughout the VA healthcare system for a period of 19 months. I am pleased that the VA has set an example for the public and private healthcare sectors by taking the initiative to use medical error data to improve patient safety at our Nation's veterans hospitals and facilities.

I will soon introduce a bill that would require the Department of Veterans' Affairs to publish every 2 years a VA Patient Safety Event Registry on all medical errors. This information will be used to identify specific aspects of patient care at the VA medical centers that can be used in their performance improvement initiatives. Again, I thank the chairmen of the House Commerce and Veterans' Affairs subcommittees for holding what I believe is a very timely and important hearing today. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman, and the Chair now yields to Mr. Stearns, who is not only the chairman of the Hospitals and Healthcare Subcommittee of Veterans' Affairs but also a very active member of the Health and Environment Subcommittee on Commerce and who yielded to Chairman Bliley previously. You are up, Cliff.

Mr. STEARNS. Thank you, Mr. Chairman, and I am just glad we are convening this hearing. I want to thank you for you leadership. You called me back last year in the late fall to talk about this joint hearing. To my knowledge and our staff, this is the first time we have had a joint hearing between the Commerce Committee and the Veterans' Affairs Committee subcommittee so I think this is a landmark occasion.

The subject we take up of course is safety in medicine. Mr. Gutierrez has pointed out the statistics which are very alarming considering that during the entire Vietnam era war the people, men and women, that were killed there was 55,000. We are talking about inadvertent deaths of anywhere from 44,000 and 98,000 in 1 year. This is an alarming statistic. So I am privileged to participate here with Mr. Gutierrez and others from the Veterans' Committee but also as a member of the Health Committee in standing.

The ongoing support Congress gives to maintain the VA healthcare system demonstrates our commitment to meet that debt. It goes without saying that every effort must be made to insure our veterans' well-being under the VA healthcare program. With that concern in mind, my subcommittee, as mentioned earlier, held important hearings on prevention of medical errors in the VA healthcare system. We found that VA has made real progress in that effort and it is gratifying to see VA's work to insure patient safety being recognized as an example for all American medicine.

Patient safety may well be a subject on which veterans have valuable lessons to share with others like other healthcare systems and providers. However, VA has certainly not become an error free zone of medical practice as is true for medicine generally. The VA faces serious challenges. It must improve its understanding of how to minimize the frequency of elderly patients falling. It needs to develop tools to better predict patients at risk of suicide. It must prevent difficult patients from harming others.

In 1997 VA established a comprehensive mandatory system for reporting adverse events. The VA and others would agree that reporting is not a solution in itself. It is said to be just a first step to identifying the underlying problem. The question arises, my colleagues, can reporting provide a basis for a reliable "hospital report card." The early data from VA registry on adverse events show marked variation in the incident of these events from place to place.

In responding to a recent survey, which I initiated, and Dr. Kizer is here, who was very helpful in this matter, 19 of the 22 VA directors who oversee all of VA's medical facilities express the view that some adverse events may continue to be under reported by their own facilities such as in cases that do not result in harm to a patient. Reporting systems certainly have their place but we should be realistic about the reliability of the data they provide.

Medicine and medical administrators are really just beginning to grapple with the challenges and difficult questions posed by the high rate of errors in the delivery of patient care. The error rates identified in recent medical literature are numbing. The situation is clearly unacceptable and we must not allow the complexities and difficulties it presents to paralyze us. Instead, I hope this hearing will help guide us toward the kind of fundamental changes needed to insure that medicine's safety record become one of America's best.

In that regard, I do believe the VA has made important advances in patient safety and has lessons to share with all of us. Too often government agencies with similar missions do not coordinate their activities. We should not let that happen. Last year in reauthorizing the Agency for Healthcare Research and Quality, AHRQ, Congress directed AHRQ to conduct and support patient safety research and build private-public partnerships.

I plan, Mr. Chairman, to introduce legislation to require AHRQ to consult with VA in developing strategies to improve patient safety as well as to explore greater use of such technologies as medical simulation systems and bar coding which VA has employed very effectively so I look forward to this hearing, and, again, Mr. Chairman, I compliment you for your leadership.

Mr. BILIRAKIS. And I thank the gentleman. The ranking member of the full Veterans' Committee, Mr. Lane Evans.

Mr. EVANS. Thank you, Mr. Chairman, and I want to thank all the chairmen for bringing us together on this important issue. First, do no harm is a familiar phrase from the Hippocratic Oath. Most of us would like to think that our physicians and other medical care staff abide by this principle and that we are safe in our hospitals. That is why it is such a brutal shock for many of us to read recent press accounts and learn that we place ourselves at jeopardy when we enter a hospital's doors.

Some studies have shown that our risk of harm from medical errors grows with the length of stay and with the complexity in our conditions and the procedures we receive. These are certainly troubling findings. As a ranking Democratic member of the Committee on Veterans' Affairs, this issue really hit home for me when I read that the preventable deaths in the VA hospitals. No one wants to hear that they or someone they care about has been the victim of a medical mistake.

According to the Institute of Medicine, however, there is no reason to suspect that the VA is any different than the private sector regarding the occurrence of preventable medical mistakes. The VA in fact is simply reflecting the state of the larger healthcare system with its reports of medical errors. A recent study reviewing all healthcare estimated that medical errors are one of the top ten causes of death of patients admitted to hospitals.

Mistakes throughout the medical industry are much more common than any of us wants to acknowledge. The VA is different, however, in that it is undertaking many initiatives to study medical errors and to improve patient safety. There is funding in the President's budget request for the VA in fiscal year 2001 to expand these efforts. The VA has done the right thing in disclosing its findings about medical errors at the risk of negative publicity, and I

believe that the VA's efforts to improve patient safety and reduce medical errors should be supported and encouraged.

The VA and the rest of the healthcare system can learn from the VA's efforts to improve patient safety. For instance, we know from the VA's data that the VA should take immediate steps to prevent apparently common problems such as patient falls and adverse drug events. It can improve efforts to restrain impaired patients from wandering and to address the needs of patients with suicidal tendencies. In short, VA is using this data to learn and to improve its patient care and that is what we should be concerned about today.

I hope that the VA will be understood and its efforts replicated throughout the healthcare industry. This would allow healthcare providers to learn from each other and consumers can only benefit from greater attention to patient safety. I look forward now to hearing from our witnesses to learn how we can address these difficult issues throughout the healthcare system. I thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank you, Mr. Evans. I realize that the opening statements up to now have been somewhat lengthy but we have a long day ahead of us, three very long panels, and I would appreciate the cooperation of the rest of the members if they can keep their remarks as short as possible. The red light will go on in accordance with the committee rules at the 3-minute mark. The Chair now recognizes Dr. Ganske for an opening statement.

Mr. GANSKE. I thank you, Mr. Chairman. I obviously will stay within my 3 minutes. I must say that I will try to take in as much of the testimony today. I do need to be on the floor some of the day. And I thank all the panelists for coming. You know, Mr. Chairman, I remember back in 1995, we had a debate on the floor on medical malpractice tort reform, and I was debating a former member of this committee, Mr. Bryant, from Texas, and he brought up the case of a surgeon who had amputated the wrong leg on a patient and wanted to know how could that be and should that physician be liable.

And my position has always been that of course a physician should be liable for a mistake like that. How could that happen? How could it be that a surgeon could amputate the wrong leg? Well, this is where we need to look at the processes involved. It turns out that in this particular case the patient had two gangrenous legs. Both legs were gangrenous. Both would need to be amputated. The wrong one was taken off first. And in my opinion that was a serious medical error and the physician should be liable for that.

By the same token, I would point out that when an HMO makes a medical decision that results in an injury like that the HMO should be liable for it. There is a case of a little boy in Atlanta, Georgia, who had a directive from his HMO that resulted in gangrene of both hands and both feet, both of which needed to be amputated. And under current Federal law the only responsibility that that health plan has is for the cost of the amputations. I don't think that is justice. That is what we need to address in the conference that we are doing on patient protection legislation.

More pertinent to this testimony, I think we need to look at the data that the IOM report is based on. One study was done in 1984, another in 1992. That is 8 and 16 years ago. They were done in States that were not necessarily representative of a national average. And I think that we need to be very careful when we are talking about untoward results of therapy versus mistakes. You know, every time that I treated a patient, I told them that there were possible complications of treatment. They could get an infection. They could have all sorts of problems. Their tendon repair could come apart. It might not turn out perfect.

And so we need to be very careful when we are talking about medical errors to distinguish between potential adverse results versus errors, because nothing turns out perfect in any endeavor. And then I would finish by saying this. I think that when we are looking at medical errors there is a real problem in hospitals. Nurses have been strung like a tight wire because managed care has put cost constraints on hospitals. They have cut back on RNs. RNs are now having to supervise a lot of non-RNs to deliver care.

When you are the only RN on the floor and you have four health aides who don't have your expertise and you have people coming at you from all different angles the potential for a mistake is multiplied.

Mr. BILIRAKIS. The gentleman's time has expired.

Mr. GANSKE. And, Mr. Chairman, I think there are some deep questions involved in how our healthcare is given.

Mr. BILIRAKIS. There are, and I agree with you.

Mr. GANSKE. We ought to look at that too.

Mr. BILIRAKIS. Hopefully we are going to look at all those things. That is the idea. We certainly plan another hearing. This is a very significant issue. The Chair recognizes the gentleman from the Veterans' Committee, a very active energetic member of the Veterans' Committee, Mr. Smith from New Jersey.

Mr. SMITH. Thank you very much, Mr. Chairman. This is obviously a very, very serious topic but in hearing Dr. Ganske talk reminded me of a situation that my brother had. He is an airline pilot, former fighter pilot, meticulous to a fault. He went in for a torn rotator cuff and he had his wife write on the shoulder that was not going to be operated on, it is not this one.

So I want to thank you, Mr. Chairman. I appreciate the opportunity this hearing presents to discuss patient safety issues, the recent report of the Institute of Medicine and the new patient safety program already underway at the VA. The report entitled To Err is Human, Building a Safer Health System suggests an issue of deep concern and of much needed nationwide reform. While the report is a global focus on medicine in general, we can certainly apply its discussion and lessons to the VA.

We are looking at a national healthcare dilemma. How can we minimize and hopefully eliminate adverse events in a society which is human and therefore not error free. Across the Nation there are millions of diagnostic tests, thousands of surgical operations and hundreds of hospitalizations daily. While the large and vast majority of these services occur without incident and lay to the restoration of health never before possible a few procedures do lead to untoward events and may even be responsible for deaths.

Still, as the GAO report will testify, little is known about the incidence of adverse events. As a matter of fact, it points out that the two studies cited by IOM, the 1992 study in Colorado and 1984 in New York, the 44,000 to 98,000 figure is an extrapolation, and I think we have to be very, very careful and very prudent in not reading too much into that kind of data.

We need to go wherever the facts and truth take us. As GAO points out, we need better recordkeeping and reporting and hyperbole by definition is a distortion. And this may be true. It may understate it, it may overstate it, it may be right on the mark but it tells me that we need more information before we make sweeping generalizations about what is happening. One death is one too many, Mr. Chairman, and I do believe we must be resolute in identifying and eliminating any identifiable cause of provider-related mortality.

In the New Jersey Veterans' Administration system, Mr. Chairman, last year 42,000 patients were seen in our two hospitals and six outpatient facilities. Adverse results related to provider error have been a concern with the New Jersey VA and they take that very seriously. There has been an ongoing review of a few cases in 1999 and thankfully none of them to the best of our knowledge led to patient deaths.

I remain quite concerned about issues of delay and propriety of treatment that have burdened New Jersey vets as they sought treatment at our facilities. Over the years my staff and I have worked on many constituent complaints and the VA has worked with us to try to resolve those. And again I look forward to the VA's testimony about the national patient safety partnership and the National Center for Patient Safety, both of which should prove very, very effective in reducing medical error.

I want to thank, Mr. Chairman, you for convening this hearing and again doing it in a joint way because I think that does help us in a synergistic way. I yield back.

Mr. BILIRAKIS. I thank the gentleman. The Chair recognizes Mr. Strickland of Ohio.

Mr. STRICKLAND. Thank you, Mr. Chairman. My remarks will be short but I would like to say how pleased I am that the Committee on Commerce and Veterans' Affairs have collaborated to convene today's important joint hearings. Indeed, medical malpractice and liability are at the heart of a vigorous healthcare policy debate in our country. I believe we have an extraordinary opportunity today to learn about the root causes of medical errors and possibly finding methods of preventing them.

I am looking forward to learning more about the difficulties confronting care providers, both in the public and the private sectors, who are working to implement effective discovery and disclosure policies regarding adverse incidents in medicine and in patient care. Many of the parties active in this particular piece of the health policy debate are here today.

In particular, I am aware of the Veterans' Administration's efforts to insure patient safety and I applaud the work that they have done to give confidence to their care providers and reassurance to their veteran patients. I welcome you here today to talk

about your concerns. I look forward to learning from you. Thank you for being here. I yield back.

Mr. BILIRAKIS. Thank you, Mr. Strickland. Dr. Norwood, opening statement.

Mr. NORWOOD. Thank you, Mr. Chairman. I would like to start by thanking all three chairmen involved in holding this hearing. The subject of medical errors is one that should involve great consideration and is very appropriate for our deliberation. We have all heard the statistic of the Institute of Medicine report that 44,000 to 98,000 Americans are killed every year by medical error, a staggering statistic indeed, one that we should be very concerned about.

What I found intriguing was that the IOM called a medical error, and let me just take a second and quote from that report. "For purposes of this report, the terms error and adverse event are defined as follows. An error is defined as failure of a planned action to be completed as intended, for example, error of execution, or the use of a wrong plan to achieve an aim that would be error of planning. An adverse event is an injury caused by medical management rather than the underlying condition of the patient. An adverse event attributable to error is a preventable adverse event. Negligent adverse events represent a subset of preventable adverse events that satisfy legal criteria used in determining negligence."

Mr. Chairman, to call that definition exceedingly broad is perhaps an understatement. A medical error could include a physical error made by a doctor. It could include a diagnostic error made by a doctor. It could include an administrative error made by a doctor, a pharmacist or even a hospital. I believe that we need to be very careful in our approach to this issue. Saying medical errors are a problem in healthcare and we would do something about them is akin to saying disease kills people and we should cure all diseases.

While I am all for curing all diseases, I recognize that there are a multitude of diseases that each require an exceedingly complex solution. Mr. Chairman, we should view medical errors the same way. The medical error is a multi-faceted and complex thing. We should be very leery, these committees should be very leery of any quick pick solutions that may be proposed. We need to know what problem we are trying to solve and if we truly expect our efforts to lead to a solution.

I relate with Mr. Smith in that opinions are not appropriate here. Facts is what we must have. This hearing is a very important step. And, Mr. Chairman, I commend you for calling the hearing and bringing this talented group of witnesses together. I look forward to this testimony, and I will yield back the balance of my time I hope in a timely manner.

Mr. BILIRAKIS. I thank the gentleman. Mr. Greenwood for an opening statement.

Mr. GREENWOOD. Mr. Chairman, in the interest of hearing from the witnesses, I will forego an opening statement.

Mr. BILIRAKIS. The Chair very much appreciates that. Mr. Barrett, opening statement.

Mr. BARRETT. Thank you, Mr. Chairman. I want to thank you also for holding this important hearing. I also want to commend the VA for the work it is doing in this area. It is obviously I think

showing its leadership in trying to deal with the problem of medical errors. Obviously this is an important issue. It is one that this committee should be focusing on. My only concern is that we don't forget about the other portion of this debate and that is the debate over HMOs and decisions that are made by insurance companies, which almost might be human error but also may result in people being denied healthcare.

And so as we move forward, I think we have to keep the pressure on to keep the patients' bill of rights on the radar screen as well. Having said that, I am interested in hearing from our witnesses today so I would yield back the balance of my time.

Mr. BILIRAKIS. Thank you so much. The gentleman from Tennessee, Mr. Bryant.

Mr. BRYANT. Mr. Chairman, thank you. I have a prepared statement, which I will submit for the record. Thank you.

[The prepared statement of Hon. Ed Bryant follows:]

PREPARED STATEMENT OF HON. ED BRYANT, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Thank you Mr. Chairman.

As I was looking over some of the materials in preparation for this hearing, I was struck by the title of the now-famous Institute of Medicine report. I think it is very appropriate: "To Err is Human: Building a Better Health System."

We are all human. We can't be perfect all the time. And the systems and procedures designed by humans won't always be perfect either. My background is in the law, and I'm quite sure I made a few mistakes over the course of my career—not very many, mind you—just a few. But a mistake in the court room is different from a mistake in the operating room . . . usually there is a lot more on the line in a medical setting.

I want to thank the Chairmen Bilirakis, Upton, and Stearns for bringing us all together today to look at ways to make our health care system better and safer for the patients it serves. I hope we can stay focused on constructive solutions, without pointing fingers and placing blame.

I know we have a lot of ground to cover, and I am looking forward to what our witnesses have to say. Thank you all for being here.

Mr. Chairman, I yield back.

Mr. BILIRAKIS. Without objection prepared statements of all members of the three subcommittees are made a part of the record.

[Additional statement submitted for the record follows:]

PREPARED STATEMENT OF HON. SHERROD BROWN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Thank you, Mr. Chairman. I am pleased the Commerce and Veterans Affairs Committees are taking time today to discuss medical errors in the United States, an issue as complex as it is compelling.

I would like to thank our distinguished witnesses for participating in today's hearing, and commend the Institute of Medicine and the Committee on Quality Health Care in America (CQHCA) for providing an excellent analysis of this important issue.

The statistics are alarming: Medical errors are the eighth leading cause of death in the United States. Each year, more than 91,000 deaths are attributed to these errors.

And medical errors drain an estimated $29 billion dollars from the health care system each year.

Forty-four million Americans are uninsured; there is a gaping hole in Medicare where prescription drug coverage should be; there are unjustifiable and unconscionable disparities in the health of different racial and ethnic groups within the U.S.; we have yet to cure cancer, AIDS, heart disease . . .

We don't have $1, much less $29 billion, to burn.

According to the IOM report, medical errors are overwhelmingly the result of systemic flaws, not negligence on the part of individual health care providers. This makes intuitive sense, and it will help focus efforts to bring down error rates.

But it doesn't make the job easy. We aren't facing one problem, we are facing many.

A heterogeneous array of events fall under the category of "medical errors:" nosocomial infections resulting from lapses in hand washing; medication errors resulting from difficult-to-decipher prescriptions, misdiagnoses; improper treatments; contaminated blood products . . . each of these types of error may call for a different solution.

There is no "quick fix" to the problem of medical errors. The IOM recommendations represent a practical approach. IOM recommends looking at the issue broadly and tailoring a set of solutions to the individual problems.

The report recommends creating a National Center for Patient Safety within the Agency for Healthcare Research and Quality. This center would develop a comprehensive strategy aimed at reducing medical errors. They would develop national goals, a research agenda, a process for disseminating information to the public on a timely basis . . . steps that make sense.

Along with Mr. Bilirakis, I sponsored legislation reauthorizing the Agency for Health Care Policy Research and modifying its mission and title to focus on quality. It is appropriate that this agency would take on the task of reducing the medical error rate.

The President has asked relevant agencies to review and comment on the IOM recommendations. Again, given the complexity of this issue, additional guidance is appropriate and appreciated.

I hope this hearing adds to the momentum building for actions to address medical errors. I also hope it drives the point home that this issue cannot be effectively addressed if it is treated cavalierly or coopted for other purposes.

We cannot do the issue justice by tacking it on to the patients' bill of rights debate, nor is it appropriate to do so.

We have deliberated over managed care reform for four years. We are just beginning to evaluate the medical errors issue.

We know how to repair the flaws in managed care. Let me repeat that: we know how to repair the flaws in managed care. We do not know how to systemically reduce medical efforts. That's why we need hearings. That's why we need research.

We have a remarkable health care system, not a perfect one. I hope we take the opportunity within the next few weeks to wrap up the managed care reform debate and fix what's wrong with that part of the system, and, with hearings like this one, begin a less protracted, but no less fruitful effort to dramatically reduce the incidence of medical errors.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. Does that complete your opening statement? Mr. Udall, the gentleman from New Mexico, opening statement.

Mr. UDALL. I would pass so we can get to the witnesses. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Is Mr. Moran handy? He is not. Mr. Rodriguez.

Mr. RODRIGUEZ. Thank you, Mr. Chairman. Let me just indicate that I think that in my particular area we had an individual that walked out, suffered from diabetes and walked out of the hospital, got lost and basically died by exposure. And one thing that was very insensitive was the initial comments that were made by the hospital and that was that he probably went out to go drinking. And so that in itself bothered me a lot. And I feel very strongly that whether you are—whether it is a private or public sector facility, we need to be held responsible to the same level, the same liability than anyone.

If my dad was going there, I would expect that he be treated with the same quality of care that he would be in the private sector. And I am looking forward to the testimony that we are going to be hearing. Thank you, Mr. Chairman. I relinquish the balance of my time.

Mr. BILIRAKIS. I thank the gentleman. That completes, I believe, the opening statements. We will move right into the first panel consisting of Dr. Donald M. Berwick, President and CEO of the Institute of Healthcare Improvement, here on behalf of the Institute of Medicine. We welcome Dr. Berwick. Dr. Kenneth Kizer, President and Chief Executive Officer of the National Quality Forum, a gentleman who we have had much to do with in the Veterans' Committee over the years. I thought he did a terrific job in that regard and it is very good to welcome you here, Doctor. And Mr. Randall Bovbjerg, is that correct?

Mr. BOVBJERG. Yes. Like iceberg.

Mr. BILIRAKIS. Like iceberg. You don't look like you are going to be much of an iceberg here today. He is the Principal Research Associate of the Urban Institute here in Washington, DC. Welcome, gentlemen. I will turn on the clock to 5 minutes. I would appreciate it if you would do your best to limit your remarks to that. Of course your written statements are a part of the record and hopefully you can compliment those in some way. Dr. Berwick, we will kick off with you.

STATEMENTS OF DONALD M. BERWICK, PRESIDENT AND CEO, INSTITUTE OF HEALTHCARE IMPROVEMENT, ON BEHALF OF INSTITUTE OF MEDICINE; KENNETH W. KIZER, PRESIDENT AND CHIEF EXECUTIVE OFFICER, THE NATIONAL QUALITY FORUM; AND RANDALL R. BOVBJERG, PRINCIPAL RESEARCH ASSOCIATE, THE URBAN INSTITUTE

Mr. BERWICK. Thank you, Mr. Chairman, and good morning, distinguished members of the three subcommittees, I am Don Berwick. I am a pediatrician and President and CEO of a non-profit education and research organization called the Institute for Healthcare Improvement. I am also Clinical Professor of Pediatrics at Harvard Medical School. I have the privilege of serving on the Institute of Medicine committee that issued this report. I also chair the National Advisory Council of the Agency for Healthcare Research and Quality.

Let me first mention the patient safety report is the first in a series of reports. The IOM committee will be issuing further reports later this year on other issues in improving quality of care in the country but we chose to report on improving safety first because it seems so fundamental. I would like to highlight six key findings of our committee's report.

First, as several members have already stated, we find that American healthcare is unacceptably unsafe today. About 3 to 4 percent of hospitalized patients we believe are harmed by care and about six or seven out of every 100 hospital patients are exposed to a serious medication error. I believe the mortality figures of 44,000 to 98,000 are defensible, that is, correct, and bracket the likely hazard in the country as a whole.

We also note that we have almost no information on safety problems outside hospitals so we don't know what the figures look like in ambulatory care, office-based surgery and so on, but we suspect hazards in those settings are also common. Our second finding is that these errors and threats to patient safety are generally not due to flaws like carelessness or incompetence in individual doctors

or nurses or other healthcare workers. People don't want to make errors. They try hard not to.

The vast majority of these errors, something probably in the range of 95 to 98 percent, are what we call system errors attributable to characteristics of equipment, job designs, work circumstances, communications, and so on. Think about it this way. If we fired every healthcare worker who was involved in an error and substituted a new person our future error rates would hardly change at all. Blame won't help.

One implication of this system's view of errors is that the accountability for safety has to lie with people who organize and run systems, board of trustees, executives and clinical leaders. We can't blame the individuals and hold them accountable for making the system safer on their own.

Our third finding is that we can do something about the problem. There is a long history of scientific research bearing on safety, research that has been well used in other industries to make their systems far safer. Healthcare has not done that. We haven't used that research. We believe that as a national target if we harness the knowledge that is available we could aim for a 50 percent reduction in patient injuries from healthcare over the next 5 years.

Fourth, it is important to understand that improving safety will require a cultural change in healthcare. To reduce errors, we have to be able to talk about errors. We have good research that doctors and nurses and others in healthcare are quite frightened to reveal the errors that they see and know about whether patients are harmed or not. We are going to have to change that. That is in distinct contrast to the aviation industry, which has made a serious effort to create a culture of safety in which discussing and reporting errors is rewarded and valued and the people making those reports know that they won't be punished for reporting what they observe.

The Veterans' Administration has shown us that this is possible in healthcare also. Our committee recommends widespread use of blame free reporting systems in healthcare but we feel voluntary reporting systems aren't enough. We have discovered widespread distrust by the public and the lack of transparency of the healthcare system today, and so we have made a fifth recommendation, that all health care organizations should be required to report to State officials some forms of patient injury, a very limited number of serious sentinel events like unexpected deaths, wrong-side surgery, and deaths from medication errors.

We are not recommending a large Federal bureaucracy. We only recommend that the Federal Government establish some standards for mandatory reports of sentinel events to States. We don't think in general those reports should identify individual doctors or nurses. We know this recommendation for mandatory reporting is controversial. If we overdo it then indeed mandatory reporting would chill the much more important voluntary reporting systems. On the other hand, we have enough public concern about accountability that we are concerned without some form of mandate we can't reassure the public.

Our sixth recommendation is for a research, development, and communication center, a National Center for Patient Safety, to ac-

celerate pace of learning and the spread of good ideas about how to make care safer. We are recommending an investment initially of $35 million in such a center, which might appropriately be housed in the Agency for Healthcare Research and Quality. So to summarize in terms of Federal action implications for our report, first we recommend a firm national commitment to improving patient safety dramatically and promptly.

Second, we recommend funding a National Center for Patient Safety. Third, we recommend Federal standards for minimum content and format for mandatory reports of a very limited number of sentinel events by organizations to States. Fourth, we recommend extending peer review protections to voluntary error reporting systems that are developed by healthcare organizations. And, finally, we do recommend an annual report to you and others by the Agency for Healthcare Research and Quality on the state of patient safety. I would like to make two final personal comments that go beyond the finding of the IOM.

Mr. BILIRAKIS. If you could do it quickly, sir, because the time has expired. Please proceed. Go ahead.

Mr. BERWICK. I am a little concerned that the Institute of Medicine committee did not have time to address two issues. The first is the requirement that organizations inform patients and families of serious injuries and errors in their care. The system thinks it does that but we have evidence that it doesn't happen routinely. The VA does have such a requirement and I think they set an exemplary standard.

The second is the knotty issue of tort reform. We know that healthcare organizations have been able to establish voluntary reporting systems effectively without changes in the tort system. However, I strongly believe that a movement toward a no fault environment for malpractice litigation would help increase safety-oriented activity immediately. I am very excited by the attention that this problem is getting. After 20 years of working on the quality arena in healthcare, I think we have a tremendous opportunity to make people safer in this country. Thank you.

[The prepared statement of Donald Berwick follows:]

PREPARED STATEMENT OF DONALD BERWICK, PRESIDENT AND CEO, INSTITUTE FOR HEALTHCARE IMPROVEMENT ON BEHALF OF THE INSTITUTE OF MEDICINE

Good morning, Mr Chairman and distinguished members of the three Subcommittees.

My name is Donald M. Berwick. I am a pediatrician and President and CEO of a non-profit education and research organization called the Institute for Healthcare Improvement, and also Clinical Professor of Pediatrics and Health Care Policy at the Harvard Medical School. For the past two years, I have served on the Institute of Medicine's Committee on Quality of Care in America, which is the group that issued the report on patient safety, *To Err Is Human.*

The patient safety report is the first in a series. The Institute of Medicine Committee on Quality of Care in America is continuing its work, and will this year issue several further reports and recommendations on how to address serious deficiencies in the quality of care. We chose to report on improving safety first, because it seems so fundamental and urgent. I must say that I hope our future reports will get as much attention as this one has.

In the next few minutes, I would like to summarize the findings of the IOM Committee, and then to point out specific implications for Federal action.

Our report has six key findings. First, we find that American health care is unacceptably unsafe today. Between three and four percent of hospital patients are harmed by the care that is supposed to help them. Out of every 100 hospitalized

patients, seven are exposed to a serious medication error that either harms them or could have harmed them. We estimate that between 44,000 and 98,000 Americans die in hospitals each year as a result of errors in their care. If the actual number is 44,000, this is the eighth leading cause of death in America. If it is 98,000, errors are the fourth leading cause of death. We note that almost all the information on safety that we have is about hospitals; we know far too little about other areas of care, like nursing homes, home health care, office based care, ambulatory surgery, and so on. Our Committee suspects that hazards in these areas are also common.

Second, we find that errors and threats to patient safety are generally not due to flaws like carelessness or incompetence in individual doctors, nurses, and other workers. People don't want to make errors, and they try hard not to. The vast majority of errors in medical care—perhaps 95% to 98%—are what we call "systems errors," by which we mean that they are characteristics of the equipment, procedures, job designs, communication systems, and so on that support safe work, or ought to. Put another way, if we simply fired every health care worker who was involved in errors, and substituted a new person, our future error rates would not change at all. Blame won't help. Only system changes can help.

One implication of a systems view of error is that responsibility for safety lies with the people who organize and run those systems—executives, clinical leaders, Boards of Trustees. It is they, and not the individual doctors and nurses, who can do the most to make patients safer.

Third, our report finds that we can do something about safety. There is a long history of great scientific research on causes of errors and ways to prevent them. Other industries rely on these sciences—human factors engineering, human psychology, industrial engineering, and others—to make their systems safer. Health care has not done so. Our Committee believes that, if we get smart about using what we know about safe designs, we can make patients much safer immediately. If we go further, and organize the right research on safe designs for health care, we can drive hazards to even lower levels. As a national target, we suggest for starters that we aim for a 50% reduction in patient injuries from health care over the next five years.

Fourth, we find that improving safety will require cultural change in health care. To reduce errors, health care needs to know about and discuss its own errors. Today, we generally don't do that. We have good research that shows that doctors, nurses, and others in health care are frightened to reveal the errors they see and know about, whether patients are harmed or not. As a result, many health care organizations sincerely believe their error rates to be far lower than they actually are. The problem has been driven underground because people are afraid to talk about it, and therefore health care has trouble learning about hazards and preventing them.

Contrast that with the aviation industry, which has made a serious effort to create a culture of safety, in which reporting errors is rewarded. The voluntary Aviation Safety Reporting System, run by NASA for the FAA, collects over 30,000 reports a year from pilots, air traffic controllers, and others. The people making these reports know that they will not be punished in any way for revealing problems, and, in fact, if there was no criminal activity or serious injury, the very act of reporting protects them legally from possible prosecution or punishment. We still have plane crashes, but aviation is 10 to 20 times safer today that a few decades ago, because it has information on its hazards.

Our Committee recommends widespread use of blame-free reporting systems, much like ASRS, by organizations and, where helpful, others. This would be a major change from the *status quo.*

But, we think, voluntary reporting systems are not enough. We find widespread distrust by the public in the lack of transparency of the health care system today. The public thinks we are hiding our flaws from them, and, in some ways, we are.

To improve public trust, we make a fifth recommendation—that all health care organizations should be required to report to state officials some forms of patient injury—a limited number of serious sentinel events, such as unexpected deaths, wrong-side surgery, and deaths from medication errors. In fact, we think that about 22 states have some form of mandatory reporting already, but these state systems at the moment lack consistency in definitions and reporting methods, and therefore we have a lot of trouble learning from the reports. In addition, few states have invested anything like the needed resources in analyzing the reports they get. The aviation system assigns highly experienced pilots to reviewing those 30,000 reports, and that is why ASRS can learn so much.

We are not recommending a large Federal bureaucracy. We recommend only that the Federal government establish some standards for mandatory reports of sentinel events to states. We also do not think that mandatory reports should identify indi-

vidual doctors and nurses; these would be reports by organizations to states that events have occurred and what is being done about them.

We know that our recommendation for mandatory reporting is controversial. If we overdo it, then a severe mandatory system could chill the development of the more important voluntary systems. On the other hand, we do not think that a voluntary system, alone, is sufficiently responsive to the public's concerns about accountability. We need to find the right balance between a system for learning—which has to be voluntary—and a system for public accountability—which has to have mandatory elements.

Our sixth recommendation is for a research, development, and communication center—a National Center for Patient Safety—to accelerate our learning and spread of good ideas about improving safety. We don't have anything like that now, and, as a result, we have neither an organized national research agenda nor an easy way to let hospitals and health care systems learn about how to get safer. Aviation has the NASA-Ames center, which includes some of the best research in the world on aviation safety. Our Committee recommends an initially modest investment—$35 million—in such a Center, and our initial suggestion is that the Agency for Health Care Research and Quality may be a good home for it.

To summarize our findings, especially with regard to helpful Federal actions, we recommend:

1. A firm national commitment to improving patient safety dramatically and promptly;
2. Funding of a National Center for Patient Safety at an initial level of $35 million per year;
3. Federal standards for minimum content and format for mandatory reporting of a very limited number of sentinel events by organizations to states;
4. Extension of peer review protections to voluntary error reporting systems developed by health care organizations;
5. Annual reports by the Agency for Health Care Research and Quality on the state of patient safety in America, to track our progress.

I would like to make two final personal comments that go beyond the findings of the IOM Committee.

First, discussions of mandatory reporting have focused largely on the need for reports by organizations to state agencies. I think there is an additional mandatory reporting issue that the IOM did not address, but that is equally important; namely, the requirement that organizations inform patients and families of serious injuries and errors in their care. Most people in health care would regard this as an ethical duty, but, in fact, we do not have evidence that this happens routinely. I think we need to promise and assure that this happens. The Veterans Health Administration does have such a mandatory standard, and I think it ought to be a model for us all.

Second, the IOM Committee did not have the time or resources to explore the knotty problem of malpractice liability and tort reform. Many in health care say that the threat of malpractice suits makes secrecy necessary, and keeps organizations and individuals from talk openly about errors. To some extent, this is simply an excuse to avoid tackling the problem of safety; I know that because there are now many organizations that have begun to change their internal cultures without any change in the tort system. On the other hand, I believe strongly that movement toward a no-fault malpractice litigation system would help increase safety-oriented activity immediately. Furthermore, if we really believe that most patient injuries come from systems, not individual people, then we ought to fix the responsibility where it belongs: with health care organizations and enterprises.

I have been working on quality of care issues for over two decades, but I have never before seen such a tremendous opportunity for improvement as we now have due to public attention to the issue of patient safety. If we act promptly and with courage, literally millions of future patients will be saved the pain and risk of injury from errors in their care.

Thank you for this opportunity to testify. I would like my statement put in to the record. I would be happy to answer any questions the Committee may have.

Mr. BILIRAKIS. Thank you very much, Doctor. Dr. Kizer, you are on, sir.

STATEMENT OF KENNETH W. KIZER

Mr. KIZER. Thank you. Good morning, Mr. Chairman, members of the subcommittee. I am Dr. Ken Kizer. I am President and CEO

of the newly formed National Quality Forum, which is a private non-profit membership organization that is committed to improving the quality of healthcare through improving the way that quality is measured and reported. I am pleased to be here today to discuss the need to improve the quality of healthcare in the United States in general and the especially urgent need to improve patient safety in particular.

I think for too long the topics of patient safety and medical error have escaped public scrutiny. At the outset I think we should acknowledge that in the latter part of the 20th Century healthcare has become one of the most complex if not the most complex of all human activities so it really is not surprising that errors would occur in healthcare when you consider the number of interactions between people, the number of interactions between complex technology much of which has a potential to cause harm as well as to help patients.

If there ever were a high risk, high hazard activity, I think modern healthcare certainly qualifies as such although it is not generally viewed that way. I am always reminded when I think of this of Mr. Gutierrez's response a couple years ago of how he viewed sitting in the doctor's office versus getting on an airplane. You can comment on that perhaps. While it is not surprising that modern healthcare is a high risk, high hazard activity, I think perhaps what is surprising is that healthcare has lagged so far behind other high risk activities in systematically implementing risk reduction and error prevention strategies, and I think that really is the essence of what we are here to talk about today.

Now in the interest of time, I am going to defer most comments. You have my written statement where I discuss some issues related to healthcare quality in general, the genesis and the activities of the forum and make ten recommendations with regard to action that we believe could improve patient safety and reduce medical errors. I would just underscore a few of those activities and preface it by saying that despite the prevalence and the cost of medical errors most healthcare executives, clinicians, boards of trustees and consumers are largely unaware of the prevalence and the magnitude and the cost of these therapeutic adverse events and this is largely due to systematic under reporting of such events and the name and blame culture as it has been called that discourages reporting and the open discussion of these.

In that regard, I think as a first priority in addressing this issue, we need to get more complete data on these events. Certainly foundational to any improvement effort is defining the nature that the scope of the problem and we have much work to do in that regard with regard to medical errors. The Institute of Medicine has recommended that a national mandatory reporting system be established that provides for the collection of standardized information about a set of adverse events, those that result in death or serious harm to patients, and also they recommended that the National Quality Forum be tasked with promulgating and maintaining a core set of reporting standards.

The IOM has further recommended that Congress pass legislation to extend peer review protections to the data related to patient safety and quality improvement that are collected and analyzed

and used solely for purposes of improving safety and quality. I support those recommendations and would strongly underscore the need for having a non-punitive approach to gaining this data that is so much needed.

I think I would also underscore the need for making patient safety a priority in the government programs that support healthcare as well as within healthcare organizations and for healthcare executives and at all levels throughout organizations in making or reducing medical errors and improving patient safety should be key strategic objectives for all of these entities. We would also support the IOM's recommendation that there be a National Center for Patient Safety established.

Quite simply, if this issue is going to be addressed it has to have a home and it has to have people that are accountable for collecting the data and analyzing the data. Now where that home resides is something that we would defer to the Congress and the administration on but certainly there has to be some infrastructure to support the effort if it is going to be a priority.

Finally, I would just comment on two other areas. There is much that could be done today. There is an effort or a need to support efforts to implement best practices and patient safety today. There is much that can be done. Recommendations have been made by a variety of entities that should be put in effect immediately. However, there is also gaps in our knowledge, substantial gaps in our knowledge, that need to be addressed by research and there is a need for research to find safer ways of providing care, for ways of communicating harm or information about potential risks and harm, and I would hope the Congress would be supportive of a research agenda in this regard as well. Thank you.

[The prepared statement of Kenneth W. Kizer follows:]

PREPARED STATEMENT OF KENNETH W. KIZER, PRESIDENT AND CEO, THE NATIONAL QUALITY FORUM

Mr. Chairman and Members of the Subcommittees, I am pleased to appear before you today to discuss the very important public health need to improve the quality of U.S. healthcare in general and the urgent need to improve patient safety in particular. For too long, the topics of patient safety and medical error have escaped public scrutiny.

It should come as no surprise to anyone that errors occur in healthcare, for in the past fifty years healthcare has become one of the most complex of all human activities, typically involving hundreds or even thousands of interactions between people and technology—even during "routine" treatments. Numerous physicians, nurses and technicians are involved in the care of almost every patient; myriad diagnostic tests are routinely performed, many of which may be hazardous to the patient; and treatment often involves complicated invasive procedures that could injure a patient in multiple ways. If ever there were a high risk, high hazard activity, modern healthcare certainly qualifies as such. Indeed, given the complexity of modern healthcare and the paucity of systematic efforts to reduce medical care-related errors, it is, in some ways, surprising that errors do not occur more frequently than they do.

Therefore, Mr. Chairman, I commend you and the Subcommittees for focusing on this important issue, and I welcome the chance to share with you some thoughts about policies and practices that might be employed to improve patient safety and the quality of U.S. healthcare and possible roles that the National Quality Forum might play in such efforts.Healthcare Quality in the U.S.

The quality of healthcare in the United States presents a paradox. On the one hand, the high level of training of U.S. healthcare practitioners today, our extensive and highly sophisticated biomedical research program, the rapid dissemination of new medical knowledge, the extent of government funding for healthcare, and the widespread ready availability of state-of-the-art diagnostic and treatment technology

have brought life-saving treatments to more Americans than ever before and are the envy of much of the world. On the other hand, a number of studies in recent years have documented serious and widespread quality of care problems in U.S. healthcare. Overuse, underuse and misuse of medical care occur too frequently in all types of healthcare delivery systems and with all types of healthcare financing.

While tens of millions of Americans reap the benefits of modern medicine each year, millions of others are exposed to unnecessary risks or are denied opportunities for improved health. Likewise, too many patients are injured or killed as a result of medical errors and therapeutic mishaps.

Quite simply, as good as American healthcare is, it could be markedly better!

Further, many experts believe that U.S. healthcare, which is by far the world's most expensive healthcare, could be significantly cheaper, if as much attention were focused on improving the quality of healthcare as was done in other U.S. industries in the latter part of the 20th century. Almost certainly, higher quality healthcare would cost less.

It is notable that interest in rigorously determining the quality of healthcare in America is only of relatively recent origin, arising largely in response to the managed care revolution and concern that the new healthcare organizational structures and reimbursement strategies brought by managed care might be creating incentives that were deleteriously affecting the quality of care. In evaluating this situation, however, the most striking finding is how little is really known about the quality of healthcare in America. (Not that it is known to be better any place else.) There is no mandatory national reporting or surveillance system, nor any regular systematic review of the state of healthcare quality to determine whether it is getting better or worse. Likewise, few healthcare systems or provider organizations even have rudimentary organized data systems that routinely inform them about the quality of care they provide.

Overall, it is highly ironic and quite remarkable that we know much more about the quality of airlines, automobiles, televisions and toasters in America than we do about healthcare, the nation's largest enterprise accounting for more than $1 trillion in annual expenditures and some 15% of the gross national product.

In recognition of these problems and in response to growing consumer and purchaser demands for greater healthcare accountability, numerous efforts have been launched in the last 10 to 15 years to promote quality improvement in American healthcare. And while incremental progress has been made, in the aggregate, despite the good work of many dedicated individuals and organizations, healthcare quality has not progressed to where it can and should be. There continues to be large gaps between the care people should receive and the care that they actually do receive.

This sentiment was clearly expressed in three independent reports published in 1998—i.e., reports by the National Academy of Sciences Institute of Medicine's National Roundtable on Health Care Quality, by investigators at RAND after an extensive review of the literature, and by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. Indeed, 1998 will probably come to be viewed as a watershed year for healthcare quality improvement because of these reports and actions they spawned.

THE NATIONAL QUALITY FORUM

One of the sequels to the 1998 reports and one of the most notable of recent efforts to improve the quality of American healthcare has been the establishment of The National Forum for Health Care Quality Measurement and Reporting, a private, non-profit, membership organization proposed by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry.

The concept of the National Quality Forum arose in recognition of a strong American sentiment against government regulation and control of healthcare quality. Of note, the Commission proposed a public-private partnership involving two new organizations—a private-sector entity they referred to as the National Forum on Health Care Quality Measurement and Reporting (better known now as The National Quality Forum [NQF]) and a public entity they called the Advisory Council for Health Care Quality. The Commission's original vision was that the Advisory Council would identify national goals for quality improvement and provide oversight on the accomplishment of those goals, while the NQF would devise a national strategy for measuring and reporting healthcare quality that would advance the identified national aims for improvement. This paired public-private relationship seemed to reasonably balance the concerns about the capacity of a private organization to meet important public needs against the negative sentiment towards vesting healthcare quality control with the government.

The NQF was birthed in the fall of 1999, following the work of the Quality Forum Planning Committee that was launched in June 1998.

With in-kind support from the United Hospital Fund of New York, the Planning Committee drafted an initial mission statement for the NQF, proposed a governance structure and sought funding from selected foundations. Start-up funds were subsequently obtained from the Robert Wood Johnson, California HealthCare and Horace W. Goldsmith Foundations and the Commonwealth Fund. A president and chief executive officer was hired in the fall of 1999, and the NQF started to operate in late 1999.

Of note, no action has been taken, so far, to establish the proposed Advisory Council for Health Care Quality, and some of its envisioned functions are now being reviewed by the NQF for implementation.

The NQF sees its fundamental mission as being the improvement of healthcare quality—e.g., to promote delivery of care known to be effective; to achieve better health outcomes, greater patient functionality or a higher level of patient safety; or to make care easier to access or a more satisfying experience. The primary strategy the NQF will employ to accomplish its mission is to improve quality measurement and reporting mechanisms—i.e., to improve the technology for measuring and reporting quality. In doing so, however, the NQF does not envision itself developing quality indicators or measures de novo. There are myriad other research, accreditation and oversight organizations and commercial interests already involved with developing measures.

The NQF has identified five key enabling objectives. These include:

(1) Developing a national strategy for measuring and reporting quality for the U.S. that is consistent with identified national goals for quality improvement;
(2) Standardizing the measures of and processes for reporting quality-related data so that data collection is consistent and less arduous for healthcare providers, and so that the data are of greater value;
(3) Promoting consumer choice by building consumer competence in using quality measures;
(4) Enlarging the healthcare system's capacity to evaluate and report on the quality of care; and
(5) Increasing the overall demand for healthcare quality data.

While there is much that needs to be done in each of these areas, the Forum sees a particularly acute need to reduce the burden and increase the value of quality reporting methods.

The NQF has convened a group of highly respected quality improvement, healthcare delivery and policy experts to help craft a strategic framework for healthcare quality measurement and reporting. This group is known as the Strategic Framework Board (SFB), and its essential mission is to determine the principles, intellectual framework and criteria for quality measurement and reporting.

In pursuing its mission, the NQF will seek to provide a clear, coordinated and coherent over-arching strategy and a set of guiding principles to inform the choice of measures that it will ultimately endorse. The NQF will strive to endorse measures that are compelling and causally related to better outcomes, and especially outcomes related to processes or activities that improve something that actually happens to patients. Indeed, the NQF believes that the true test of a quality indicator or measure is how well, and for what cost, the measure and its reporting actually helps improve care. The more ways that a measure promotes better outcomes, the better.

The NQF will also strive to ensure that its over-arching strategy has a sound theoretical framework that will inform and guide a strategic and proactive research agenda.

In approaching its work, the NQF will explore issues of quality across the entire spectrum of healthcare and will seek to coordinate quality measurement between and among the various levels or elements of the system— e.g., health plan, hospital, medical group, nursing home, individual practitioner, home care etc.

Likewise, the NQF believes that it must always ensure that the consumer's perspective is heard during the discussion of quality measures. In an effort to continuously actualize this, the NQF's Board of Directors is designed to have a majority of its members representing consumers and purchasers. This is an important structural precept that should facilitate keeping the consumer's perspective ever present.

Finally, in approaching its work, the NQF is committed to working constructively with the many other parties involved in the healthcare quality measurement and reporting area, including especially the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Committee for Quality Assurance (NCQA), to make certain that its work is not duplicative, but rather collaborative and helpful to the important work already begun by these entities. Improving healthcare quality is a matter of national importance that requires all of us to work

together; there is neither time nor resources to pursue any strategy other than one of complete cooperation.

MEDICAL ERRORS AND PATIENT SAFETY

Recently, as a result of the Institute of Medicine's seminal report on the subject in November 1999,[1] considerable public attention has been focused on medical errors and other diagnostic or treatment-related mishaps that endanger patient safety—these will be further referred to here collectively as "therapeutic adverse events". Indeed, the evidence is clear that therapeutic adverse events kill tens of thousands and injure or disable hundreds of thousands of Americans every year. They are a major public health problem that warrants immediate and decisive action, and the urgency for action is heightened by the fact that, in many cases, solutions to prevent their occurrence are known. In other cases there is a need for research to find the best practices that would prevent their occurrence.

Importantly, while therapeutic adverse events are just a subset of the larger healthcare quality problem, they are especially important since ensuring patient safety is an ethical imperative for healthcare professionals individually and collectively. Indeed, providing a safe therapeutic environment is an essential attribute of and foundation for high quality care.

Despite their prevalence and cost, most healthcare executives, clinicians and consumers are largely unaware of the prevalence and cost of therapeutic adverse events. Many factors account for this lack of awareness, including especially the systematic underreporting of such events and the prevailing "name and blame" culture founded on the myth of perfect performance. This "name and blame" culture causes fear of punishment, reprisal and/or peer disapproval when an adverse event does occur, and it has been particularly counter-productive to dealing with the issue in a forthright manner.

It is widely known that error is inherent to anything that humans beings do, and substantial evidence exists that errors are the result of poorly designed processes and systems that fail to account for the inherent limitations of human performance. Indeed, because medical errors typically involve problematic processes or systems rather than the incompetence or malice of individual practitioners improvement strategies that punish clinicians for reporting errors are misguided.

In my opinion, ten things, at a minimum, must be addressed if medical errors are to be reduced. These include the following:

1. Get more complete data. Foundational to any improvement effort is defining and measuring the extent of the problem. At present, medical errors are grossly under-reported, and there is extremely limited data about their occurrence. Creating an error data collection system is essential to the success of efforts to reduce their occurrence. Likewise, sharing information about errors with frontline clinicians is needed to further their understanding of the issues, as well as to promote collaboration and a sense of shared mission.

The Institute of Medicine recommended that a national mandatory reporting system be established that provides for the collection of standardized information about adverse events that result in death or serious harm to patients, and that the NQF be tasked with promulgating and maintaining a core set of reporting standards. The IOM further recommended that Congress pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected, analyzed and used solely for the purposes of improving safety and quality. I support those recommendations, and I would strongly underscore the need for having a non-punitive approach to gaining this data.

In considering the data, it is important to remember that reporting such events is for both public accountability and quality improvement purposes, and not everything reported for quality improvement purposes warrants public reporting. There is a set of adverse events or untoward situations about which we could obtain widespread consensus on the need for reporting for public accountability (e.g., maternal death during childbirth, restraint-related strangulation, wrong-site surgery, to name a few), but there is a larger pool of events or circumstances that, at least at this time, should be maintained confidential for quality improvement purposes.

2. Make patient safety a priority. Government health programs, healthcare organizations and healthcare executives should make reducing medical errors and improving patient safety key strategic priorities. This should occur at all levels of government and at all levels of healthcare organizations or institutions.

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[1] Institute of Medicine. *To Err is Human: Building a Safer Health System.* Washington, DC. National Academy Press. 1999.

Patient safety work should be built into the schedule of managers and should be a defined executive responsibility. Patient safety issues should receive as much attention by healthcare facility governing boards as do issues like financial performance, market share and strategic planning. Healthcare facility management should be held accountable for patient safety performance just as they are held accountable for other performance.

3. Create a patient safety infrastructure. If medical error data are to be collected and if patient safety is to be a priority, then it must have a home within healthcare facilities, healthcare organizations and relevant government agencies, and there must be individuals that are responsible for managing the data and associated programs. The NQF supports the notion of their being a national Center for Patient Safety, although we defer to the Congress and the Administration as to where such a center should be housed. Wherever it is located, though, it must be provided with adequate resources to accomplish its mission.

4. Create a culture of safety. Healthcare executives and managers should strive to create a culture of safety in their institutions or organizations.

A healthcare culture of safety can be defined as an integrated pattern of individual and organizational behavior, and the associated underlying philosophy and values, that continuously seeks to minimize hazards and harm to patients that may result from diagnosis and/or treatment-related processes. A culture of safety identifies safety as a priority and aligns organizational objectives and rewards accordingly.

A number of characteristics define a healthcare culture of safety. For example, in a culture of safety there is open acknowledgement that modern healthcare is a high risk activity and that everyone in healthcare has a responsibility for risk reduction and error prevention. Errors are recognized and valued as opportunities for improvement, and there is a non-punitive and safe environment in which errors can be learned from. There is honest and open communication about safety issues with well known mechanisms for reporting and learning from errors, and confidentiality of information. Likewise, in a culture of safety there are mechanisms for restitution and compensation for injuries that result from errors, and clear organizational commitment, structure and accountability for safety improvement.

5. Implement patient safety best practices. Healthcare leaders and organizations should implement medical error "best practices" when such have been identified—e.g., such as those identified by the Massachusetts Hospital Association, National Patient Safety Partnership and Institute for Safe Medication Practices. This is especially so for medication safety practices, where a number of practices have been shown to definitely reduce errors.

6. Professional misconduct must be recognized and dealt with. Gross negligence, malfeasance or unethical behavior should be recognized as a grave threat to patient safety and should be dealt with accordingly. Licensure, credentialing and privileging bodies should more aggressively discipline practitioners who have demonstrated impaired performance of this nature.

7. Healthcare regulators and accreditation organizations should embrace measures that enhance patient safety. Regulations and guidelines should encourage root cause analysis and facilitate non-punitive reporting. Similarly, pharmaceutical and medical device manufacturers should be required to complete and disclose human factors testing of naming, packaging and labeling of medications and post-market surveillance of adverse events.

8. Patient safety self-assessments should be conducted. All healthcare facilities should routinely conduct self-assessments for risk reduction and error prevention. When available, structured and standardized self-assessment instruments should be utilized—e.g., the self-assessment instrument developed by the Institute for Safe Medication Practices for medication safety practices.

9. Patient safety research should be funded and otherwise supported. While a number of interventions are available that could improve patient safety in the short term, there is a great need for additional research in the area of medical error reduction and patient safety. Research is needed in ways to make care processes safer, in how to make reporting systems optimally useful, and in ways of communicating information about healthcare hazards that do not unduly alarm patients, to name some fertile areas of research. Likewise, while basic research is needed in many areas, there is also a great need to investigate technology transfer and the application of safety lessons from other industries to healthcare. A good model for the latter are the Veteran Health Administration's Patient Safety Centers of Inquiry.

10. Medical education should address patient safety. Patient safety needs to be incorporated into the fabric of health professional training at all levels. Indeed, a significant part of the problem regarding the failure of physicians to report med-

ical errors stems from attitudes and beliefs instilled during medical school. The fact that everyone makes mistakes, regardless of how well trained or how smart one is, and that modern healthcare is an inherently high risk, high hazard activity should be promoted throughout one's training, along with how mistakes should be managed.

Professional organizations and credentialing bodies should also give consideration to requiring continuing education specifically in patient safety, such as is required of practitioners in the veterans healthcare system.

CONCLUSION

Clearly, reducing medical errors and improving patient safety in U.S. healthcare present many challenges, including the very real fears that so many caregivers have of reporting therapeutic adverse events, the fear of liability and tort claims, the lack of systems thinking and the poor understanding of so many medical "treatment systems" and uncertain support for a non-punitive approach to dealing with errors. Despite these challenges, however, improvement in patient safety is eminently achievable, as has been demonstrated in the veterans healthcare system.

In closing, Mr. Chairman, I would note that too often Americans equate high technology healthcare with high quality healthcare. In some cases, this nexus is true, but in many other situations more sophisticated technology simply creates a delusion of higher quality, while increasing the risk of medical error. As healthcare becomes more and more reliant on complicated technology there will be increasing need for vigilance against errors. Many actions need to be taken to ensure that such vigilance is actualized and that healthcare in the 21st century becomes safer than it is today. The ten actions described above would be a good beginning in this regard.

Again, thank you for the opportunity to testify before you this morning. I would be pleased to answer your questions.

Mr. BILIRAKIS. Thank you very much, Doctor. Mr. Bovbjerg.

STATEMENT OF RANDALL R. BOVBJERG

Mr. BOVBJERG. Thank you very much, Mr. Chairman. It is a pleasure to be here. My basic position on medical error and medical injury is probably the same as everyone else in the room. I am against it. The real thing that divides people is what they think will work. I think this is really quite a non-partisan issue. It is a pragmatic issue. But there are two competing world views here. There is the general——

Mr. BILIRAKIS. Speak directly into the mike, if you would, please, sir.

Mr. BOVBJERG. There is the inherited from the past system of name and blame and disclosure that we have heard about and there is the new motivation of taking more of a systems or corporate approach and at least trying to create a culture of safety without blame within it. There is a tension here and the IOM report deserves tremendous credit for raising the visibility of this issue for finally making it less deniable that there are problems out there and for at least starting to sketch what we could do about it.

The sketch remains somewhat conceptual, however, and there is an awful lot of work yet to be done. I want to cover three areas. I did cover three areas in my written statement. Let me hit on real quickly now. First of all, information is one strategy. Clearly, feedback of information is crucial. The voluntary and mandatory reporting that the committee recommended are a core method for dealing with these things. I happen to think that a real problem here is the reporting of the information and encouraging people to give the information reliably and timely. I think the voluntary systems are almost certainly an improvement over what there is now.

I think the mandatory one builds upon what there is now but doesn't copy it exactly. I personally would not go for the full and open disclosure of the mandatory reporting that has been described. The mandatory ones that are out there now generally have confidentiality and even so they get terrific under reporting as described in the statement. Beyond the information issue is the motivation issue. There is a lot that can be done. One can hire Dr. Kizer, Dr. Berwick to come in and help one get going but there is a major issue at motivating people to do this. It is not happening.

There is still a lot of complacency. There has been progress made but it is not done. That is one reason for the support for the disclosure and the disciplinary action and the lawsuits is this motivation. The difficulty with that is that we have had that for a long time and we are where we are. We have that type of system. It has done what it can do and that leaves us with the problems that we have. The real difficulty in terms of the information piece is that this type of oversight tends to drive information underground.

I would recommend that people think a lot harder, and IOM has started this but only just started, think a lot harder about what else we can do, and that is beginning too. Quality measures that are broader and more objective that sweep in information about errors within them, real demands by purchasers that systems be created to deal with this, and on a confidential basis reviewing that and keeping people's feet to the fire. I think that generalized type of approach is apt to be very important. We can't let the complacency continue. I think if what you do with the fire is instead to create a branding iron and want to brand everyone with a big red letter E and put them on the Internet, they are not going to cooperate with you quite as readily. So I think it is quite important exactly what is going to be done with these data.

Then finally is the issue of implementation or management. You can have all the good intentions in the world. You do have to have—you take a systems approach but you have to have a system. Someone has to be doing this. And there is quite a bit of difference between the VA model and it is certainly a pleasure to a policy analysis like me to see a government agency in the forefront and actually leading the private sector in many ways but there is a big difference between that model of an integrated system and the private sector model of a much more decentralized system.

The hospital is a place to start but even hospitals differ. And of course as has been mentioned, we have got a long way to go before we get to outpatient. So we are well on the way. I think we need to get started. We need to keep up the pressure. Let us not move immediately to full disclosure and put all our eggs in that basket. Let us make sure we get the information out and move slowly in these ways. Thank you.

[The prepared statement of Randall R. Bovbjerg follows:]

PREPARED STATEMENT OF RANDALL R. BOVBJERG,[1] PRINCIPAL RESEARCH ASSOCIATE, THE URBAN INSTITUTE

Thank you for inviting me to testify today on "Medical Errors: Improving Quality Care of Care and Consumer Information." My testimony addresses voluntary and

[1] This statement represents the view of the author and not that of the Urban Institute, its sponsors or trustees.

mandatory reporting of information about errors and associated confidentiality issues.

The Emergence of Patient Safety. Researchers on injury and liability issues have long recognized that medical injury and medical error occur too often. If they were a disease, they would have their own Institute at NIH. Moreover, injuries far exceed traditional efforts to fix them—medical peer review, regulatory discipline, or legal liability and risk management. Fortunately, many injuries not prevented by current oversight systems nonetheless seem preventable.

Better prevention requires a new mix of information, motivation, and implementation. The big question now is what mix of policy tools can best address prevention in various medical settings, for various types of care and their characteristic problems. Observers and policy makers differ in their conceptualization of problems and in the emphasis they would put on different policy tools. I urge you today to consider that a multiplicity of tools may be appropriate, each in their own way, but that we proceed carefully and avoid working at cross purposes.

This hearing continues the lively debates sparked last November by the Institute of Medicine (IOM) report *To Err Is Human.* This book has performed an extremely valuable service. More successfully than any of the prior efforts on which it builds, the IOM panel has highlighted existing knowledge on the extent of preventable injury, mainly in hospital care. This alone has put patient safety higher on the policy agenda than ever before. This is an extremely exciting and important development.

Better yet, the book describes emerging methods of preventing medical errors from hurting patients and lays out a vision of patient safety as an alternative approach to error. The book focuses more on systems design and operation than on individuals. It emphasizes the manifold nature of errors and how prevention calls for developing and implementing a variety of techniques to identify problems and achieve solutions. It also seeks to de-emphasize retrospective blame finding as a policy tool in favor of front-end safety design, catching errors before they can reach patients, and building in self-monitoring and continuous improvement for the future.

In short, the IOM panel presents a very attractive vision of patient safety as a general approach, with specific examples from a few clinical areas. Actually getting clinicians and clinical managers to act in this fashion is a tall order. There are many real-world examples of significant progress, but there is a long way to go. Another tall order is balancing the social demand for external accountability with the prescription to downplay blaming. In short, more is known about problems than about what approaches to improvement works best. But that's normal. The ability to diagnose problems always runs ahead of the ability to prescribe cures.

Speaking personally, my own research for twenty years addressed malpractice mainly as a matter of law and liability insurance. I wrote about how those systems perform, and how actual and proposed reforms affect that functioning. A particular interest has been no-fault alternatives, which have the potential for efficiencies as well as for sending clearer signals to practitioners about the extent and nature of medical injuries. It has long troubled me that medical-legal research has always found significant levels of preventable injury—starting with the first systematic study of medical injury and negligence in the early 1970s.

My own first project specifically on injury prevention began just two years ago. Since then, I've learned much more about the practical issues of making changes in clinical and administrative systems to protect patients. One very recent advance is that "patient safety" is now readily understood to mean protecting patients from medical injury in many ways. Only two years ago, even well informed clinicians and risk managers usually thought of "safety" as having to do with hazard-free premises—well lighted parking lots, non-slippery stairwells, clearly marked fire exits, and the like. "Risk management" usually meant defending against lawsuits and coping with other legal system demands on clinicians, like Medicare compliance issues. There was little attempt to actively address any factor that might hurt patients.

All this seems to be changing as some medical leaders are learning more about promoting safety, not just avoiding malpractice. Efforts are underway in many institutions across the country, not just hospitals but also large physician groups. This type of work is much more exciting in terms of direct improvements for patients than lots of debates I've been in about law and insurance or the pros and cons of tort reform.

Learning from Reporting Systems across Institutions. This morning, the main topic is the potential role for medical error reporting. Sharing information across sites through reporting can help build the knowledge base for improvement. One must start with information about how different types of medical errors occur and how they reach patients in order to begin to prevent them. Medical providers have important information—what clinicians knew and did or didn't do, the circumstances of a case, the environment in which it occurred. One key to improve-

ment is to be able to study occurrences, errors that led to injury or might have done so. Much can be learned by self study and literature review, especially in hospitals or large physician groups. Sometimes, however, larger scale is needed. Hence the interest in reporting systems to compile information on error in medicine.

Institutional care is the focus of most existing reporting systems and the IOM proposal—especially hospital care. It's plausible that the need for more information is even greater for non-institutional care, where individual and small groups of practitioners lack the advantages of scale and scope of larger entities. Outpatient care is generally believed to have less potential to hurt patients than more complex hospital care for sicker patients. Still, "failure to diagnose" liability cases are among the more expensive claims, and there are also many issues of follow up and coordination of care among independent offices. Outpatient care, however, remains a raw frontier for safety development.

For the IOM panel, I and my colleague David Shapiro, an M.D., J.D. expert from California, examined some aspects of reporting systems. We researched a number of leading voluntary systems, concerns about their ability to maintain confidentiality, and what existing and potential legal protections could enhance confidentiality. We inevitably also learned about some mandatory programs, though with less detail. Our conclusions are fairly presented in chapter six of the IOM book (pp.94-113): Liability law gives broad scope to litigants to discover information relevant to their claims, or even that might lead to relevant information. When quality-oriented information is kept confidential within a health care entity (mainly hospitals) and used for peer review purposes, it is typically not discoverable. Risk-management information for defense of claims also has some protection from discovery.

These protections are seldom absolute, however, and sharing data on problems outside the entity raises legal vulnerabilities. Information need not be definitive to be useful. One attorney noted that it is helpful just to know that a patient's hospital chart was submitted to the peer review committee, despite the absence of information about the confidential review or its findings. Just seeing the stamp "referred to peer review" on the chart used to make it much easier to get an expert witness to review the case. Hospitals learned of this effect and stopped using such stamps.

This illustrates a key observation about data on errors. People are very reluctant to report on themselves or colleagues unless they have a reasonable expectation of confidentiality. Whatever one's views about the appropriateness of open confession of error, it is a practical reality that few medical practitioners want to do it within what they perceive as a litigious or vengeful environment. All our interviewees at reporting systems stressed the importance of confidentiality in getting practitioners to report; fears of legal and other repercussions are very strong. All said they thought reporting of errors falls vastly short of the true extent of error.

It is difficult to get people to discuss potential failures at all, much less report them to regulators empowered to discipline them, especially if litigators may also get hold of them. Hesitation is built into behavior even without disclosure. Note, for example, that the first information a liability insurer or hospital risk manager often gets that something may have gone badly wrong in patient care is an inquiry or notice of suit from a patient's attorney. Reporting by the practitioners involved has traditionally been very low—even though they are contractually obligated to report claims, even though they're reporting only to the people whose job it is to defend them, and even though the reports are internal and confidential.

Stronger confidentiality protections would probably improve voluntary data sharing. That's why the IOM panel recommended new federal legislation. If cross-state reporting is to expand greatly, this may indeed be required. There are existing legislative models of confidentiality protection on which to base new rules, including those applying to peer review and to the National Practitioner Data Bank. The panel recommended a decentralized approach, as different expertises and scales of operation are appropriate for different types of problems—drug errors, blood transfusions, emergency medicine, and so on.

Many states have created mandates for hospitals to report serious injuries to a state regulatory agency, often along with other matters, including epidemics and fires. Typically, a case is confidential unless the agency takes formal action against the institution. Legal requirements and conditional confidentiality may plausibly increase reporting overall, though this is undocumented. But it seems clear that even a long-standing mandate, as in New York or California, elicits only a few thousand reports of unnatural deaths or serious injuries a year (see Appendix D of the IOM book, pp. 210-217). The rate of error and serious injury found by hospital chart review in those states is far higher. Mandatory reporting may or may not find more problems than does the liability or peer review system.

For purposes of learning from reported mistakes, incomplete reporting may not be critical. A clinical or administrative manager at hospital X can see that others

also have a lot of problem Y and hence decide to take action. An area for much greater work is how to report or otherwise generalize knowledge about solutions as well as problems.

Reporting systems cannot measure the true incidence of particular problems, however, because they don't know either of the two key factors: They cannot count how many errors truly occurred (say, in a state or in a type of hospital). Nor do they know how many patient encounters it took to generate the observed level of reported cases. For this reason, it's a bit troubling that incomplete systems can be used to discipline medical providers.

Reporting Systems as Motivators of Change. This observation leads to a second issue about safety—how to motivate change among doctors and hospitals. Here, the IOM panel touched briefly on the importance of corporate leadership (chapter eight, pp. 143-144) and appeals to professionals' desire to excel in quality, now including attention to error prevention. These are good things. However, considerable outside pressure seems needed as well. It's taken a long time, after all, for most medical leaders to begin to accept that major improvements seem possible, despite all the rhetoric about American medicine as the best in the world. And complacency about performance continues; many hospital executives seem to think they are doing enough about injuries already.

Enter state regulators as motivators. The threat of sanction after investigation of a reported serious occurrence is surely meant to encourage change. How well this works goes beyond the scope of the IOM book and is worthy of much more attention. How well staffed and funded are the relevant agencies? What are their capabilities to investigate, especially promptly and outside their home offices? How much are individual cases studied as against patterns of problems? Can regulators recognize when other factors than error affect reporting (e.g., nurses' labor dispute with hospital)? What sanctions do regulators use? How much acceptance is there of the appropriateness of their findings among the regulated entities? Do the regulatees in fact change? How do regulators try to generalize advice to the industry at large? The questions go on and on.

Given the wide range of unanswered questions, the appropriate federal action at this point seems to be to learn more about what states are doing and accomplishing rather than to mandate federal minimum standards. According to news reports, the Administration has decided to oppose mandatory, open reporting at this stage. I agree with that position.

Proponents of traditional and expanded litigation normally assert that motivating preventive efforts is their key contribution—what lawyers call deterrence. This must be at least partly true: The highly successful anesthesiology guidelines, even the patient safety movement itself, was partly a reaction to liability pressures. Formal research has found little evidence of deterrence, however. Support for the hypothesis that exposure to fault liability promotes safety comes from some studies comparing no-fault with fault-based systems for auto accidents. Yet the tie between lawsuits and motivation to promote safety seems weak. Hospitals and other entities within a particular jurisdiction all face the same basic legal rules, yet they differ greatly in their willingness to tackle patient safety as a management priority. Moreover, to repeat: whatever the level of deterrence has been accomplished by liability pressures, it hasn't done enough to protect patients. And it tends to inhibit open sharing of data and methods for safety, even internally.

One last comment here: Regulation and litigation are not the only tools available to motivate change. It's appropriate for buyers of health care to demand much more of providers. That is another major topic on its own. It seems possible to start with some outcomes measures, such as rate of late discovery of cancer, and more pressure for providers to adopt processes thought to help reduce errors. Again, to the extent feasible, at this stage of development it seems preferable to emphasize support for improved processes rather penalties for poor outcomes. Hospital accreditation is doing some of that already, but buyer pressure offers another useful approach, one barely touched upon in the policy debate thus far.

Implementing Change. Changing clinical and administrative processes to protect patients calls for good management, beyond good information and motivation to act. It is one thing for leaders or outside experts to proclaim devotion to patient safety and discuss methods in general terms, quite another to make changes in everyday practice. It is notoriously difficult to manage health care providers, and the appropriate system to manage is not clear, especially outside of hospital-based and large physician group practice. Very few private entities have anything like the corporate organization of Veterans Affairs, where top leadership has begun substantial change. Management issues merit much more attention.

Readers will note that this testimony has become sketchier as it proceeds from theory to actual implementation of change. There is a reason for that. Theory is running ahead of practice. Much remains to be learned, but the promise is bright.

Mr. BILIRAKIS. Thank you very much, sir. Dr. Berwick, I was pleased that you made your last two comments, that I had to sort of rush you through, principally because I picked those up in your written statement and had planned to go into them with you. And, in fairness, I again repeat that you said that they represent your personal viewpoints and go beyond the findings of the IOM committee. First, you state that you consider the VA a model for us all and that certainly is a compliment to Dr. Kizer and others in that it has a mandatory requirement that serious injuries and errors be reported to patients and their families.

And of course the point made by Mr. Bovbjerg I think is a very significant point in terms of the distinctions between work of the VA and the private sector. But then you also state or perhaps maybe imply that some form of tort reform is necessary. You write that you believe strongly that movement toward a no fault, and you said that again orally, malpractice litigation system would help increase safety-oriented activity immediately. Well, I think those are two very significant statements and I wanted you to use most of my time to possibly elaborate on those.

Mr. BERWICK. Thank you, Mr. Chairman, and for reminding us that these are my personal comments. On the issue of mandatory reporting, I think we are confusing two very important issues. One is the public reporting to some authority of sentinel events for the purpose of public accountability but I think meshed in with that is this additional issue if a patient is harmed by care that is intended to help them, do they have a right to know about that.

I think the professions and the organizations would say yes but I am not personally assured that we are doing this, and I would like some kind of assurance and think the public deserve it that if one is injured by care, one is told that. The VA is leading the way in that and is able to show that such a system can work. The second issue of tort reform is a much more difficult one. If we truly believe that most of the harm is done to patients by their care occur from systems then the accountability is a system level accountability.

A tort reform system addressed to individual miscreants misses the point. It is not fixing the accountability where it belongs that leads me to prefer a kind of enterprise liability to an individual. More than that, the malpractice environment is use by this industry as an excuse for not studying in depth and sharing information about its errors and so as long as that excuse is there, I fear we will lack the momentum that we could establish. If we had tort reform it would take the excuse away and we would have daylight on the problem more easily.

I am cautious about that because as I say there are some organizations that have been able to establish robust voluntary reporting systems through courageous executive leadership without a change in the malpractice climate but I don't think heroic behaviors of that kind are going to be very common.

Mr. BILIRAKIS. Well, you know, Doctor, many years ago during my earlier years in the Congress, I had prepared a proposal that

would be a no fault system similar to workmen's compensation. The Workmen's Compensation Program was probably rocky initially but it is working. And that is, I guess, what you are proposing and I commend you for that.

Mr. BOVBJERG. Mr. Chairman, I could also submit more on that from earlier work——

Mr. BILIRAKIS. Sure, please do.

Mr. BOVBJERG [continuing]. To deal with a no fault system. I will give you an article from the Journal of the American Medical Association proposing such a system for obstetrics to replace the current one.

Mr. BILIRAKIS. I would like to see that very much. Thank you. Thank you, Mr. Bovbjerg. In the IOM report, at least to my knowledge, you did not compare what is happening in this country versus other industrialized nations, England, Canada, etc., etc. Any comments from any of the three of you regarding that?

Mr. BERWICK. We have had several studies—we are aware of several studies in the UK, Scandinavia, and most importantly Australia replicating the same methodology that was used in Colorado and Utah and in New York, which used identical methods. The Australian study showed rates of injury in the Australian medical care system of little more than double those in the U.S. system which has caused great concern in that country. We have very early findings in the UK showing similar error rates.

Mr. BILIRAKIS. Double?

Mr. BERWICK. No, similar to the U.S.

Mr. BILIRAKIS. Similar to the U.S. Anything further, Dr. Kizer, Mr. Bovbjerg?

Mr. KIZER. I was just going to make the point that there is very little known from elsewhere in the world with the exception of the countries that were mentioned and in those countries they certainly can't be looked to as ways of doing it better perhaps, that their data suggests that the problem is comparable or worse than what we have.

Mr. BILIRAKIS. My time is up. Mr. Green, to inquire.

Mr. GREEN. Thank you, Mr. Chairman. Dr. Kizer, we are hearing a lot about the need to create a non-punitive recording system to gather data on medical errors so we can learn from our mistakes but the discussion has focused on confidentiality protections for the information. However, protecting the reported information won't necessarily address other reasons people don't report, not necessarily the fear of lawsuits but the fear of embarrassment because of one's fear that their supervisor will find out, fear of losing their job or losing a possibility of promotion. Would you agree it is important to offer individuals protection from retaliation as well as for the agency?

Mr. KIZER. I think that has to occur. Now whether it occurs by statute or by personnel policies and the culture that is created, I think that may be the question that you are asking. I know part of what was tried to be effected in the VA was to create a culture and to have personnel policies that were supportive of reporting errors of openly discussing the information and that did not necessarily require any statutory or regulatory changes.

Mr. GREEN. So the protection was not just to the agency, the VA, the local hospital, but also to the individual staff members?

Mr. KIZER. That is correct although I would in saying that underscore the point that while there may be a very small minority of individuals who do grossly negligent or unethical things that whatever protections are accorded to individuals that those protections should not be an excuse or a way for unethical behavior or malfeasance to be condoned.

Mr. GREEN. Well, again, that should apply to the institutions as well as to the individual.

Mr. KIZER. Yes. I think the differences at one level, those policies or protections would be accorded. There is much that can be done within institutions just by policy of the institution to get where we need to go without any changes in laws or regulations.

Mr. GREEN. I notice one provision in the Patients' Bill of Rights that recently passed the House would provide protections for healthcare workers who report quality problems or errors to the appropriate body, and I believe this is an important protection for the individuals to improve that quality of care and reduce the errors. And, again, to follow up on the chairman's concern, and that was my question about whether the international numbers, whether it is Australia or another industrialized country, are comparable to what was shown in the IOM study. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman. Mr. Stearns to inquire.

Mr. STEARNS. Thank you, Mr. Chairman. Dr. Kizer, as you and I both know, we had hearings on this and you testified and when we talked to you, you went back and set up sort of a National Safety Center, to use your term, something in Veterans' Affairs to make sure that all this was reported. But as I recollect, a lot of the hospitals didn't participate. They wouldn't do it on a regular basis and you didn't feel the information was forthwith in coming. So I guess my question is, is there enough on the veterans' side for us to extrapolate to the private sector and what could have been more successful on the veterans' side to make it work better?

Mr. KIZER. How many hours do we have? Very quickly, I think that there is experience from the VA that is transferable and there is much that can be learned there but I would echo what Mr. Bovbjerg said that the VA as an integrated system is different than much of what occurs out in healthcare. As one example, medication errors, the VA made a policy to implement some technology that cost some dollars, millions of dollars, across the system to reduce medication errors. Because of the way the VA is financed and the way the funds are distributed that was—the system realized the return on investment.

If you took that same analogy to the private sector today hospitals that have to would invest in that. The return on investment would go back to the health plans and the hospitals would be unlikely to see any of the return on investment. There are numerous examples like that where if you look at the fractionated non-system that we have in the private sector as opposed to a fully integrated system such as the VA, while there are lessons there, there are differences that have to be recognized as well.

I think going back to the other point that you made about the difference in reporting, I think we have to recognize that this is a

long-term effort that requires changing the entire culture. You and I had discussion both in the hearings as well as off line that I think I made the point to you, a couple of points, that, one, the VA was not—the rates were not much different than I saw in the private sector as a former regulator of hospitals, and, second, that this was something that if we did it right and the reporting that the numbers would go up dramatically.

And indeed that is what you have seen with the system that has been put in place in the VA. But even so, if you may recall the medical inspector's report the highest—the two networks with the highest and the lower rate of reporting and a difference by a factor of 10, both were in the State of New York, a State that happens to have two networks dividing them. So even though in the same system with all the same encouragements and the same assertations, you can see within a relatively small geographic area marked differences in reporting largely to do with again the culture that exists in those areas as opposed to the rules or what not of the system.

Mr. STEARNS. Dr. Berwick, we in our Veterans' Affairs committee, we had a Ph.D. come to our hearing and said you are safer in an airplane than you are in a hospital and Mr. Gutierrez made his comment at that point. What do you think of what Dr. Kizer mentions in terms of a National Safety Center, and perhaps in line with this to get this cultural change is to make it a no fault. You would not deny the ability of the patient to sue, his constitutional right, but you would have a no fault accountability so that all of this would come in and it could be used on a system basis to determine what we could do not only to change the culture but the procedures.

Mr. BERWICK. Aviation is an industry that has a culture of safety and had made tremendous progress in improving safety for passengers. I think the aviation is at least ten fold safer now than it was 20 or 30 years ago for passenger miles despite the fact it is a much more complex industry today. It committed to safety. They have achieved it larger through science. The aviation industry understands how systems work and what system properties are safer than others. They understand how to make communication fail safe. They understand how to make equipment reliable. They understand the——

Mr. STEARNS. So you support a National Safety Center that Dr. Kizer mentions?

Mr. BERWICK. Absolutely, yes. If we can apply that same science in healthcare the progress would be immense.

Mr. STEARNS. Mr. Bovbjerg, what is your comment about a National Safety Center?

Mr. BOVBJERG. Oh, it makes terrific sense to me. Again, I would emphasize here we have an industry in the airlines in whose interest it is to make changes and which will directly benefit from that. It is a little less clear in healthcare. The pilots, stewardesses, mechanics, and so on, who report in the aviation industry directly benefit in a way that the doctors and nurses and so on don't. The discoverability of plane crashes is very high. The discoverability of errors is not in medicine. So I think there are differences but surely one can learn by looking at this.

I think Don and many others have done that, are learning. The issue is how do you get people to surface this stuff so that you can begin to learn and change. And now it is difficult and it is difficult even internally when a hospital or a staff model HMO or a large physician group tells the doctors and nurses let us know early about problems so we can intervene so we can do something.

They beg and very often this doesn't happen and the first time that a risk manager in a hospital or a physician group hears about a problem is when the plaintiff's lawyer calls. That is not good and that is with confidentiality and so on. There is a lot of work to approve reporting and to generate this information. It is quite sporadic and unreliable now.

Mr. BILIRAKIS. Thank you. Thank you, Mr. Bovbjerg. Mr. Strickland to inquire.

Mr. STRICKLAND. Thank you, Mr. Chairman. Mr. Berwick, I wanted to focus on your support for a no fault liability system and I make reference to the To Err Is Human report and the incredibly dramatic reductions in deaths in the area of anesthesiology. I would just like to share those statistics. Some studies in Australia, the United Kingdom and other countries today indicate that anesthesia mortality rates are about one death per 200,000 to 300,000 anesthetics administered compared with two deaths per 10,000 anesthetics in the early 1980's, an incredibly dramatic reduction in the loss of human life.

But isn't it true that one of the reasons that anesthesia has moved in such an aggressive way to improve the performance has been the fact that they have been faced with liability and that that is one of the motivating factors in focusing attention on the need to bring about these dramatic improvements in healthcare?

Mr. BERWICK. Historically I believe you are correct. The concern about high malpractice rates was one of the motivating factors but I don't think it by any means was the only one. I also noticed that the liability for anesthesia deaths is also nested in the institution itself so I think that it supports the notion that organizational liability is constructive.

Mr. STRICKLAND. And that leads me to a second question that I think is related to the systems or enterprise liability and that is where would the source of revenue likely come from, and I use for the purposes of contrast workers' compensation system is funded by a tax on employers, the vaccine injury program is funded by a tax on vaccine, automobile no fault insurance is funded via a mandate that drivers carry insurance in order to obtain a driver's license and so on. Where would we likely find the resources or the money to pay for a no fault system in your opinion?

Mr. BERWICK. It is only an opinion. Mr. Bovbjerg has better data than I do. Understand now though according to the same studies that have yielded information on errors there is a tremendous mismatch between the way the tort system works now and just compensation to patients. Most suits do not involve errors and most errors don't arrive at suit.

In addition, most of the compensation doesn't ever reach the patient so there is a lot of wasted money in that system right now. Exactly how the numbers work out, I am not an expert at it and

I don't know but we don't have a system right now that is matching injury to compensation at all.

Mr. STRICKLAND. Thank you very much. I yield back my time.

Mr. BILIRAKIS. I thank the gentleman. Mr. Smith.

Mr. SMITH. Thank you, Mr. Chairman. I want to thank our witnesses for their testimony. You know, Mr. Chairman, I chair the Subcommittee on International Operations and Human Rights. We have had about 100 hearings since I have chaired it, and we have a number of contentious issues from embassy security. The President just signed our bill in November which provides $900 million additional per year over 5 years for embassy security. I raise this because we deal with a lot of issues on that committee or that subcommittee where people make assertions. And I usually and members of our panel usually act as devil's advocates to try to separate fact from fiction.

And I think it is extremely important, and a lot of our issues deal with health, global health statistics that come from the United Nations, from UNDP or UNICEF and others, good laudable organizations but you always want to know whether or not you are dealing with an absolute or as nearly close to reality as humanly possible because statistics do drive policy. And in looking, Dr. Berwick, at your study and then reading the GAO, it does raise questions about methodology that I really think need a thorough explanation as to whether or not we really do have a figure that truly represents what is going on in America.

The GAO points out, as I said in my opening statement, that the widely cited estimate of 44,000 to 98,000 deaths per year are attributable to medical errors that come from extrapolation of the results of two studies in the U.S. and they were—one was in 1984 and one was in 1992. I was in my second term in 1984 and probably the information that was used then was dated because obviously there is lead time in getting that to a usable format.

Certainly it would seem, and maybe I am wrong on this, and that is why I want to get to the bottom of this, that this is old data and yet the sweeping statement, and Tom Brokaw is doing something tonight on this, he may begin by saying that American healthcare is unacceptably unsafe today and also that upwards of 98,000 Americans die in hospitals this year as a result of errors of their care.

If that is true, we have an epidemic that absolutely has to be solved but I am wondering about the methodology, whether or not this data is real. And it seems to me if it is just these couple of studies as GAO said there is little known about the incidence of adverse events maybe you can tell us if there is other information that is fed into this, how recent is it. If you could tell us what criteria for labeling as patient death as a hospital physician medical error. How do you provide for provider error and how did you link it to a death? What States, hospitals and providers were scrutinized or is it just these couple of studies that then this information was gleaned from.

And HMO early discharges and all the other problems that we are seeing crop up in this decade or at least in the 1990's relevant to HMOs. I know because I have gone through two catastrophic episodes with my parents who died over the course of years from

cancer that we fought with the HMO. In one case an HMO denied 35 times the payment that we after going through the gatekeeper and following, we were always dealing with early discharge or this not being provided. That could make it even worse than the 100,000, I don't know.

But it seems to me that before we send up that red flag, and again you may have a great answer for this, we have got to have a basis of fact, a collection of statistics mutually reinforcing that clearly lead to the consequences or least the conclusions that have been drawn here. If you could answer that, I would appreciate it.

Mr. BERWICK. Thank you, Mr. Smith. I welcome scrutiny of the data of course. The Colorado and Utah study and the New York study were enormous studies. The New York study was a review of 30,000 records and the Colorado study of an entire population in those two States so these are not small research studies. The methodologies were very precise, definitions carefully done, and I think they do give us a pretty good idea in those two areas what the rates are.

I have no reason to believe that the rate varies very widely, the rate of injuries varies very widely from those two studies. Even if they were off by half, if the number of deaths is 20,000 instead of 40,000 and it is as likely to be higher as lower, we would still have a serious problem. We have many small confirmatory studies of medication errors and their consequences done in organizational levels which repeatedly find these rates.

The convergence of the Colorado and Utah studies and New York is remarkable, 3.7 percent injuries in New York, 3.2 percent in Colorado and Utah. They differed in lethality but not in the actual occurrence. The data bases were 1984 and 1992. The studies were actually more recent than that. You are absolutely right. We don't have large studies on more recent data but the committee is aware of the increasing complexity in number of medications available, equipment, technologies and procedures which would lead us to estimate that the risks have probably gone up, not down since that time with or without the managed care pressures.

Mr. SMITH. Can you tell us, I know my time is running out, what were the criteria for labeling a patient death as hospital physician medical error?

Mr. BERWICK. Well, both studies begin with a definition of adverse event. Adverse event means an injury from care that prolonged hospitalization by at least a day or caused a week or more of disability. That is the formal definition. Then those were reviewed by trained and calibrated physician reviewers who sorted those into systemic avoidable errors built into the way the care was offered or something unpreventable like giving a patient who might have a reaction to penicillin the first time they ever saw it.

About 70 percent of the errors were attributable to system properties that were in principle avoidable. That is what they call preventable. The deaths were then attributed to the preventable injuries, the number of those that killed people, and that is where you get the 44,000 and 98,000 numbers.

Mr. SMITH. I have more questions but I see my time is up.

Mr. STEARNS [presiding]. The gentleman's time has expired. Mr. Rodriguez, 5 minutes.

Mr. RODRIGUEZ. Thank you, Mr. Chairman. Let me first of all indicate that I like the recommendations that were made. One of the disagreements that I have is that when you look at any problem, you look at both the individual and the responsibility that the individual has and the buck has to stop somewhere. And I agree with you that we have to look at it systemically and we have to also view it in terms of the perspective, in terms of the culture and we need to do that.

But at the same time we also need to look at the individual perspective. I like the idea of the national center but I would also like it if it was also localized because unless you have a local board in that hospital to look at the data. I mean the medical profession does that. They look at the bad apples. They are the ones that report the bad apples and some of them do a good job, some of them don't.

Other review boards have looked in terms of the police, in terms of abuse, and that has worked pretty well, and I think we can come up with some ideas in that area. I would also add that you are right in terms of the fact that right now I think we have a cap of 250,000 on a person's life, at least that is my understanding. I don't know if I am correct on that or not, but I think that when we look in terms of liability we need to personalize it. If it is one of our family members, we need to hold those people accountable, whoever they are and we need to hold that system accountable too.

And I think that is important, and I just want to thank you for being here and I think we are on the right track in terms of trying to identify some of those things. I want to yield, I know I have a little time, to Mr. Gene Green from Texas.

Mr. STEARNS. The gentleman yields to Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman. Just a follow-up. When I asked the question about the Patients' Bill of Rights, I didn't actually get on the record. I noticed your head was nodding, each of you were nodding yes that you agreed that protection for healthcare workers who report quality problems or errors. Is that correct? If you could answer verbally so we can get it in the record.

Mr. BOVBJERG. Yes.

Mr. KIZER. Yes.

Mr. BERWICK. Yes.

Mr. GREEN. Okay. And one follow-up question for whatever time is left. Dr. Berwick, doctors claim that one of the reasons they don't talk openly about errors either to the patient or to other medical practitioners is because they are afraid of potential lawsuits, and I understand that, yet in keeping information about medical mistakes underground doctors often violate their own code of ethics. The American Medical Association code of ethics quotes concern regarding legal liability which might result following truthful disclosure should not affect the physician's honesty with a patient so concern over the liability shouldn't be a legitimate reason to keep information about mistakes from patients. Would you agree, I mean in an ideal world?

Mr. BERWICK. Absolutely, yes.

Mr. GREEN. And I understand that but I also understand that often times it is difficult for anyone to admit their own mistakes but the medical ethics do require that.

Mr. BERWICK. Yes, they do.

Mr. GREEN. Okay. Thank you, Mr. Chairman.

Mr. RODRIGUEZ. One other comment. I was also concerned that not enough recommendations were made in terms of whether it is lack of resources that are needed out there, additional training that might be needed, and whether we have an obligation in terms of what we need to do because I know a lot of people are overworked or burned out and a lot of other things that are out there. And maybe not enough of that was reported in terms of at least from my perspective because I know people are out there working real hard and getting burned out.

Mr. BILIRAKIS. Would the gentleman yield for a moment?

Mr. RODRIGUEZ. Yes.

Mr. BILIRAKIS. Dr. Ganske got into this but his time was up. I thought he might be back to possibly get into it again. While we need to examine no fault reporting, we also need to look at the root cause and I guess that is what Mr. Rodriguez is referring to. And I don't know that the IOM report spent enough time on that. And I know we have other panels coming up and we can go into this with the VA, etc. At the same time the root cause has got to be addressed too, not just the reporting of it, the liability areas, etc. Thank you.

Mr. RODRIGUEZ. Reclaiming my time if I have any left, let me just indicate that in those situations we know that the root cause is not just one, it is a combination of things and we recognize that. And from one institution to another, from one hospital to another, it will vary, and so I think we need to probably move as quickly as possible with some of these things and please let us know if we need some additional resources to make that happen.

Mr. STEARNS. I thank the gentleman. Did you wish to answer that, Dr. Berwick?

Mr. BERWICK. Thank you, Mr. Chairman. This is a very important point. There is a nexus of root causes which are latent in the system. The reason we want a voluntary system is to surface errors before they hurt people and it is very important to know that we need a culture which doesn't wait for the harm but which says this could have harmed someone. And that is where you get most of the benefit in a reporting system. You are absolutely right. We need people to be safe to talk about latent errors.

Mr. STEARNS. The gentleman from California, Mr. Cox.

Mr. COX. Thank you, Mr. Chairman. Dr. Berwick, you mentioned in your testimony that if we fired every healthcare worker who is involved in error incident, we would not change our error rate. And I think the message from the entire panel is that what we are trying to do is encourage voluntary disclosure, something that doesn't happen right now. Getting to my colleague's question from New Jersey, Mr. Smith, until we change these things we are not even going to be particularly confident in the data that we are collecting because we know we can do a much better job of collecting it and certainly thereafter of analyzing it if we could encourage more voluntary compliance.

Everyone has directly or indirectly acknowledged that the existing legal incentives all run the wrong way at least as far as individuals are concerned. If an individual is going to be penalized and

not rewarded for participating in this kind of voluntary disclosure then rather obviously we are not going to get it. Do we need to pursue your airline analogy a bit, Geneva Convention for healthcare?

Mr. BOVBJERG. In a sense and in one way the medicine panel's recommendation to focus on deaths and very serious injuries, at least death cases tend not to be quite so expensive as the others when they do surface. They are more likely to be found now and so that is a little less threatening than throwing open the whole flood gates to everything. But, yes, I think in the long run if you want to build a total culture you are going to have to address the legal system and the disciplinary system which are part of the reason that people are reluctant to talk about errors.

But people are reluctant to talk about errors under any circumstance. You have to make it easy for them. You have to sell it on them and people like Tom and Ken, they are very good at this, that it is in their interest and they can help their patients. You sell the prevention. You sell the good. You don't sell where you can avoid being dragged into malpractice.

Mr. COX. Anybody wish to further comment on that? We are of course operating in an industry where insurance plays a significant role. Why is it that the external pressure placed on the industry from insurers whose interest it is of course to minimize the injuries so they don't have to pay for them has been inadequate.

Mr. BOVBJERG. Insurers, of course, generally unlike the VA are on year-to-year contracts. The VA has got a lifetime relationship with its veterans by and large. An insurance company or HMO doesn't. My own sense without having detailed knowledge of it is also that anything that smacks of error and malpractice has greatly angered the providers on whom the insurers rely to deliver the services and they are reluctant to get into that.

I think that the big employer plans and some of the big organized plans now are starting to and that is a very welcome development. What they can do is relatively limited compared to the people right there on the ground who have the clinical control and actually see things happen have the chance to catch things before they happen but there certainly are things that health plans and insurers could do. They are just somewhat more limited, I think, than what the clinicians and the organized systems that have hands on responsibility can do.

Mr. COX. I think, Mr. Bovbjerg, you mentioned in your testimony the extensive discoverability of information that would otherwise would be useful for correcting these problems of investigating errors, their causes and their potential remedies. Do you have any recommendations to make with respect to existing discovery rules?

Mr. BOVBJERG. Well, I think I support the IOM panel's recommendation. If one really wants to provide confidence that things are not going to be discovered on an individual basis it is going to take a statute. There are protections. There are ways to interpret existing statutes at the State level to protect this type of scheme especially outside the institution but it is something of a stretch and I think that it is going to take both practical methods of protecting the data where you have some anonymous reporting, some identification of data, and probably some legal protection to really get a whole lot more reporting.

Mr. COX. Last, if I may, the emphasis of this panel and in fact the focus of this topic is on making the system or the aggregation of individuals working in healthcare in America work better and have better patient outcomes and fewer mistakes. The point that you have made I think competently is that if we focus more on systemic errors and problems in the delivery itself and less on blaming the individual nurse or the individual doctor or so on will actually do better.

The tort lawyers come at this from a different point of view. They want to know who is going to pay in this case. Dr. Berwick mentioned enterprise liability as opposed to individual liability. How does that occur if nobody is to blame who works for the enterprise?

Mr. BERWICK. We are attributing the vast majority of hazards to systems. Somebody is responsible for the safety of those systems and that is the executive trustees and senior leaders of the enterprise. As individuals they may not be able to be reached but they are responsible.

Mr. COX. So would you then make them personally liable in litigation?

Mr. BERWICK. It is beyond my competence to say personally liable but I know the action to make patients safer has got to occur in the executive suite. If it doesn't start there, it isn't going to happen. That is why the VA has made——

Mr. COX. Well, let me make it a little easier to understand my question. If we are concerned about encouraging voluntary reporting, if people don't like voluntarily to report because they will then be to blame, if we are trying to resolve that problem by saying you are not to blame but we are going to make the enterprise liable, how do we ever make the enterprise liable if nobody that works there is to blame?

Don't we have to—I mean doesn't the tort lawyer still have to go in and find out that something was wrong, that this system didn't work, this person who was responsible for it screwed up and as a result there was a bad outcome. Can it be possible that the enterprise was liable when nobody was at fault, when no person did anything wrong?

Mr. STEARNS. Let the gentleman's question—his time has expired.

Mr. COX. That is it for my question. It is up to the chairman whether you wish to expire the time for the answer.

Mr. STEARNS. Does anyone want to tackle that answer?

Mr. BOVBJERG. The short answer is yes, I would be glad to talk with you on our time afterwards.

Mr. STEARNS. Okay. Well, I thank the first panel for their indulgence and it was very helpful. And now we will call up the second panel, which is Dr. Thomas Garthwaite, who is the Deputy Undersecretary of Health for Veterans' Affairs Administration, Dr. Bagian, who is Director of National Center for Patient Safety, Dr. Audrey Nelson, from the VA Hospital in Tampa, Dr. Janet Heinrich is from the GAO office, and Ms. Diane Cousins, who is Vice President of Practitioner and Product Experience Division of U.S. Pharmacopeia.

So I welcome all of you to the second panel. We are delighted that you are attending, and we would appreciate your opening

statement within the 5-minute time limit. And Dr. Garthwaite, you and I have had an opportunity on these discussion panels before so let me start off with you. Welcome.

STATEMENTS OF THOMAS GARTHWAITE, DEPUTY UNDERSECRETARY OF HEALTH, VETERANS HEALTH ADMINISTRATION, DEPARTMENT OF VETERANS' AFFAIRS; ACCOMPANIED BY JAMES BAGIAN, DIRECTOR, NATIONAL CENTER FOR PATIENT SAFETY; AUDREY L. NELSON, DIRECTOR OF PATIENT SAFETY, CENTER OF INQUIRY, JAMES A. HALEY VA HOSPITAL; JANET HEINRICH, ASSOCIATE DIRECTOR, HEALTH FINANCING AND PUBLIC HEALTH ISSUES, GENERAL ACCOUNTING OFFICE; AND DIANE D. COUSINS, VICE PRESIDENT, PRACTITIONER AND PRODUCT EXPERIENCE DIVISION, U.S. PHARMACOPEIA

Mr. GARTHWAITE. Thank you, Mr. Chairman. Thank you for inviting us to testify today on the critical issues of patient safety. Almost 3 years ago under the visionary leadership of Dr. Kenneth Kizer, who you have just heard from in the first panel, the VA began a major initiative to establish a system and a culture to improve the safety of our healthcare system, and by sharing our results, to improve the safety of healthcare for everyone.

Our written testimony details our extensive efforts and I will not reiterate it. I would like to comment on VA's approach to three areas that continue to be debated—accountability systems versus learning systems, mandatory versus voluntary reporting, and public disclosure versus the need for candor.

First, we all make errors. Healthcare providers certainly do. Dr. Bagian, who will speak to you next and who is an astronaut and a physician, can tell you that even rocket scientists make errors. Since the release of the Institute of Medicine report considerable debate has centered on finding an appropriate balance between assuring accountability for errors versus designing better systems to prevent errors and to minimize the consequences of errors. We believe that the institution delivering care has a responsibility to assume that individuals will make errors. Those institutions must find the systems that allow the errors to occur and improve the design of those systems.

Those institutions also have a responsibility to detect incompetent providers and to take appropriate action. In VA we have sought to approach the error portion by first openly informing patients or families about errors. Second, to insist on mandatory reporting and analysis of adverse events within a process protected from public disclosure of individual patients and practitioners.

Third, to identify early in a process any intentional unsafe acts for administrative review and action. Fourthly, to provide ongoing analysis of adverse events for possible systemic fixes and new standards including research at our patient safety centers of inquiry. Fifth, to implement new safety standards across our system and to share those broadly in the general healthcare sector. And, sixth, to sign performance contracts with our senior executives holding them accountable to implement new processes and procedures to improve patient safety.

On the accountability side of the systems versus individuals issue, we continue to hold individuals accountable for their competence through a set of other processes including credentialing, privileging, re-privileging, administrative investigations, performance management systems, personnel management systems, reporting to State licensing bodies and reporting tort claim information in the National Practitioner Data Bank.

A second issue that has triggered considerable debate is whether reporting should be mandatory or voluntary. The expert panel, which helped design our system and the experience of the aviation industry, led us to conclude that both systems are important and together yield more useful information than either can alone.

A third issue which has been central to many of the discussions of what should be done to improve patient safety is a need to find the balance between the public's right to have information to choose a safe healthcare system for their care versus the need to create a culture of open disclosure without blame of individuals for system weaknesses.

Take mandatory reporting of error rates as an example. Since the occurrence of error is not always obvious and is more likely in more highly complex and technical procedures, error rates would be predicted to be highest in systems that take care of the most medically complex patients, that perform the most advanced procedures, and that have the most aggressive reporting systems. These are often the systems that we would want to use for our own treatment. Yet, simple reporting of error rates would mislead us.

We believe that additional study will be necessary before meaningful data that guide rather than mislead the public will be available. VA has chosen to use its unique position as a publicly accountable healthcare system to lead in the effort to insure the safety of patients. We also use our strengths as a major research and educational organization to conduct research on safety and to add human factors and organizational design to the curriculum of clinical administrative students in the VA. Thank you.

[The prepared statement of Thomas L. Garthwaite follows:]

PREPARED STATEMENT OF THOMAS L. GARTHWAITE, DEPUTY UNDER SECRETARY FOR HEALTH, DEPARTMENT OF VETERANS AFFAIRS

Mr. Chairmen and Members of the Committees, I am pleased to appear before you to discuss VA's ongoing activities and initiatives to ensure the safety of patients who receive care from VA. In December 1999, the Institute of Medicine (IOM) released a report "To Err is Human: Building a Safer Health System." The report reviewed existing studies and concluded that as many as 98,000 preventable deaths occur each year in United States' healthcare due to error. The IOM recommended creating a new National Center for Patient Safety that would focus on research and policy related to errors in healthcare, improved error reporting systems, improved analysis/feedback methods, performance standards for healthcare organizations and individuals, and other specific governmental actions. Importantly, they cautioned that the focus must be on creating a culture of safety that will require improving systems, not assign blame.

VA interpreted the IOM report as a validation of our commitment to improving patient safety in our healthcare system. All of the IOM recommendations applicable to VA have either been in place or were in the process of being implemented prior to the release of the report. While VA has had quality and safety related activities ongoing for many years, it was in 1997 that our formal patient safety program was launched (see Attachment 1). Leaders in the field of patient safety and medical error outside VA have participated in the design of our system and recognize VA as a pioneer in these efforts.

During 1997, VA intensified its already extensive efforts in quality improvement by launching a major initiative on patient safety. We recognized that programs to improve quality and safety in healthcare often share purpose and corrective actions. However, we believed that patient safety required a new and different approach. We set out to create a new culture of safety in which our employees detect and tell us about unsafe situations and systems as part of their daily work. Once we know about unsafe situations and systems, we are committed to design and implement new systems and processes that diminish the chance of error.

Highlights of Patient Safety Activities at VA: 1997-Present

VA recognized that patient safety is not a VA-specific issue, therefore we asked other health care organizations to join us in an effort to understand the issues and to act for patient safety. As a result, the National Patient Safety Partnership (NPSP), a public-private consortium of organizations with a shared interest and commitment to patient safety improvement, was formed in 1997. The charter members, in addition to VA, included the American Medical Association, the American Hospital Association, the American Nurses Association, the Joint Commission on Accreditation of Healthcare Organizations, the Association of American Medical Colleges, the Institute for Healthcare Improvement, and the National Patient Safety Foundation at the AMA. Five additional organizations have subsequently joined the charter members in the Partnership: the Department of Defense Health Affairs, National Institute for Occupational Safety and Health, the Food and Drug Administration, Agency for Healthcare Quality and Research, and the Health Care Financing Administration. This group addresses high impact issues that are of importance to a broad cross section of the healthcare industry. An example of the Partnership's activity was the establishment of a clearinghouse for information related to the effect of Y2K computer issues on medical devices. The NPSP also called public and industry attention to Preventable Adverse Drug Events and promulgated simple actions that patients, providers, purchasers and organizations could take to minimize their chance of an adverse drug event. (See Attachment 2) The partnership serves as a model of what a private-public collaboration can do to improve patient safety.

In 1998, VA created the National Center for Patient Safety (NCPS) to lead and integrate the patient safety efforts for VA. As the IOM report advises, VA created this center as a commitment to patient safety as a corporate priority with a direct reporting relationship to the Under Secretary for Health. The NCPS employs human factors engineering and safety system approaches in its activities. The first task for the Center was to devise systems to capture, analyze and fix weaknesses in our systems that affect patient safety.

We sought to design reporting systems that would identify adverse events that might be preventable now or in the future. In addition, we sought systems to identify and analyze situations or events that would have resulted in an adverse event if not for either luck or the quick action of a healthcare provider—we call such events "close calls." We believe that "close calls" provide the best opportunity to learn and institute preventive strategies, as they will unmask most system weaknesses before a patient is injured and avoid the liability issues implicit in investigation of injury. This emphasis on "close calls" has been employed by organizations outside of healthcare with great success.

VA consulted with experts (Expert Advisory Panel for Patient Safety System Design) obtaining advice to enhance the design of VA's reporting systems. These experts in the safety field included Dr. Charles Billings, one of the founders of the Aviation Safety Reporting System, as well as other experts from NASA and the academic community. They advised us that an ideal reporting system a) must be non-punitive, voluntary, confidential and de-identified; b) must make extensive use of narratives; c) should have interdisciplinary review teams; and d) most importantly, must focus on identifying vulnerabilities rather than attempting to define rates of error. VA has used these principles to design the patient safety reporting systems we have in use or in development.

Based on the expert advice and on lessons learned from our first generation mandatory adverse event reporting, the NCPS has developed a comprehensive adverse event, close call analysis and corrective action program which includes an end-to-end handling of event reports. This system not only allows for the determination of the root causes, but also captures the corrective actions as well as the concurrence and support of local management for implementation. The system includes a number of innovations such as algorithms and computer aided analysis to determine the root cause of adverse events and close calls. The Joint Commission on Accreditation of Healthcare Organizations and the American Hospital Association are currently evaluating parts of the system for use.

The improved event reporting system is being pilot tested in VA's VISN 8. Extensive training is used as the new system is introduced to assure full understanding of the search for the root cause and redesign of the system. To date, response from the pilot site is positive. The quality managers and clinicians using the system believe that the new methods analysis of error will make a significant difference in the care of veterans.

A complementary, de-identified voluntary reporting system is in the process of being implemented. It is patterned after the highly successful Aviation Reporting System that NASA operates on behalf of the FAA. It will be external to VA and will allow employees and patients to report unsafe occurrences without fear of administrative or other action being taken against them.

Based on lessons learned, VA has promulgated specific procedures and policies aimed at reducing risk of error. These include such things as restricting access to concentrated potassium chloride on patient care units, use of barcode technology for patient identification and blood transfusions in operating rooms, and for verification procedures prior to injection of radio-labeled blood products. (Attachments 3-6) Based on the observation of a VA nurse when she returned a rental car, VA developed a system for using wireless bar coding to improve medication administration. That system was piloted at the Topeka VA Medical Center and will be in all VA hospitals by June of this year. At least two-thirds of medication errors can be prevented with this system.

In 1999, VA established four Patient Safety Centers of Inquiry. These Centers conduct research on critical patient safety challenges. Activities at the Centers of Inquiry range from fall prevention and operating room simulators to understanding the role of poor communication in patient safety. The Center in Palo Alto, which is affiliated with Stanford University, is a recognized leader in the area of simulation and has been featured prominently in the media. Their simulated operating room allows surgeons and anesthesiologists to train and do research without endangering a patient. VA expects to create additional simulation facilities to train its physicians and other healthcare professionals. One simulator with appropriate staff could train about 600 anesthesiologists and residents-in-training per year. This means that virtually all VA anesthesiologists/anesthetists can be trained in a year on clinical situations that could not be simulated safely in patients. As a result of analyzing common variations during simulated operations, the center has developed a checklist card of facts that should be kept close at hand. These checklist cards will be attached to all anesthesia machines across VA.

VA is partnering with the Institute for Healthcare Improvement to build learning collaboratives aimed at reducing medication errors, a major issue identified in the Institute of Medicine report. IHI collaboratives will affect several hundred VHA personnel each year. Other IHI collaboratives have resulted in measurable improvements and similar results are anticipated with medication errors.

Another key VA strategy to reduce medical errors involves the development of a new curriculum on safety. VA is moving forward with plans to provide education and training relevant to patient safety not only to those already in practice but also at the medical, nursing, and health professional school level. This will be the first time an extensive safety curriculum will be developed and broadly implemented. VA is particularly well situated to lead the educational effort due to the extensive role it plays in the education of healthcare professionals in the United States. (VA is affiliated with 105 medical schools and up to one-half of all physicians train in a VA facility during medical school or residency.) Additionally, we have instituted a performance goal and measure to provide VA employees 20 hours of training on patient safety this year.

VA instituted a Patient Safety Improvement Awards Program to focus interest on and reward innovations in identifying and fixing system weaknesses. Not only does this produce ideas for patient safety improvements that might otherwise go unnoticed but it further reinforces the importance that VA places on patient safety activities. (Attachment 7)

In 1995, VA instituted a Performance Measurement System that uses objective measures of patient outcomes to set goals and reward achievement. Since 1998, VA has incorporated a performance goal and measure for its executives for accomplishment in patient safety activities. Last year, each network had to implement three patient safety initiatives to be fully successful and six initiatives to be outstanding.

Other performance goals and measures assess the use of Clinical Practice Guidelines. By holding entire medical centers and geographic networks responsible for measured outcomes, we are able to institute reminder systems and redundancies that lead to dramatic improvements in performance. For example, patients who receive medications known as "beta-blockers" following a heart attack are 43 percent less likely to die in the subsequent two years and are rehospitalized for heart ail-

ments 22 percent less often. A goal of providing this therapy to 80 percent of eligible patients has been set in the private sector, and recent medical literature reports rates of use as low as only 21 percent in some settings. In the VA, over 94 percent of heart-attack patients receive this life-saving medication.

Another example of the power of using systems rather than relying on individual adherence to clinical guidelines is in immunization. It is estimated that 50% of elderly Americans and other high-risk individuals have not received the pneumococcal pneumonia vaccine despite its demonstrated ability to minimize death and hospitalization. VA's emphasis on preventive healthcare has led to achieving pneumonia vaccination rates that exceed standards set for HMOs by almost 20% and nearly double published community rates. Similar accomplishments have been achieved in providing annual influenza vaccinations.

We believe that patient safety can only be achieved by working towards a "culture of safety." Patient safety improvement requires a new mindset that recognizes that real solutions require an understanding of the "hidden" opportunities behind the more obvious errors. Unfortunately, systems' thinking is not historically rooted in medicine. On the contrary, the field of medicine has typically ascribed errors to individuals and embraced the name-blame-shame-and-train approach to error reduction. Such an approach by its very name forecloses the opportunity to find systems solutions to problems. Other industries such as aviation have recognized the failings of this approach and over many years have succeeded in transitioning from a similar blame and faultfinding approach to a system-based approach that seeks the root causes of errors. VA realized how pivotal culture is to improving safety and in 1998, conducted a culture survey of a sample of employees. Of interest, the shame of making an error was a more powerful inhibitor of reporting than was fear of punishment. Employees readily forgave mistakes in others but were intolerant of their own. We plan to survey culture broadly in VA for several years to track the progress of our efforts.

VA created a database of adverse events and asked our Medical Inspector to review it. The report has been widely, yet often inaccurately, quoted or critiqued in the media. The database was created to discover common and important adverse events in order to focus our efforts in patient system redesign. Commonly, the media assumed that all the adverse events (and deaths) were due to error. They were not. Neither the report nor the database cataloged which adverse events were preventable with today's state of knowledge and therefore could be characterized as errors. For example, most of the adverse events were falls, suicides and fatal events (attempted suicides, suicide gestures), or medication errors. It is not possible with today's knowledge to operate a national system of nursing homes and acute-care hospitals treating the elderly and chronically ill without a number of falls. Yet, we know that it is important to look for common factors to allow us to reduce the frequency of falls in the future. Similarly, psychiatrists have tried unsuccessfully to predict which patients will commit suicide. By looking at our data we hope to be able to predict high-risk patients in the future and therefore be able to prevent suicides. We have already learned that men with a recent diagnosis of cancer, who live alone and who own a gun, are more likely to commit suicide. We plan to study the use of additional interventions in this subgroup of patients at high risk of suicide.

Conclusion

With no successful models in large healthcare systems to guide us, VA turned to other high risk, high performance industries to learn principles for safety. We have borrowed both methods and people from safety-conscious settings such as aviation and space travel and from underutilized disciplines like human factors engineering. These efforts have already produced significant improvements in VA, and we believe will do the same in all healthcare settings.

We would prefer that all of healthcare had begun to address the issue of patient safety long ago. For too long, the emphasis has been on holding individuals accountable and hoping that well-intended and well-educated professionals wouldn't make human mistakes. As the IOM aptly states in the title of its report: "To err is human." We are pleased to be on the leading edge as healthcare takes a systems approach to patient safety. We are anxious to discover new ways to make VA and all healthcare safer. We appreciate your support of these efforts and intend to keep you fully informed of our progress.

ATTACHMENT 1

VHA National Patient Safety Improvement Handbook

Foreword

It has been reported in the medical literature that as many as 180,000 deaths occur in the United States each year due to errors in medical care, many of which are preventable. In order to take actions that will improve this situation, it is necessary to have a clear picture as to what is actually happening so that appropriate steps can be taken that will prevent such occurrences. For this prevention effort to be effective, it will be necessary to establish methods of gathering and analyzing data from the field that will allow the formation of the most accurate picture possible. It is believed that only by viewing the health care continuum as a 'system' can truly meaningful improvements be made. A systems approach that emphasizes **prevention, not punishment**, as the preferred method to accomplish this goal will be used. Armed with this type of information the most appropriate conclusions can be drawn from which prudent solutions can be formulated, tested, and implemented. Ultimately, this effort can be successful only if emphasis on safety and responsibility for improving it resides at all levels of the organization. This activity requires a true team effort. People on the frontline are usually in the best position to identify a number of issues and their solutions while those in managerial roles are often in positions that allow the implementation and wide dissemination of lessons learned. Only by creating and/or maintaining open lines of communication can the improvements developed be successfully implemented. If we don't work together, real success will not be possible. If we are not receptive to changing our way of doing things, we can't succeed.

What we're talking about here is building a "culture of safety". Such a cultural change does not happen over night. It can only happen as a result of countless efforts on everyone's part to approach the way we look at things differently. We must constantly question if we can do the things in a better, more efficient, and safer manner. We must never let 'good enough' be good enough. We must be relentless in our pursuit of finding ways to improve our systems. We don't believe people come to work to do a bad job or make an error, but given the right set of circumstances any of us can make a mistake. We must force ourselves to look past the easy answer that it was someone's fault to answer the tougher question as to why the error occurred. It is seldom a single reason. Through understanding the real underlying causes we can better position ourselves to prevent future occurrences. As has been said, "Experience is the best teacher" but is also one of the most expensive teachers as well. To minimize that expense we must communicate the lessons we learn throughout the system so that others can learn from our experience without forcing them or our patients to learn these same things unnecessarily through their own bitter experience. While we do a good job now and should be proud of the service we provide, there are always ways we can do it better in the future.

The VA is in an exciting position in the field of healthcare. We have the opportunity to lead the way in improving the overall care patients receive through the Patient Safety Initiatives that exist now and that will exist in the future. The impact we can have is enormous but to do this requires courage on our part. I use the word courage because to report events that not only resulted in actual problems but also those situations, referred to as a "close call', where problems were averted but the potential for an actual incident did exist is not the status quo in healthcare or most other industries. It will require us to learn not to look to fix blame but rather to look to answer the questions what, why, and how do we prevent it. This will require trust on everyone's part and that won't and can't happen over night. It will be the product of many small steps and small victories. But to happen at all, we have to have the courage to take the first steps and remain committed to the overall goal of improving safety in the way we provide care to our patients and run our system. We are sailing into uncharted waters and will no doubt have to make many changes as we learn. The important thing is that we begin the journey or else we condemn ourselves and our patients to the realm of "good enough".

James P. Bagian, M.D., P.E.
Director, VHA National Center for Patient Safety

VHA National Patient Safety Improvement Handbook
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VHA National Patient Safety Improvement Handbook

1. Purpose

The Patient Safety Improvement (PSI) Handbook's purpose is to provide a clear roadmap that can be used to guide the VHA in the accomplishment of its goal of minimizing the chance of the occurrence of untoward outcomes consequent to medical care. Through the use of procedures, methods, clarifying examples, and appropriate feedback loops at all levels of the organization (with accompanying rationale) it is hoped that this overall goal can be achieved. Incorporation of a widely understood methodology for dealing with these safety related issues will allow for clearer more rapid communication of information both up and down the organization thus speeding the process of safety improvement. For this to occur, training must take place to complement the contents of this handbook, reading it alone is not sufficient.

2. Scope

This handbook will delineate what type of events are to be considered and how they should be dealt with as well as defining the disposition of events not covered by this handbook. It will also specify the method by which the need for conducting a root cause analysis will be determined and what the procedure for communicating related findings throughout the organization is. These procedures will address the management component as well as the frontline needs.

3. Definitions

a. **Adverse Events** – Adverse events are untoward incidents, therapeutic misadventures, iatrogenic injuries or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic or other VHA facility. Adverse events may result from acts of commission or omission (e.g., administration of the wrong medication, failure to make a timely diagnosis or institute the appropriate therapeutic intervention, adverse reactions or negative outcomes of treatment, etc.). All adverse events require reporting and documentation in the National Patient Safety Registry (NPSR), however, the type of review is determined through the Safety Assessment Code (SAC) Matrix scoring process, as outlined in Appendix SAC. Some examples of more common adverse events include: patient falls, medication errors, procedural errors/complications, completed suicides, parasuicidal behaviors (attempts/gestures/threats), and missing patient events.

b. **Sentinel Events** - Sentinel events are a type of adverse event. Sentinel events, as defined by JCAHO, are unexpected occurrences involving death or serious physical or psychological injury, or risk thereof. Serious injury specifically includes loss of limb or function. Major permanent loss of function means sensory, motor, physiologic, or intellectual impairment not previously present that requires continued treatment or life-style change. The phrase "risk thereof" includes any process variation for which a recurrence would carry a significant chance of serious adverse outcomes. Sentinel events signal the need for immediate investigation and response. Some examples of sentinel events include: death resulting from a medication error or other treatment related error; suicide of a patient in a setting where they receive around-the-clock care; surgery on the wrong patient or body part regardless of the magnitude of the operation; and hemolytic transfusion reaction involving the administration of blood or blood products having major blood group incompatibilities. (Note: Events considered to be JCAHO "sentinel events" are included in the catastrophic cells of the SAC Matrix.)

c. **Close Calls** – A close call is an event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention. Such events have also been referred to as "near miss" incidents. An example of Close Calls would be: surgical or other procedure almost performed on the wrong patient due to lapses in verification of patient identification but caught at the last minute by chance. Close Calls are opportunities for learning and afford the chance to develop preventive strategies and actions. Close Calls will receive the same level of scrutiny as adverse events that result in actual injury. All Close Calls require reporting and documentation in the National Patient Safety Registry (often referred to as "the **Registry**"), however, as for adverse events, the SAC Matrix scoring process and score determines the type of review.

d. **Intentional Unsafe Acts** – Intentional unsafe acts, as they pertain to patients, are any events that result from: a criminal act; a purposefully unsafe act; an act related to alcohol or substance abuse, impaired provider/staff; or events involving alleged or suspected patient abuse of any kind. Intentional unsafe acts should be dealt with through avenues other than those defined in this handbook (i.e., Administrative Investigation (AI) or other administrative channels as determined by the Facility Director). Guidance on what to do when criminal acts are suspected is described in paragraph 5.d. Intentional acts will be entered into the National Patient Safety Registry along with the results of any review or investigation as they pertain to patient safety. (This will ensure that preventive patient safety measures, where appropriate, can be shared and/or instituted across VHA.)

e. **Root Cause Analysis (RCA)** – Root Cause Analysis is a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls. This specific type of focussed review known as a Root Cause Analysis will be the form of focussed review that is used for all adverse event or close calls requiring analysis since it further refines the implementation and increases the quality and consistency of our focussed reviews. To avoid confusion, the term Root Cause Analysis (RCA) will be used to denote this type of focussed review and will adhere to the guidelines provided in this handbook (see Appendix RCA).

NOTE: The term Root Cause Analysis needs to be used in documents so that they will be confidential under Title 38 United States Code (U.S.C.) 5705 and its implementing regulations.

RCAs have the following characteristics:

1. the review is interdisciplinary in nature with involvement of those closest to the process;

2. the analysis focuses primarily on systems and processes rather than individual performance;

3. the analysis digs deeper by asking "what" and "why" until all aspects of the process are reviewed and all contributing factors are (progressing from looking at special causes to common causes), and;

4. the analysis identifies changes that could be made in systems and processes through either redesign or development of new processes or systems that would improve performance and reduce the risk of event or close call recurrence.

To be thorough, an RCA must include:

1. a determination of the human and other factors most directly associated with the event or close call and the processes and systems related to its occurrence; (there is rarely only one underlying cause)

2. analysis of the underlying systems through a series of "why" questions to determine where redesigns might reduce risk;

3. identification of risks and their potential contributions to the event or close call, and;

4. determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist.

To be credible, an RCA must:

1. include participation by the leadership of the organization (this can range from chartering the RCA team, to direct participation on the RCA team, to participation in the determination of the corrective action plan) and by individuals most closely involved in the processes and systems under review;

2. be internally consistent (i.e., not contradict itself or leave obvious questions unanswered), and;

3. include consideration of relevant literature.

Appendix RCA provides details about RCA structure, process and outcomes.

4. Goals

The goals of the PSI Program are to prevent injuries to patients, visitors, and personnel, and to manage those injuries that do occur to minimize the negative consequences to the injured individuals. The way this will be accomplished is by taking small steps in the way we do things so that we establish the level of faith and trust in our system to let these behaviors become a true part of us. This will and should be a never-ending process. In this way a "culture of safety" can be formed. The key building blocks for accomplishing these goals are:

a. Comprehensive identification and reporting of all adverse events, Sentinel Events, and close calls (see paragraph 5).

b. Reviewing adverse events, Sentinel Events, and close calls to identify underlying causes and system changes needed to reduce the likelihood of recurrence (see paragraph 6). The determination of cause will be aimed at the system issues not directed at use as a punitive tool. The requirements for initiating a review will be determined by the priority scheme as defined by the Safety Assessment Code (Appendix SAC).

c. Disseminating patient safety alerts and lessons learned regarding effective system modifications throughout VHA (see paragraph 6) in an effective manner.

d. Prospective analysis of service delivery systems before an adverse event occurs to identify system redesigns that will reduce the likelihood of error.

5. Identification and Reporting of Adverse Events, Sentinel Events, and Close Calls

a. Each VISN will ensure that its designated facility manually or electronically reports at least the following events:

1. Adverse Events (see Definitions, paragraph 3a).

2. Sentinel Events (see Definitions, paragraph 3b).

3. Close Calls (See Definitions, paragraph 3c).

b. Facility staff will also report any unsafe conditions of which they are aware, even though the conditions have not yet resulted in an adverse event or close call. These would include potential system weaknesses that were identified through prospective hypothetical analyses ("what if" types of questions) using techniques such as failure modes and effects analysis (FMEA).

c. Adverse events, Sentinel Events, and Close Calls shall be reported within the facility to the risk manager (or other appropriately designated party) within 24 hours of their detection. The risk manager (RM) will then use the Safety Assessment Code Matrix (SAC) to determine what action is required. This action could range from reporting to the VISN, National Center for Patient Safety (NCPS), and JCAHO with associated RCA performed and corrective action plan, to a decision to do nothing at the present time due to the low priority accorded the event from its SAC score. Appendix SAC details how the SAC score is used and paragraph 6 shows the procedure that will be followed for handling events that are reported along with the associated time constraints and products required as well as to what organization reports will be made. Events affecting personnel, visitors, and groups of patients as well as individual patients are covered here as well. If a safety alert to other facilities seems needed, this should be indicated (this is covered in the Appendix RCA).

If in the course of conducting a RCA it appears that the event under consideration is the result of an Intentional Unsafe Act the RCA team will refer the event to the facility director for appropriate further consideration as is described in paragraph 3.d. above. In such a situation the RCA team will then discontinue their efforts, since the facility director will have assumed the responsibility for any further fact finding or investigation, while still maintaining the information they have already collected confidential as per Title 38 United States Code (U.S.C.) 5705. This means that members of the RCA team in question could not serve on an AI team that might be convened by the facility director to consider this particular issue.

d. If a crime is suspected to have been committed, appropriate officials should be notified as soon as possible by management (see Title 38 Code of Federal

Regulations (CFR) Sections 14.560 and 14.563, MP-1, Part I, Chapter 16 and MP-1, Pt. I, Ch. 2, subpar. 208.02). To the extent possible the surrounding area should not be disturbed so that evidence is available for review by the police and other authorities. However, care needed by the patient should always be provided as quickly as possible, regardless of its effect on the site. As required by 38 CFR Sections 14.560 and 14.563, allegations of crimes against the person or property, or other non-fraudulent criminal matters shall be referred to the Regional Counsel, who will then refer the matter to the appropriate law enforcement agency. Serious crimes (felonies or misdemeanors) committed on hospital or domiciliary grounds must be reported directly to the United States Attorney or local agent of the Federal Bureau of Investigation. Allegations of fraud, corruption or other criminal conduct involving VA programs and operations must be referred to the Office of the Inspector General. Notification should also be given to the Deputy Assistant Secretary for Security and Law Enforcement and to the VISN office. The VISN office will inform the CNO.

If a crime is suspected to have been committed, facility security and medical staff may need to assist law enforcement agencies with preserving evidence (e.g., blood alcohol levels, weapons, controlled substances). Local policies and procedures for maintaining the chain of custody of evidence apply in those instances.

e. Staff who submit close call and adverse event reports will receive feedback on the actions being taken as a result of their report. The feedback should be of a timely nature and come from the risk manager (or other appropriately designated party). Prompt feedback to reporters has been credited in other reporting systems with being one of the cornerstones that establishes trust in the system in that it demonstrates the seriousness and commitment on the part of the system to the importance of the reporting effort. The bottom line here is for the reporters to be made acutely aware that their effort of reporting was not just a paperwork drill. The nature of this feedback can range from a simple acknowledgement that the event is under consideration, to providing information as to the corrective action that is planned or has been accomplished.

f. Each VISN and facility will adopt strategies to motivate and facilitate staff identification and reporting of adverse events and close calls, even when staff errors contributed to the event. Emphasis should be placed on the value of close calls in identifying needed system redesigns. Identification and reporting of adverse events and close calls, including those that result from practitioner error, need to be a routine part of everyday practice. Employees need to understand that human errors are commonly due to systems type problems. They especially need to understand that the most conscientious, knowledgeable, and competent professionals can make errors.

g. The National Patient Safety Registry will be used to track and monitor reported events. The field will accomplish initial entry of data into the Registry. This is so the accuracy of the data recorded will be as high as possible and avoids translation and transcription errors that could occur if this function was accomplished at some other level in the organization. Further, it is intended that the data entry should occur at the facility level, where technically possible, for the same reasons as described above.

6. Review and Analysis of Reported Events

a. A procedure has been worked out so that the review and analysis system for handling reports proceeds in an understandable manner and takes into account the various requirements of the VHA and accrediting organizations. The process is schematically outlined in Figure 1 below:

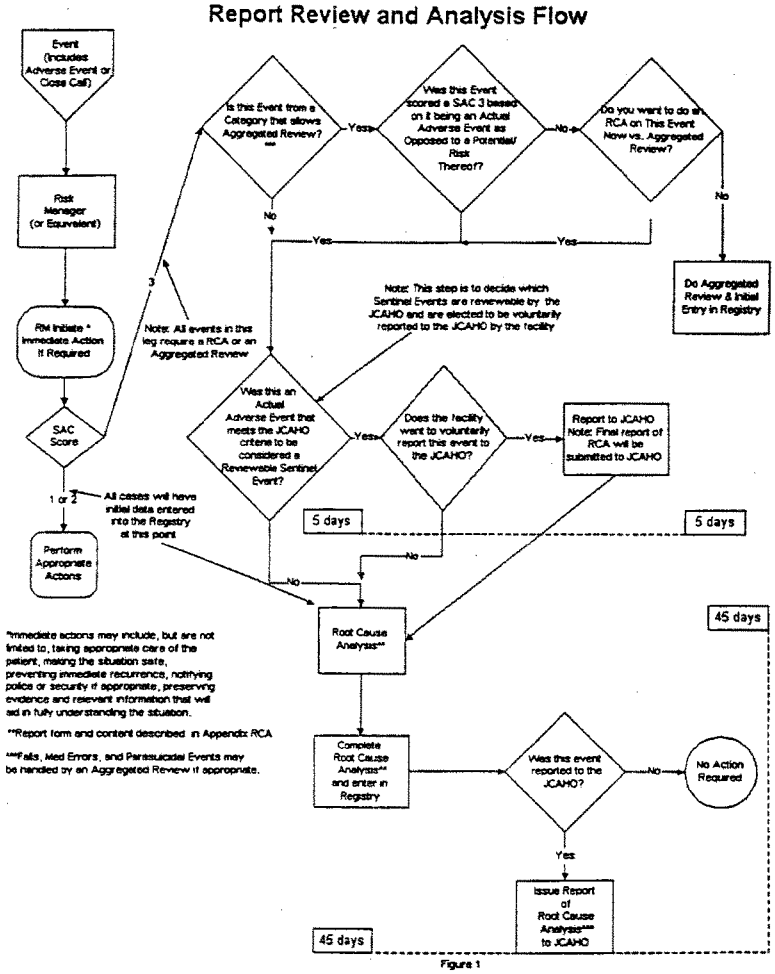


Figure 1

The following description will 'walk you through' the chart above. The first step taken by the RM after any required immediate action is to assign a SAC score (see Appendix SAC) that then defines the further actions that are necessary.

Events receiving a score of 2 or 1 will be acted on as thought appropriate by the facility. You will need to either eliminate, control, or accept the risks associated with these events. These actions can range from performing an RCA to no further action required.

All events receiving a SAC score of 3 will receive either a traditional RCA or an Aggregated Review as described below and the initial report of the event will be entered into the Registry where it can be accessed by the VISN, CNO, and the NCPS.

A quarterly Aggregated Review may be used for three types of events. The three types of events are: falls; medication errors, and; parasuicidal behavior (see Appendix Aggregated Reviews). The use of aggregated analysis serves two important purposes. First, greater utility of the analysis (i.e., trends or patterns not noticeable in individual case analysis are more likely to show up as the number of cases increases). Second, it makes wise use of the RCA team's time and expertise. The NCPS will use this information to compare to other data it has and determine if any immediate action as far as the issuance of alerts, etc. is indicated. It must be noted that any event may be subjected to a traditional RCA even though it is in a category that is permitted to use the aggregated approach if this course of action is thought to be appropriate. Further, events that are in those categories that are eligible for Aggregated Review and have received a SAC score of 3 based on what has occurred rather than a potential/risk thereof will have a RCA performed and not be allowed to use the aggregated approach.

If the event in question is an actual adverse event meeting the JCAHO definition of Reviewable Sentinel Event the facility will then make the determination if they will report it within 5 calendar days of occurrence to the JCAHO (this may entail consultation with other entities, such as the VISN, as is defined by local policy) as is indicated by the first dotted line in the chart. In either case, the event receives an RCA and results are reported to the Registry and if previously reported to the JCAHO, to them as well. The report of the outcome of the RCA will be completed within 45 calendar days and forwarded as described above.

It is worthwhile noting that only two reports might result, that is the one before the RCA is performed and that after the RCA is completed. This was specified so as to reduce the burden on the frontline folks to that which was already required of them to prioritize (SAC score) and do their RCA.

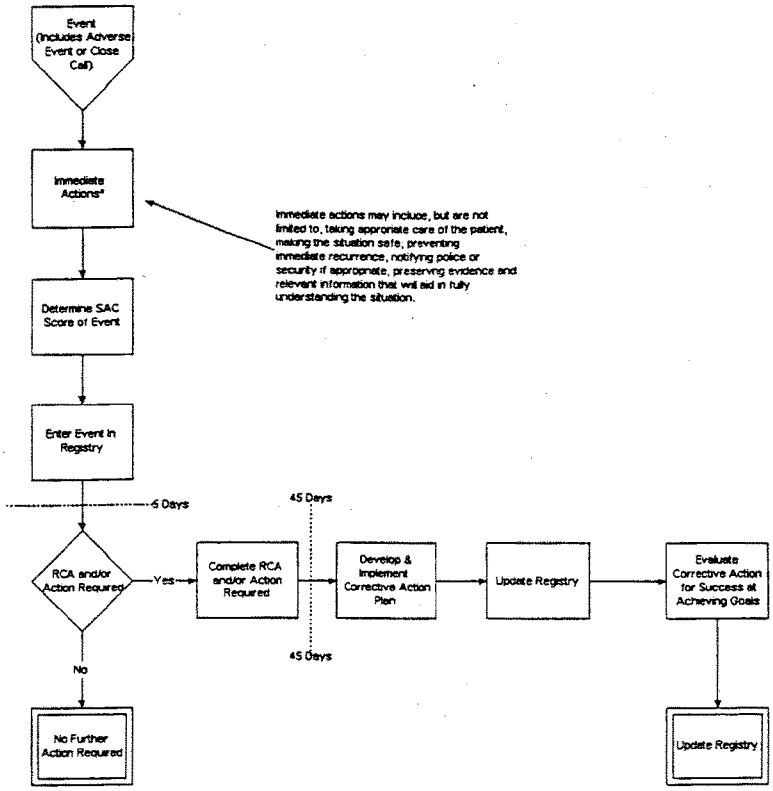
To summarize, facilities have the option to report to JCAHO as explained in JCAHO policy. The RCA report delineated in Appendix RCA will be used and will

be retained by the facility even after the results have been entered into the Registry so that they can be made available for future review as required.

The point where the real benefit of this entire process will be realized is after the RCA is completed and the corrective actions that can be taken to prevent the future occurrence of similar events are defined and implemented. These corrective actions will fall into the categories of eliminate, control, or accept and the rationale for selecting one approach over another should be documented. Once implemented, a plan for evaluating the effectiveness of the implemented change must be enacted to insure that this change has the desired effect and the subsequent results communicated to the VISN and NCPS (see Figure 2) through entry in the Registry or other appropriate means.

Figure 2

Overview of Work Flow for Event Reporting and Follow-up



As noted above, all events will be entered into the Registry. In this way all events reported will be captured in the Registry even if they have SAC scores less than 3 while remembering that 3's will receive RCA's as described above. Accordingly, the opportunity will then exist to better understand the system and appropriately focus our attentions in the future.

b. The NCPS will be responsible for disseminating the lessons learned and alerts from the RCAs and the Registry. The NCPS will also develop methods that the field may find advantageous to implement based on this and other information.

c. The NCPS will chair the PSI Oversight Committee (PSIOC) which will be comprised, at a minimum, of a representative of Office of Quality and Performance (OQP), Office of Medical Inspector (OMI), Chief Network Officer (CNO), and Patient Care Services (PCS). This committee will meet monthly to:

1. Review data from the registry for trends.
2. Review RCAs and AIs of selected cases from the Registry where indicated to guide future policy development.
3. Review selected process improvements for general applicability and disposition.
4. Recommend topics that deserve further examination or issues that require further action. This could include recommendation of quality or performance measures to address issues that have been identified.
5. Assign follow-up responsibility for issues identified in activities (1) through (4). ***Note***: *The input of subject matter experts will be obtained as needed.*

d. The Office of Medical Inspector shall monitor RCAs and AIs to assess their adequacy and to identify problems with processes of care which warrant attention. The OMI may conduct reviews and site visits at the request of the Secretary of Veterans Affairs, the Under Secretary for Health, the Deputy Under Secretary for Health, the Inspector General, veterans and their families, the VISNs and medical facilities, and other stakeholders, such as Congress and Veterans Service Organizations. The OMI also may conduct reviews and site visits based on its own judgement.

7. INFORMING PATIENTS ABOUT ADVERSE EVENTS

a. Background Information

1. VHA is obligated to inform patients and their families, only as authorized by applicable confidentiality statutes, about injuries resulting from adverse events and the options available to them. There is also evidence that patients desire acknowledgment of errors from their caregivers and that doing so reduces the likelihood that patients will take legal or administrative action. Any information disclosed must not come from documents and data protected by Title 38, United States Code (U.S.C.), Section 5705. Also, in addition to the restrictions dictated by the Privacy Act, certain information generally cannot be revealed even after a patient's death under 38 U.S.C. Section 7332,

and includes information related to the patient's treatment for substance abuse (including alcohol), sickle cell anemia disease, and HIV status.) Furthermore, the patient's name and home address cannot be released under certain circumstances to individuals other than the patient. Questions about release of information to the patient and the patient's family should be referred to the facility's Health Information Service, who may consult with the Regional Counsel, where applicable.

2. The two primary options available to injured patients or their survivors are claims for compensation under 38 U.S.C., Chapter 11, Section 1151, and tort claims under the Federal Tort Claims Act, Title 28 U.S.C., sections 1346 (b), 2671-2680.

   (a) Claims under 38 U.S.C. Section can result in payment of monthly benefits for additional disability or death incurred as the result of VHA facility care, medical or surgical treatment or examination, if the disability or death was proximately caused by negligence or an unforeseen event. Claims under section 1151 provide for the payment of a monthly benefit based on the percentage of disability and eligibility for VA medical care. Claims for 1151 benefits are processed by VBA Regional Offices.

   (b) Tort claims may result in a settlement by Regional Counsels, General Counsel, United States Attorney, or in a judgement if a Federal court determines that negligence by medical practitioners caused injury or death (and jurisdictional requirements are met). The claimant frequently receives money in a lump sum payment, but structured settlements, which can include annuities, medical trusts, future payments, and reversionary interests, are also used where appropriate. Tort claims can result in monetary awards for pain and suffering, which are not necessarily included in veterans benefits. Tort settlements or judgements can also be used to provide for family members in ways that veterans benefits statutes do not allow. However, an attorney is usually retained, and attorney fees capped at 20 (administrative settlements) to 25 (litigation) percent of the damages reduce the award the veteran or survivors receive. Tort claims are processed by the Regional Counsels.

   (c) Veterans and survivors may pursue both section 1151 and tort claims. However, if both claims are successful, 38 U.S.C. Section 1151 benefits will be offset until the amount that would

have been paid equals the amount of the tort claim settlement or judgement.

b. Communication with Patients Regarding Adverse Events

1. VISNs will ensure that their facilities have a process in place to promptly inform patients and their families, consistent with the legal requirements and restrictions as stated in paragraph 7.a. above, about pertinent clinical facts associated with injuries resulting from adverse events, assuring them that measures have been taken to maintain life and minimize disability and discomfort. Typically the attending physician or designated member of the treatment team will be the ones to communicate with the patients or family initially.

2. VISNs and facilities will ensure that their staff provide appropriate and timely communication with patients and their families regarding adverse events that involve potential organizational liability. Potential organizational liability should be assessed based on discussions with practitioners and the Regional Counsel. The patients and their families shall be advised of appropriate remedial options. These options should include locally available interventions (e.g., arranging for second opinions, expediting clinical consultations, inpatient admission) and referral of patients to the 38 U.S.C. Section 1151 claims process and the tort claims process.

3. One mechanism to facilitate such communication is a standing PSI group, e.g., the Chief of Staff or designee, Regional Counsel, Veteran's Benefit Counselor, patient representative, and PSI staff, that assesses liability issues and coordinates conferences with patients and families. To provide prompt responses, the group needs to be able to meet on short notice. Another approach is to have PSI staff assume these responsibilities with support and consultation from facility management and Regional Counsel.

4. A collaborative relationship between Regional Counsel and VA medical center staff is necessary to ensure that appropriate and timely communication with patients occurs. Each VISN should ensure that their staffs develop an understanding with its Regional Counsel regarding the procedures for obtaining Regional Counsel input prior to discussing an adverse event with a patient.

8. TORT CLAIMS

a. Each facility shall ensure that its staff conduct peer reviews of all new tort claims and share the findings with their Regional Counsel.

b. State licensing board and National Practitioner Data Bank issues will be coordinated with the office of the Director of Medical/Legal Affairs.

Appendix Close Call

Close Call System Definitions

What is a Close Call?

1. A close call is an event or situation that could have resulted in an accident, injury or illness, but did not. Close calls can involve patients, staff or visitors. Close calls can occur in patient care settings and anywhere else in a VA facility.

2. We have all experienced close calls on the job. A few examples are listed below.

> A nurse almost gives an overdose of insulin, but recognizes and prevents the error when double-checking the order. (During the double check, they realize that they had confused the "U", for units, with a "0".)
>
> An environmental management employee notices a jug of industrial strength cleaner mistakenly left in the shower stall on a locked psychiatric unit. They return it to proper storage before any patient can use it inappropriately.
>
> On the way to the parking lot, a motor pool employee notices that a barricade, preventing anyone from using a sidewalk under repair, has fallen down and been shoved aside. The employee replaces the barricade and then notifies engineering service of the hazardous situation before anyone trips and falls.

What is not a Close Call?

1. There are a few events or situations that are not close calls. These events or situations are handled through administrative review or investigation. These excluded events or situations are:

> Intentionally unsafe acts
>
> Criminal acts
>
> Acts related to alcohol or substance abuse, impaired provider/staff
>
> Events involving alleged or sustained patient abuse

Appendix JCAHO

THE JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS' (JCAHO) DEFINITION OF REVIEWABLE SENTINEL EVENTS THAT MAY BE REPORTED TO JCAHO

The following criteria define the subset of sentinel events that are voluntary reportable, at the facility's discretion to the Joint Commission. Only those sentinel events that affect recipients of care (patients, clients, and residents) and that meet the following criteria fall into this category:

1. The event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition, [1,2] or

2. The event is one of the following (even if the outcome was not death or major permanent loss of function):

a. Suicide of a patient in a setting where the patient receives around-the-clock care (e.g., hospital, residential treatment center, crisis stabilization center).

b. Infant abduction or discharge to the wrong family.

c. Rape.[3]

d. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities.

e. Surgery on the wrong patient or wrong body part. [4]

[1] A distinction is made between an adverse outcome that is related to the natural course of the patient's illness or underlying condition (not reviewable under the Sentinel Event Policy) and a death or major permanent loss of function that is associated with the treatment, or lack of treatment, of that condition (reviewable).

[2] "Major permanent loss of function" means sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment or life-style change. When "major permanent loss of function" cannot be immediately determined, applicability of this policy is not established until either the patient is discharged with continued major loss of function, or 2 weeks have elapsed with persistent major loss of function, whichever occurs first.

[3] The determination of "rape" is to be based on the healthcare organization's definition, consistent with applicable law and regulation. An allegation of rape is not reviewable under the policy. Applicability of the policy is established when a determination is made that a rape has occurred.

[4] All events of surgery on the wrong patient or wrong body part are reviewable under the policy, regardless of the magnitude of the procedure.

Note: As JCAHO policies are dynamic, it is important to be sure that the most recent JCAHO Sentinel Event Policies and definitions are used in making any determination.

DRAFT – Not For General Distribution

Appendix Aggregated Reviews

Aggregated Reviews
Falls, Medication Errors and Parasuicidal Behavior

Background: Quarterly Aggregated Reviews, completed within 45 days of the end of the quarter and conducted by a chartered RCA Teams, may be used for three types of reported events or close calls (actual SAC 1s/2s and close call SAC 3s). All actual SAC 3s require individual RCAs. The three types of aggregated reviews are: falls; medication errors, and; parasuicidal behaviors.

The use of Aggregated Reviews serves two important purposes. First, greater utility of the analysis (i.e., trends or patterns not noticeable in individual case analysis are more likely to show up as the number of cases increases). Second, it makes wise use of the RCA Team's time and expertise.

Of course, a facility may elect to perform an individual RCA rather than an Aggregated Review on any of these three types of adverse events or close calls that they think merits that attention, regardless of the actual SAC score.

A tailored real-time minimum data set (Aggregated Review Log) will be compiled for falls, medication errors and parasuicidal behaviors by designated staff in follow-up to reported events or close calls, during each quarter. Capturing this data may require medical record review, medication administration record review, and brief discussion with staff members most knowledgeable about the events or close calls. The Aggregated Review Logs will be provided to the designated RCA Teams as soon as they are convened, and will serve as their initial data source. (By using these logs, the RCA Teams may not routinely need to retrospectively consult individual patient profiles or individual medical records.)

It is anticipated that by utilizing this aggregated approach and building the reviews over succeeding quarters, common themes may be more readily identified and the effectiveness of actions taken to prevent these events or close calls from happening again may be more easily evaluated.

Descriptions of each Aggregated Review Log are provided below, and copies of the Logs are attached to this Appendix.

Falls: Falls are defined according to local/facility definition.

An individual RCA will be performed for any reported inpatient or outpatient fall occurring on facility property that results in an actual SAC 3, for all enrolled patients.

Reported falls and close calls on facility property (actual SAC 1s/2s and close

call SAC 3s) involving enrolled patients will be included in an Aggregated Review on a quarterly basis (completed by the RCA Team within 45 days after the end of the quarter). These Aggregated Reviews will be entered in the Registry.

The following elements are included in the Falls Aggregated Review Log:

Case (1 ... X)

ID# (First Initial, Last Initial, last 4 SSN)

Age

Sex

Event (Day, Date, Time)

OPT or INPT/Unit (designation of inpatient or outpatient status at time of event, and if inpatient, unit where the patient was assigned at the time of the event)

Functional & Cognitive Factors (a listing of factors related to falls, requires a "yes"/"no" response for all applicable items: prior fall; designation as "high risk" for falls; needs assistance with ADLs mobility, transfer, toileting, dressing, eating; gait or balance limitations; incontinent; confused/memory limitations; related medical conditions; medication effect, and; other)

Assistive Devices (a listing of devices related to falls, requires a "yes"/"no" response for all applicable items: cane; crutches; transfer device; walker; wheelchair; bathing device; mechanical lift; eye glasses; hearing aid, and; other)

Communication Issues (a short list of areas where communication or information exchange can break down, requires a "yes"/"no" response for all applicable items: staff to staff; staff to patient, and; staff to family/other)

Environmental Factors (a listing of physical plant issues related to falls, requires a "yes"/"no" response for all applicable items: use of restraints; use of protective devices; inadequate footwear; bed siderails; floor condition; obstacles; fall while the patient was reaching for a needed item; inadequate patient or family/other education; unfamiliarity with the environment; inadequate lighting, and; other)

What Happened & Treatment Plan Changes (free narrative)

Comments (free narrative)

Medication Errors: Medication errors are defined according to local/facility

definition.

An individual RCA will be performed for any reported inpatient or outpatient medication error that results in an actual SAC 3, for all enrolled patients.

Reported medication errors or close calls (actual SAC 1s/2s and close call SAC 3s) involving enrolled patients will be included in an Aggregated Review on a quarterly basis (completed by the RCA Team within 45 days after the end of the quarter). These Aggregated Reviews will be entered in the Registry.

The following elements are included in the Medication Aggregated Review Log:

Case (1 ... X)

ID# (First Initial, Last Initial, last 4 SSN)

Age

Sex

Event (Day, Date, Time)

OPT or INPT/Unit (designation of inpatient or outpatient status at time of event, and if inpatient, unit where the patient was assigned at the time of the event)

Processes Related to Event (a listing of key steps in the medication process, requires a "yes"/"no" response for all applicable items: ordering; transcribing; dispensing; administering, and; documenting)

What Happened? (a listing of medication errors, requires a "yes"/"no" response for all applicable items: medication given despite known allergy; omission; overdose; incorrect patient identification; incorrect medication identification; incorrect dose; incorrect route; incorrect schedule, and; equipment failure)

Medication (name/dose/route/schedule for the correct medication, and, the actual/close call medication)

Treatment Plan Changes (free narrative)

Comments (free narrative)

Parasuicidal Behaviors: There are two primary categories of suicidal events: completed suicides, and; parasuicidal events (i.e., any suicidal behavior with or without physical injury - - short of death - - including the full range of known or reported attempts, gestures and threats).

An individual RCA will be performed for any completed inpatient suicide (at the time it occurs) and for any completed outpatient suicide (at the time of facility notification) for all enrolled patients. In other words, all actual known suicides of enrolled patients will receive a RCA. And, all actual known suicides of enrolled patients will be reported in the Registry.

All reported parasuicidal events or close calls (actual SAC 1s/2s and close call SAC 3s) involving enrolled patients will be included in an Aggregated Review on a quarterly basis (completed by the RCA Team within 45 days after the end of the quarter). These Aggregated Reviews will be entered in the Registry.

The following elements are included in the Parasuicidal Aggregated Review Log:

Case (1 ... X)

ID# (First initial, Last initial, last 4 SSN)

Age

Sex

Event (Day, Date, Time)

OPT or INPT/Unit (designation of inpatient or outpatient status at the time of event, and if inpatient, unit where the patient was assigned at the time of the event)

Date of Last OPT TX (date of most recent prior outpatient treatment, this does not include an appointment that was scheduled but was a "no show")

Diagnoses (a listing of current/active diagnoses)

Tx Team (a short list of treatment team options, for providers that were assigned to the patient at the time of the event, requires a "yes"/"no" response for all applicable items: mental health/psychiatry; specialty/sub-specialty, and; primary care)

What Happened? (free narrative)

Family & Other Supports (free narrative)

Treatment Plan Changes (free narrative)

Comments (free narrative)

Safety Assessment Code (SAC) Matrix Appendix SAC

Severity Categories

Key factors for the severity categories are: extent of injury; length of stay; level of care required for remedy, and; actual or estimated physical plant costs. These four categories apply to actual adverse events and potential events (close calls).
For **actual adverse events**, assign severity based on the patient's actual condition.

If the event is a **close call**, assign severity based on the most likely "worst case", systems level scenario. (For example, if you entered a patient's room before they were able to complete a lethal suicide attempt, the event is catastrophic, because the most likely "worst case" is suicide.)

Catastrophic	Major
Patients with Actual or Potential: Death or major permanent loss of function (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying condition (i.e., acts of commission or omission). Suicide (inpatient or outpatient) Rape Hemolytic transfusion reaction Surgery/Procedure on the wrong patient or wrong body part Infant abduction or infant discharge to the wrong family Death or major permanent loss of function that is a **direct result** of injuries sustained in a fall; **or associated with** an unauthorized departure from an around-the-clock treatment setting; **or the result** of an assault or other crime **Visitors and Staff** *Death; **or** Hospitalization of 3 or more (includes outpatients)	**Patients with Actual or Potential:** Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying conditions (i.e., acts of commission or omission). Disfigurement Surgical intervention required Increased length of stay of more than 3 patients Increased level of care for more than 3 patients **Visitors** More than 3 visitors requiring evaluation and treatment **Staff** More than 3 lost time or restricted duty injuries or illnesses **Equipment or facility** **Damage more than $100,000
Moderate	**Minor**
Patients with Actual or Potential: Increased length of stay for up to three patients; **or** Increased level of care for up to three patients. **Visitors** Evaluation and treatment for up to three visitors **Staff** Less than three lost time or restricted duty injuries or illnesses **Equipment or facility** Damage more than $10,000 but less than $100,000	**Patients with Actual or Potential:** No increased length of stay or increased level of care **Visitors** Evaluated and no treatment required **or** refused treatment **Staff** No lost time or restricted duty injuries or illnesses **Equipment or facility** Damage less than $10,000

Safety Assessment Code (SAC) Matrix Appendix SAC

Probability Categories

Like the severity categories, the probability categories apply to actual adverse events and close calls.

In order to assign a probability rating for an adverse event or close call, it is ideal to know often it occurs at your facility. Sometimes, the data will be easily available because it is routinely tracked (e.g., falls with injury, medication errors, etc.). Sometimes, getting a feel for the probability of events which are not routinely tracked will mean asking for a quick or informal opinion from staff most familiar with those events. Sometimes it will have to be your best educated guess.

Frequent – Likely to occur immediately or within a short period of time (may happen several times in 1 year).
Occasional – Probably will occur in time (may happen several times in 1 to 2 years).
Uncommon – Possible to occur in time (may happen sometime in 2 to 5 years).
Remote – Unlikely to occur (may happen sometime in 5 to 30 years).

How the SAC Matrix Looks

Severity & Probability	Catastrophic	Major	Moderate	Minor
Frequent	3	3	2	1
Occasional	3	2	1	1
Uncommon	3	2	1	1
Remote	3	2	1	1

How the SAC Matrix Works

When you pair a severity category with a probability category for either an actual event or close call, you will get a ranked matrix score (3 = highest risk, 2 = intermediate risk, 1 = lowest risk). These ranks, or Safety Assessment Codes (SACs) can then be used for doing comparative analysis, and, for deciding who needs to be notified about the event.

Notes

1. All known reporters of events, regardless of SAC score (1,2, or 3), will receive appropriate and timely feedback.

2. The Risk Manager (or designee) will refer adverse events or close calls related solely to staff, visitors or equipment/facility damage to relevant facility experts or services on a timely basis, for assessment and resolution of those situations.

3. A quarterly Aggregated Root Cause Analysis may be used for three types of calls (this includes all events or close calls other than actual SAC 3s, since all actual SAC 3s require an individual RCA). These three types are: falls; medication errors, and; parasuicidal behavior. The use of aggregated analysis serves two important purposes. First, greater utility of the analysis (i.e., trends or patterns not noticeable in individual case analysis are more likely to show up as the number of cases increases). Second, it makes wise use of the RCA team's time and expertise.

Of course, the facility may elect to perform an individual RCA rather than Aggregated Review on any adverse event or close call that they think merits that attention, regardless of the SAC score.

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*29 CFR 1960.70 requires each federal agency to notify OSHA within 8 hours of a work-related incident which results in the death of an employee or the in-patient hospitalization of 3 or more employees.

**The Safe Medical Devices Act of 1990 requires reporting of all incidents in which a medical device may have caused or contributed to the death, serious injury, or serious illness of a patient or another individual.

ATTACHMENT 2

— National Patient Safety Partnership —

Statement Regarding

Its Initiative to

Reduce Preventable Adverse Drug Events

May 12, 1999

Various studies have shown that adverse drug experiences or events affect between 2 and 35 percent of hospitalized patients. Preventable adverse drug events represent a significant subset of these, if not a large majority of them. Little is known about the incidence of adverse drug events in outpatients, although they have been shown to be a significant cause of hospitalization and, consequently, increased health care costs. Indeed, adverse drug events are a cause of increased healthcare costs in all care settings.

For this initiative, a preventable adverse drug event (PDE)[1] is defined as an event that can be anticipated and forestalled and that will cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding or dispensing; distribution; administration; education; monitoring; and use.[2] Overall, PDEs are a serious public health and medical care problem because of the large number of drugs, doses, and drug treatment regimens currently available and the many changes in the manner that healthcare is provided today.

The National Patient Safety Partnership is a public-private partnership dedicated to improving healthcare in general and patient safety in particular by reducing adverse events and untoward outcomes of healthcare or healthcare-related processes. The members of the Partnership believe there are significant patient safety improvements that can be made through the prevention of avoidable adverse events associated with the prescribing, dispensing and administering of medications.

The members of the National Patient Safety Partnership believe that prevention of medication-related adverse events will be maximized when the outcomes of specific actions for improvement can be reliably predicted based on a strong body of evidence. It realizes that the current evidence base needs strengthening and believes that iterative improvement accompanied by outcomes analysis can advance the state of the science toward that goal. Based on current knowledge, the Partnership has identified a number of "best practices" or "model practices" that could substantially reduce the potential for occurrence of PDEs, and the Partnership calls on healthcare consumers, patient advocacy groups, the pharmaceutical industry, healthcare practitioners and healthcare organizations to make a commitment to adopt the practices listed below and to work together to implement them, as well as to develop additional ways to reduce PDEs.

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[1] The differences between a PDE and the Food and Drug Administration's (FDA) broader statutory definition of an adverse drug experience or event should be recognized. The National Patient Safety Partnership's principal interest is advancing practices that prevent adverse events whereas the FDA's principal interest is understanding drug/drug interactions and the biologic activity of drugs so they are fully labeled. At 21 CFR section 314.80 FDA defines an adverse drug experience as any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action.

[2] Adapted from the USP Quality Review – Definition of Medication Errors

Model Practices to Prevent Adverse Drug Events[3]

Current Best Practices For Patients/Consumers

The members of the National Patient Safety Partnership believe that all patients should be actively involved in their care and decisions concerning their care. There are many actions that patients can take, but the following two are stressed as ways to ensure that medication-related information is exchanged in a way that increases the probability of safe care.

1. Patients (or their personal advocates) should always inform their physician or other healthcare practitioner of all medications they are taking (NB: This includes prescription medication, over-the-counter medication and dietary supplements.) as well as about any and all allergies or previous adverse drug experiences they have experienced before accepting any new medication. Patients should not assume that information previously provided has been communicated or has been considered prior to a medication being prescribed or administered.

2. Patients (or their personal advocates) should request information about medications in terms that they can understand, both at the time the medication(s) is/are being prescribed and when they are received. This applies to prescription and over-the-counter medications. Patients should ask for information about the intended use or purpose of the drug, possible drug-drug interactions, potential hazards associated with taking several medicines (e.g., more than 3 drugs at the same time), and about changes in the appearance of any medications they have been taking (such as when a prescription refill is a different color from what had previously been taken). Before accepting or receiving a prescription, the patient should always ask the following questions:

   - Is this the drug my doctor (or other health care provider) ordered? What is the trade and generic name of the medication?
   - What is the drug for? What is it supposed to do?
   - How and when am I supposed to take it and for how long?
   - What are the likely side effects? What do I do if they occur?
   - Is this new medication safe to take with other over-the-counter or prescription medications, or dietary supplements, that I am already taking? What food, drink, activities, dietary supplements or other medication should be avoided while taking this medication?

In addition, at the time prescription medications are received from pharmacies, patients should ask if the drug they are receiving is the one their doctor or other health care provider ordered and ask that both the trade and generic names be listed on the prescription label.

[3] The ordering of these "Best Practices" is not intended to suggest relative importance. The "Best Practices" are identified on the basis of eight techniques or criteria that have been shown to be important in reducing errors in general and medication errors in particular. The eight criteria are 1) ensuring timely access to information; 2) standardization; 3) simplification; 4) reduced reliance on memory; 5) reduced reliance on practitioner vigilance; 6) broad application; 7) cost effectiveness of the intervention; and 8) established success of the intervention. The 16 practices are used in the Institute for Healthcare Improvement Breakthrough Series.

Current Best Practices For Providing Organizations and Practitioners

The members of the National Patient Safety Partnership believe that healthcare organizations and practitioners are committed to safeguarding patients and call upon both organizations and individual practitioners to further advance the following practices and to support and advocate for these actions in areas and organizations in which they are not utilized.

3. Educate patients, family members and other caregivers about all medications (both prescription and over-the-counter, including dietary supplements) that are used. (Emphasis should be placed on the hazards of polypharmacy, drug-drug interactions and possible adverse effects.) Patients and caregivers should be encouraged to ask for information about all medications and dietary supplements, especially when new medications are prescribed or changes in medications are made.

4. Prominently display critical patient information, such as drug allergies and medication regimens, on every patient record.

5. Emphasize the need for dose adjustment in children and elderly patients. In some elderly patients, a reduction in dose may be required because of age-related changes in body mass and organ function.

6. Limit accessibility to and control the use of highly toxic or other high-hazard drugs such as potassium chloride or concentrated epinephrine.

7. Insist on the development and use of protocols for highly toxic or hazardous drugs or those with a narrow therapeutic range. (Computerized drug order entry systems can be especially important in facilitating this with alerts, restrictions or suggestions for safer substitutes.)

8. Computerize drug order entry whenever possible. If computerized drug order entry is not feasible, then use pre-printed order forms for drugs in inpatient settings and, where appropriate, in ambulatory care settings.

9. Utilize pharmacy-based intravenous (IV) admixture programs.

10. Avoid the use of abbreviations whenever possible; if abbreviations are used, they should be standardized throughout the organization and their use minimized.

11. Standardize approaches and processes for drug storage locations, internal packaging or labeling and delivery, and require use of the standardized approaches and processes.

12. Use unit dose drug distribution systems for inpatient care; also use such systems for outpatient care, where appropriate.

Current Best Practices For Purchasers

The members of the National Patient Safety Partnership believe that while most of these practices advocated in this initiative would cost little or nothing to implement, they do recognize that an investment will be required for some and call upon healthcare organizations and the pharmaceutical industry to make any needed investment in the interest of patient safety.

13. Require machine-readable labeling, such as a barcoding system, complete with pertinent information such as lot number and expiration date.

14. Preferentially purchase products that have labels with name of drug, concentration and warnings prominently displayed and that otherwise incorporate human factors evaluation into naming, labeling and packaging processes. (For example, the use of large type or contrasting colors to avoid look-alike packaging or unheeded warnings.)

15. Preferentially purchase and utilize "unit of use" packaging in inpatient settings; also use such packaging in outpatient (ambulatory care) settings, where appropriate.

16. Preferentially purchase intravenous (IV) solutions with contents and concentration prominently displayed on both sides of the container.

Even Better Practices in the Future

Finally, the members of the National Patient Safety Partnership believe it is imperative that the healthcare and pharmaceutical industries launch and sustain collaborations directed toward systematic approaches to the prevention of PDEs. The Partnership challenges these industries to seek opportunities for research and to seek collaborations to identify better practices in the future, to prioritize practice interventions, and to define practices that can predictably effect improvement in terms of increased safety and cost-effectiveness. Integral to such an activity is a non-punitive culture that encourages reporting of adverse or unexpected events to relevant oversight bodies, including internal quality management systems and regulatory agencies, and that provides feedback about resulting lessons learned and system changes aimed at preventing future such events. To be truly successful these activities must be ongoing since no solution that is found to any problem can be thought of as the "solution for all time". A spirit of continual and relentless examination and reexamination will be necessary to insure that our processes and techniques are appropriate today and that they continue to evolve as necessary to be appropriate in the future as well.

ATTACHMENT 3

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 99-031

July 14, 1999

THE AVAILABILITY OF POTASSIUM CHLORIDE FOR INJECTION CONCENTRATE USP

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policy regarding the use of potassium chloride for injection concentrate USP.

2. BACKGROUND

a. In recent years, numerous reports have been published in the medical literature of adverse events and deaths caused by errors in the use of potassium chloride for injection concentrate USP. This matter has been discussed on numerous VHA Headquarters pharmacy conference calls. Many facilities have already removed potassium chloride for injection concentrate USP and other hypertonic injectables from patient care areas.

b. VHA policy requires that a pharmacy-managed IV admixture program be responsible for the labeling, preparation, and distribution of IV admixtures. Understanding that some IV admixtures may not be prepared by the Pharmacy Service, practices and policies must be in place to ensure the IV admixtures not prepared by the Pharmacy Service are compatible with the policies that govern the pharmacy-prepared IV admixtures.

3. POLICY: VHA policy regarding potassium chloride for injection concentrate USP is as follows:

a. Potassium chloride for injection concentrate USP will not be stored on any wards, intensive care units, surgical suites and similar sites as ward stock.

b. Potassium chloride for injection concentrate USP will only be utilized as part of a pharmacy-managed IV admixture program; therefore, storage of the medication will be in the pharmacy and is the responsibility of the Pharmacy Service.

c. To meet patient needs, the use of manufactured "pre-mixed" large volume solutions, including those with potassium chloride, may be used in conjunction with a pharmacy-managed IV admixture program.

4. ACTION

a. All Department of Veterans Affairs (VA) medical facilities will ensure that any potassium chloride for injection concentrate USP is removed from all wards, intensive care units, operating suites, and clinics.

b. All VA medical facilities will establish medication use policies that include guidance regarding safe handling of potassium chloride for injection concentrate USP. Additionally, these policies shall specifically state that it is VA policy not to have potassium chloride for injection concentrate USP and other hypertonic injectable solutions on the wards and similar sites, that normal or routine VA practice is for IV solutions to be mixed centrally, that cardioplegic solutions

are prepared by, or supplied by, Pharmacy Service only, and that unit dose drug distribution is required for inpatient areas.

c. At VA medical facilities that perform heart transplant and open heart surgery, cardioplegic solutions are to be prepared by, or supplied by, the Pharmacy Service.

(1) Those solutions prepared by Pharmacy Service will be hand-delivered to the operating room (OR) by Pharmacy Service. These solutions are to be clearly labeled, "For Cardioplegia Only" and contain the patient's name. They may be secured in one location in, or adjacent to, the cardiac surgery suite, i.e., the OR automatic medication dispensing machine or the locked perfusionist's cabinet. Access is to be limited to the cardiac surgeon, cardiac anesthetist and/or cardiopulmonary bypass technician (perfusionist) and the OR pharmacist.

(2) The Chief, Anesthesia Service is responsible for:

(a) Identifying the secure location in the cardiac surgery suite;

(b) Assuring that access is limited to those individuals requiring access to this highly concentrated therapeutic agent;

(c) Ascertaining that the correct solution is used in the correct patient (as in the use of blood or blood products);

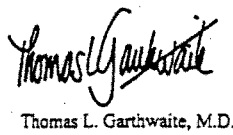
(d) Providing for the disposition of any unused cardioplegic solutions; and

(e) Developing, publishing, and maintaining a local policy that assures the accountability and safety of the drug.

5. **REFERENCE:** None.

6. **FOLLOW-UP RESPONSIBILITY:** The Chief Consultant for Pharmacy Benefits Management Strategic Healthcare Group (119) is responsible for the contents of this directive.

7. **RESCISSIONS:** Directive 98-026, is rescinded. This VHA Directive expires July 31, 2004.



Thomas L. Garthwaite, M.D.
Acting Under Secretary for Health

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ATTACHMENT 4

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 98-049

November 5, 1998

BAR CODING PATIENT WRISTBANDS

1. **PURPOSE:** This Veterans Health Administration (VHA) Directive defines policy for bar coding a patient's full social security number on the patient identification wristband.

2. **BACKGROUND:** The requirements for a Blood Product Verification function, in response to a working group review of "system" changes which would reduce blood transfusion errors in the operating room, have been developed. The group proposed that a universal identifier be bar coded onto the patient identification wristband. A revision to the Veterans Information Systems Technology Architecture (VistA) Surgery software package necessitated that as of February 1, 1998, a bar code that displays the patient's full social security number must be printed onto the patient identification wristband.

3. **POLICY:** It is VHA policy to issue to each patient on hospital admission a patient identification wristband on which there is a printed bar code displaying the patient's full social security number.

4. **ACTION**

a. All patients reporting for hospital admission or ambulatory surgery must be issued a patient identification wristband that contains the patient's full name, social security number and a bar code that displays the patient's full social security number.

b. Printers capable of generating wristband bar codes must be installed in locations that process patients for hospital admission and ambulatory surgery.

c. Additional information, e.g., ward designation, is optional. If the ward designation is used, it will refer only to the ward identification and will not reference the professional service specialty.

4. **REFERENCES:** VHA Manual M-1, Part I, Chapter 4.

5. **FOLLOW-UP RESPONSIBILITIES:** The Director, Health Administration Service (10C3), is responsible for the contents of this VHA Directive.

6. **RESCISSIONS:** VHA Directive 97-064 is rescinded. This VHA Directive will expire on November 5, 2003.

Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health

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THIS VHA DIRECTIVE EXPIRES NOVEMBER 5, 2003

ATTACHMENT 5

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 98-033

July 16, 1998

TRANSFUSIONS PERFORMED IN OPERATING ROOMS

1. PURPOSE: This Veterans Health Administration (VHA) Directive established policy for the identification process to be used in all VHA operating rooms, (inpatient and ambulatory) prior to the administration of blood or blood products.

2. BACKGROUND: VHA policy has established standard operating procedures (SOPs) to be used when transfusing blood products. These include specific visual verification by two individuals that the unit of blood or the blood product is in fact the one that has been assigned to this particular patient. The Standard Form (SF) 518, Blood or Blood Component Transfusion, documents this process. Nevertheless, there have been rare blood product transfusion related deaths in VHA Operating Rooms (OR) due to patient and/or blood product identification errors. As part of VHA's patient safety policy to provide high quality, safe, appropriate health care, this policy introduces the requirement to perform an additional independent mechanical verification of the identity of the patient and the blood product. This mechanical process utilizes the Veterans Health Information Systems Technology Architecture (VistA) software to read the bar coded identification on the blood product. This will be performed in addition to the current visual verifications. The visual identification by two individuals and this mechanical check will provide an error proof identification process.

3. POLICY: All laboratories in facilities performing surgery must have implemented and use the VistA Blood Bank Package. The identity of each unit of blood and blood products will be entered into the VistA Blood Bank files. At the time the blood product is assigned to an individual, the assignment information must also be entered into the VistA Blood Bank files. Each Veteran Integrated Service Network (VISN) will ensure that all facilities performing surgery have implemented this policy by September 1, 1998.

4. ACTION

a. All patient wristbands will be printed with the bar coded full Social Security Number (SSN) of the patient.

b. All inpatient or ambulatory surgery operating rooms in which procedures are performed which will, on some occasions, require the transfusion of blood products shall be equipped with bar code readers for direct interaction with the VistA Surgical package.

c. When a patient enters the OR, the patient's full SSN bar code on the wristband will be machine read and entered into the VistA Surgical files as a component of the surgical menu options.

d. Should the patient require blood or blood products, two members of the surgical team will visually validate that the blood product is correct for that specific patient. Specifically, they will match the name and SSN on the patient's wristband to the information on the SF 518 and match the information on the blood product to the information on the same SF 518.

THIS VHA DIRECTIVE WILL EXPIRE JULY 16, 2003

e. Upon completing the visual validation, the blood product will then have its identifying bar code mechanical scanned. If the resulting computer message indicates that the database does not have an assignment of this particular unit to this particular patient, a warning message will be displayed indicating that the staff must personally verify that the specific blood product unit is appropriate for this specific patient prior to administration.

5. **REFERENCES:** None.

6. **FOLLOW-UP RESPONSIBILITY:** Agatha Francis, Enforcement officer (115) is responsible for the contents of this directive. Questions may be directed to (202) 273-8420.

7. **RESCISSION:** This VHA Directive expires July 16, 2003.

Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health

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ATTACHMENT 6

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 99-003

February 3, 1999

ADMINISTRATIVE PRACTICES FOR ENSURING SAFE INJECTION OF RADIO-LABELED BLOOD PRODUCTS

1. PURPOSE: This directive articulates Veterans Health Administration (VHA) current policy regarding the administration of all radio-labeled blood products (e.g., Indium-111 labeled white blood cells, Technetium 99m - HMPAO labeled white blood cells, Chromium-51 labeled red blood cells, and Technetium 99m labeled red blood cells) to patients.

2. BACKGROUND: The prevalence of blood-borne diseases such as hepatitis and human immunodeficiency virus (HIV) require that specific and controlled procedures be utilized to protect patients from needless risk when blood samples are removed, tagged with radio-pharmaceuticals, and re-injected for diagnostic or research purposes.

3. POLICY: According to Title 10, Code of Federal Regulations (CFR), Parts 19, 20, 21, 30 and 35, and Department of Veterans Affairs (VA) Manual MP-2, Part XX, responsibility for developing local policies for the control and supervision of the administration of radio-labeled blood products is assigned to the VHA medical facility's constituted Radiation Safety Committee (RSC).

4. ACTION: To avoid misadministration of radio-labeled blood products and ensure safe injection practices, the following procedures are to be followed:

a. A written requisition from a physician shall be obtained for the procedure, and the physician shall verify the request on the patient's chart or computerized patient record.

b. The patient's identity shall be verified with the participation of two healthcare personnel by two of the following measures when obtaining a blood sample: by confirming the patient's name and Social Security Number (SSN), examining the wrist and/or armband, and querying the patient as to their identity by asking for spelling of their name. *NOTE: Do not merely ask if the patient is "X" and accept a "YES" response or if available; employ bar code verification.*

c. The original blood product container shall be identified with an adhesive label bearing the patient and/or recipient's full name, SSN, date, and signature of the person drawing the blood. Where and when available, bar code verification shall be utilized.

d. Prior to the administration of the prepared radio-labeled blood product, the container that is clearly labeled with an adhesive identification label, the patient's identity shall be again verified by two individuals by two different measures, including bar code verification, as appropriate. Ideally, one or both individuals who initially identified the patient should be present at the time of administration of the blood product.

THIS VHA DIRECTIVE EXPIRES FEBRUARY 3, 2004

e. A copy of VA Form 10-0130, Administration of Radio-Labeled Blood Products, is attached for local reproduction. After the initial distribution is received, additional stock may be obtained from the Forms and Publications Depot through normal channels. This form documents the preceding identification procedures and should be completed in the sequence described and remain part of the patients nuclear medicine record.

NOTE: The radio-pharmaceutical vendors may provide forms accompanying the agent. Such forms do not eliminate the need for Nuclear Regulatory Commission (NRC) records or VA Form 10-0130.

f. The performance plan for each nuclear medicine technologist shall emphasize the importance of assuring patient safety by including patient identification and verification prior to the administration of all radio-labeled blood products by requiring 100 percent compliance in the performance of this function.

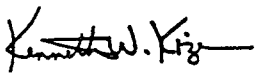
g. Each nuclear medicine technologist shall receive a copy of the policy, receive appropriate training, and sign to verify that the policy and procedure have been reviewed and are understood. Annual mandatory reviews of the policy and procedure with each employee shall be documented.

h. Any misadministration of a radio-pharmaceutical product must be reported via the facility Patient Safety Improvement Program mechanism through the Quality Management office and, if criteria are met, the NRC.

5. REFERENCES: Title 10 CFR, Subpart A, 35.1 and 35.33.

6. FOLLOW-UP RESPONSIBILITY: The Director, Nuclear Medicine and Radiation Safety Service (115B) is responsible for the contents of this directive. Questions should be directed to Deputy Director, Nuclear Medicine Service, Ann Arbor, MI at (734) 761-7885.

7. RESCISSION: Circular 10-93-005 is rescinded. This VHA directive will expire on February 3, 2004.



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ATTACHMENT 7

DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420

IL 10-98-015
In Reply Refer To: 105

July 9, 1998

UNDER SECRETARY FOR HEALTH'S INFORMATION LETTER

VHA PATIENT SAFETY IMPROVEMENT AWARDS PROGRAM

1. The Veterans Health Administration (VHA) is committed to improving healthcare quality in VHA treatment facilities and in the healthcare industry overall.

2. One important element of the Department of Veterans Affairs (VA's) healthcare quality improvement effort is its Patient Safety Improvement Initiative. This initiative includes, among other things, promulgating the Patient Safety Improvement Directive (formerly entitled the Risk Management Directive, VHA Directive 1051); establishment of the Forensic Medicine Strategic Healthcare Group; inclusion of patient safety-related measures in the Veterans Integrated Service Network (VISN) Directors performance agreements; creation of the National Patient Safety Partnership; provision of funding and other support for industrywide conferences and expert working groups on patient safety; establishment of a new health system management fellowship aimed at developing clinical leaders in healthcare quality improvement; and funding new quality of care clinical research projects.

3. Historically, the healthcare industry has not viewed itself as a high-risk industry and has not utilized the same type of rigorous, systematic review of each adverse event or untoward outcome as has been done in other high-risk industries like aviation and nuclear power. For example, there is no oversight entity for the healthcare industry like the National Transportation Safety Board that deconstructs and analyzes each airline accident to isolate the critical causative factors and to develop approaches to minimize future occurrences through technical design changes, system or process changes, or improved training. Similarly, unlike the nuclear power industry, healthcare has not widely used detailed process engineering that carefully analyzes alternative scenarios to prospectively establish the safest, most risk-free method to handle potentially hazardous situations. The aviation and nuclear power industries have controlled the risk of adverse events by focusing meticulous attention on the design of their operating systems to make it difficult for personnel to make mistakes, and easy to correct mistakes before they result in an untoward outcome. The result, contrary to public perception, is that these high-risk industries have reduced their risk of an adverse event 1,000 to 10,000 times lower than what occurs in healthcare. Clearly, one of the major challenges facing healthcare today is to become a "high reliability" industry such as aviation and nuclear power generation.

4. While various indicators suggest that the veterans healthcare system has a better record on patient safety than the healthcare industry overall, adverse events or untoward outcomes resulting from medical treatment occur too frequently at VHA facilities. VHA is committed to systematically identifying and analyzing these occurrences in an effort to reduce their frequency

to the lowest level possible. VHA is uniquely positioned in the United States to serve as a national laboratory to find solutions to patient safety problems and to lead national efforts to improve patient safety. Illustrative of VHA's unique characteristics are the fact that VHA has medical treatment facilities located in every state; is a fully integrated healthcare system; has mechanisms in place to capture the relevant patient safety data; is intimately involved with physician and other health professional training; has a widely acclaimed research program; and is open to widespread scrutiny by virtue of it being a public system.

5. As a further way of identifying the root cause(s) of adverse outcomes and developing improved processes or procedures to minimize potential patient safety risks, the VHA Patient Safety Improvement Awards Program was established.

6. The Patient Safety Improvement Awards Program is designed to increase the emphasis on this important aspect of clinical practice by financially rewarding individuals, teams, services or institutions which identify adverse events or potential patient safety situations and improve processes or practices that minimize or eliminate the risk of an untoward outcome. The awards are intended to provide an incentive to employees to develop and document improved processes and to export them as "best practices" throughout the veterans healthcare system, and the healthcare industry.

7. The VHA Patient Safety Improvement Awards Program will provide a financial reward ranging from $500 to $25,000, along with other recognition, to recipients. The exact amount of the award will depend upon the extent to which the improved process can be adopted in, or adapted to, other patient care settings and the severity of the potential hazard it reduces or eliminates. Larger rewards shall be targeted for improvements that reduce or eliminate life-threatening risks and have system-wide application. Award nominations will be accepted in the following categories:

a. Direct Care Provider Category – Individual or Team

(1) This category recognizes submissions from individuals or teams which provide direct, hands-on clinical care to patients, and which can identify and implement steps to lessen the likelihood of medical errors, adverse outcomes or anomalous clinical occurrences. It is expected that this category will generate the largest number of award submissions. Individual or team nominations in this category may include persons who provide indirect care or support.

(2) Individuals and teams are eligible for awards of up to $5,000 in this category.

b. Indirect Care and Support Activities Category - Individual or Team

(1) This category recognizes submissions from individuals or teams which provide indirect clinical support, such as pharmacists or laboratory personnel, or which provide support activities making the overall environment safer, such as safety specialists or bio-medical engineers. It may also include activities which eliminate risk from the various processes supporting the provision of patient care such as Medical Records or Information Resources Management.

(2) This is established as a separate category in order to focus attention on these indirect care and support activities as a potential source of patient safety improvements.

(3) Individuals and teams are eligible for awards up to $5,000 in this category.

c. Single Service or Product Line Category

(1) This category recognizes submissions from discrete organizational entities, such as the Medical Service or Surgical Service, or product lines, such as an Ambulatory Care Service Line, which has developed and implemented policies, procedures, or training which significantly improves the level of patient safety throughout the organizational element. The specific processes, approaches, or behaviors must be reflected in the overall operation of the service or product line.

(2) Services or product lines are eligible for awards up to $10,000 in this category.

d. Multiple Service, Facility or Institutional Category

(1) This category recognizes submissions that involve two or more services or that are from a complete entity on an organizational basis, e.g. Medical Center or Outpatient Clinic. It recognizes programs that permeate the entire operation of the facility, either through changes in culture, total process engineering, or other systematic approaches. The award submission would have to demonstrate significant, sustained improvements to patient safety over a baseline, and also demonstrate that accidents and misadventures were reported in a full, complete manner.

(2) Institutions are eligible to receive awards up to $25,000 in this category.

e. Equipment, Tools or Supplies Categories – Individual or Team

(1) This category recognizes individuals or teams which identify equipment, tools or medical supplies which eliminate risk or otherwise significantly improve patient safety. Given the widespread availability of information on such items, awards under this category must demonstrate a high level of initiative, i.e. locating and identifying a very new or little known item, or recognizing that a modification to an item currently available could make it safer.

(2) Individuals or teams are eligible for up to $2,500 in this category.

8. Individuals, teams, services or institutions are invited to submit descriptions of their safety improvements. Submit six copies of each nomination to the VHA Headquarters Management Support Office (10A2A), ATTN: Dot Brady, 810 Vermont Avenue NW, Washington, DC 20420. Nominations from field activities are to bear the endorsements of the Medical Center Director and Network Director. Submissions from VA Central Office activities are to bear the endorsement of the appropriate Chief Officer. Final approval of nominations will be made by the Office of the Under Secretary for Health. Submissions should be limited to no more than ten pages and should include at least the following items:

a. Name of nominee, address, phone number and telefax number

b. Nomination category

(1) Direct Care Provider Category - Individual or Team.

(2) Indirect Care and Support Activities Category – Individual or Team.

(3) Single Service or Product Line Category.

(4) Multiple Service, Facility or Institutional Category.

(5) Equipment, Tools or Supplies Categories - Individual or Team.

c. Nominator's name, title, address, phone number and telefax number

d. Description of the specific event or circumstance(s) that triggered the process or system improvement

e. Description of the specific and/or general safety hazard eliminated

f. Description of the approach used to develop the new process; i.e., whether based on a retrospective review of a specific incident or based on prospective review or process reengineering

g. Estimate of the potential number of untoward incidents that could be avoided if adopted throughout the system, or assessment of the applicability of the new process at other VA health care facilities and its impact on patient injuries at those facilities

h. Listing of specific equipment, supplies, or staff training required to implement the revised process or system improvement

NOTE: Photographs, flow charts or diagrams, floor plans, blueprints or other materials that help illustrate the proposal are welcome, and may be submitted with the narrative justification.

9. Proposals will be judged on the following criteria:

a. Severity of the safety hazard eliminated,

b. Potential frequency of the hazard eliminated,

c. Elegance of the solution, in terms of simplicity and investment or maintenance required,

d. Clarity of the analysis of cause of incident or misadventure, and

e. Evidence that solution was effective in reducing hazard

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10. This is an on-going program with no limit on the number of awards. Proposals which are not selected for national recognition but which have merit will be referred back to the VISN or facility for recognition at the local level.

11. For additional information, please contact Dot Brady (10A2A), Management Support Office, on 202-273-8873.

Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health

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ATTACHMENT A

ADMINISTRATION OF RADIOLABELED BLOOD PRODUCTS

Patient Identification

Patient: _____, _____ _____
Last First Middle Inital

SSN: ___-___-___

Procedure Information

Procedure: _____

Requested by:_____ M.D.

Approved by: _____ M.D.

Patient ID Verification
(check two)

___Patient spelling of full name

___Patient ID bracelet

___DOB by patient matched record

___Address by patient matches record

___SSN by patient matches record

___Patient is non-responsive
provide source of data
_____

Sample Collection

The patient named above has been correctly identified, and the blood container receiving the blood sample is correctly and clearly labeled with the patient name, SSN, procedure, and date.

Witnesses
(1)_____
Name

_____
Position

(2)_____
Name

_____
Position

_____
Date

Label Preparation

The blood sample for the procedure requested above has been correctly identified, the sample has been labeled, and the product added to a correctly and clearly labeled container.

Witnesses
(1)_____
Name

_____
Position

(2)_____
Name

_____
Position

_____
Date

Label Reinjection

The patient named above has been correctly identified, the patient identification on the labeled blood product corresponds to the patient identified and the product has been reinjected.

Witnesses
(1)_____
Name

_____
Position

(2)_____
Name

_____
Position

_____
Date

Mr. STEARNS. Dr. Bagian, we had assumed that the two of you would be together. Did you have an opening statement that is more abbreviated? We are hoping that since you are accompanying Dr. Garthwaite that the two of you would share the 5 minutes. Maybe that was not explained to you so if not, I would be very happy to offer you an opening statement but I prefer it not to be a full 5 minutes.

Mr. BAGIAN. I will try to be as brief as I can, sir, if that is okay.

Mr. STEARNS. Sure.

STATEMENT OF JAMES BAGIAN

Mr. BAGIAN. Let me just get to the response to some of the comments that were made earlier. First, we certainly think reporting is important but one has to remember the purpose for reporting as has been mentioned earlier is what you learn from the reports and then what you do to prevent the problem. The real key is at the end of the line after the report occurs, what do you do about it. A report by itself doesn't do very much.

We looked at both mandatory and voluntary reporting systems and we think both are important and we have actually a mandatory system that is in place but we have tried to encase in that system some of the qualities that we believe make it more successful, that is, that we make a very clear definition for the people that report so they understand how it will be used so they are not fearful. In fact, one of the ways we understood this better was we did cultural surveys and published these results almost a year and a half ago approximately.

One of the things we found was that people's reticence to report was not just that they fear punishment, deliberate punishment, but it was shame. When we asked people are you ashamed if other people know you have erred 49 percent said yes, they were ashamed. They strongly agreed that shame was the barrier. Whereas when we asked them on the other hand how do you view others that have erred, only 4 percent held that against them, thought less of them for that.

So it points out that it is not just through rules that say you will be held harmless from punishment, it is actually the opinion of your peers or your colleagues that has a large role. The role of close calls also was mentioned earlier. I don't think that is the term that was used but that is the event that doesn't occur where disaster or tragedy is averted at the last moment. That is something where you can learn quite a bit. In aviation they have shown that often you can get even more information that is of value from a close call because people are more likely to honestly talk about that and openly, because no disaster occurred and they actually saved the day at the last minute.

One has to be aware when you have these kind of reports, and there is data out there, in one particular series they showed in an industrial setting where they had close call reporting when they just started to institute it, they had about one close call for every 233 employees. Four years later after they had emphasized this is an important modality, they had one close call every 54 employees, almost a five fold increase.

Now if someone mentioned on the news, you could imagine the report that night could be, wow, this industry is out of control because they have had a five fold increase in close calls but in fact if you look at the outcome they were measuring which was lost time injuries. Lost time injuries were reduced by two-thirds at the same point. The emphasis here is not on the number of reports. It is on what you do with those reports and how you reduce your vulnerability. Reporting systems tell you vulnerabilities and as Mr. Smith pointed out "we want to have good statistics."

It is hard to know the denominator, that is, the incidence, but one is even too much and if you can identify a systems problem then you aggressively attack that and we put processes in place to do just that and follow through with the accountability piece at the management level as Dr. Berwick spoke about earlier. So we think the key is to understand reporting systems or vulnerabilities and then what do you do about it. That the important thing is to get closure. And while we will never have full reporting, we never will, nobody ever can, you want to do the best you can with that to make things better and we think that can be done. And I will stop there.

Mr. STEARNS. Dr. Nelson.

STATEMENT OF AUDREY NELSON

Ms. NELSON. Mr. Chairman and members of the committee, I am very pleased to appear before you to discuss one VA innovation, specifically the Patient Safety Center of Inquiry located in Tampa, Florida. I am the Director of that center and I am a nurse researcher by background. Funded for 3 years starting in March, our center focuses on safe mobility for frail elderly and persons with disabilities, two very vulnerable patient groups.

Our research area is to look at preventing patient falls and promoting safe wheelchair transfers. The unique aspects and strengths of our center I will summarize in five points. First, we have a state-of-the-art biomechanics laboratory which allows us to very carefully analyze risks related to falls and dynamics of patient wheelchair transfers. This lab was funded by the VA 2 years ago.

Second, the problems that we are studying affect many Americans, not just veterans. Therefore, we have made it a point of partnering with industry, public, government agencies, and, more importantly, consumers in solving some of these very practical problems. Third, problems that affect veterans happen more commonly with regard to falls in the community, not in hospitals, and we are making it a real point to come up with solutions that are appropriate for veterans living in the home as well as those that are in long-term care facilities or hospital-based settings.

An example is the project that we have just submitted on an evidence-based practice fall prevention program which looks at instituting a community-based fall program in all VISN 22 and VISN 8. Fourthly, our research center has taken a very practical approach not only to conducting research but also in getting that research out and into clinical practice and embedded into what people are doing in a very quick fashion. We are product-oriented. We are working at developing clinical pathways, protocols, resource

guides, new equipment and other techniques and devices that have immediate application.

Last, our center is somewhat unique in that we are looking to technology for answers. We have partnered with a variety of disciplines outside the traditional healthcare arena to help us in looking at new technology and new answers for preventing some of these injuries and issues. An example is our work in developing a safe patient room of the future which will be housed at the Museum of Science and Industry which looks at integrating patient care equipment across all of patient care activity domains in a safe fashion that would support patient independence as well.

In summary, finding these patient safety centers of inquiry have encouraged us to develop a cadre of researchers dedicated to patient safety topics. This will accelerate the pace of learning and the application of this research to practice. Thank you.

[The prepared statement of Audrey L. Nelson follows:]

PREPARED STATEMENT OF AUDREY L. NELSON, DIRECTOR, VISN 8 PATIENT SAFETY CENTER OF INQUIRY, JAMES A. HALEY VETERANS HOSPITAL

Mr. Chairmen and Members of the Committees, I am pleased to appear before you to discuss an example of a VA innovation to support patient safety, the establishment of Patient Safety Centers of Inquiry. Our center is one of the four centers that were funded for three years starting in March 1999. The VISN 8 Patient Safety Center of Inquiry focuses on **Safe Mobility for Frail Elderly and Persons with Disabilities.** Specifically, our center's focus is on efforts to prevent patient falls and promote safe wheelchair mobility. Falls are a critical problem in health care, accounting for 25% to 84% of all adverse events in hospitals.

The mission of our center is to support clinicians in providing safe patient care by designing and testing clinical innovations, technological solutions, and patient safety improvement systems. Our research efforts will target two patient populations with compromised mobility: frail elderly and persons with disabilities.

We have identified two primary goals: (1) to improve functional status and quality of life for frail elderly and persons with disabilities by addressing mobility enhancement and safety issues, and (2) to build a "culture of safety" to support clinicians in providing safe patient care and safe working environments. To address these goals, our research efforts have focused in four key areas:

- Develop and Test Clinical Innovations Related to Safe Mobility
- Design Technological Solutions Related to Safe Mobility
- Redesign Patient Safety Systems
- Facilitate Innovation Diffusion

Our center includes staff with expertise in a variety of disciplines, including: architecture, computer science, epidemiology, ergonomics, industrial design, health economics, industrial engineering, interior design, law, mechanical engineering, medical equipment manufacturing, medicine, nursing, social sciences, technology brokerage, and quality/risk management. Many of our project teams include consumers.

We are actively collaborating with partners in industry and government, as well as public and private sectors. In addition to consumers, key partners include: ARJO,® the Joint Commission on Accreditation of Health Care Organizations (JCAHO), Food and Drug Administration (FDA), Museum of Science and Industry, Paralyzed Veterans of America (PVA), University of South Florida, VA Healthcare Analysis & Information Group, and VHA Office of Quality & Performance. In the future, we plan to partner with the Agency for Healthcare Research & Quality (AHRQ), National Institutes of Health (NIH), and the National Aeronautics and Space Administration (NASA).

We have a number of projects underway to address safe mobility. A few of these projects are outlined below:

- Establish Gait and Balance Clinics to prevent falls in high risk veterans
- Evaluate Tai Chi as a strategy for Fall Prevention
- Evaluate a Tele-monitoring program to Prevent Falls for Veterans with Parkinson's Disease
- Develop a Resource Guide to Identify Alternatives to Bed Rails for Frail Elderly
- Develop a Resource Guide for Safe Patient Movement
- Develop Clinical Pathways to prevent falls

- Design an Evidence-Based Program for Fall Risk Assessment & Prevention
- Convene an Expert Panel to set Research Agenda for Patient Falls
- Evaluate Fall Risk Assessment Tools
- Develop Clinical Practice Guidelines to Preserve Upper Extremity Function in Wheel Chair Users
- Pilot test the National Patient Safety Handbook
- Identify barriers to reporting patient safety incidents/near misses
- Describe the epidemiology of falls in a variety of health care settings
- Develop a report on the direct and indirect costs of patient falls in VA
- Conduct a biomechanical assessment of safe wheelchair transfers to preserve upper extremity function in persons with spinal cord injuries
- Conduct a biomechanical assessment of the gait of individuals who repeatedly fall
- Redesign patient lifting equipment to prevent patient and caregiver injuries
- Participate on the AHRQ sponsored Expert Panel to set the Research Agenda for Health Care Environments
- Establish a Consensus Validation Conference for "Technology to Support Safe Patient Care" (hope to partner with VA's Rehabilitation Research & Development Service, NIH, AHRQ, NIOSH)
- Establish a web-based VA Safety Information Center
- Design of a safe patient care room of the future, evaluate its effectiveness in the VA healthcare environment, and display this prototype at the Museum of Science and Industry

Conclusion:

We believe that VA deployment of resources and expertise will allow us to address the significant safety challenges related to safe mobility for frail elderly and persons with disabilities. Our efforts will impact persons living in the community as well as persons in acute, long-term care, or assisted living facilities. We are working closely with consumers, as well as partners in industry, government agencies, and the private sector to provide practical solutions to patient safety problems. We will work with VA's National Center for Patient Safety to disseminate these innovations throughout VHA, the larger health care arena, and to the general public. We appreciate your support of these efforts, and would be delighted to share our progress in the future.

Mr. STEARNS. Dr. Heinrich, welcome. Just pull that microphone right close to you. Thank you.

STATEMENT OF JANET HEINRICH

Ms. HEINRICH. I am pleased to have the opportunity to testify as you consider adverse medical events in our healthcare system. Adverse events have been receiving considerable attention with the report of the Institute of Medicine "To Err Is Human". Efforts to identify adverse events and evaluate the causes are important strategies to reduce harm to patients. Recent GAO reports have considered a range of surveillance systems for medical products. These studies have implications for the design of surveillance systems to detect adverse events and medical errors.

First, while adverse events are recognized as a serious problem, the full magnitude of the threat to the health of the American public is not known. The best information we have on the incidence of adverse events of all types comes from the two studies that have been mentioned, the first, from the sample of medical charts in New York, and the second in Colorado and Utah. That is where the widely cited estimate of 44,000 to 98,000 deaths per year attributed just to medical errors comes from.

And they do extrapolate the numbers from these studies to the rest of the country, not taking into account the variation in clinical practice patterns. There is even less information known about adverse events in ambulatory settings or other health care settings. Second, the task of gathering valid information about adverse events is an extremely difficult one. All systems that rely on

healthcare providers to take the initiative to make a report, in other words, both passive and spontaneous reporting systems, have serious limitations and this is true whether or not providers are required to report these events.

In our review of the research on adverse drug events, we learned what is known about the strengths and limitations of these reporting systems. It is well known that all spontaneous reporting systems experience a high level of under reporting. For example, the FDA believes that its system for gathering voluntary information about adverse drug events receives reports for no more than 10 percent of all events. And the States that mandate adverse reporting receive highly variable numbers of reports for example, approximately 15,000 in New York and 4,000 in California, even though California has 72 percent more people.

And certainly the VA in its report of its system also experienced significant variability in reporting. Commonly cited reasons for under reporting include fear of being blamed, the potential for legal liability or an expectation that the report will have no effect. Protecting the confidentiality of reports, reporters and information, is often suggested as a way to increase reporting.

A pilot study conducted by FDA on adverse events for medical devices included confidentiality of reporters as one component. Adverse event reports increased by tenfold, but it was much harder to follow up on missing or ambiguous information. A truly confidential reporting system places a significant burden on reports to contain all information needed to follow up in protecting the public's health. Under reporting is only part of the problem. We also know that there is a significant bias in terms of which events are reported. In the area of drug-related events, we found that a wide variety of factors such as how long a drug had been on the market could affect the likelihood of reporting.

To get valid and complete information on the incidence of adverse events we need data that do not come from a spontaneous reporting system. This requires a proactive examination of random samples of patients and their records as was done in New York, and Colorado and Utah. Many of the injuries suffered by patients as a result of medical treatment are not due to errors but reflect the inherent risk of treatments that are administered correctly. It can be difficult to identify these adverse reactions and to distinguish them from medical errors or from the course of the patient's illness. We know, for example, that one-half to two-thirds of adverse drug events occur when drugs have been used appropriately. Events that result from what is deemed appropriate treatment need study so that better treatment guidelines can be developed.

In conclusion, surveillance systems that uncover and document adverse events can collect valuable information but they are not sufficient by themselves to improve medical care. The data need to be carefully analyzed and interpreted to create a good understanding of the reasons why events occur. A thoughtful analysis can lead to the specific changes in our healthcare systems that will reduce the likelihood of adverse events. This concludes my prepared remarks, Mr. Chairman, and I of course will be happy to answer any questions.

[The prepared statement of Janet Heinrich follows:]

PREPARED STATEMENT OF JANET HEINRICH, ASSOCIATE DIRECTOR, HEALTH FINANCING AND PUBLIC HEALTH ISSUES, HEALTH, EDUCATION, AND HUMAN SERVICES DIVISION, UNITED STATES GENERAL ACCOUNTING OFFICE

Mr. Chairman and Committee Members: I am pleased to have the opportunity to testify today as you consider issues related to adverse medical events in the nation's health care system. Adverse events are receiving considerable attention now as a result of the recent Institute of Medicine report on medical errors.[1] Adverse events are injuries to patients caused by medical treatment; medical errors are mistakes in medical care that may or may not lead to harm. Efforts to identify adverse events and evaluate their causes are important components of strategies to reduce harm to patients. Several of our recent reports have considered surveillance systems for medical products, particularly drugs and medical devices. For example, last week we released a report that synthesizes current research on adverse drug events (ADE).[2] We have also evaluated the Food and Drug Administration's (FDA) system for monitoring problems with medical devices.[3]

In summary, I believe that the results of our work have important implications for addressing adverse medical events including the design of surveillance systems to detect adverse events and medical errors. First, while adverse events have been recognized as a serious problem, the full magnitude of their threat to the health of the American public is unknown. Second, gathering valid and useful information about adverse events is extremely difficult. For example, all systems that rely on health care providers to take the initiative to make a report—known as passive or spontaneous reporting systems—have serious limitations. This is true whether or not providers are legally required to report adverse events; that is, both mandatory and voluntary spontaneous reporting systems share this limitation. Furthermore, many of the injuries patients suffer as a result of medical treatment do not stem from errors but reflect the inherent risks of treatments that are administered correctly. It can be difficult both to identify these adverse reactions and distinguish them from medical errors or from the course of a patient's underlying illnesses.

LITTLE IS KNOWN ABOUT THE INCIDENCE OF ADVERSE EVENTS

Relatively little information exists on the incidence of adverse events of all types, including, for example, those caused by drugs, medical device malfunctions, and diagnostic mistakes. Aside from small studies of individual institutions, the best available information comes from two studies of statewide samples of hospitalized patients. The first assessed adverse events in New York in 1984, and the second employed a comparable approach to examine the incidence of adverse events in Utah and Colorado in 1992.[4] The widely cited estimate that 44,000 to 98,000 deaths per year are attributable just to medical errors comes from an extrapolation of the results of these two studies to the United States population as a whole. Although these studies are the best available, national estimates based on them have not taken into account regional variations in clinical practice patterns and patient characteristics.

The largest category of adverse events caused by medical treatment, about one-fifth of the total, consists of those brought about by drugs. Although it is clear that a wide range of commonly used drugs cause adverse drug events with potentially serious consequences for patients, relatively little is known about the frequency of ADEs. In part, this reflects the reality, which we discuss later, that identifying a medication as the cause of an adverse event can often be difficult and uncertain. Consequently, the available information on ADE incidence tends to be fragmentary and inconsistent. Data routinely collected on ADEs during clinical trials or after drugs have been marketed are intended to identify which ADEs are associated with particular drugs and do not focus on how often ADEs take place. Information on the overall incidence of ADEs from all drugs is limited to a few research studies that typically examine the experience of patients in one or two specific institutions—generally hospitals or sometimes nursing homes—leaving the overall incidence of ADEs in outpatient care largely unexplored.

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[1] Institute of Medicine, *To Err Is Human: Building a Safer Health System* (Washington, D.C.: National Academy Press, 1999).

[2] *Adverse Drug Events: The Magnitude of Health Risk Is Uncertain Because of Limited Incidence Data* (GAO/HEHS-00-21, Jan. 18, 2000).

[3] *Medical Device Reporting: Improvements Needed in FDA's System for Monitoring Problems With Approved Devices* (GAO/HEHS-97-21, Jan. 29, 1997).

[4] T.A. Brennan and others, "Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I," *New England Journal of Medicine*, Vol. 324, No. 6 (1991), pp. 370-76, and E.J. Thomas and others, "Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado," *Medical Care*, forthcoming.

The most broadly based information on ADE incidence comes from the two studies that I mentioned earlier. These studies applied a particularly restrictive definition of ADEs in finding that they occurred at a rate of 0.56 for every 100 patients admitted in Colorado and Utah and 0.72 per 100 admissions in New York. The studies counted only ADEs that resulted in disability, prolongation of a patient's hospital stay, or death, meaning that a significant fraction of the patients less seriously injured by drugs was omitted. Other studies that used broader definitions, but applied them in the context of specific institutions, found a range of 2 to 30 ADEs per 100 hospital admissions. There are still fewer published studies examining ADEs in nursing homes, and all are limited to one or two individual providers. Two of these studies reported an incidence of 0.44 to 0.71 ADEs per patient month, rates roughly comparable to the rate reported in one study of hospital ADEs that presented ADE incidence in terms of time spent in the hospital.

USEFUL AND VALID INFORMATION ABOUT ADVERSE EVENTS IS DIFFICULT TO OBTAIN

Recent proposals to increase our understanding of adverse events have focused on improving adverse event reporting systems. However, some of the inherent limitations of these systems are difficult to overcome. Further, it can be difficult to ascertain whether patient injuries or harm come from adverse events or their underlying illness, and many adverse events are not the result of medical errors.

Limitations of Spontaneous Reporting Systems

The Institute of Medicine has recently issued a set of recommendations on measures that the various components of the U.S. health care system can take to reduce the incidence of medical errors. Among their proposals was the suggestion that two types of medical error reporting systems be instituted: a mandatory system focusing on medical errors that resulted in serious injury or death and a voluntary system for reporting events in which errors occurred but led to at most minor injuries. While the proposal for voluntary systems has received widespread support, many provider and professional groups have raised concerns about establishing a national program of mandatory reporting of serious adverse events.

In our recent review of the research on adverse drug events, we learned what is known about the strengths and limitations of adverse event reporting systems of both the mandatory and voluntary variety. It is well known that all spontaneous reporting systems experience a high level of underreporting. For example, FDA believes that its system for gathering information about ADEs, the Adverse Event Reporting System (AERS), receives reports for only about 1 to 10 percent of all ADEs. Indeed, FDA relies on AERS primarily to generate "signals" of new adverse drug events that the agency can then investigate through other data sources.

Even mandatory systems can manifest extensive underreporting. For example, the Institute of Medicine collected detailed information on mandatory adverse event reporting programs in 13 states. According to these data, the state programs receive highly variable numbers of reports. For example, between 15,000 and 20,000 reports are submitted annually in New York, compared with approximately 4,300 in California. The Institute of Medicine did not cite any studies assessing the extent of underreporting in the various state programs, but it noted the general presumption that to varying degrees all are affected by it. Thus, no one knows at this point what proportion of reportable cases is actually reported to any of the state systems.

There are many possible reasons for underreporting. Among those commonly cited are the fear of being blamed, the potential for legal liability, and an expectation that reports will not have any effect. In addition, depending on the definition of adverse events, and how that definition is interpreted, there may be considerable variability among health care providers and institutions about the kinds of events that are reported. Some of the examples of serious adverse events to be covered by the Institute's proposed mandatory reporting program are relatively unambiguous—a maternal death, for instance. But others, such as "serious injuries associated with the use of a new device, operation, or medication," are not as clear because they are based on judgments of the causes of patient injury, not an easily observed clinical outcome.

Various measures can be taken to address some of these disincentives to reporting and thereby increase the number of reports submitted. These include protecting the confidentiality of reporters and making it easier to file reports. Both were part of a pilot study FDA sponsored of a new system for collecting reports about adverse events for medical devices. That study received adverse event reports at a rate ten times greater than in the current medical device surveillance system, even though the current system mandates the reporting of the same types of events. However, because the reporters may be unknown in a confidential reporting system, it is much harder to follow up reports in order to clarify important information that may be ambiguous or missing. A truly confidential reporting system places a significant

burden on adverse event reports to contain all the information that a regulatory agency, or a product's manufacturer, needs or will need in the future to understand the potential public health risk.

Moreover, underreporting is only part of the problem. The bigger difficulty is that the subset of adverse events that are reported does not accurately reflect the universe of all adverse events. The available studies indicate that there is substantial bias in reporting. In the area of drug-related events, we found that a wide variety of factors could affect the likelihood of reporting. For example, more reports are received during a drug's first few years on the market than later, and drug manufacturers with extensive postmarketing surveillance efforts gather more reports than other companies do. Therefore, it is not legitimate to infer that patterns or trends that emerge in reported events reflect what is happening with adverse events overall.

To get valid information on the incidence of adverse events, we need data that do not come from a spontaneous reporting system. This generally involves a proactive examination of a random sample of patient records, as was done in both the New York and Utah and Colorado studies that I mentioned earlier. In fact, the Institute of Medicine report supports having a new organization, a Center for Patient Safety, collect data on the incidence of adverse events through studies of this type. More such studies are needed if we are to have accurate data on the magnitude of the problem that adverse events represents.

However, studies based on large, representative samples of patient records tend to be expensive and time consuming to complete. Therefore, there will always be the temptation to draw implicit inferences from the more readily available data from the existing adverse event reporting systems about where medical errors are most likely to occur and how much progress, if any, has been made in reducing them. The Institute of Medicine's recommendation to implement standard definitions and formats for the mandatory reporting of serious adverse events is likely to encourage greater reliance and use of those reports. Standardizing definitions cannot overcome the nonrepresentative quality of reported adverse events. Standardized definitions and formats will, however, enhance the utility of adverse reports for other types of analyses that are not concerned with incidence. For example, they will facilitate analyses of multiple instances of a particular type of adverse event. Such analyses can help identify the key underlying factors that explain why these adverse events occur.

Even with the limitations of mandatory and voluntary reporting systems, the information they generate can help in reducing medical errors and associated adverse events. In some cases, the fact that a particular kind of adverse event occurred one or more times and has been reported is sufficient to motivate action and dictate its direction. In those cases, incident reporting systems can function effectively and may have substantial advantages. However, it is often important to understand the frequency of a particular type of error and whether that has changed over time. In these cases, the incomplete data coming from reporting systems may not be sufficient. It is better to rely then, if possible, on data that derive from an examination of a sample of patient records.

Many Adverse Events Are Not Caused by Medical Errors

Efforts to reduce adverse events should not focus exclusively on those caused by errors. The available studies indicate that just over half of adverse events of all types are caused by errors in treatment. The study of New York hospital discharges found that 58 percent of adverse events were preventable, compared with 53 percent in the corresponding study of Utah and Colorado hospital patients. This means that nearly as many adverse events result from appropriate medical treatment as from errors.

The proportion of adverse events involving drugs that is due to medical error is even lower. Available data suggest that one-half to two-thirds of ADEs occur when drugs have been used appropriately. Many of these ADEs are the result of a drug's known pharmacological properties and are often listed on the medication's label. For example, hemorrhaging is the most common adverse reaction for warfarin, a drug that reduces the risk of heart attack, stroke, and other conditions by decreasing the clotting ability of blood. Other adverse reactions, including allergic reactions, are less predictable, caused by sensitivities in individual patients who have no history of adverse reactions to a specific drug. Still other adverse reactions are related to previously undetected risks. These include drug-drug and drug-food interactions that become evident as a drug is used by many types of patients, having many kinds of concurrent illnesses, and taking many other medications, as well as over-the-counter drugs and dietary supplements. FDA's system for collecting voluntary re-

ports on adverse experiences with marketed drugs is designed specifically to uncover these kinds of previously unknown risks.

Many types of drugs can cause adverse reactions. Some drug classes are associated with a substantial number of adverse reactions mainly because they are prescribed to many patients. These include antibiotics, narcotic analgesics, drugs to control hyperglycemia in type II diabetics, psychotropic drugs such as antidepressants and tranquilizers, and nonsteroidal anti-inflammatory drugs (NSAIDs). However, some classes of drugs have notably lower rates of adverse reactions despite high rates of use. Antihistamines and the statin drugs prescribed to lower cholesterol levels are rarely associated with serious adverse reactions.

Patients who are very ill, including those with several concurrent diagnoses, have a greater risk of adverse reaction than others do. Not only are they more fragile but their illnesses may require several simultaneous treatments. In addition, they may be receiving more aggressive treatments that are known to entail significant risks. Some reports have found that elderly persons and women have more adverse reactions than younger persons and men. However, it is possible that age and gender are merely related to other risk factors instead of independently increasing the likelihood of an adverse reaction. In some studies, controlling for the number of medications being taken substantially diminishes any relationship between age and adverse reactions.

As with medical errors, passive surveillance systems are inadequate for measuring the frequency or rate of adverse drug reactions. Other kinds of studies are required to develop this information. Thus, adverse reactions that develop after the prolonged use of a drug require studies with long follow-up periods to determine whether the adverse events are related to the drug. Similarly, rare adverse reactions require studies with very large numbers of patients to accumulate a sufficient number of problematic cases, and adverse symptoms that mimic those of a patient's underlying condition require carefully controlled clinical trials. For example, the Cardiac Arrhythmia Suppression Trial found that antiarrhythmia medications doubled the risk of cardiac arrest and death in heart attack survivors. This was not detected in clinical practice (nor fully captured in spontaneous reporting systems) because patients with heart disease regularly have arrhythmias and heart attacks, providing a ready alternative explanation that masked the causal role of the drugs. It has been estimated that these medications caused up to 50,000 premature deaths.[5]

In conclusion, surveillance systems that uncover and document adverse events can collect valuable data, but they are not sufficient, by themselves, to improve medical care. The data need to be analyzed and interpreted to create a better understanding of the reasons for adverse events. Sometimes one adverse event, if carefully examined, can provide insights of this sort. At other times, analysts need to assess multiple examples of a particular type of event to discern the critical causal factors. However, for both types of analysis, the quality of the data that are collected is critical. Accurate information on the process of care provided and the patient's response to that care is required to determine the key factors that led to an adverse event. Thoughtful analyses can then use these data to identify specific changes in health care systems and processes that can reduce the likelihood of adverse events caused by both medical errors and the normal risks of adverse outcomes inherent in all medical interventions.

This concludes my prepared statement, Mr. Chairman. I will be happy to respond to any questions that you or members of the committees may have.

Contacts and Acknowledgments

For future contacts regarding this testimony, please call Janet Heinrich at (202) 512-7119. Key contributors include Martin T. Gahart and Eric A. Peterson.

Mr. BILIRAKIS. Thank you very much, Doctor. Ms. Cousins. Please pull that microphone closer, if you would.

STATEMENT OF DIANE D. COUSINS

Ms. COUSINS. Good afternoon, Mr. Chairman, and members of the committees. I thank you for this opportunity to testify today. My name is Diane Cousins. I am a pharmacist and the Vice President for the Practitioner and Product Experience Division of the

[5] See D.S. Echt and others, "Mortality and Morbidity in Patients Receiving Encainide, Flecainide, or Placebo," *New England Journal of Medicine*, Vol. 324, No. 12 (1991), pp. 781-88.

United States Pharmacopeia. I have directed this division for the past 18 years. USP is a not-for-profit organization whose sole mission is to promote the public health. USP establishes and disseminates legally enforceable standards of quality for medicines and related articles including nutritional supplements, herbals and blood products.

USP's expertise as a standard-setting body is recognized in Federal law. Thus, USP has for many years participated in a public, private relationship, a very unique one, with the Federal Government, especially the FDA. Since 1971, USP has operated reporting programs as a free service to health professionals in support of our standard-setting activities. As a partner in the FDA's Med Watch program, USP shares all its reports with the FDA at no cost to the government.

Since 1991, the USP has operated a medication errors reporting program, a spontaneous practitioner-based system in cooperation with the Institute for Safe Medication Practices. The program has collected more than 4,000 reports that have identified errors in various healthcare settings, including retail pharmacies, nursing homes and home healthcare. Through the program we found that errors can be committed by experienced and inexperienced staff, by health professionals, support staff, students, and even patients and their caregivers.

The causes of error may be due to human error, to product names or design or to the medication handling and delivering systems in which individuals operate and interact. In August 1998 USP developed a complimentary program to the medication errors reporting program called MedMARx. USP found that hospitals would be willing to submit reports if reporting could be done anonymously and in a standardized format that would allow them to track, trend and compare their experiences to other participating hospitals.

Today I have been asked to demonstrate MedMARx to the committees. Although this is a slide presentation MedMARx is actually an Internet program. When hospitals first access MedMARx, the system randomly assigns a specific permanent facility ID which becomes the hospital's pin number of sorts in the system. Although USP knows what hospitals are enrolled and what IDs are in the system, USP has no way to match a hospital to a specific facility ID thereby maintaining anonymity.

After entering MedMARx for the first time hospitals create a facility profile which captures characteristics such as bed size, type of facility, staffing, and services offered for both inpatient and outpatient. MedMARx includes hospitals of bed sizes ranging from under 25 to more than 800. Currently over 150 hospitals are participating including institutions of the Department of Veterans' Affairs and the Department of Defense. MedMARx uses a standardized definition of medication error. Our experience shows that hospitals define errors differently.

For example, some hospitals define error as deviation from the prescriber's order, thus presuming the order is correct. Other hospitals only capture errors in administration and not in dispensing or prescribing. As the GAO report on adverse drug events notes, a broad definition for error means that the total number of errors

will inherently be higher. Using a standardized category index hospitals classify errors on the severity of outcome to the patient. Four of the nine categories are shown here and include potential errors in category A and near misses in category B.

Category C and D errors reach the patient but do not cause harm. The remaining categories reflect some degree of harm including fatalities. Note that all errors from potential to fatal are captured in a single data base providing added value to MedMARx users. The next four slides capture the fields for basic report entry. The volume of data captured in each report is tiered so that more data is collected as the severity of the outcome increases.

MedMARx's data shows that most common types of error are missed doses and wrong doses. MedMARx captures causes of errors, contributing factors and location of the error. The data show that a top cause of error is performance deficit meaning that healthcare professionals were trained to know better yet erred nonetheless. Contributing factors reportedly associated with this cause are distractions and workload increase, an important point in this environment of cost containment.

Because MedMARx was designed as a systems approach to medication error reduction the program does not capture names of individuals involved in the error but rather examines the level of staff involved in the error which provides opportunity for focus policy development, training and education. These final fields and basic record entry capture the learning that can be achieved by reporting to a national data base. Hospitals are not only able to see the errors entered by other hospitals but also to learn what actions were taken and the details of those actions.

At this point, the hospital can continue to enter information about the product and the patient. And for your information, the patient's age, not the date of birth, is captured as a risk factor and will be useful in studying errors in pediatric and elderly populations. Various formats of output are available in the search area including spreadsheets, graphs and date export. A hospital can search its own data, other hospitals' data, or all data.

The hospital selects certain search criteria, then generates the output. This example shows where in the medication use process the errors occurred and severity of those errors. To read the two records causing temporary harm, for example, which is category E that were committed at the prescribing phase, you would click to drill down on that area of the chart, then click again on the hyperlink to access the specific record. In conclusion, this presentation of the MedMARx program illustrates only part of USP's vision for a national data base.

This year USP is partnering with Champion Hospitals to identify best practices and safer processes. USP believes that MedMARx can become a rich repository of experiences that can be of great value especially to regulators, manufacturers, educators and researchers. Congress can play an important role in strengthening voluntary reporting systems. Based on USP's experience, we believe that hospitals and providers would be more willing to supply information about medical errors if they are confident that their self-critical analysis will not be used against them in litigation.

We strongly support the recommendation in Chapter 6 of the IOM report that Congress act to make such communications privileged and confidential. We understand that Congresswoman Connie Morella will soon introduce a bill to implement this recommendation and we urge support for her proposal. This change in Federal law will not shield incompetent practitioners from liability but will encourage the development of a robust reporting system that can prevent errors and enhance patient safety in the long run. USP looks forward to playing an active role in providing solutions to this national issue through its reporting programs. Thank you, Mr. Chairman, for this opportunity to address the committee, and I look forward to your questions.

[The prepared statement of Diane D. Cousins follows:]

PREPARED STATEMENT OF DIANE D. COUSINS, VICE PRESIDENT, PRACTITIONER AND PRODUCT EXPERIENCE, U.S. PHARMACOPEIA

The United States Pharmacopeia (USP) is pleased to have the opportunity to provide this statement to the House Commerce Subcommittees on Health and Environment and Oversight and Investigations and the Veterans' Affairs Subcommittee on Health. USP strongly supports Congressional consideration of actions it might take to ensure the significant reduction of preventable medical mistakes that occur throughout the continuum of the prescription, dispensing, administration, and use of medicines. USP further believes that development and implementation of federal legislation and regulatory policies, which will direct and guide public and private initiatives at the national, state, and local levels, must be achieved to ensure patient safety from medical mistakes, and to reduce substantively the multi-billion dollars that such mistakes currently cost the health care system each year.

USP comments, offered for consideration, cover the following:

- Information about the U.S. Pharmacopeia's 30-year record of stimulating voluntary health care practitioner reporting and using the analysis of those reports to improving patient safety.
- Background on USP's ability to affect change in drug product labeling, packaging, and nomenclature when such are identified as contributing to medication errors.
- An explanation of USP's new MedMARx® program—a national, Internet-based, anonymous medication error reporting system, introduced in July 1998, and now used by over 150 U.S hospitals.
- A recommendation for Congressional action that can directly and quickly remove one of the most significant barriers to hospital and practitioner reporting of medication errors.

USP'S MEDICATION ERROR REPORTING EXPERIENCE

Background

USP, founded in 1820, is a volunteer-based, not-for-profit organization whose sole mission is to promote the public health by establishing and disseminating officially recognized standards of quality and authoritative information for the use of medicines and related articles for professionals, patients, and consumers. It is composed of approximately 500 members representing state associations and colleges of medicine and pharmacy, ten agencies of the federal government, and about 75 national professional, scientific and trade organizations, and members-at-large, including government agencies from other countries that recognize USP standards and non-U.S. pharmacopeias. The USP's expertise as a standards-setting body has been recognized by Congress in the enactment of the Drug Import Act of 1848, the Pure Food and Drug Act of 1906, the Federal Food Drug and Cosmetic Act in 1938, and by the Food and Drug Modernization Act in 1997, and others. Standards published in the official compendia, *U.S. Pharmacopeia and National Formulary (USP-NF)* are also referenced in most state pharmacy laws governing practice.

USP began developing information relating to proper medicine use, in 1970, as support to its standards-setting activities. The *USP DI*, the compendia of USP drug information, is today recognized by the Federal Omnibus Budget Reconciliation Acts of 1990 and 1994 as a reimbursement resource for Medicaid Agencies considering issues associated with off-label uses of medicines and guidance for patient counseling. Based upon its federal recognition, and its reputation as a credible, authori-

tative, and non-biased source of information developed by approximately 800 volunteer experts, *USP DI*® also serves as a reimbursement resource for insurers and third party payers, and as the basis for drug formulary decisions.

The process by which drug standards and information are developed is open, participative (notice and comment) and subject to integrity safeguards, including conflict of interest disclosure.

USP Practitioner and Product Experience Programs

Because of our concern with the quality of drug products on the market, in 1971, the USP co-founded the Drug Product Problem Reporting Program—a national program in which health professionals were asked to voluntarily report problems and defects experienced with drug products on the market. Often the product problems or defects had to do with inadequate packaging or labeling—labeling that could lead to confusion on the part of health professionals or lead to errors; for example, look-alike color or design labels (color and design) and sound-alike drug names. Today, we continue to operate our Drug Product Problem Reporting, and a newer program, the Veterinary Practitioners Reporting Program, which collect voluntary reports on human and animal drug products.

Eight years ago, in 1991, USP decided to focus more intensely on the problem of medication errors and what it could do to prevent them. Our focus today is on both the product and on the system in which the product is prescribed, dispensed, administered, and used. USP does not set practice standards per se, but practicably, many of our standards do indirectly affect professional practice and many practice standards are based on *USP-NF* standards.

The USP learned that The Institute for Safe Medication Practices (ISMP) was seeking support of a national organization to bring its program, The Medication Errors Reporting (MER) Program, to the national level. USP agreed to coordinate the national program for ISMP. The

MER Program is now one of four USP voluntary, spontaneous reporting programs for health care practitioners. The MER Program is operated under the umbrella of the USP Practitioner and Product Experience Division.

Since late 1991, the MER Program has received more than 4,000 voluntary reports of actual and potential medication errors. We also continue to receive medication error reports through USP's other reporting programs. These reports have identified errors in various health care delivery environments, including hospitals, nursing homes, physicians' office, pharmacies, emergency response vehicles, and home care. Through these reports, we have seen that errors are multi-disciplinary and multi-factorial. They can be and are committed by experienced and inexperienced health professionals, support personnel, interns, students, and even patients and their caregivers. Medication errors can and regularly do occur anywhere along the continuum from prescribing to transcribing to dispensing and administration. The causes of errors may be attributed to human error, to product names or designs, and to the medication handling and delivery systems in which the products are used and individuals operate and interact. For purposes of voluntary reporting, USP does not seek to limit the types of errors that may be reported, because all information received may have some future value in determining how to reduce or prevent errors. We do not, however, actively solicit reports of adverse drug reactions, but USP cooperates with the Food and Drug Administration as a MedWatch partner and refer all reports submitted to USP.

We recognize that an actual error may be reported as a potential error because of liability concerns, or a facility's risk management policies, so each report is treated with the utmost seriousness by USP, no matter how it is characterized by the reporter. As each MER report is received, it is shared with the product manufacturer and with the Food and Drug Administration. USP does not require, in the MER Program, that the name of the reporter, patient identity, or facility be provided. If provided, however, USP respects the desire of the reporter to keep his or her identity confidential and will purge the identity of the individuals or institutions named in the report in accordance with the instructions of the reporter. Reporters are advised of any actions resulting from their report either individually or through USP's *Quality Review* publication, which is disseminated to all persons who have reported to the MER Program and is publicly available on USP's web site.

USP'S ABILITY TO AFFECT CHANGE

USP has 30 years of experience and demonstrated effectiveness in designing and operating voluntary reporting systems for health care professionals relating to drugs and their use, and using those data to improve product standards and safe drug use information.

Standards-Setting Authority

Encouraging the reporting of errors is only one aspect of USP's efforts to promote safety of the medication use system. USP evaluates and implements, through its standards-setting authority, changes in drug products to prevent the recurrence of errors. The following examples describe some of the changes or other steps taken by USP in response to MER Program reports.

- Death reported due to the accidental misadministration of concentrated Potassium Chloride Injection led to (1) changing the official USP name to Potassium Chloride for Injection *Concentrate* (emphasis added) to give more prominence to the need to dilute the product prior to use; (2) labels must now bear a boxed warning "Concentrate: Must be Diluted Before Use;" and (3) the cap must be black in color (the use of black caps is restricted to this drug product only), and (4) the cap must be imprinted in a contrasting color with the words, "Must be Diluted."
- Deaths reported due to the confusion and resultant injection of the anticancer drug, Vincristine Sulfate for Injection, directly into the spine instead of into the vein, resulted in changes in the requirements for packaging by pharmacies and manufacturers preparing ready-to-use doses. Each dose, whether prepared by the manufacturer or the pharmacist, now must be wrapped in a covering labeled "FOR INTRAVENOUS USE ONLY" and that covering may not be removed until the moment of injection.
- Deaths reported due to the name similarity of *Amrinone* and *Amiodarone* have lead USP and the United States Adopted Names (USAN) Council to consider changing the official and nonproprietary names of one, or both, products. {See attached *Quality Review*: "Proposed Drug Name Changes for Error Protection."}
- Deaths reported due to the inadvertent mix-up of neuromuscular blocking agents (which paralyze the respiratory system) with other drugs, have led to recommended changes in standards for labeling and packaging of the therapeutic class of neuro-muscular blocking agent products.
- Medication Error Reporting reports of deaths identified the need to establish dosing limitations for the sedative-hypnotic Chloral Hydrate for use in children, and for the anti-gout drug Colchicine. These dosing limitations have been incorporated into the USP DI information in a special section in each drug monograph to caution health professionals on each drug's proper use based upon reports of errors received through the program.

{See attached examples of *Quality Reviews* that describe other medication errors identified through the MER Program and for which USP has identified and communicated to health care professionals information and prevention strategies: "Three is a Crowd;" "Insulin Oversight" and "Vincristine Sulfate Monographs Revised—Dispensing Pharmacy Practice Affected."}

Throughout its 180-year history, USP has focused on improving the quality of our medicines and their appropriate use. All of USP's programs focus on these goals. The standards in the official compendia, the *USP-NF*, define the identity, strength, purity, quality, packaging and labeling of drugs and their dosage forms. The USP is a member, with the American Medical Association, American Pharmaceutical Association, and the Food and Drug Administration of the United States Adopted Names Council (USAN) and publishes USAN names in the *USP Dictionary of Drug USAN and International Drug Names*, which is an international resource for pharmaceutical manufacturers, regulators, and health care practitioners. As noted elsewhere in this testimony, USP has taken actions, independently and in concert with USAN, to change the names of drugs and dosage forms when they have resulted in medication errors.

Reported medication errors also have brought about other changes in USP standards and guidance to practitioners. For example, (1) USP discontinued recognition in the *USP-NF* of the apothecary system, a centuries old system of measuring weights and measures, in favor of the metric system in order to avoid misinterpretations that led to overdoses; (2) USP has made changes in general label requirements for marketed drug products, strengths less than one unit must be expressed as a decimal preceded by a zero (e.g. 0.1 grams, not .1 grams) to avoid ten-fold overdoses; and (3) USP standards also require that the strength of a product when expressed as a whole number be shown without a zero trailing the decimal to avoid ten-fold overdoses by the lack of recognition of the decimal point (e.g. 1mg, not 1.0 mg).

Collaborative Relationships: Food and Drug Administration; National Association of Boards of Pharmacy; Colleges of Pharmacy

Prior to the formation of the Food and Drug Administration (FDA) Office of Post Marketing Drug Risk Assessment, the Agency developed a formal mechanism for receiving and evaluating MER reports—the Subcommittee on Medication Errors. USP

and FDA also created a joint advisory panel on the Simplification and Improvement of Injection Labeling to reduce medication errors. The Food and Drug Modernization Act of 1997 recognizes product labeling recommendations of that joint initiative.

In 1991, to expand the scope of the MER Program, USP developed a joint program with the National Association of Boards of Pharmacy. The Boards of Pharmacy database is maintained by USP and assists each Board of Pharmacy to determine the relative extent of errors in its state and contributes to the overall incident collection effort.

In addition to using the MER program to stimulate changes in enforceable standards and information, USP has used the MER information to develop educational tools for the health professions. In 1993, a curricular resource entitled—*Understanding and Preventing Medication Errors*—was distributed at no charge of colleges of pharmacy throughout the U.S. USP also has attempted to reach the public directly to teach patients how to protect themselves from medication errors through the development of a public service campaign—*Just Ask . . . About Preventing Medication Errors.*

National Coordinating Council for Medication Error Reporting and Prevention

USP has worked diligently during the past eight years, particularly in the standards-setting area, to build coalitions among health care organizations and to provide health care expert review of medication errors. In 1995 USP spearheaded formation of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). USP is the founding organization and continues to serve as NCC MERP Secretariat. To date, NCC MERP, comprises of 17 national organizations and federal agencies that share a common mission to promote the reporting, understanding and prevention of medication errors. Member organizations include practice organizations of medicine, nursing, and pharmacy, the licensing board of pharmacy and nursing, organizations of the pharmaceutical industry, the Department of Veterans Affairs, the Joint Commission, regulators, the FDA, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), the American Hospital Association, and USP. In the years since its inception, the Council has produced internationally recognized work products, such as:

- a standardized definition of "medication error." [See *Quality Review*: National Council Focuses on Coordinating Error Reduction Efforts]
- a categorization index to classify medication errors by the severity of the outcome to the patient
- a taxonomy of medication errors
- recommendations to reduce the error prone aspects of prescription writing; product labeling and packaging; and broad recommendations related to the dispensing and administration phases of the medication use process.

The Council is now re-examining how the standardized definitions noted above and in the attached *Quality Review*: "Use Caution—Avoid Confusion" can be honed, based upon experience gained from the MER and MedMARx (see below) Programs to provide clearer differentiation between categories. In addition the Council is examining issues of process failures in the use of verbal orders, benchmarking and inter-organizational comparisons, and error rates.

Ad hoc Advisory Panel on Medication Errors

In 1996 USP appointed an Advisory Panel on Medication Errors, an interdisciplinary group of health care practitioners who: review reports submitted to the USP Medication Errors Reporting Program; make recommendations for USP standards-setting; and make recommendations and participate in the activity of the NCC MERP. Mr. Michael Cohen, ISMP President, served as the first chair of this Panel and continues to serve as a member.

In 2000, USP will constitute a new expert committee on "Safe Medication Use" that will fulfill a broader scope of responsibilities of the Advisory Panel that it will replace. The new expert committee will review data and provide guidance for the development of best practice solutions that will result in the reduction and prevention of medication errors.

USP DI and Drug Information Expert Advisory Panels

The USP DI database is recognized internationally as containing the most up-to-date and authoritative information on off-label uses, warnings, contraindications, etc. New USP programs that will enrich the USP DI database will focus on the special needs to standardize products and develop information for neonatal, pediatric, and geriatric patients and populations. A unique contribution of the pediatric effort, developed in conjunction with experts in pediatric medicine communications is the "Ten Guiding Principles on the Use of Medicines by Children and Adolescents."

These principles have been distributed broadly and are being used in educational materials by pharmaceutical manufacturers and volunteer organizations. [See Guiding Principles Ruler enclosed.]

USP'S MEDMARX PROGRAM

In early 1998, USP developed a nationwide program for hospitals to report medication errors. Hospitals were eager to submit reports to USP if reporting could be done anonymously and in a standardized format that would allow hospitals to track trends, and compare their data to other participating hospitals. USP's goal was to develop a model for hospitals first, ensure success of the model, then broaden the model to include other health care settings, e.g. long-term and ambulatory care settings, and other types of reporting such as medical error and adverse drug reactions.

On July 27, 1998, USP made MedMARx™ available to hospitals nationwide. MedMARx is an internet-accessible, anonymous reporting program that enables hospitals to voluntarily report, track and trend data incorporating nationally standardized data elements (i.e., definitions and taxonomy) of the USP Medication Errors Reporting Program, the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), and the American Society of Health-System Pharmacists. MedMARx is structured to support an interdisciplinary systems-approach to medication error reduction and fosters a non-punitive environment for reporting.

Hospitals are encouraged to use MedMARx as part of the organization's internal quality improvement process, thereby extending their "peer-review" group to the group of hospitals in the program. Hospitals review the errors entered by other institutions in "real time" and also can view any reported action taken by another institution in response to an error or to avoid future similar errors. This feature affords institutions the opportunity to examine errors in a proactive manner. For example, the institution can review the error profile of a drug or class of drugs before a product is added to the institution's formulary to determine if certain risk prevention measures or training programs should be instituted prior to the drug's availability within the institution. Or, if the error profile is significantly serious, a determination to *not* stock the drug can be made. MedMARx also supports the performance improvement standards of the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), which requires institutions to look outward at the experiences of others in order to reduce risk.

Currently over 150 hospitals have enrolled in the MedMARx program and other progressive hospitals and health systems are joining rapidly. Profiles of the participants show that hospitals of various types and sizes spanning fewer than 50 beds to approximately 1000 beds are enrolled. MedMARx hospitals include institutions of the Department of Veterans Affairs and the Department of Defense, and state-owned facilities.

The USP commitment to MedMARx is broader than merely collecting data. In the coming year, USP will enroll champion hospitals participating in MedMARx in a long-term project to propose indicators of quality in the medication use process and to identify best *practice* standards and best *process* standards for the medication-use system.

A RECOMMENDATION FOR CONGRESSIONAL ACTION

USP is heartened by the national attention resulting from release of the Institute of Medicine Report—"*To Err is Human—Building a Safer Health System*." USP is particularly gratified at the immediate action being taken by the House Commerce Committee's Subcommittees on Health and Environment and Oversight and Investigations and the House Committee on Veterans' Affairs Subcommittee on Health. We are pleased to offer the following specific recommendations:

- **Focus Attention on the Quality of Health Care System**

As the first step in preventing medication errors, the priority should be on fixing the system, not the blame. The IOM report is clear that mandatory programs at state and federal levels have not effectively captured the full number of errors occurring. The report argues that the public needs some assurance of a minimum level of protection (i.e., through reporting, investigations and follow-up) and that health care organizations need to be "incentivized" to improve patient safety. In fact, mandatory reporting could provide a false sense of protection if the mandatory programs are no more effective than those already in existence. Therefore, perhaps the question at this time should be: "What needs to be done to improve the quality of healthcare systems that will provide these assurances and incentives?" Numbers and statistics from such mandatory programs may not be as useful to the public and, in fact, may erode the confidence of the public if shear numbers are used as

a gauge of quality. What confidence can a citizen have in the health care system when the error profiles for both (or maybe the only) rural hospital(s) in their area show that harmful errors have occurred there? "To Err Is Human" leads us to believe that no hospital is likely to be error free. The fact that a harmful error has not yet occurred in a facility is no assurance that it will not occur, or that it has, in fact, occurred but has not been recognized as such or reported. To better serve the public, it would be far more useful to have the knowledge and assurance that the hospital has adopted safer processes and best practices when errors have occurred in order to reduce the possibility of errors. We believe a system that provides a public indicator that these best practices are adopted, in effect a facility's "report card," would be a more effective tool for consumers to help choose the best and safest health care facilities for themselves and their families.

A national voluntary reporting system ensuring confidentiality in support of the above framework should help accomplish this by reporting and documenting actions taken in response to an error. A more robust database will also provide opportunities for risk prevention and designing error out of medication use processes. As an incentive to report, information submitted to the system should be treated as privileged per federal statute as is currently the case in states that provide for peer-review protection. What should be mandated for hospitals and other healthcare facilities is not reporting, per se, but the development of quality control systems (of which reporting is a part) that implement these best practices and improvements to prevent and correct system weaknesses. For example, the federal government can create a public report card using the inspection and survey processes of state boards of pharmacy, HCFA, and JCAHO. Incentives for facilities can be provided by third party payers and insurers that require the adoption of such standards and practices into every healthcare system as a contingency of reimbursement under Medicare and Medicaid programs.

Finally, under all circumstances, every victim and/or the family should have the legal right to be told by the health care professional or facility if an error has been committed in the deliverance of their care that has resulted in harm to the patient, increased hospitalization, or medical or therapeutic intervention.

- **Protect the Confidentiality of Data Submitted to National Voluntary Reporting Programs**

Among the IOM Report's discussions and recommendations is recognition that the absence of federal or state protection from disclosure of medication error reported information poses a major barrier to voluntary reporting of errors, or potential errors. Health care practitioners are concerned about reprisals and practitioners and health care institutions and delivery systems are concerned about liability. USP believes, therefore, that Congress can make a significant contribution to the development and successful implementations of systems that facilitate voluntary medication error reporting and tracking through immediate consideration of legislation that would protect information developed in connection with error reporting by hospitals and other institutions and health care settings. USP currently is developing such legislative language for House and Senate consideration.

CONCLUSION

In closing, I wish to assure Committee and Subcommittee members that USP shares with Congress the goal of a safe medication use system. USP has made a public and long-term commitment to working proactively with all stakeholders toward that goal. We particularly look forward to working with Congressional leadership on the issue of fostering effective systems that support best practices, accountability, and confidentiality to stimulate greater reporting, analysis, and system changes to prevent medication and medical errors and to ensure confidence in our health care delivery system.

Mr. BILIRAKIS. I thank the panelists. I will start out with the first series of questions. Dr. Cousins, I was just intrigued when you were talking about the report card. I was wondering if you would elaborate on that. Would other members of the panel also like to comment, perhaps, on your report card. Go ahead.

Ms. COUSINS. The report card is mentioned in our written testimony. Essentially in the debate of mandatory versus voluntary as posed in the IOM report, it is clear that the mandatory systems to date have not yet been effective. In fact, having such a system that is modeled the way previous systems have been modeled could in

fact give a false sense of protection to the public. Perhaps we would reframe that question and ask what would be done to assure the public that systems are safe. To that end, I would imagine that the public data base posed in IOM might, for example, serve me as a patient if I were to look at what hospitals in my area might have errors and look at their safety profile.

I might find, in fact, that the only two hospitals to my region both show that there have been errors at the facilities. So what assurance does that really give me that the quality of care that I had at either of those institutions of my choice might meet my standard. I might also say that if I see no reports for those hospitals, what would that tell me? Well, it doesn't really tell me much. Does that give me any assurance that that wouldn't happen to me, that there wouldn't be a serious or fatal error when I am admitted.

We feel that in order to get to the issue of safer systems, we need to provide some kind of way for patients to be able to analyze information in a more understandable way and so the concept of a report card would provide oversight by those that are responsible for various settings like National Association of Boards of Pharmacy for retail pharmacies or perhaps the Joint Commission for Hospitals whereby their survey results are public but specific in areas for medication error prevention and the adoption of the lessons that we have learned to help prevent those errors in the future.

Mr. BILIRAKIS. Anyone else on the panel that would like to comment on that? Dr. Garthwaite.

Mr. GARTHWAITE. I think I would largely concur with that. I think the public would be most interested in and would be most helped if systems adhere to certain principles. Do they adhere to telling patients if they commit error, do they communicate that to the patient, do they have a system to report their experience so that the fewest number of people have to be injured in order to learn lessons? Have they implemented all applicable safety standards including those related to adverse drug events, and do they have in place an effective safety program?

I think if your health care system has all those in place you would have some reasonable assurance that they are making progress at identifying error, putting in place standards of safety, and they may have other measures of quality that might also be helpful on a report card.

Mr. BILIRAKIS. Dr. Bagian, as a former F–15 pilot, an astronaut, and an expert in the whole area of computer simulation, I would be curious if you think that computers could use simulation to help bring medical errors down.

Mr. BAGIAN. Well, yes, sir. Just one correction. I wasn't an F–15 pilot.

Mr. BILIRAKIS. Okay.

Mr. BAGIAN. Yes. We think simulators have huge value. The reason for simulation in aviation as it is in medicine are basically three fold. You simulate in areas where the events either happen too infrequently to provide an adequate training opportunity, where the event is too hazardous, certainly in patient care that would fit as it does in aviation, and the other is the cost involved to do that. Medicine qualifies in those areas.

At the Palo Alto VA, in fact, we have a simulation facility there where both training and research is done where we have an entire operating room setup that is indistinguishable from a real OR as far as the type of equipment used. It is real equipment. There is a mannequin there that has eyes, the pupils dilate, they expire gases, reflect the metabolic state of the patient so to speak so it actually changes the concentrations of carbon dioxide or oxygen accordingly, the anesthetic gas the same way. So it really acts in all ways as a human would under various situations.

And then you can impose various problems, you know, illness, complications, a reaction to a medication, for example, various things such as that. And this enables you to not only train but to try to observe what are the most effective strategies to deal with certain normally uncommon but very severe situations. We think this is the way to really do a lot of your training in a high hazard area. For instance, with codes, cardiac arrest treatment, you can do this many times where people can learn without having real patient problems so we think there is tremendous utility to simulation. Absolutely.

Mr. BILIRAKIS. Thank you. I would just conclude, Dr. Garthwaite, that I think when we looked at the President's budget for 2001 the staff and I were concerned there is no increases in the VA research funding. This would effectively shrink the research program. And I guess considering patient safety is a No. 1 topic, why hasn't the President increased funding in that area?

Mr. GARTHWAITE. Well, we believe within the allocation we can prioritize funding in different areas and we are prioritizing health services research on patient safety. In addition, some of the studies are at the level of more administrative evaluations which I think we can fund out of medical care dollars to some degree.

Mr. BILIRAKIS. Mr. Barrett for 5 minutes.

Mr. BARRETT. Thank you, Mr. Chairman. I appreciate you all being here. Dr. Garthwaite, nice to see you. Dr. Heinrich, I am not always really that excited about saying when I have made a mistake, and I don't know that I am that different from a lot of people in that if you make a mistake you would just as soon forget it and you probably are a little less likely to want to acknowledge it if you think it might have some ramifications on your career, so even if we have a good reporting system where individuals can voluntarily report their errors and they feel safe doing so, aren't there some real sort of human nature limitations that come—other types of limitations in relying on reporting systems?

Ms. HEINRICH. Certainly in our review of the spontaneous reporting systems, we found that there are a variety of issues that affect the ability of people to report and to wish to report. First of all, there is the issue of the complexity of medical care and the fact that it is very difficult to really attribute a particular result to a particular event. As we said, many of the adverse events are because of adverse reactions when medical care was appropriate.

I also think that one of the issues that my colleagues here have brought up was related to definitions of those events. I think that there are many different definitions of what is being requested in terms of reporting systems and those vary from institution to institution. And then of course we have heard that fear is of great con-

cern in terms of reporting. We did note that when we looked at the experiment, the pilot study that the FDA did when they were doing the medical devices when they did include confidentiality there was an increase in reporting, but there was also then the problem of having more difficulty in following up when the information wasn't complete so that they could take some kind of corrective action.

Mr. BARRETT. This issue is obviously a hot issue. The media has been paying a lot more attention to it and I think people are just generally more interested. And I guess I was under the impression that the data we are working with now is not coming primarily from self-reporting, it is coming more from scientific studies. And so I am wondering as you sort of look into the future, how important is it for us to continue the scientific studies or other than a self-reporting system what do you see as an effective mechanism to provide us with the data that we need?

Ms. HEINRICH. If we are really going to understand the magnitude of the problem, we do need those special studies and they are expensive. The very best data that we have as we said before, are from the statewide studies that were done, the one in New York and then the studies that were done more recently in Colorado and Utah. They are taking good random samples of patients who have been in a hospital over a period of time, and as I think was said from the previous panel those studies have very clear definitions and the interpretation of the medical records was done by experts. This kind of study is expensive but we clearly need to do more of them.

Mr. BARRETT. Dr. Garthwaite, what is your view on this?

Mr. GARTHWAITE. I agree with Dr. Bagian's point that we need to find the errors and the weaknesses in the systems from whatever means possible. Scientific studies are very helpful in estimating the magnitude of the problem. Once you find vulnerability, the key is whether you can design a fix and implement it. We understood that the timing of administration of medications, the writing of the prescription or order for medication, the interpretation by a whole series of people along the line was prone to error.

What we found was that one of our hospitals had designed their own system for bar coding that eliminated a lot of the human factors. With that knowledge what we needed was the courage to find the funds to implement that nationwide once we determined that that was going to prevent the bulk of medication administration errors in our healthcare system. So I think we learned that relatively readily. It didn't take a huge number of studies to find the problem. It is a commitment to redesign the system and fix it.

Mr. BARRETT. Well, you both have mentioned the need for investment and obviously we can collect data until the cows come home but if we don't have an investment in developing that data. What kind of an investment are you talking about here, Doctor?

Mr. GARTHWAITE. Our plan for the year 2000 is to invest about $118 million out of our budget in safety-related activities. That covers the gamut and the largest amount of that is in training our employees to think about safety, to understand the reporting system, and the nature of errors, to think about close calls and to report them, and that means training 180,000 people essentially to change the way they do business.

That is critical. It involves Jim Bagian's staff. It involves the Centers of Inquiry for Research. It involves some funding for some scholars in this area because we don't think that physicians have been trained adequately in general in the United States yet, and it involves the computer support for the reporting systems we put into place. So we have a fairly comprehensive plan that is expensive, but it is the right thing to do. In the long-term we will save because mistakes are expensive and paying for the extra care caused by the mistakes is expensive.

Mr. BARRETT. Thank you.

Mr. STEARNS [presiding]. The gentleman's time has expired. Mr. Smith from New Jersey.

Mr. SMITH. Thank you very much, Mr. Chairman. First of all, I want to thank and praise in the strongest possible terms the good work of the VA in being proactive. I just now read the handbook. I heard about it and now I see it and look at it in more detail and it seems to be a very comprehensive document. And obviously the proof will be in the implementation but I have every confidence that you will do it and do it well.

I do have a question, Dr. Garthwaite, or perhaps Dr. Bagian, a question about once there is a near miss or some other problem that is discovered, what does the counseling actually look like in the VA hospital?

Mr. BAGIAN. I will be happy to answer that, sir. What happens is when the report first comes in, and I will use the term risk manager, some places we call it a quality manager or process manager but the individual with whom those reports reside when they come in from numerous avenues. They then make a determination and the first thing that we make very clear is they make a determination "is this an intentionally unsafe act," and we have paragraph 3.d. I think is where the definition is if I recall.

And what you do is you say intentionally unsafe acts are just those that appear to be intentionally unsafe. That means we don't use the word reckless because that has certain legal meanings. We say if it appears that somebody did something that was unsafe in an intentional manner, that doesn't come in the safety system. That needs to be addressed another way. We say cases where the caregiver, the provider, was impaired due to alcohol or substance abuse that goes a different route. Alleged patient abuse, that goes a different route, and criminal activity goes a different route.

As long as it doesn't fall into one of those four categories, and very, very few do, I might add, then it comes into the safety system. The safety system, then we do a very thorough root cause analysis, which it is a computer-aided tool that helps the individuals in a team, we impanel a team, they are told and actually by letter from the facility director that they are to serve on this team, what their capacity is. They then are charged to go out and to gather whatever information is necessary to understand what the root contributing causes are.

Then they not only do that but come up with what the appropriate corrective actions are, the plan for implementation including funding or whatever else is necessary to make this happen. Then, and this all goes into a report, they will check to make sure it works. It is one thing to say here is a solution. It is another thing

to prove that it in fact works. We think it will but until you prove it you really don't know.

And then the critical phase we have is, the facility director has to sign and either concur with each individual corrective action or not concur, and they may not. And there are good reasons they may not but then they have to report their rationale why they didn't. It is not just "because." They have to say, you know, what the real because is and then the group comes to some agreement as to what the alternative corrective action will be. And then they classify their corrective actions as to if it eliminates the problem, controls the problem or they accept the problem. They say, hey, we don't have a solution right now.

And that way anything that is not eliminated and verified to be eliminated you can look at in the future and you will have a way to look at it to say was this the best control. Anesthesia was brought up earlier, by I forget which gentleman here. Anesthesia, had a big problem in the early 1980's. There was no pulse oximetry. Inadvertent disconnect from the breathing circuit was one of the primary causes of complications and once pulse oximetry existed, which was in the mid-'80's, that suddenly went way down.

So you have a good technique in the 1980's and you are telling everybody to be careful. I was an anesthesiology resident then. I can tell you, be very careful you are cautioned. Nobody goes in to hurt a patient but it happens. When they came up with a mechanism that also helped you it went way down so it was a system solution. So we put that all embedded in there so there is a system that rolls up. We can look at it, we can help them with that, and we think that makes a more robust system. Does that kind of answer it?

Mr. SMITH. Very well, and hopefully the VA will be able to provide at least a path for others to follow because you are obviously the most integrated network of healthcare in the country. I have a question for Dr. Heinrich. Your comments obviously seem to—are adverse to the IIO's comments with regards to the 44,000 to 98,000. In that you point out that there is just a little evidence available out there.

It is my understanding that the New York study, there were 71 deaths, and I could be wrong on that but that is my understanding and then that was extrapolated out to 98,000. I mean what kind of science are we dealing with here in terms of methodology from your point of view? Again, some of those studies are old as I pointed out earlier but the New York death rate or the deaths attributable to the hospitals, the care, 71. What is your feeling on that?

Ms. HEINRICH. Well, as you have noted, we did express some concern about the extrapolation of studies in these three States to the rest of the country. We have pretty good information about the variability in medical care across our country so I think there is some concern in making an extrapolation like that.

Mr. SMITH. The problem is, if I could take one final second, most of the press have left. We don't want hyperbole. We want good patient safety based on good science. The VA certainly is being proactive and I think we are all very proud of that fact that they are doing that but we don't want to have misinformation out there so that it has the unwitting consequence of people saying I am not

going to the hospital because I don't want to get sick or die when that is not the case. We want good honest figures and I think that study may unwittingly again do a disservice by not being more reliable.

Mr. STEARNS. The gentleman's time has expired. Mr. Strickland, recognized for 5 minutes.

Mr. STRICKLAND. Thank you, sir. I have two questions, one for Ms. Cousins and one for Dr. Heinrich. The first question, Ms. Cousins, USP is proposing legislation that would allow hospitals to report information to MedMARx without waiving peer review privilege granting confidentiality information. This would insure that hospitals are protected from having information disclosed but the question I have is granting these protections to an institution won't address all the problems associated with individuals who may choose to report because they are afraid, because they don't want to be embarrassed because the supervisor may find out, because they may lose their job, not get a promotion, a variety of reasons.

And my question is do you believe that protections for individuals who do reporting are something that we need to be concerned about and discuss, and if so what kind of steps can be taken to assure that practitioners are given the kind of assurance that they need that would encourage them to come forward?

Ms. COUSINS. I believe what we are proposing would cover all healthcare sites, not just hospitals, and also would cover the individuals involved so it would be any information that is created in support of a medication error event submitted to national reporting programs, not just actually MedMARx but all of those programs that we would operate so we are looking at the broader picture.

I believe that what needs to happen to give confidence to those involved in the healthcare system is really an overall review of their internal processes to establish these systems. We find that the first thing that happens when they bring MedMARx into an institution is that they need to separate sometimes for the first time the performance of individuals from the ability to capture information on errors so that first step within a facility gives the individuals confidence that there won't be reprisal regarding their positions.

And then we talk often times with hospitals that say, well, how do I go about separating and how do I pursue those disciplinary problems or those performance problems so that is something we work out with each hospital based on what they might be doing internally but really that is the first step is to make that division and then that I think demonstrates the commitment of the administration to that kind of a system and then the system is built around identifying the errors separately.

Mr. STRICKLAND. Reporting could be done by individuals who are directly involved in the error.

Ms. COUSINS. Yes.

Mr. STRICKLAND. And I assume reporting is also done by individuals who may not have been involved in the error but who have observed that, people we have referred to as whistleblowers. What kind of protections would you envision that would be necessary for individuals who may not be directly involved in the particular error but who have observed that and feel that it should be reported?

Ms. COUSINS. Again, I think the protections for the information as we are proposing but we do in fact have cases where other individuals who either observed the event or were involved in the event tangentially do share reported information with us and openly so I think it is really the information that we are looking to protect.

Mr. STRICKLAND. I would just make the point that in the patient's Bill of Rights, which was recently passed by the House individuals who would choose to come forth and report incidents would enjoy protections from retaliation for having done so. Dr. Heinrich, if we are really going to learn from our mistakes, and we certainly want to, it seems to me that we are going to need to have the ability to collect a lot of information about what went wrong and why it went wrong, i.e., inadequate staffing, for example. I hear a lot of information from nurses saying that they are being stretched too thin and their responsibilities are being given to people with lesser training and so on and so forth.

How important is it to have the ability to follow up to gather follow-up information regarding these error reports and do we see a problem in our ability to gather follow-up data in existing systems and what limitations on gathering follow up information would be the result of having anonymous or confidential reporting systems?

Ms. HEINRICH. I think your question hits a very critical point and that is that the surveillance systems in and of themselves aren't so helpful. It is your ability to go back and really understand the cause, the circumstances, or the systems and how they operate that impact on adverse events. I think it is interesting that now, certainly in hospitals and other healthcare environments, it is required that we have records of adverse events. And again we know that they are probably under reported by a significant amount.

What I question or what we question is the kind of really proactive analysis of that information that there is either at the institutional level or at the State level or at the national level.

Mr. STEARNS. The gentleman's time has expired. The chairman of the Health Subcommittee, Mr. Bilirakis.

Mr. BILIRAKIS. Thank you, Mr. Chairman. Doctor, first I want to welcome the panel and to thank them for taking the time to be here. Of course thanks to Dr. Nelson particularly for leaving that much better weather down there in our Tampa Bay area to come up here. Welcome. Dr. Heinrich, you have questioned, the extrapolation from three States, etc. Does GAO have any opinion as to a better answer in terms of the numbers? Or did you just merely review what was done and then give us your opinion regarding it, but not go any further than that?

Ms. HEINRICH. That is absolutely correct. The studies that we are referring to are the studies that give us the very best information on the magnitude of the problem. And as others have said, we know even less about what is going on in ambulatory care and nursing homes, for example.

Mr. BILIRAKIS. Some time ago I think we requested some sort of a GAO study. Well, anyhow the point is that there is no better information available that you know of.

Ms. HEINRICH. That is correct.

Mr. BILIRAKIS. Dr. Nelson, just again very quickly, I wonder how well the VA's revised patient safety handbook has been received by

the staff in Florida's VISN network. In other words, have the VA employees accepted it and are they using it? Do you have an opinion about that?

Ms. NELSON. Yes. We are the first pilot site for the patient safety handbook and I participated in the training sessions for the quality managers and risk managers and they were very enthusiastic about the potential. I guess they started in the fall so, yeah, they are just getting into it right now but the response has been very favorable.

Mr. BILIRAKIS. Great, good to hear that. Well, again, very fundamentally to Dr. Garthwaite and Dr. Bagian, as the VA healthcare system has evolved away from an inpatient hospital system, and we know that it has, the VA has increased the amount of care provided to veterans through contracts with other healthcare providers. So I guess my question is are these providers required to tell veterans when they have made an error, are they required to report errors to the VA even though they are contract and not really directly employed by the VA?

Mr. GARTHWAITE. That is a good question. I need to find out the answer to that for you. I will get back to you. I can't answer with certainty. I should be able to.

Mr. BILIRAKIS. Do you know if the medical inspector's report on the VA patient safety event registry includes information from these contract healthcare providers?

Mr. GARTHWAITE. It wouldn't, I don't believe. It was done a couple years ago and it was really a report of our internal rollup of events.

Mr. BILIRAKIS. So there may be a gap there that should be looked at.

Mr. GARTHWAITE. I appreciate that. I will look into that.

[The following was received for the record:]

The VA's patient Safety Event Registry did not include separate identifiers for contract healthcare facilities in FY 1997 and 1998. The three identifiers used were: patient, outpatient and long-term care. In a few instances contract nursing homes were identified. VHA's new system will be capable of identifying care location.

Mr. BILIRAKIS. Well, thank you. The annals of internal medicine suggest that hospitals can forestall expensive litigation by admitting mistakes and offering fair compensation before the patient or the patient's family even realizes the error. The VA Medical Center in Lexington has a policy that calls for full disclosure to patients injured either accidentally or through medical negligence. I believe that the results seem to be good in that regard, right? Has the VA implemented this policy nationwide and if not why hasn't it?

Mr. GARTHWAITE. Yes. That is current VA policy. Lexington carries out this policy but they more proactively set up who does that and took additional steps to assure that there was some consistency to how that was done with their district counsel and with the specific members of their medical staff so I think we have learned from that.

That report came out I think in either December or January, late December. Although we made the rest of our networks and the other providers aware of that, we haven't had an opportunity to review what the advantage is system wide of implementing their process.

Mr. BILIRAKIS. So you haven't contemplated whether you might mandate that throughout the entire system?

Mr. GARTHWAITE. We have already mandated that everyone is informed and so what we need to understand is what are the nuances of the way they have done it that help. Very clearly if you feel fairly treated as a patient, if people admit they have made a mistake and help provide you remedies for that mistake your need——

Mr. BILIRAKIS. Good bedside manner, so to speak. I know that is what I have seen over the years. Frankly, doctors with a fine bedside manner that show caring are sued less than others. I know my time has expired and maybe we won't go into any response to this but I am concerned what kind of factors do you look at when you conduct a root cause analysis?

Do we look at factors like—and other areas have been mentioned—number of hours or shifts an employee worked prior to the event, etc.? I don't really want to take up too much time. If you have a quick response and the chairman will allow it.

Mr. BAGIAN. If I may, I can give a quick response. Yes. In fact, we can show you another time if you like, we have a whole human factors module that goes in here where we ask some prompting questions, was fatigue a problem, was scheduling a problem, was equipment, things like that, and then it gives them a whole host of questions that get right into that exactly so it is not left for their memory. It is a human factors tool. It steps them through a number of questions so that we do very specifically delve into just those things, sir. Yes.

Mr. BILIRAKIS. Thank you. Thank you, Mr. Chairman.

Mr. STEARNS. The gentleman's time has expired. Dr. Snyder is recognized for 5 minutes.

Mr. SNYDER. Thank you, Mr. Chairman. I am sorry I was late getting here. The Armed Services Committee was meeting with Secretary Cohen and General Sheldon this morning. But in deference to you in my time to ask questions of Secretary Cohen, I did bring up the issue of medical errors since they also have a closed system and have opportunities, I am sure, for improving things. I will make one comment. In the Armed Services Committee room, we don't let the smell of food in the room during the noon hour.

I don't know what it is here but we got the distinct impression we are being tempted. You know, some time in my past I went through a phase over a few months of asking people involved in the business what was the worse mistake they ever made. You know, these are friends. I remember talking to a nurse one time and her first job had been as a nurse's aide in a nursing home before, you know, literally hiring people off the street and teaching them how to administer meds.

And she gave a dose of morphine 1 day and a short time later the patient was dead. And it was only years later when she was in nursing school learning how to administer drugs doses did she realize she had missed a decimal point and almost for sure killed that patient. My favorite one was an emergency room that had an active resuscitation going on and they were administering oxygen. I think it was some kind of humidifying agent.

And they realized later after the patient had expired that they had instead of using like normal saline or something had grabbed the preservation fluid for pathology samples. But the best part of it was when it was called to the staff's attention in the emergency room, they said, you know, that happened last week too because the bottles were right next to each other, very similar, and in the course of a code you just grab that same bottle. But somewhere is two very well-preserved sets of lungs that didn't survive.

I remember talking to a young man one time in his residency that worked as a military doctor and he said to me one time, he said, you know, I know I have killed people, he said, but it was always in the context of trying very, very hard to do the right thing. I think that is what everybody is about it how do you help people who try very, very hard not to do the wrong thing. So it seems like this report that came out is a real opportunity for our country and for healthcare facilities and healthcare providers and for patients to do the right thing.

I have some fear we may get all bogged down in our politics and, you know, all the different advocacies that can come to bear on this problem in general but that is just the nature of the system. One specific question I wanted to ask, and I apologize if this has been discussed earlier, but I come from a State that has both rural and metropolitan areas. We have a fair number of hospitals of varying sizes. If I am a hospital administrator out there and I have read this book and I think, gee, every hospital thinks we are doing—we are safety conscious, we are doing the right thing, this report seems to indicate that perhaps we are not doing anywhere near what we ought to do.

What should I do as a hospital administrator or a doctor working in a hospital or medical facility, what should I do starting today? What recommendations do you have for people out there who want to do the right thing?

Ms. COUSINS. Two things I would recommend. I think the first thing, everyone would probably agree, would be the culture change. There needs to be support from the top, from the administration, that it is safe to share your experiences and to share them outright. The second thing is that I think we have learned so much from our medication errors reporting program and through the good work of the Institute of Safe Medication Practices, there has been so much education done and yet the lessons we have learned have not been adopted.

So if I was in the administration I would seek out those things that have been put out to the public as recommendations or guidelines or guidances or general information about the kinds of errors we are seeing and insure that my facility is adopting the things that make good sense for us.

Mr. GARTHWAITE. I would totally agree with that. I think that as an administrator you have to realize that your job is not to hire perfect human beings and hope you can catch them making a mistake. Your job is to hire human beings and recognize they are going to make mistakes and understand it is your job to try to help design systems to support them in doing their job that minimizes the chance of making a mistake and that minimizes the consequences if a mistake is made.

And so you should go back and say Formalin and normal saline have to be in different colored bottles and they must not be stored next to each other because that would be confusing. What we did was find that concentrated potassium chloride because of the potential for error in mixing and calculating the dose shouldn't be done sporadically, it should be done by someone who does it all the time so it should be in the pharmacy, never on the wards, and we removed it all from the wards. We also found that bar codes prevent you from making mistakes such as confusing which patient gets the medication, what dose of the medication is given, and the time of the administration of medication.

It is all those system things that are really at the root of all this. It is critical for an administrator to recognize that, say that, and when someone is willing to come forward and say there is something broken in the system, reward them for it, don't punish them. Thank you.

Mr. SNYDER. Thank you. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman. If there aren't any further questions with this panel, we will release you again with our thanks. You have been of immense help. The last and third panel, the third and last panel, Mr. Daniel Perry, Executive Director of the Alliance for Aging Research on behalf of the Foundation for Accountability, Dr. Dennis S. O'Leary, President of the Joint Commission on Accreditation of Healthcare Organizations, Dr. William Golden, President of the American Health Quality Association, Dr. Michael L. Langberg, Senior Vice President, Medical Affairs, Chief Medical Officer, Cedars-Sinai Health System on behalf of the American Hospital Association, and last and not least, Ms. Mary Foley, RN, President of the American Nurses Association.

Well, as you have heard, your written statements are a part of the record. We will set the clock at 5 minutes. I would appreciate it if you would stay as close to it as you possibly can and obviously hopefully you will be complimenting and supplementing your written testimony. And we will kick it off with Dr. Perry.

STATEMENTS OF DANIEL PERRY, EXECUTIVE DIRECTOR, ALLIANCE FOR AGING RESEARCH, ON BEHALF OF FOUNDATION FOR ACCOUNTABILITY; DENNIS S. O'LEARY, PRESIDENT, JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS; WILLIAM E. GOLDEN, PRESIDENT, AMERICAN HEALTH QUALITY ASSOCIATION; MICHAEL L. LANGBERG, SENIOR VICE PRESIDENT, MEDICAL AFFAIRS, CHIEF MEDICAL OFFICER, CEDARS-SINAI HEALTH SYSTEM, ON BEHALF OF AMERICAN HOSPITAL ASSOCIATION; AND MARY FOLEY, PRESIDENT, AMERICAN NURSES ASSOCIATION

Mr. PERRY. Thank you, Mr. Chairman. I will summarize my written statement. My name is Dan Perry, and I serve as Chairman of the Board of Trustees for the Foundation for Accountability, commonly known as FACCT. FACCT is a 4-year-old not-for-profit organization dedicated to helping Americans have reliable information they can use to help make better health decisions. FACCT was created by and continues to be governed by large healthcare purchasers and consumer organizations.

In my professional life, as you have stated, I also serve as Executive Director of the Alliance for Aging Research here in Washington. Safe health is the first concern of every patient and it must be recognized also as a vital public interest. We applaud the work of the Institute of Medicine and the interested congressional panels in raising public awareness about the unacceptably high rates of medical errors in our health system. And we are pleased that so many healthcare leaders have come forward to acknowledge the seriousness of the issue and the need for corrective action.

However, we are not confident that the health professions and the leading healthcare institutions are capable of correcting these problems without external pressure, pressure that could be provided by individual patients and by the public's collective expectations of better healthcare. Wherever we have looked at health plans, medical groups, integrated health systems we find inconsistent and inadequate care being delivered to too many people. We also find a general unwillingness to share quality information with the public and a discomfort with the basic premises of public accountability which is that health professionals and organizations must disclose how they are doing.

Our research and others confirms that safe medical care is a central concern of most Americans. A survey by the American Society of Health System Pharmacists revealed that 61 percent were very concerned about being given the wrong medication in a hospital. The AMA has found that 42 percent of Americans believe that they or a family member or a friend has been the victim of a medical error. A 1996 survey by AHCPR reported that 86 percent of Americans want information about the quality of their doctor and 83 percent would like information about the quality of their hospital.

Certainly each of us is deeply concerned about quality and wants to have information that would enable us to make good decisions for ourselves and our families. Yet, the leading healthcare organizations often resist such initiatives. The leaders of American healthcare, that is clinical directors, organization executives, policy researchers, have been aware of high medical error rates at least since 1991.

In considering the tragic proportions of our patient safety problems, Congress should not labor under the presumption that skilled and concerned professionals will suddenly solve problems that have been well known for many years particularly when market pressures offer little reward for a commitment to quality care. Eighty-seven years ago Louis Brandeis argued that sunlight is said to be the best of disinfectants. The IOM has bravely embraced this principle in its recommendations, favoring a "nationwide, mandatory reporting system about adverse events that result in death or serious harm." The IOM further states that the result of analyses of individual reports should be made available to the public, and I am still quoting, "the public also has the right to be informed about unsafe conditions. Requests by providers for confidentiality and protection from liability seem inappropriate in this context" says the IOM. Medical ethics dictates that doctors have a duty to disclose errors to patients and relatives, regardless of liability concerns, as you heard this morning.

Shouldn't a patient facing a vital healthcare decision selecting a hospital for surgery or choosing a nursing home for an ailing parent be able to factor in that facility's safety record when making that decision. If any person or agency knows based upon reliable methods that one hospital or one nursing home provides safer care than another that information should be disclosed to a prospective patient. While we have a moral responsibility to let patients and families know about the risks they may face when entering a healthcare facility, we should also recognize that the health system itself will not become accountable until information on institutional performance is public.

Entrenched cultural, technical, and management systems permit unsafe systems to prosper and to escape scrutiny. So long as health care organizations face no economic consequences or risk of public embarrassment when they fail to address safety problems, they will continue to put safety at the bottom of the priority list. As the Philadelphia Inquirer recently editorialized, "if the counteroffensive against medical mistakes is shrouded in secrecy-as the error rate still is today-that will limit the pressure on hospitals to improve.

There is little doubt that public disclosure increases an institution's sense of urgency and accountability about a problem. Congress needs to make sure the medical establishment comes clean."

Mr. BILIRAKIS. Please summarize, Dr. Perry.

Mr. PERRY. I would summarize by saying that if we have both the responsibility ethically to the patients and their families and also to the system, which we would like to see improve and that improvement will only come when there is public understanding of the variability and the risks that they may face. Thank you.

[The prepared statement of Daniel Perry follows:]

PREPARED STATEMENT OF DANIEL PERRY, CHAIRMAN, BOARD OF TRUSTEES, FOUNDATION FOR ACCOUNTABILITY

My name is Dan Perry. I serve as Chairman of the Board of Trustees of the Foundation for Accountability, commonly known as FACCT. FACCT is a four-year old non-profit organization dedicated to helping Americans have reliable information they can use to make better health care decisions. FACCT was created by and continues to be governed by large health care purchasers and consumer organizations. Our Trustees include private sector leaders such as General Motors, AT&T, AARP, the National Coalition for Cancer Survivorship, and the National Alliance for the Mentally Ill as well as public purchasers such as the Federal Employee Health Benefit Program, the Health Care Financing Administration, and several state governments. In my professional life, I also serve as Executive Director of the Alliance for Aging Research here in Washington.

Safe health care is the first concern of every patient, and must be recognized as a vital *public* interest. We applaud the work of the Institute of Medicine and the interested Congressional panels in raising public awareness about the unacceptably high rates of medical errors in our health system. And we are pleased that so many health care leaders have come forward to acknowledge the seriousness of the issue and the need for corrective actions.

But we are not confident that the health professions and leading health care institutions are capable of correcting these problems without external pressure—pressure provided by every individual patient and by the public's collective expectation of improved care. The leaders of U.S. health care—clinical directors, organization executives, policy researchers—have been aware of high medical error rates since at least 1991, but cultural, structural and economic barriers have impeded internally generated solutions. In particular, FACCT believes that the culture of secrecy that has shielded health care performance from public view must be challenged if patient safety is to be improved.

The Foundation for Accountability has developed and applied various measures of the quality performance of our health care system. Much of our own work has fo-

cused on the quality of care for chronic illnesses and for children's health. Wherever we look—at health plans, medical groups, integrated health systems—we find inconsistent and inadequate care being delivered to too many people. We also find a general unwillingness to share quality information with the public, and a discomfort with the basic premises of public accountability—that health professionals and organizations must disclose how they're doing. In the managed care industry, for example, only about 50% of eligible HMOs report the industry standard quality measures to the national accrediting body—and one-third of those refuse to make their data public. The nation's PPOs have been unwilling to collect or publish any quality information. In a recent California initiative to capture simple patient satisfaction data from hospital patients—fully funded by a foundation—only about half of the hospitals were willing to have their patients surveyed. Today, only about one-third of US hospitals have installed computerized medication order systems—and only one per cent require their doctors to use those systems!

At the same time, our research and others' confirms that safe medical care is a central concern of most Americans. A recent survey by the American Society of Health System Pharmacists revealed that 61% were very concerned about being given the wrong medication in the hospital. The AMA found that 42% of Americans believe that they or a family member or friend has been the victim of a medical error. A 1996 AHCPR survey reported that 86% of Americans want information about the quality of their doctor and 83% would like information about the quality of their hospital.

Certainly each of us is deeply concerned about quality and wants to have information that would enable us to make good decisions for ourselves and our families. Yet the leading health care organizations often resist most such initiatives. The risk of public embarrassment, the difficulty of creating effective management systems in our highly fragmented health care world, and the cost and uncertainty of investing in computer technology prevent even the best intentions of so many health care professionals from achieving meaningful changes. In considering the tragic proportions of our patient safety problems, Congress should not labor under the presumption that skilled and concerned professionals will suddenly solve problems that have been well-known for many years—particularly when market pressures offer little reward for a commitment to quality care.

Louis Brandeis argued—eighty-seven years ago—that "publicity is justly commended as a remedy for social and industrial diseases. Sunlight is said to be the best of disinfectants." The Institute of Medicine bravely embraced this principle in its Recommendation 5.1, favoring a "nationwide, mandatory reporting system—about adverse events that result in death or serious harm." The IOM further stated that "the results of analyses of individual reports should be available to the public," (p. 75) and that "the public also has the right to be informed about unsafe conditions. Requests by providers for confidentiality and protection from liability seem inappropriate in this context." (p. 88)

Public disclosure of quality of care problems is important for two reasons—one ethical, one structural.

First, patients have an absolute right to know about the risks they face when receiving medical care.

Second, the health system will not improve until consumers recognize the deficiencies of today's health care system—in their own backyard and in understandable terms—and demand changes.

Our failure to honor these two principles contributes to the persistent alienation of the public from health policy and the continued difficulty the nation faces in improving the performance of its health system.

Medical ethics dictates that doctors have a duty to disclose errors to patients and relatives, regardless of liability concerns. Similarly, we should view the advance disclosure of risks, including the risks of error, as an intrinsic part of informed consent. The IOM and others have estimated that on the order of 3-4% of all hospital admissions involve some kind of avoidable error. For a mid-sized community hospital serving 20,000 admissions per year, that represents as many as 800 cases in a year, enough to constitute a measurable index of quality. In states such as Connecticut, mandatory reporting systems have produced as many as 14,000 reports per year in the nursing home system alone—so we know that mandatory reporting can work. Shouldn't a patient facing a vital health care decision—selecting a hospital for surgery or choosing a nursing home for an ailing parent—be able to factor in the facility's safety record when making that decision? If any person or agency knows, based on reliable methods, that one hospital or nursing home provides safer care than another, that information should be disclosed to a prospective patient.

While we have a moral responsibility to let patients and families know about the risks they may face when entering a health care facility, we should also recognize

that the health system will not become accountable until information on institutional performance is public. Entrenched cultural, technical, and management systems permit unsafe systems to prosper and escape scrutiny. So long as health care organizations face no economic consequences or risk of public embarrassment when they fail to address safety problems, they will continue to put safety at the bottom of the priority list. As the *Philadelphia Inquirer* recently editorialized, "if the counteroffensive against medical mistakes is shrouded in secrecy—as the error rate still is today—that will limit the pressure on hospitals to improve. There's little doubt that public disclosure increases an institution's sense of urgency and accountability about a problem . . . Congress needs to make sure the medical establishment comes clean." [1/25/2000]

Finally, the avoidance of public accountability for medical error has damaging, if subtle, consequences for our society. By treating error rates as protected information subject only to professional review and action, we perpetuate the false notion that patients should be passive users of a system that possesses adequate management and professional controls to assure their safety. Patients remain unable to make good decisions, to make trade-offs between various dimensions of risk, benefit, and cost, and they remain unable to exert any pressure on the health system to change.

Our health system is insulated from public scrutiny or constructive incentives. No one—doctors, hospitals, HMOs—is recognized or rewarded for achieving better results or providing safer care. Consumers have no useful information to guide them to providers who are likely to give them better care. In the absence of quality information, corporations and consumers continue to favor providers that are cheaper or more convenient, even though we know incredible variations in quality persist. Our personal and collective health is threatened by a system that fails to monitor and disclose its own performance and fails to respond to public concerns. Our health system will not materially improve until the public demands high quality care and evidence that it's being delivered. Congress should act on the IOM recommendations and establish a mandatory national reporting system for medical error, and ensure that understandable, relevant information about patient safety is available to every American consumer.

Mr. BILIRAKIS. Thank you, sir. Dr. O'Leary.

STATEMENT OF DENNIS O'LEARY

Mr. O'LEARY. I am Dr. Dennis O'Leary, President of the Joint Commission on Accreditation of Healthcare Organizations. I am very pleased to have the opportunity to address you today concerning medical errors. This is perhaps the most pressing quality issue we face in healthcare today. The Joint Commission accredits over 18,000 organizations whose services include acute care, long-term care, ambulatory care, behavioral health care, laboratory services and home care.

This broad experience gives the Joint Commission a panoramic view of the strengths and weaknesses inherent in our healthcare delivery system. My testimony will discuss briefly the important features of the Joint Commission's Sentinel Event Program but stress the reality that without congressional assistance the Joint Commission's error reporting program and others like it will continue to fall well short of their intended goals. Simply stated, the Joint Commission's Sentinel Event Program should be viewed by policymakers as a treasure cove of lessons learned in designing any program to promote medical error reduction.

There are two messages that I would like you to take away from my testimony today. The first is that medical error reduction is an information problem. We believe that the solution to reducing the numbers of medical errors resides in collecting, analyzing and applying existing information about medical errors. The second message is that we will not be successful in securing access to this information if the Congress does not establish Federal protections

that will permit the surfacing evaluation and sharing of that information.

The Joint Commission initiated its formal Sentinel Event Program in 1996. In so doing, the Joint Commission saw a clear need to understand the epidemiology of medical errors and to initiate a systems approach to developing error reduction strategies. We designed the Sentinel Event Program to have four information-driven functions. The first encourages the reporting of specifically defined sentinel events. A sentinel event is our label for an unanticipated death or major permanent loss of function in a patient not related to the natural course of the patient's underlying illness.

Because there must be incentives for error reporting, we do not penalize the accreditation status of an organization that surfaces an error and performs the required due diligence. However, despite the incentive to report errors to the Joint Commission, the fear of public castigation and litigation are significant impediments for most healthcare providers. We have therefore experienced very limited reporting to our data base. The second element of our program is a requirement that the organization conduct an indepth analysis following the occurrence of a sentinel event to identify the underlying causes of the error and to form the basis for an appropriate action plan.

These root cause analyses, which we believe hold the critical answers to future error reduction efforts, focus primarily on organization systems and processes. Unfortunately, the majority of today's reporting systems, both voluntary and mandatory, fail to require or encourage the performance of these intensive assessments. Not surprisingly, organizations are hesitant to share these root cause analyses with the Joint Commission or anyone else.

We must recognize that preparing a document that lays bare the weaknesses and healthcare provider system is akin to writing a plaintiff's brief. Therefore, we cannot expect uniform preparation of these documents without Federal protections against their inappropriate disclosure. The third feature is monitoring. The Joint Commission monitors the action plans of accredited organizations, which have experienced serious medical errors to insure that planned system changes are in fact implemented.

We view the monitoring function as a key element of public accountability. The public must have confidence that there is an external body overseeing patient safety issues in the organizations that are delivering their care. Because error-related data and information undergird the system of accountability and oversight, we also believe that any national reporting program must insure appropriate data sharing among all of the responsible oversight bodies.

Efforts should at least be made to better utilize the existing private sector and public sector structures through improved data sharing and encourage the broad dissemination of what has been learned from medical mistakes. The last feature of the Sentinel Event Program is dissemination of lessons learned from errors so that all organizations may reduce the likelihood of similar adverse occurrences. The Joint Commission does this through a series of sentinel event alerts.

To date, we have issued alerts on medication errors, wrong side surgery, restraint-related deaths, blood transfusion errors, inpatient suicides, infant abductions, and post-operative complications. We have preliminary data indicating that these have significantly reduced the frequency of certain serious errors. The Joint Commission is pleased that the IOM report is galvanized the professional and policymaking communities around this critical set of quality issues.

However, there is danger that in rushing to address a serious public policy issue all of the elements necessary to success may not be considered. The Joint Commission Sentinel Event Program contains those elements and it demonstrates very clearly that no reporting system for serious errors can fulfill its objectives without congressional help. We therefore urge the Congress to create statutory protections from disclosure and discoverability of the indepth, causal information that must be gathered in any mandatory or voluntary reporting system.

Without clear Federal protection from disclosure of root cause analysis information no reporting system can achieve its goals for error reduction. Today we have the opportunity to dramatically reduce the numbers and types of errors in the healthcare system but we must have your help to reach this goal. Thank you.

[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 am pleased to have the opportunity to address each of the three House subcommittees regarding "Medical Errors: Improving Quality of Care and Consumer Information." Medical errors is one of the most pressing quality issues we face in the health care industry as we approach the next millennium.

The Joint Commission is the nation's oldest and largest standard-setting body for health care organizations. We accredit over 18,000 organizations that provide a wide range of services, including hospitalization; long term care; ambulatory care; behavioral health care; laboratory services; managed care; and home care. Based on its broad experience, the Joint Commission has a panoramic view of the strengths and weaknesses inherent to our health care delivery system. We believe that the problem of medical errors is endemic to the way health care is carried out, but that we have the tools and commitment with which to sharply reduce their incidence.

My testimony will focus on the Joint Commission's Sentinel Event Program which was designed to reduce medical errors among all of our accredited organizations. I will discuss briefly its important features, and relate how the program has assuredly saved lives and prevented injury. But I will also stress the fact that without Congressional assistance, the Joint Commission's error reporting program will continue to fall significantly short of its intended goals. Simply stated, the Joint Commission's Sentinel Event Program should be looked to by policy makers for "lessons learned" when designing any national, state or local program of medical error risk reduction.

There are two messages that I would like you to take from my testimony today. The first is that medical error reduction is an information problem. I will expand on this message by describing the attributes of the Joint Commission's Sentinel Event Program, which specifically build on this point. We believe that the solution to reducing the number and types of medical errors resides in developing mechanisms for collecting, analyzing, and applying existing information. If we are going to make significant strides in enhancing patient safety, we must think in terms of what information we need to obtain, create, disseminate and apply to the problem.

The second message is that we will not be successful in performing these information-driven activities if the Congress does not pass federal protections that will encourage the surfacing, evaluating, and sharing of that information. I will discuss this issue in the concluding portion of the testimony.

THE SENTINEL EVENT PROGRAM

Concerned about a spate of serious medical errors that came to its attention during 1995, the Joint Commission initiated its formal Sentinel Event Program in 1996. It is noteworthy that the recently released Institute of Medicine Report, "To Err is Human: Building a Safer Health System." lists many of the same events that spurred us into action four years ago. Many of these errors achieved high media visibility, but it became abundantly clear that these were the tip of the iceberg, and that even the most premier health care institutions were not immune to serious mistakes.

It would be easy to attribute what appeared then to be a rise in errors to the increasing complexity of health care combined with escalating financial challenges in the health care industry. Certainly, health care has been experiencing restructuring, resource constraints, rapid technological advances, and an explosion of medical knowledge that makes it more difficult for practitioners to keep up with the latest knowledge and skill sets. As important as these factors may be, they should more aptly be considered exacerbating conditions rather than root causes of error. In fact, the very high dependence on human interventions and interactions characteristic of health care makes it prone to error. An industry so reliant upon human factors such as memory, emotions, communication, skills, and physical well-being must be supported by organizational and technologic systems to reduce the likelihood of mistakes.

The Joint Commission saw the need to take a leadership role in helping health care organizations better understand the epidemiology of medical errors as well as the need for a systems approach to effective error reduction strategies. Therefore, the Sentinel Event Program was launched with the primary goal of applying scientific methodology to the problem to bring about a significant reduction in the numbers and types of medical errors.

We designed the Sentinel Event Program with four information-driven functions:

1. Encouragement to report specifically defined sentinel events;
2. Requirement of the conduct of an in-depth systems ("root cause") analysis following the occurrence of a sentinel event to elucidate the underlying causes of the error and to form the basis for an appropriate action plan;
3. Monitoring of the organization to assure its compliance with patient safety standards and implementation of the action plan; and
4. Dissemination of lessons learned from errors so that all organizations may reduce the likelihood of similar adverse occurrences.

Reporting of Sentinel Events

It is imperative that any medical error reporting program operate under a pragmatic and carefully crafted definition of what is a reportable event. Standardization of the information to be collected is an important prerequisite for aggregating events in a consistent and meaningful fashion. Further, without a pragmatic definition, a reporting program would be flooded with hundreds of thousands of lesser injuries that would overwhelm the system. With this in mind, we identified a subset of sentinel events [1]—including their nomenclature and taxonomy—that would be reported to the Joint Commission on a voluntary basis.

These reportable events affect recipients of care (patients, residents, enrollees) and meet the following criteria:

- the event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition, or
- the event is one of the following:
  - suicide of a patient in a round-the-clock care setting,
  - infant abduction or discharge to the wrong family,
  - rape,
  - hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities, or
  - surgery on the wrong patient or wrong body part.

The foregoing definition of a reportable event minimizes the external reporting burden to health care organizations while focusing on the most serious occurrences that have a high likelihood of being preventable. The fact that the Sentinel Event program seeks to collect data on the most serious errors, or "crashes," distinguishes

[1] The Joint Commission defines a sentinel event as "any unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injuries include a loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

the Joint Commission's reporting program from the voluntary programs encouraged in the IOM report, which would collect information only on the "near misses."

An important feature of the Sentinel Event Program is the non-punitive reporting environment it seeks to create. Hoping to foster a positive culture that will promote error reduction efforts, the Joint Commission has designed the Sentinel Event policies not to penalize the accreditation status of an organization that surfaces an error and performs the appropriate due diligence required under the policy. The resulting atmosphere provides incentives that favor the surfacing of information about errors that eventually contributes to error reduction strategies that can be used by other organizations.

Despite the incentive to report errors to the Joint Commission, the fear of public hangings and litigation are significant impediments for the majority of health care providers. Therefore, we have experienced only limited reporting to the Joint Commission's database. Over the years, our Sentinel Event Program has made procedural accommodations to protect sensitive error-related information, such as having our surveyors review reported errors onsite rather than having information sent to the Joint Commission's central office. But these manipulations are only stop gap measures that we believe must be replaced by federal protections for error-related information.

I am going to return to the need to create a positive culture for reporting later in this testimony, because I believe it is the most important contribution that Congress can make to reducing medical errors nationwide. The Joint Commission has been especially pleased by the past support by some members of the Commerce committee for legislation that would promote a non-punitive environment for surfacing and learning from errors.

Systems Analyses to Discover Root Causes

While reporting is voluntary, the production of a root cause analysis following a sentinel event is a mandatory feature of the Sentinel Event Program. An accredited organization that experiences a sentinel event must produce an intensive analysis that encompasses a no-holds-barred vetting of all of the causes underlying the event. We call these responses root cause analyses—a term borrowed from the engineering world's reliance on a systems approach to both solving problems and producing desired outcomes.

A root cause analysis focuses primarily on systems and processes, not on individual performance. While an individual is almost always the most proximal cause of a mistake in health care, it is also almost always the case that the fundamental causes of error relate to systems failures distal to the error itself. For example, systems may fail to provide simple checks and balances; or they may be missing critical safeguards; or may have design flaws that actually promote the occurrence of errors.

These intensive analyses are rich learning processes that can elucidate multiple factors that ultimately contributed to the error. Many of these are not readily apparent until the root cause analysis is undertaken. Therefore, the analysis must be comprehensive, thorough, and engage the personnel involved in all aspects of the care giving and support processes. These are also time consuming investigations, and their complexity may require external technical assistance to do well. The Joint Commission has developed several comprehensive guides on how to conduct a good root cause analysis, and continues to be the leading source of guidance for health care organizations in this area.

Unfortunately, the majority of reporting systems—both voluntary and mandatory—fail to require or encourage the performance of these intensive assessments. This was evident during our review of many state reporting programs. A reporting system that ends with the report of the event itself is not a credible program and will not contribute to error prevention. Root cause analyses also offer extraordinary insights into how processes must change to control unwarranted variations, and they tell stories of what systems must be developed to guard against the occurrence of similar human error. Root cause analyses hold the promise of prevention. They are also the necessary substrate from which risk reduction action plans are created.

Not surprisingly, organizations are hesitant about sharing these root cause analyses with the Joint Commission or anyone else. Although many organizations have done so, we must recognize that preparing a document that lays bare the weaknesses in a health care provider's system is akin to writing a plaintiff's brief for purposes of litigation. Therefore, we cannot expect uniform preparation of these documents without accompanying federal protections against their inappropriate disclosure.

Monitoring Action Plans and Safety Standards

The Joint Commission monitors the action plans of accredited organizations which have experienced serious medical errors, in a manner similar to the way we monitor any quality of care area in need of improvement. This ensures that there is an independent review of the milestones associated with anticipated systems changes. Monitoring is an important part of the strategy for preventing errors, to ensure that the response to an error does not terminate in only the report itself or a discussion of what went wrong. We want to see an organizational response that results in preventive actions.

The Joint Commission developed explicit patient safety standards that became applicable to accredited organizations beginning in January 1999. These new standards were specifically created to establish patient safety as a high priority in provider organizations.

The new standards require that the leadership of a health care organization establish processes for identifying and managing sentinel events and put these into practice. The standards also require that the organization monitor performance of particular processes that involve risks or may result in sentinel events, and intensely analyze undesirable patterns or trends in performance. The standards make patient safety a visible responsibility of health care organizations and a requirement for accreditation. Compliance with these new patient safety standards is evaluated through our onsite inspection process.

We view the monitoring function as a key element to public accountability. The public must have confidence that there is an external body requiring attention to patient safety within the organization that is delivering their care. We believe that the public views safety as a threshold concern. While citizens probably do not wish to have detailed data about safety prevention in each health care organization, they should reasonably expect that responsible oversight bodies are acting conscientiously and effectively on their behalf. This includes aggressive and timely follow-up to the occurrence of a serious medical error and holding the organization accountable for making necessary systems improvements. That assurance must be provided to the American public.

At the same time, it is error-related data and information that undergird and drive this system of accountability and oversight. Therefore, we believe that any national response to the IOM report must ensure appropriate data sharing among all of the responsible oversight bodies which perform any of the functions discussed in this testimony. The health care quality oversight system has a variety of private sector and public sector players today. Efforts should at least be made to better utilize existing structures through improved data sharing and encourage the broad dissemination of what has been learned from medical mistakes.

Dissemination of Lessons Learned

To have a positive national effect on patient safety, information gleaned from errors must be aggregated, analyzed and disseminated to the health care community at large. The Joint Commission began its series of *Sentinel Event Alerts* to share the most important lessons learned—known risky behaviors as well as best practices—from its database of error-related information. To date we have issued *Alerts* in a number of areas, including medication errors; wrong site surgery; restraint-related deaths; blood transfusion errors; inpatient suicides; infant abductions; and post-operative complications.

We are confident that these *Alerts* have saved lives. Unfortunately, we cannot calculate real decreases in error rates with scientific certainty, because the full scope and frequency of serious adverse events is simply not known. However, we have some data which illustrates the effects of our Sentinel Event program in selected areas. For example, we have seen a notable significant effect from our first *Alert* dealing with the importance of appropriate storage and handling of potassium chloride (KCl)—a substance that is deadly when given in concentrated form and is easily mistaken for less benign substances. In analyzing the causes of KCl-related deaths in 1997, it became evident that accidental injection of KCl stored on hospital floors was an important cause of unanticipated deaths. The Joint Commission issued its *Alert* on the subject in February 1998. The number of reported deaths has dropped from about 12 the year before to only one in 1998 and one in 1999.

We believe that significance should be attached to how information is disseminated and by whom. The risks associated with potassium chloride have long been known to practitioners. But when the principal accreditor of provider organizations issued a major alert, it caught the attention of organization leaders and health care practitioners. Moreover, it was clear to the recipients of the information that the Joint Commission would be paying attention to this particular issue and following up during onsite evaluations of the organization's performance. This program of

Alerts is an example of the type of vehicle necessary to achieve behavior change in health care organizations.

NEED FOR CONGRESSIONAL ACTION

The Joint Commission is pleased that the IOM report has galvanized the professional and policy making communities around this critical set of quality issues. Such synergy of purpose among stakeholders is a prerequisite for solving complex, multifactorial problems that depend upon information sharing among the parties. Dramatically reducing the numbers and types of errors will take a concerted effort by all who play a role in the health care system.

However, there is always the danger that in rushing to address a serious public policy issue, all of the elements necessary to success are not considered. The Joint Commission's Sentinel Event program contains those elements, but it demonstrates very clearly that no reporting system for serious errors can fulfill its objectives without Congressional help. We urge, therefore, that Congress create statutory protections from disclosure and discoverability of the in-depth, causal information which must be gathered in any mandatory or voluntary reporting program for serious adverse events.

The Joint Commission took this position publicly several years ago in seeking federal confidentiality protections for the root cause analysis information produced in response to a serious medical error. Soon after we began our Sentinel Event Program, many organizations expressed grave concerns that existing peer review statutes would not adequately protect the production and sharing of the intensive analyses. In fact, the Joint Commission's subsequent review of state laws verified that they were inconsistent and often unclear about the extent to which health care organizations can share with accreditors or other third party external review organizations any assessments of cause and still maintain peer review protections.

Therefore, the Joint Commission began seeking federal legislative protection which would make clear that information developed in response to a sentinel event—and shared with an accreditor—would be provided clear protections from disclosure and discovery. We are convinced that without such clear federal protection from disclosure of root cause analysis information, no reporting system will achieve its goals for error reduction. We believe this to be true for both mandatory and voluntary programs, for serious errors or programs for near misses.

Fear of reprisals, public hangings, and loss of business will continue to impede both reporting and the production of in-depth, intensive investigations of the root causes behind medical errors. Rather than surfacing reports of errors, our blame-and-punishment-oriented culture drives them underground. Congress can make an extremely critical contribution to solving the information problem by passing legislation to address these legitimate fears.

We also encourage you to consider all of the elements contained in the Joint Commission's Sentinel Event program as components necessary to the successful address of the problem of medical errors, irrespective of whether solutions are considered at national, state or local levels. To actually accomplish the tasks presented in this testimony, many stakeholders must play roles. This will take significant data sharing between the public and private sectors to ensure that all of these functions can be effectively carried out.

Thank you for the opportunity to present our views.

Mr. BILIRAKIS. Thank you very much. Dr. Golden.

STATEMENT OF WILLIAM E. GOLDEN

Mr. GOLDEN. Yes, good morning, Mr. Chairman. As Principal Clinical Coordinator for a Medicare Peer Review Organization, I am very pleased to be here today to discuss the issue of medical errors. While I spend substantial time at the Arkansas Foundation for Medical Care, I am also Professor of Medicine at the University Medical School in Little Rock. The PRO has extensive experience in performance measurement and conducts quality improvement, HEDIS measurements, and patient satisfaction surveys for Medicaid as well as for Medicare.

We have supplied the Joint Commission Oryx Program with 10 percent of its national core measures proposed for its system. Today as President of the American Health Quality Association, I

would like to address issues that reflect the concerns and the capabilities of the QIOs, which are members of the HQA, an association of organizations and individuals dedicated to healthcare quality improvement. QAOs are private, community-based, work in all healthcare settings, outpatient and inpatient nursing homes and are in all 50 States, including District of Columbia and the U.S. territories.

We all work together on our 3-year programs and contracts with the Health Care Financing Administration to improve quality of care for Medicare beneficiaries. Over the last 10 years the PROs have evolved into a national network of quality improvement experts that systematically evaluate the delivery of healthcare in a region and institute projects to educate and alter the clinical behavior of institutions, health professionals and patients.

We have assembled staffs of clinical experts, nurses and physicians, data and statistical professionals, medical record abstraction teams. We have an extensive infrastructure of relationships with community hospitals and physicians who have expertise in outreach strategies. In fact, the studies that you heard today from Colorado and Utah were performed—the abstraction and the data was collected by PRO staff.

The IOM points out two kinds of errors, errors of omission, errors of commission involved with the prevention, diagnosis and treatment of illness. Much of the PRO system currently works to reduce errors of omission in prevention, diagnosis and treatment. Examples include improving the rates of mammography, increased use of pneumoccal vaccine and influenza vaccine, making sure patients get appropriate drugs after a myocardial infarction to avoid subsequent myocardial infarctions, antibiotics for the treatment of pneumonia, making sure patients get appropriate therapy for congestive heart failure, better monitoring of diabetes and its complications.

We even do work on areas of commission. One project right now is to eliminate the use of a dangerous drug used in the acute treatment of stroke. We have attached 22 performance indicators that we are currently working on nationwide to improve care and reduce errors in the Medicare program. The PROs serve as a good model for a national patient safety program because these indicators affect a large percentage of elderly Americans. They have a strong scientific basis and they also are a standardized system that allows comparison and performance between regions, between States, pre and post project activity.

We have seven recommendations for improving patient safety and to reduce errors in this country. One is to expand the current performance monitoring system that the PROs are currently involved with. There are many areas that we could focus activity including adverse drug events, hospital acquired infections, pulmonary embolism, post-operative hemorrhage. We agree that the Agency for Healthcare Research and Quality, HCFA, the QIOs and other professional groups should work together to define the highest priority areas for scrutiny for error prone healthcare processes.

We need focus and we need to define what we are going after to achieve results. It is important that a system of monitoring that we have to expand upon would not impose undue burdens to these hospitals because the current system using administrative data

sets and data abstraction teams can conduct and collect most of this information with minimal burden to the institutions.

Our second suggestion is to require mandatory reporting of catastrophic errors. Some of these random and adverse accidents that occur, which we have been hearing about, do not get fully reported, and we believe that a data base would be very useful for us to find root causes and to allow institutions that have not seen the errors to learn from errors at other settings and put in place patient safety practices to reduce the incidence of these events in the future.

We would like to assure accountability of the system and that these medical error collection systems should be handled by a qualified expert organization that is independent of the hospital providers and is capable of analyzing incidence of errors and the response to those errors and find best practices. PROs are especially accountable to the system because we are under Federal contracts to improve the performance of the healthcare system in their region.

Fourth, we want to assure confidential treatment of reported errors, as many have mentioned. We want to encourage reporting, not discourage and punish people for helping develop a safer system. And we believe that a collection system at the State level would be of assistance. Confidentiality of course is important. We would like to establish a mechanism to find unreported errors by surveillance much like we saw in the Colorado and Utah studies where random surveillance of charts by qualified experts could find these errors and collect more information to improve the system.

We can promote best practices by finding institutions that have implemented good practices and share them with others. One system that we had in our State reduced the use of myocin to reduce hospital infections and that has now become a national model after being shared with our institutions. And finally we want to separate malpractice reform from error reduction. We believe that is a very complex topic but these suggestions that we have made today can go a long way to make the system safer for patients, and malpractice reform is almost a separate topic that goes apart from these issues here that can improve the system for all of us. Thank you.

[The prepared statement of William E. Golden follows:]

PREPARED STATEMENT OF WILLIAM E. GOLDEN, PRESIDENT, THE AMERICAN HEALTH QUALITY ASSOCIATION

Good morning, Mr. Chairman. As the Principal Clinical Coordinator for a Medicare Peer Review Organization, and as a physician who has treated hundreds of veterans in VA medical centers, I am particularly happy to have this opportunity to participate in a joint hearing of the Commerce Committee and the Veterans' Affairs Committee on the important problem of medical errors.

While I spend most of my professional time working for the Arkansas PRO, I am also a Professor of Medicine and Director of General Internal Medicine at the University of Arkansas Medical School. The Arkansas PRO has extensive experience in performance measurement and conducts quality improvement, HEDIS measurement, and patient satisfaction surveys for the state Medicaid program. We are also a recognized vendor for the Oryx Program of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). In fact, we created three of JCAHO's thirty performance measures in the proposed national core program.

I am here today as President of the American Health Quality Association (AHQA), a national membership association of organizations and individuals dedicated to health care quality improvement. Our member Quality Improvement Organizations (QIOs) are private, community-based organizations that promote health care quality

in all health care settings. QIOs work in all 50 states, the District of Columbia and the U.S. Territories.

The QIOs have several lines of business including work with state governments and private health plans. The work that unites them all, however, is their 3-year, competitively awarded contracts from HCFA to evaluate and improve the quality of care delivered to Medicare beneficiaries. For this work, our members are more commonly referred to as Medicare Peer Review Organizations, or PROs.

Congress established the PROs in 1983 to look for single case problems. During the 1990s, the PRO system evolved to become a national network of quality improvement experts that systematically evaluate the delivery of health care in a region and institute projects to educate and alter the clinical behavior of institutions, health professionals and patients. QIOs are staffed with clinical experts, communication experts, and data and statistical professionals who work together to analyze and collaborate with the health care system in their communities.

Today's PRO system is uniquely qualified to serve as the core of a new national system for improving patient safety. One of the greatest strengths of the PRO system is its extensive infrastructure of relationships in every region of the country. PROs work individually with hospital staffs and physicians offices. They are also increasingly engaged with home health care systems, nursing homes, academic health centers, and community groups such as heart associations and cancer coalitions.

In addition to technical expertise, they have developed public relations and outreach strategies with professional associations, public health authorities and state officials. This is critical for helping hospitals and other facilities implement improvement strategies as well as tailoring messages to the public about improving their health (e.g. public awareness of receiving pneumococcal vaccinations or getting regular eye examinations to reduce the risk of diabetes-related blindness). This is also critically important for the effectiveness of the PROs' required projects with underserved and disadvantaged populations. These projects often require forms of outreach and communication that are culturally appropriate.

The Institute of Medicine (IOM) report released last November targets both medical errors of omission—care not provided that should have been—as well as errors of commission. In addition, the IOM Committee also states that errors occur and should be detected in all phases of medical care: prevention, diagnosis and treatment.

The Medicare PRO Program as a Model Error Reduction Program. Medicare's national PRO system has been identifying, measuring and reducing error rates for several years. The PRO program is now embarking on an expanded three-year mission to identify and eliminate medical errors. The new program is focused largely on errors of omission—such as prescriptions that were not ordered for prevention of heart attack—and on errors in all three categories mentioned by the IOM. For example, in the prevention area, PROs are working to promote immunizations to prevent the most common fatal infection, pneumococcal disease. In the area of missed diagnoses, the PROs will be working to increase mammography screening and diabetic retinopathy testing. An example of PRO work to reduce treatment errors is that PROs will be emphasizing timely administration of antibiotics for newly hospitalized pneumonia patients.

I have attached a complete list of the 22 performance indicators in each of six clinical topic areas for which the PROs must reduce error rates. These PRO performance indicators serve as a useful model for a new medical error reduction system for several reasons. These clinical topics were carefully chosen because they affect a large percentage of older Americans and because the scientific basis for the desired therapy or action is well established. A national error reduction program should also focus on high priority problems and adopt a science-based approach.

In addition, the standardized national set of performance indicators assures national comparability of data within and between all states, which is critical to accurately measure improvement. We believe this is a sound model for a national system of identification and reduction of medical errors.

Recommendations. Based on our experience working within a national system to identify quality problems and work collaboratively with providers to bring about improvement, here are our recommendations for a new system for improving patient safety.

1. Expand Monitoring System for Error Prevention. Congress should expand the current system utilized by Medicare to monitor a targeted list of health care processes and patient conditions known to be associated with a disproportionate amount of medical errors. This system will identify many errors and adverse events which have not yet resulted in dramatic or catastrophic patient outcomes.

The published literature identifies some categories of preventable adverse events that are both relatively frequent and frequently preventable, and might be targeted by a national monitoring system. Some examples include adverse drug events, hospital acquired infections, deep venous thrombosis, postoperative hemorage. The Agency for Healthcare Research and Quality (AHRQ) and the Health Care Financing Administration (HCFA) should collaborate with representatives of our national network of Quality Improvement Organizations (QIOs), as well as professional and provider groups to define the highest priority areas of scrutiny for error-prone health care processes, and to develop a standardized system for measurement.

Congress will be asked to consider the burden of error reporting. The system of monitoring that I have described can be accomplished without imposing significant additional reporting burdens on hospitals or other providers. PROs can accomplish much of the data gathering necessary by expanding their current mechanisms for review of medical records and abstraction of key data for analysis. Quality improvements based on this kind of monitoring will probably continue to be the major method by which patient safety is enhanced. Because the PRO program has already established the relationships with hospitals necessary to perform this function, there is very little new work that hospitals must do to facilitate an expanded program to address errors in patient care planning and execution.

2. Mandatory Error Reporting. We have recommended that Congress devote substantial resources to monitoring and educating providers about the adverse events that have strong potential to harm patients, rather than wait for patient harm to occur. But the smaller number of more dramatic events that result in patient harm must also be addressed by an error reduction system because the results of such errors are so often tragic and irreversible. This subset of adverse events often captures the attention of local health professionals and often results in demands for system changes to eliminate recurrence.

Health facilities should report the rare and seemingly random adverse events that result in patient harm to a regional entity to create a database. Monitoring and analysis of such a database can offer insight into better system design for all of our communities. The reporting of such errors allows for hindsight analysis to be available throughout the health system, so that more people can benefit from the analysis than just those in the local environment that witnessed the adverse event. The PROs are well qualified to manage and interpret such a database in each state, and have proven adept at educating providers and practitioners about ways to avoid errors in the future.

3. Ensure Accountability. Congress should hold providers accountable for measurably reducing the incidence of errors. A qualified expert organization, completely independent of hospital providers, should analyze the incidence of errors and judge whether improvements are being made. The PRO program is already performing this function on a more limited scale. For the period 2000-2002, PROs will be accountable under their Federal contracts for measuring and reducing the frequency of missed prescriptions to prevent strokes and heart attacks, or missed lab tests to help control diabetes. If a PRO cannot accomplish sufficient measurable improvement, it may lose its Federal contract. In a new medical error system, Congress can rely on the QIOs to measure error rates and identify providers that have made no progress in eliminating errors. Providers that are making no progress on errors could be reported to a regulatory body such as the appropriate federal or state agency, or to the Joint Commission for Accreditation of Healthcare Organizations (JCAHO).

4. Assure Confidential Treatment of Reported Errors. Reports identifying specific providers and individuals should generally not be disclosed. Part of the reason for this is that "naming names" tends to fix blame, even when this is inappropriate. The IOM report [page 45] noted, "Complex coincidences that cause systems to fail rarely have been foreseen by the people involved." This suggests that it is more important to understand system failures than to attempt to affix blame on one or more individuals involved in a system failure.

It is critically important to not to discourage, let alone punish, the active search for errors. Several studies demonstrate that errors are much more numerous than anyone can know without actively digging to find them. The IOM relied on two large studies of the prevalence of medical errors. PROs, in fact, did the medical record abstraction for the second study, based in Utah and Colorado. Both studies found a large number of preventable adverse events through careful review of the medical record. But these researchers also noted that many other errors could not be found in the medical record alone. When researchers at the LDS Hospital in Salt Lake City wanted to find out the true incidence of adverse drug events in their institution, they started by counting the incident reports filed by doctors, nurses, and pharmacists. They came up with about 20 reports a year. But after extensive mining

of lab data, prescription records, and interviews with hospital personnel, they found the true incidence of adverse drug events was over 580 events a year. The hospital then tracked down the causes of these problems and reduced their true error rate below the original apparent rate.

The LDS project puts the idea of public reporting in context. If hospital personnel know that any error they find involving patient harm will be subject to public reporting, few will undertake the costly and difficult investigations that are necessary to discover errors. If public disclosure and punishment await those who dig effectively to find the true extent of errors, few errors will be found, and fewer still will be eliminated.

Congress has repeatedly recognized the importance of maintaining confidentiality for sensitive internal hospital quality improvement activities. For example, Federal law ensures that confidential data reported to PROs shall not be disclosed. Congress can ensure confidential treatment of this information by requiring that error reports be sent to the PRO in each state. The current PRO statute protects such information from unauthorized disclosure. Public reporting of errors should be reserved for those institutions identified by the PRO that cannot or will not improve error rates.

At the state level, aggregate information without identifiers for individuals or institutions could be released to the general public. Data reported at the national level would first be encrypted for aggregate public reporting and would then be considered a publicly accessible dataset.

5. Establish a Mechanism to Find Unreported Errors. Experience with other mandatory reporting systems for errors and health quality problems reveals that no mandatory reporting system will receive all appropriate reports. A separate mechanism to identify unreported errors is needed. One such system is already in place nationwide. Individual PROs periodically request records and analyze them for indicators of errors such as delayed administration of antibiotics in newly hospitalized pneumonia patients, and missed opportunities to prescribe medications to heart attack and heart failure patients. In addition, the national PRO program also utilizes clinical data abstraction centers (CDACs) to accomplish this task. These centers also observe strict confidentiality in managing the records, and have achieved a high degree of reliability in finding and reporting errors to PROs, which then work with the hospitals to prevent their recurrence. This system can be utilized to find many more types of errors.

Institutions should be required to provide information in response to a PRO request to actively identify or pursue information that may not be readily identifiable in standardized reports. This mechanism will help to ensure the integrity of the mandatory reporting system, as it may uncover reports that should have been filed with the PRO but which were not.

6. Promote Best Practices. Once errors are found, their causes must be understood, and solutions must be implemented. This is now accomplished through the national Medicare PRO program by collecting from each PRO their successful interventions to improve care, and then sharing it with all the rest. In this way, every PRO can approach local institutions with the benefit of the best knowledge of all the PROs and providers that have previously tried to solve a problem. By assisting hospital personnel in finding best practices, the PROs go far beyond merely holding hospitals accountable for their failures.

7. Separate Malpractice Reform from the Error Reduction Program. Tort reform and facilitation or limitation of litigation is a matter for a separate set of public policy deliberations. All information should be reported to the PROs for the purpose of assuring that measurable quality improvement is accomplished. Neither regulatory remedies nor liability law need be affected by reports to the PRO or by the confidentiality protections afforded such reports.

AHQA believes these are the basic elements necessary for creating a systematic approach to reducing medical errors that will assure both medical professionals and patients that the problem is being addressed fairly and effectively. The key to a successful solution to this problem will be giving the medical community the opportunity to fully identify the possible extent of their errors and do the work necessary to systematically and measurably improve. Without this measurable improvement, the problem will continue to be discussed but never solved and consumers will never be assured that the quality of their medical care will become any better. The nation's QIOs can provide the accountability and results that the system will require.

Thank you again for the opportunity to share this information with Congress. I look forward to continued discussion as you work to improve the safety of patients across America.

National Health Quality Improvement Projects of Medicare PROs 1999-2002

Clinical Topic	Quality Indicators (proportion of beneficiaries receiving:)	Data Sources (Medicare FFS Only)	Expected Health Outcomes
Acute MI	Early administration of aspirin on admission. Early administration of beta blockers on admission. Timely reperfusion. ACE inhibitors for low left ventricular ejection fraction. Smoking cessation counseling during hospitalization. Aspirin at discharge. Beta blockers at discharge.	Hospital medical records for AMI patients.	Inpatient mortality rates Mortality rates at 30 days Mortality rates at 1 year Readmission rates with AMI
CHF	Angiotensin-related drugs for left ventricular ejection fraction when appropriate.	Hospital medical records for heart failure patients.	Inpatient mortality rates Mortality rates at 30 days Mortality rates at 1 year Readmission rates w/ CHF
Pneumonia	State Influenza vaccination rate. State Pneumococcal vaccination rate Inpatient Influenza vaccination (or screening). Inpatient Pneumococcal vaccination (or screening). Blood culture before antibiotics are administered. Appropriate initial empiric antibiotic selection. Initial antibiotic dose within 8 hours of hospital arrival.	Flu and pneumonia immunizations—Claims or survey similar to CDC's BRFSS. Other indicators: Hospital medical records for pneumonia patients.	Hospital admission rates Hospital readmission rates Inpatient mortality rates Mortality rates at 30 days Readmission rates with Pneumonia
Stroke/TIA and Atrial Fibrillation.	Discharged on warfarin, aspirin or other antiplatelet drug (stroke or TIA only). Discharged on warfarin (chronic atrial fibrillation only). Avoiding inappropriate use of sublingual nifedipine (stroke or TIA only).	Hospital medical records for stroke, TIA, and chronic atrial fibrillation patients.	Inpatient mortality rates Mortality rates at 30 days Readmission rates with stroke/TIA
Diabetes	Biennial retinal exam by an eye professional. Annual HbA1c testing. Biennial lipid profile.	Claims for all diabetic beneficiaries.	Mortality rates at 1 year Rate of development of diabetic retinopathy Rate of development of ESRD
Breast Cancer	Biennial mammography screening.	Claims for all female beneficiaries.	Percent of new cases of breast cancer detected at stage 1

Mr. BILIRAKIS. Thank you, Doctor. Dr. Langberg.

STATEMENT OF MICHAEL L. LANGBERG

Mr. LANGBERG. Mr. Chairman, my name is Dr. Michael Langberg. I am the Senior Vice President and Chief Medical Officer of Cedars-Sinai Health System in Los Angeles. The Cedars-Sinai Medical Center is the largest, not-for-profit acute care hospital in the western United States. Together with more than 2,000 physicians associated with our system, Cedars-Sinai provides care to an urban population of considerable diversity. I have spent almost all of my professional career at Cedars-Sinai as a general internist.

Since 1996, I have served as its chief medical officer and am responsible for overseeing system wide quality initiatives and information systems. In the course of this I have developed a deep knowledge of the complexity of modern health care and have a

broad background in improving the quality and the safety of patient experience. I am here today on behalf of the American Hospital Association. The AHA realizes that the entire health community has to address the serious issues raised in the Institute of Medicine's report on medical safety.

I also want to share with you some of what the hospitals and health systems are doing in this critical area. To begin, I would like to remind the committee and the American public that hospitals provide care to millions of patients safely every year. People who deliver healthcare, the doctors, the nurses and others, are highly trained, receive continuous education and strive every day to deliver safe and compassionate care.

They believe in the dictum, first, do no harm, but healthcare today is extraordinarily complex and even our best intentions can have unwanted and unintended consequences. The IOM report, To Err Is Human, points out that as good as our systems are for preventing and reducing medical errors of all kinds, we can and must do better. We applaud the members of the IOM committee for developing a report that shines a bright light on the problem of medical errors and are heartened by the quick response this has received.

We agree with the report in urging all to avoid blaming individuals for past errors and instead to focus on preventing future errors by designing safety into the system. This stresses two principles that we have learned reduce errors and increase patient safety. First, to err is human. We must understand and improve the systems in which people work to make errors less likely. As a result, reducing errors requires us to design and implement more error resistant systems.

Second, we have to create an environment where caregivers feel they can come forward when an unfortunate mistake does occur. We need to create a non-punitive environment that allows the candid discussions of errors, their sources and their causes. If we cannot discuss our mistakes, we cannot learn from them or prevent them.

The AHA also agrees that stepped up efforts are needed. There are many organizations today that specialize in the area of reducing and preventing medical errors. We at the AHA are working with some of these experts. In December the AHA announced an initiative to target and improve medication safety. Why? Because medication-related errors are one of the most common sources of all medical errors. As part of this initiative the AHA formed a partnership with a highly respected organization in this field, the Institute for Safe Medication Practices.

This non-profit research and education organization and its President, Michael Cohen, have been dedicated for over 25 years the continual reduction of medication errors throughout the healthcare system. We are pleased that they will provide leadership and the technical expertise for AHA's initiative. As part of our effort, we will share with every one of our members successful practices for improving medication safety. We have already sent a quality advisory on improving medication safety to our 5,000 hospital and health system members.

This advisory includes background on the issue, resources our members can turn to for help, and a three-page list of successful practices for improving medication safety. We will follow up on how the successful practices are being implemented with a medication safety awareness assessment. We will also serve as a clearinghouse for information and resources and are planning a national summit involving other organizations and hospital leaders to discuss widespread efforts to improve medication safety.

In summary, Mr. Chairman, the IOM's report is timely. It brings together a number of stakeholders all at the same time to collectively address this important issue. As the report notes, large complex problems require thoughtful multi-faceted responses. The AHA is pledged and committed to keep its member hospitals and health systems responsive to this critical issue. I will be happy to answer any questions.

[The prepared statement of Michael L. Langberg follows:]

PREPARED STATEMENT OF MICHAEL LANGBERG, SENIOR VICE PRESIDENT FOR MEDICAL AFFAIRS AND CHIEF MEDICAL OFFICER, CEDARS-SINAI HEALTH SYSTEM ON BEHALF OF THE AMERICAN HOSPITAL ASSOCIATION

Mr. Chairmen, I am Michael Langberg, M.D., senior vice president for medical affairs and chief medical officer of Cedars-Sinai Health System in Los Angeles. I am here today on behalf of the American Hospital Association's (AHA) nearly 5,000 hospital, health system, network, and other health care provider members. We are pleased to have the opportunity to testify on an issue of critical importance for hospitals and the patients and communities they serve: the Institute of Medicine's (IOM) report on medical safety, and what hospitals and health systems are doing to improve patient safety.

The Cedars-Sinai Health System includes a number of physician officers distributed across the Los Angeles metropolitan area. Cedars-Sinai Medical Center is the largest not-for-profit acute care hospital in the western United States. Together with the 2,000 physicians associated with our system, Cedars-Sinai provides care to an urban population of considerable racial, ethnical, social, linguistic, religious and economic diversity.

I have spent almost all my professional career at Cedars-Sinai on the faculty in General Internal Medicine, originally as Director of Medical Education. In 1996, I assumed the role of chief medical officer overseeing system-wide quality initiatives and information systems. I have developed a deep knowledge of the complexity of modern health care, and have a broad background in improving the quality and safety of the patient experience. I believe that much of what is outlined in the IOM report is accurate. The report has focused attention at a time when many other activities are under way to address these issues, which many of the members of the IOM panel first brought to national awareness several years ago.

BACKGROUND

For thousands of years, healers have lived by the motto primum non nocere—first, do no harm. The nurses, doctors, and others on the patient care team in hospitals strive every day to deliver the safe, compassionate care that patients deserve. But in today's complex, high-tech world of medicine, our best intentions can have unwanted and unintended consequences. The IOM report, "To Err is Human: Building a Safer Health System," points out that, as good as our systems are for preventing and reducing medical errors of all kinds, we can and must do better.

THE IOM REPORT AND HOSPITALS

We applaud the members of the IOM Committee on Health Care in America for developing a report that shines a bright yet objective spotlight on the problem of medical errors. The IOM report is important, outlining the significance of the medical error problem in this country.

It acknowledges that medicine is delivered by people who are highly trained and receive continuous education to stay on top of their respective areas of discipline. Hospitals and caregivers already work under strict internal quality control procedures, in addition to federal, state, local and independent oversight. Hospitals have

important systems in place—checks and balances to reduce the potential for human error. For example, they have quality teams, physicians and nurses who examine unexpected deaths, treatment errors and accidents, to identify and correct the cause. And most hospitals have teams of experts whose sole focus is to develop and oversee safety policies to prevent accidents before they happen.

In addition, there are many organizations that specialize in the area of reducing and preventing medical errors. The AHA is working with several of these organizations so that we can help hospitals and health systems benefit from their knowledge and expertise. Among them: the National Patient Safety Partnership—a public/private partnership of organizations; the National Coordinating Council for Medication Error Reporting and Prevention; and the American Medical Association National Patient Safety Foundation. We're doing this because, as the IOM report points out, a vigilant, ongoing, stepped-up effort to improve patient safety is needed.

We agree with the report that we need to avoid "blaming individuals for past errors" and instead "focus on preventing future errors by designing safety into the system." We also agree that, as the report states, "professional societies and groups should become active leaders in encouraging and demanding improvements in patient safety." The AHA is committed to being just that kind of leader, so that America's health care system does indeed focus not on blame, but on prevention.

The IOM report focuses on the broad issue of medical safety. The AHA, at a White House event in December with President Clinton, announced an initiative to improve medication safety, because medication errors are one of the most common sources of overall medical errors. We used the opportunity to point out that whatever happens at the national level will only be valuable if it helps the women and men like me and those I work with at the Cedars-Sinai Health System—people who are on the front lines of health care—do their jobs even better.

Speaking of action at the national level, we understand the committee's interest in determining whether further legislation is needed to address medication errors. But before moving to consider new legislation, we urge Congress to consider the reporting mechanisms currently in place—by organizations like the Veterans Administration, the Joint Commission on the Accreditation of Healthcare Organizations, and the Institute for Safe Medication Practices—to collect and use information on errors. Congress should know how these current mechanisms work and consider ways to improve them, if necessary, before proposing new reporting systems.

The AHA believes we need to be clear about what our objectives are in collecting information on events that may be related to errors. Reporting should be a tool for reducing and preventing errors. It should be designed to stimulate organizations and practitioners to analyze what went wrong and make the necessary changes to ensure that the mistakes do not happen again. In addition, lessons learned from one error should be widely shared with others. Provider accountability should be tied to these objectives.

The quantity of reports is not nearly as important as the quality. One need not read 500 reports of workers mixing up two similar sounding medications, before it becomes obvious that the two medications need better labeling. Our goal should not be to ensure that every provider report every event, but rather to encourage dialogue to learning.

AHA ACTIVITIES

More than a year ago, the AHA board and many of our hospital leaders attended a national forum in Cleveland. The topic: improving patient care. Though we have long been involved in improving the quality of care provided in the nation's hospitals, we came away from that particular meeting with a strong sense from hospital leaders that, on a national level, we could do more—we needed to address these issues head on.

But the issue of medical error is very broad in scope. We set our sights specifically on improving medication safety—reducing and preventing medication errors that result from things like different drugs being packaged in similar containers, use of confusing abbreviations on labels and prescriptions, illegible doctor handwriting, and more.

Against the backdrop of all this activity came the IOM report, which led overnight to increased awareness of the importance and seriousness of this issue. The release of the report came as we were preparing to kick off our initiative to take a comprehensive look at hospitals' ability to prevent medication errors and help them make improvements where needed.

As part of our initiative, we formed a partnership with a highly respected organization in this field, the Institute for Safe Medication Practices (ISMP). This nonprofit research and education organization is dedicated to reducing the incidence of

medication error throughout the health care system, and will provide leadership and technical expertise for the AHA's initiative.

ISMP provides independent review of errors reported through the Medication Errors Reporting Program (MERP), which ISMP was instrumental in founding. Through MERP, health care professionals across the nation voluntarily complete pre-addressed mailers or dial a toll-free number (800-23-ERROR) to report actual and potential medication errors with complete confidentiality. As an official MedWatch partner, ISMP shares all information and prevention ideas with the U.S. Food and Drug Administration (FDA) and other professional and policy organizations. Working with practitioners, regulatory agencies, health care institutions, professional organizations, and the pharmaceutical industry, ISMP provides timely and accurate medication safety information and works toward improvements in drug distribution, naming, packaging, labeling, and delivery system design.

The following four objectives are key to our medication safety campaign with ISMP.

Develop a non-punitive process for discussing errors

Most of what has been learned in recent years about how to reduce errors and increase patient safety is based on two principles. First, individuals, by the very nature of being human, are vulnerable to error. Although they are the focus of the error, errors happen because of the systems in which these individuals work. As a result, reducing errors will require us to design and implement more error-resistant systems.

Second, we have to create an environment in which we learn from failure. This requires us to identify an effective mechanism for candid discussion of errors. This cannot be achieved in an environment of punishment or fear. Doctors, nurses and other caregivers should not be penalized for stepping forward after an unfortunate mistake is made. A more open environment can only occur when health care providers are afforded adequate legal protections.

Today, when health care providers are required to disclose confidential internal information to health care oversight agencies, they may jeopardize state law that protects internal quality analysis discussions and expose themselves to crushing legal liabilities. There is no incentive to share this information with others to prevent similar events in other institutions. We believe protections that currently apply to such information should also apply when it's disclosed. We believe that evidentiary, confidentiality and other legal reforms should be considered to help foster an evironment that promotes candor.

Candor is absolutely critical if we are to be truly successful in identifying, learning from and reducing not only medication errors, but all medical errors, and making the health care system safer. We need to create a non-punitive culture at all levels that supports the collection of information about errors, along with candid discussion of errors, their causes, and ways to prevent them from happening again. A safe, non-punitive environment will encourage people to report and discuss errors—the first step in lessening the chance they will happen in the first place and making sure they do not happen again.

Share successful practices with every hospital and health system

We sent to every AHA member the attached "Quality Advisory on Improving Medication Safety." The advisory includes background on the issue, a long list of resources our members can turn to for help, and a three-page list of "successful practices" for improving medication safety. Some of these practices can be adopted easily and quickly, such as providing staff with information about ordering, dispensing, administering and monitoring medications, not storing certain concentrated solutions on hospital wards, and helping patients better understand what they are talking, why, and how to use it safely.

Others are longer-term practices that, with time and money, can create significant changes throughout our members' organizations. Among these are the development of a voluntary, non-punitive system to monitor and report errors that might occur within hospitals, and the computerization of medication administration systems.

We compiled the list of successful practices with the help and advice of some of the best experts in the field—including the ISMP, the Institute for Healthcare Improvement, the Massachusetts Coalition for the Prevention of Medical Errors, the National Coordinating Council for Medication Error Reporting and Prevention, the National Patient Safety Partnership and many others.

Develop a "medication safety awareness test" for use by hospitals

To follow up on how the successful practices are being implemented, we are working with ISMP to develop a "Medication Safety Awareness Test" to help our members assess their progress. This tool will also help the AHA get an idea of what

other help its members may need, and help us track and demonstrate hospitals' success at improving medication safety.

Serve as a clearinghouse of information and resources for hospitals

The AHA will continue making available to its members up-to-date information on improving medication safety. We will gather information from outside sources and work with other national organizations to develop information and data. We are planning a medication safety "summit," gathering other organizations and hospital leaders together to discuss widespread efforts to improve medication safety. And we will be adding to our Web site (www.aha.org) a special area containing all the information, data, best practices, and other resources we compile in our medication safety improvement campaign.

CONCLUSION

Mr. Chairman, the IOM report is very timely. It comes as America's health care system enters a new century of caring for people. It marks an opportunity for us to rebuild the public's confidence and trust in the health care system they rely on every day. And it reminds us that, despite setbacks, we still deliver the greatest health care in the world.

But it also notes that "large, complex problems require thoughtful, multifaceted responses." Reducing and preventing medication errors, and improving the overall safety of the health care system, will demand the thoughtful collaboration and participation of everyone involved in the health care field: hospital leaders, pharmacists, drug manufacturers, doctors, nurses, government agencies, other organizations, and consumers. America's hospitals and health systems are committed to this effort.

Mr. BILIRAKIS. Thank you very much, Doctor. Ms. Foley.

STATEMENT OF MARY FOLEY

Ms. FOLEY. Thank you. I want to first start to take a moment to mention committee member, Congresswoman Lois Capps, who could not be here with us today because of the death in her family. I just recently had the opportunity to meet with the Congresswoman and we discussed a number of nursing issues. We did talk about the IOM report and the medical errors issue as it relates to nurses and she has indicated a strong interest in investigating the faulty systems in place that often result in medical errors. The ANA appreciates the work that Congresswoman Capps is doing in this area and looks forward to continuing this important discussion with her.

My name is Mary Foley and I am President of the American Nurses Association. I am also the former Director of Nursing, Chief Nurse Executive at St. Francis Memorial Hospital in San Francisco, California. The ANA appreciates the opportunity today to discuss patient safety and medical errors. And it is an issue of great importance to us, one that is not missed by the front line healthcare workers who I describe as the patient and safety monitors on a 24-hour a day basis.

ANA is the only full service professional organization representing the Nation's 2.6 million registered nurses and our membership includes staff nurses, nurse practitioners, clinical nurse specialists, nurse midwives, registered nurse anesthetists and nurse administrators and educators as well. We have been very pleased with the release of the report by the Institute of Medicine, problems that they have identified as not new to the registered nurse population or to ANA and we have long recognized these problems and have worked to address issues related to nursing care that enhanced patient safety and outcomes for many years.

We are encouraged by the release of this report in the effort to spur public dialog and reach consensus on solutions to these pressing issues. As has been stated, the majority of medical errors do not result from individual recklessness but from basic flaws in the way the health delivery system is organized. Stocking patient care units in hospitals, for example, with full strength drugs, even though they are toxic and less diluted, has resulted in deadly mistakes.

Illegible writing in medical records has resulted in administration of a drug for which the patient has a known allergy. Our evolving and increasingly complex healthcare system often lacks adequate coordination and appropriate systems to insure patient safety. For example, when a patient is treated by several practitioners they often do not have complete information about the medicines prescribed or the patient's illnesses or even take time to read the chart to find that information out.

Despite increasing evidence the systems fail. Institutions are continuing to assign and emphasize individual blame for errors, misjudgments and patient dissatisfaction. Hospital systems and administrators are assuming that the appropriate way to deal, and I know not all of us do this or did that, that the most appropriate way to deal with the complexity of errors made in the delivery of health care is to manage the workers through oversight and discipline as opposed to identifying and resolving the true problem in the spirit of partnership.

ANA has long advocated for investigation of system changes that may result in egregious errors by individual practitioners noting that healthcare systems have downsized, restructured and reorganized to the point where processes initially put in place to protect the public are breaking down. As these systems increasingly are failing to protect the patients the severity of discipline applied to individual providers for mistakes is increasing. Healthcare organizations must approach problem-solving strategies through shared accountability and partnerships.

ANA supports many of the IOM study recommendations including the creation of a center for patient safety. Such a center would provide a focal point for safety and quality activities by focusing on safety issues applicable to the full range of providers and health delivery systems and we support this entity and we believe it must include adequate representation by nurses and other healthcare professionals who are the front line providers.

The center must support research to determine what leads to errors. Specifically, they must be charged with collecting data on organizational practices and other factors that may be associated with the occurrence in errors. In our current knowledge, no one can state with certainty what practices could or more likely lead to errors. Some practices are more obvious than others. ANA has voiced criticism, however, of the report for its lack of attention to the staffing component of the issues. We in 1994 initiated at the ANA a quality of safety initiative and we have been collecting data about the relationship between the outcome of patient care in relation to the number of nurses and the number of patients.

Inadequate or inappropriate staffing may mean too few registered nurses, a lack of appropriate training or orientation for an

RN assigned to a unit or the inappropriate use of unlicensed assisted personnel. Adequate numbers of staff are necessary to reach a safe level of patient care services. Ongoing evaluation and benchmarking related to staffing are necessary elements in the provision of quality care. At a minimum, the center for patient safety should collect data related to the average ratio of patients to registered nurses and licensed nurses and the unlicensed personnel load, measures which differentiate between the severity of patient illness, mortality and morbidity rates, readmission rates, incidence of post discharge professional care and length of stay in order to examine the relationship of these variables to occurrence of healthcare errors.

Mr. BILIRAKIS. Please summarize, Ms. Foley, if you would.

Ms. FOLEY. Sure. Thank you. I think you have identified a major theme in our statement that while there is certainly great merit in the Institute of Medicine report, I have appreciated the many comments of the members today who recognize that the relationship between the workload, the opportunity for a professional, in our case for the nurse, to be truly responsible may have a resource relationship in terms of the number of staff, their preparation, and their ability to be attentive to the professional duty and to be the patient advocate that we want to be.

So we really look forward to working with these committees. It was a wonderful event to see them come together today. And we appreciate the opportunity to be at the table and to speak in support of those elements that we find would help patient care and identify areas for improvement in the report.

[The prepared statement of Mary Foley follows:]

PREPARED STATEMENT OF MARY FOLEY, PRESIDENT, AMERICAN NURSES ASSOCIATION

The American Nurses Association (ANA) appreciates the opportunity to discuss our concerns about patient safety and medical errors. This issue is one of great importance to the nursing profession. As front line health care workers, nurses have substantial contributions to make in the effort to reduce health care errors. ANA is the only full-service professional organization representing the nation's 2.6 million registered nurses, including staff nurses, nurse practitioners, clinical nurse specialists, certified nurse midwives and certified registered nurse anesthetists through its 53 state and territorial nurses associations.

To Err is Human: Building a Safer Health System To Err is Human (IOM, December 1999) describes a fragmented health care system that is prone to errors and detrimental to safe patient care. This problem is not new to registered nurses and the American Nurses Association (ANA). ANA has long recognized this problem and has worked to address issues related to nursing care that enhance patient safety and outcomes for many years. We are encouraged, however, by the release of this report in an effort to spur public dialogue and reach consensus on solutions to these pressing issues.

The human cost of medical errors is high. Based on the findings of one major study, medical errors kill some 44,000 people in U.S. hospitals each year. Another study puts the number much higher, at 98,000. Even using the lower estimate, more people die from medical mistakes each year than from highway accidents, breast cancer, or AIDS. Moreover, while errors may be more easily detected in hospitals, they affect every health care setting: day-surgery and outpatient clinics, retail pharmacies, nursing homes, as well as home care. Deaths from medication errors take place both in and out of hospital settings—more than 7,000 annually—exceeding those from workplace injuries.

The majority of medical errors do not result from individual recklessness, but from basic flaws in the way the health delivery system is organized. Stocking patient-care units in hospitals, for example, with certain full-strength drugs—even though they are toxic unless diluted—has resulted in deadly mistakes. Illegible writing in medical records has resulted in administration of a drug for which the patient

has a known allergy. Our evolving and increasingly complex health care system often lacks adequate coordination and appropriate systems to ensure patient safety. For example, when a patient is treated by several practitioners, they often do not have complete information about the medicines prescribed or the patient's illnesses.

Despite increasing evidence that systems fail, institutions are continuing to assign and emphasize individual "blame" for errors, misjudgments and patient dissatisfaction. Hospital systems and administrators are assuming that the appropriate way to deal with the complexity of errors made in the delivery of health care is to manage the workers—through oversight and discipline—as opposed to identifying and resolving the true problem in the spirit of partnership. ANA has long advocated for investigation of system changes that may result in egregious errors by individual practitioners, noting that health care systems have downsized, restructured and reorganized to the point where processes, initially put in place to protect the public, are breaking down.

As these systems increasingly are failing to protect patients, the severity of discipline applied to individual providers for mistakes is increasing. For example, in a 1996 Colorado case, medication errors were no longer treated as the domain of the hospital and the state licensing board, but drew the attention of the media and the court systems. Three registered nurses were charged with criminally negligent homicide when a medication error resulted in the death of a child ("Colorado Case Blurs Line", 1997). Although criminal prosecution for medication errors is not a common practice, the fact that such cases exist point to the adherence to promoting a culture of individual blame. Health care organizations must approach problem solving strategies through shared accountability and partnership for quality improvement. A shared accountability approach diminishes focus on individual blaming and enhances long-range process improvements.

Specific recommendations of the IOM report follow with ANA's response to each recommendation:

4.1 IOM recommends that Congress should create a Center for Patient Safety within the Agency for Health Care Research and Quality. The Center should: 1) set the national goals for patient safety, track progress in meeting those goals, and issue an annual report to the President and Congress on patient safety; and 2) develop knowledge and understanding of errors in health care by developing a research agenda, funding Centers for Excellence, evaluation methods for identifying and preventing errors, and funding dissemination and communication activities to improve patient safety.ANA supports the creation of a Center for Patient Safety as an oversight body to advance standards, policies and actions related to reducing health care error. Such a center would provide a focal point for safety and quality activities by focusing on safety issues applicable to the full range of providers and health delivery systems. This entity must include adequate representation by nurses and other health professionals who are the front-line individuals in patient care.

This Center must support research to determine what factors lead to errors. Specifically, the Center must be charged with collecting data on organizational practices and other factors that may be associated with the occurrence of errors. In our current knowledge, no one can state with any certainty what practices could or are more likely to lead to errors. Some practices are more obvious than others. For example, bad handwriting or open stock of certain powerful drugs have been observed to be the cause for errors in health care delivery. Other causal factors that may contribute to health care errors may not be as apparent. For example, the IOM report lacks important information on the relationship between system errors and appropriate nurse staffing. In fact, ANA has voiced criticism of the report due to its inadequate attention to the staffing component of this issue.

Inadequate or inappropriate staffing may mean too few registered nurses, lack of appropriate training or orientation for an RN assigned to the unit or inappropriate use of unlicensed personnel. Adequate numbers of staff are necessary to reach a safe level of patient care services. Ongoing evaluation and bench marking related to staffing are necessary elements in the provision of quality care. At a minimum, the Center for Patient Safety should collect data related to: average ratio of patients to registered nurses and licensed practical nurses, and unlicensed personnel, measures which differentiate between severity of patient illness, mortality and morbidity rates, readmission rates, incidence of post-discharge professional care, and length of stay, in order to examine the relationship of these variables to occurrence of health care errors.

Another issue that the Center for Patient Safety should examine the relationship between the errors rates and continuous hours worked by health care professionals. Just as there is concern about the number of hours worked by medical residents, ANA has become increasingly concerned by hospitals increased reliance on the use

of overtime, particularly mandatory overtime, by its registered nurse staff. In today's health care workplace, 16 hour shifts are becoming increasingly commonplace and 24 hour shifts are not unheard of. Too many hospitals have come to rely on the use of overtime for a substitute for adequate supply of staff.

The vital importance of registered nurses at the bedside, is a critical piece in preventing medication errors. The registered nurse at the patient's bedside is the patient's safety net. ANA agrees with the study's recommendation that health care organizations should implement proven medication safety procedures. However, an area of inadequate staffing that needs to be addressed in this recommendation, is the inappropriate use of unlicensed assistive personnel, UAP. The role of the UAP is important. The UAP assists the registered nurse, not provide nursing duties that are within an RN's scope of practice. More health care facilities, especially state facilities are increasingly relying on UAP's to administer medications.Currently, a number of states have legalized medication administration by unlicensed personnel in state institutions and subacute. For example, the Commonwealth of Massachusetts General Law Chapter 94C,7g authorizes unlicensed personnel to administer medication to patients within the Departments of Mental Retardation and Mental Health. The oversight of a registered nurses is not mandated by the state. The Massachusetts Nurses Association has been battling with the Massachusetts state legislature for many years regarding this issue. Financial cost appears to be the reason the Commonwealth does not raise the standard of care for their most vulnerable patients. Massachusetts is not the only state that relies on UAP's to administer medications, New York, Maine, Illinois and others have similar laws. ANA recommends that the Center of Patient Safety review the inappropriate use of UAP's administering medications in each state. Another area where the administration of medication by unlicensed individuals is increasing is in schools. In 1996, there were approximately 45,000 school nurses, mostly part-time for 87,125 school buildings and millions of school children. Due to the low number of school nurses working in the school systems, many students receive their medication from school administrators.

5.1/5.2 IOM recommends that a mandatory reporting system should be established that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm. Reporting should initially be required of hospitals and eventually be required of other institutional and ambulatory care settings.

ANA supports the IOM's proposal that errors which lead to death or serious injury be the subject of mandatory reporting as an initial step in formalizing this system. In the long term, such mandatory reporting should include additional data beyond the sentinel events. ANA believes it is critical to evolve a comprehensive system of mandatory reporting to ensure that all factors in a system can be studied and assessed. What differentiates a fatal error from a minor error may be luck or chance. From a system's perspective, it is critical to understand the causal factors in any error in order to analyze them and prevent them in the future—whether that error resulted in an easily remedied situation or whether that error resulted in death. ANA agrees that it makes sense to start the operations of any mandatory system at one level of reporting, but the Congress must examine and direct how quickly a more comprehensive approach can be implemented.

Whether reporting is mandatory or voluntary, there must be provisions that protect a nurse's right to speak out about activities and/or practices that threaten the health and safety of patients.

6.1 IOM recommends that Congress should pass legislation to extend peer review protection to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality.

ANA understands the rationale for making this recommendation and some form of limited immunity may be appropriate in some instances. We are concerned, however, that any immunity be tailored narrowly enough to ensure that it helps attain the goal of patient safety, but doesn't provide a means for hospitals to hide or escape their accountability in health care errors.

7.1 IOM recommends that performance standards and expectations for health care organizations (regulators/accreditors and public/private purchasers) should focus greater attention on patient safety.

ANA strongly supports the establishment of performance standards and expectations for health care organizations. In particular, ANA supports systems for evaluating the impact of reorganization efforts on patient care, the overall patient care environment and the ability of health care providers to continue to practice in safety.

7.2 IOM recommends that performance standards and expectations for health professionals should focus greater attention on patient safety.

ANA long advocated for continuous education of health care professionals on patient safety issues as well as assuring that registered nurses stay current in their practice as approaches that can help reduce errors and promote patient safety. Toward this end, we have supported and worked on approaches to measuring continuing competence of registered nurses that would meet this goal. We do not see how the IOM proposal for relicensure contributes to measuring the competence of professionals since so many professionals practice within speciality areas and periodic relicensing does not assure measure of continuing competency in one's speciality field. Relicensure is one approach to many approaches to measuring continuing competency that has been discussed. It is premature and unhelpful to identify that as the only approach to be promoted as an overall effort to reduce error.

The American Nurses Credentialing Center (ANCC) recently released an international survey of certified registered nurses in the U.S. and Canada. A statistical significant portion of the survey respondents reported that certification enabled their surveillance and early intervention practices—thereby reducing health care error. The competence of health care providers is an important issue, but ANA would support a variety of approaches to this issue.

7.3 IOM recommends that the Food and Drug Administration should increase attention to the safe use of drugs in both pre- and post-marketing processes.

ANA supports this recommendation. ANA has long supported safer manufacturing and distribution of drugs, medical devices, and equipment. Through participation in the National Patient Safety Partnership Initiative for Preventing Adverse Drug Events earlier this year, nurses spoke for these specific issues and took part in developing and disseminating best practice recommendations and consumer guidelines.

8.1 IOM recommends that health care organizations and the professionals affiliated with them should make continually improved patient safety programs with defined executive responsibility.

ANA strongly supports any effort that makes patient safety a coordinated focused effort of the health care system. The establishment of safety programs must include balanced and appropriate representation of the key players and this means more than token nursing representation. Nurses are pivotal to improving patient outcomes and excellent evaluators of the work environment for deficits and solutions for quality improvements. There must be clear responsibility at the top levels of associations and organizations to make sure that needed practices are articulated and implemented.

8.2 Health care organizations should implement proven medication safety practices.

ANA supports the implementation of medication safety practices that are based on sound science and evaluation of those practices. Such improvements should be public information and reach to the core or root cause, not merely be a band-aid approach. For example, having a pharmacist accompany a nurse at medication administration time is not the answer if in fact there is only one nurse for 15 patients and he/she has 2 admissions and 3 discharges at medication time. There are other factors that must be accounted for such as appropriate staffing in this recommendation.

ANA thanks the Committee for sponsoring these hearings on such a critical issue in the health care delivery system today. ANA believes through a variety of strategies and collaboration that we can address this important issue in today's health care system.

Mr. BILIRAKIS. Thank you very much, Ms. Foley. Let me just start off with you. You didn't mention this in your oral remarks. If I read your testimony right, you acknowledge the need for some form of limited immunity. If you did mention it in your oral remarks I missed it but, in any case do you acknowledge that, the need for some form of limited immunity to encourage healthcare organizations to participate in voluntary reporting and reduction systems?

Ms. FOLEY. I did not mention it in the oral remarks. If you are asking a question related to the lack of blame or discipline for the individual practitioner, we certainly support that. And in a blame environment folks are not going to be coming forward. The question

was asked earlier how do people find out about errors. A nurse coming on to the next shift may walk in the room and find the inappropriate intravenous bag hanging, wrong patient name, wrong drug, wrong mixture of medication. The individual making that report would be very troubled by that. Perhaps they may be pointing blame at their prior co-worker. They, however, could be assisting in solving a problem in the future. Perhaps it was a pharmacy error or a delivery error. So I do believe that ANA does support certainly for the individual provider——

Mr. BILIRAKIS. In the illustration you mentioned, to whom would that immunity apply, which nurse?

Ms. FOLEY. Well, certainly the individual wishing to make the report that they had a finding, that there had been an error that had occurred. In this case that person would really be a party to making an improvement and I think we would have to look at the system that allowed the error to happen in the first place.

Mr. BILIRAKIS. You are pretty clear in that regard.

Ms. FOLEY. Without applying blame or individual responsibility. We are certainly aware that healthcare professionals have to be responsible for their practice, and they wish to be and they wish to be accountable for their practice. And I think we are struggling as an association to define where the liability and the protections for that go while we still want to promote the reporting. So I am not sure I have the definitive answer today.

Mr. BILIRAKIS. You don't have an idea of what you may mean by limited immunity, what sort of limited immunity——

Ms. FOLEY. No, I think limited is open to definition.

Mr. BILIRAKIS. You are limited in terms of——

Ms. FOLEY. And we look forward to participating more in that discussion among our own association members.

Mr. BILIRAKIS. Thank you Dr. Langberg. I appreciate your testimony, of course, and the depth of your experience as a physician practicing in a large urban hospital system. On page 7 of your written testimony, and you talked about this, you said confidentiality and other legal reforms, tort reform and liability in any case, should be considered to help foster an environment that promotes candor in reporting medical errors.

Ms. Foley mentioned limited immunity, which I guess is consistent with what I understood you to mean. What specific kinds of legal reforms do you think would be useful in this context?

Mr. LANGBERG. I think from the AHA's perspective the key point that we are trying to identify is creating an atmosphere that will promote the reporting of events and not be punitive. The experience we have had both as has been reported, and I can speak specifically in my institution has been that the more people fear either legal or job-related consequences the more they are unlikely to report. The more they are unlikely to report, we ultimately don't know and we can't ultimately identify solutions to problems.

So at this point I would have to say that the nature of the kind of immunity or protection we are speaking about from a legal point of view, I will defer getting into specific detail on. I think the key is no matter what we ultimately create as far as any kind of reporting obligations that we make sure to encourage rather than inhibit.

Mr. BILIRAKIS. Yes, and that is good and that is of course what Ms. Foley's point was too. But you would throw it upon the shoulders of Congress then to determine what those protections should be and without any suggestions as to what they may be. And then no matter what we come up with it would probably be criticized in one way or another. This is why I ask those questions.

If you have any ideas—whether you want to state them today or whether you want to do it in writing, please submit them.

Mr. LANGBERG. I will be happy to respond in writing after today's hearing. I would point out that there are existing protections. I know in California there are protections for peer review, confidentiality, and there are also Federal protections in that regard. I think those are examples of the kind of protections that we have experienced as having a great support for the disclosures that people in professional capacities can give.

As far as your comment on putting it at the feet of Congress, I think that we in the AHA and among the colleagues you have heard today probably have different opinions about ways to go about this particular question of immunity or disclosability reporting. I think what I would encourage is an opportunity for Congress to hear inclusive of the different perspectives we all represent.

Mr. BILIRAKIS. Yes, I don't think we have done very much in the area of healthcare that the American Hospital Association and all of the other healthcare organizations have not been a part of. Mr. Barrett.

Mr. BARRETT. Thank you, Mr. Chairman. Ms. Foley, under the current system nurses are required to report certain events like needle stick injuries but from what I understand often times even these injuries are not reported. What is your analysis, what is the reason for that?

Ms. FOLEY. In part, fear of discipline and claims, very wild claims unfortunately. We have had nurses who had an accidental needle stick and actually have been accused of self inflicting it for retribution against their facility. We have had some really outrageous stories of what I would call the worst of practices in the environments, not the best of practices by any means. There is a concern that once the report is there that there was a magic number back in the early nursing days, you know, three medication errors and you would be out.

There is usually no such hard and fast rule but those beliefs exist in people's minds and in some environments unfortunately they are trying very actively to discourage mistakes in such a way that it discourages the reporting.

Mr. BARRETT. I guess the needle stick one sort of sticks in my mind more than any one, no pun intended. Because I see two powerful incentives for the nurse to report it. First, obviously if there was any type of exposure to hepatitis C or HIV just for medical reasons alone to do it. And, second, if ultimately there is going to be any sort of disability dispute not having a record I think would make it more difficult for the nurse to get payments and so to me it sort of brings in the question of how if in a situation where you have the two most powerful incentives for a person to self report, you are still not getting it. I wonder how effective ultimately this is going to be.

Ms. FOLEY. I believe if the system approach is used and institutions and our industries are encouraged to participate in a meaningful way that there would be an atmosphere in which there would be trust and the culture of reporting and the culture of supportive changes. You know, when someone has a needle stick it may be because the equipment is flawed. It may have nothing to do with personal use practices. And unfortunately we are still as we find in a lot of working industries, there is a blame the victim, blame the worker, they must have made the mistake, they must have done something wrong.

I work on a program where we recreate the scenarios in which injections are given and we try to create every impossibility to do it safely when we are testing new products because we want to find out is that product going to help you when your hands are slippery with blood or the lights are dim or the table is moving or the ambulance is rocking down the hill. Some of those opportunities to test devices and do a system approach for the improvement would take away the blame that if an injury occurred perhaps you better look at why it occurred and not at the person as the result or as the problem.

Mr. BARRETT. We have had a little bit of a love fest here today in regards to the VA and the reporting system that they have, and that is good. But if you look at the VA, its structure isn't necessarily like the structure of hospitals or healthcare providers outside of that setting. Obviously there is more control, more authority in the VA system. Dr. Langberg, what would we need to have in place outside of the VA system to have an effective system?

Mr. LANGBERG. The experience that we have had at Cedars-Sinai really relates directly to the work that the Joint Commission has done, a sentinel event on the sentinel event policy, and I want to actually publicly acknowledge Dr. O'Leary for his leadership in creating that process. Over the last couple of years we have assiduously developed a program to get individuals to report things that they see, whether they are sentinel events as defined by the Joint Commission or near misses. We define that collection of things as significant adverse events.

Whether or not they know it to be true as long as they think it might be true, we have developed a policy and a practice to do that. Our original experience at the beginning of this was that few reports were made and as we developed education educating all the staff and all the physicians in the institution, we found that there was almost a geometric increase in reports. I would say at least half of those reports upon preliminary evaluation are not close to being a significant adverse event but a good proportion of them were and we were able to use a root cause analysis methodology again that was originally proposed by the Joint Commission to learn from those.

The experience we have, in answer to your question, is that it take a culture change within an institution to encourage people to report and to make them believe that if they report not only will they not suffer consequences but that the information will actually be used to improve taking care of patients in the institution. Culture is not an on or off experience. It is not a switch one can throw that you have it tomorrow when you don't have it today. It takes

time. It takes education. It takes consistent behavior on the part of management and employees and physicians and it takes education and commitment. And that has been in our experience the keys to the solution.

Mr. BARRETT. Thank you, and thank you, Mr. Chairman.

Mr. BILIRAKIS. Thank you. Chairman Stearns.

Mr. STEARNS. Thank you, Mr. Chairman. Dr. O'Leary, what are the critical elements of an effective reporting system?

Mr. O'LEARY. I think the critical elements of a good reporting system are first of all to define what is to be reported very crisply so that we are going to get a clear drop of the things that are really important and not a lot of wheat and shaft. The numbers we are dealing with are huge potentially and we need to be able to focus on the critical elements. Second, as I think has been emphasized here, we have to have a requirement for root cause analyses. The reporting of the events themselves does not give you the information you need to solve problems. The root cause analyses are where the action really lies.

Third, we have to protect the confidentiality of the reported information or we are simply not going to get it. I would be happy to elaborate on that further but that is a critical element, and I think that has to be provided not in the rubric of tort reform but under the rubric of peer review protection statute, something that we have in most of the States in the country but which are very uneven. Some are strong and some are very weak and we need something uniform, I would say, from the Federal level.

Fourthly, we need data sharing amongst all responsible parties to say that there are a lot of different players in this system. Not all hospitals or all health provider organizations in this country are accredited by the Joint Commission. We are a major player but there are other major players as well. And, finally, we have to be able to disseminate lessons learned and best practices across the delivery system. We have to harvest the information we glean out of our root cause analyses.

Mr. STEARNS. Anyone else on the panel, when Dr. Cousins talked about the public would be better served by a hospital report card which focused on a facility's adoption of a set of best practices rather than by an error score card, anyone else on the panel that would like to give comments to that prior testimony? Yes. Dr. Golden.

Mr. GOLDEN. The experience that I have had working with hospitals in my state, there is—report cards have limitations on adverse events because they are often dealing with small numbers and you can have unfortunate implications from very small numbers. On the other hand, we work with the institutions in our State to assess how they are responding to our projects and how they implement them. And so we right now are essentially giving hospitals in our State in a way a report card of their ability to implement quality improvement.

And they have been very responsive to that and have been very interested in assessing how they are responding to the challenge of clinically pertinent data to improve their processes and it has been very successful. We have had about 35 projects in that area and many QIOs are doing similar kinds of activities.

Ms. FOLEY. Part of the nursing quality and safety initiative was to develop a nursing care report card. We have activities now in six States and we are really going to be working closely with the Hospital Association in some future dialog to try to expand the project. It does measure our nurse sensitive indicators that we have shown through research that a patient's effect will change dependent on the relationship of adequate numbers of nurses. Pain management is a very clear example. When there isn't adequate staff the pain is usually not assessed and treated appropriately and quickly.

Falls is another indication perhaps that there isn't adequate observation of an individual's risk for injury. And so we have identified the nursing care report card elements as an opportunity for consumer judgment of a facility based on staffing and some of the outcomes that they will experience as patients or that their family would experience.

Mr. STEARNS. Dr. O'Leary, if you or I, or you or Chairman Bilirakis, you were a Member of Congress, and after this hearing—were you here on the two prior panels, did you hear them?

Mr. O'LEARY. Yes, I did.

Mr. STEARNS. What would you do in terms of a piece of legislation? Do you think a piece of legislation is required? Do you think we could legislate something here out of the Commerce Committee or out of the Veterans—not out of the Veterans but out of the Commerce, Mr. Bilirakis' committee, we could legislate something here in terms of a national safety center or in terms of a report card. What is your feeling?

Mr. O'LEARY. Well, if I get one bite of the apple it is the Federal protection for the reported information. Quite frankly, I don't believe that any of the recommendations in the IOM report can be meaningfully implemented without that kind of protection. We have to create—we have to force a safe environment for surfacing these problems and be able to, as Dr. Langberg has said, talk about them, talk about them inside our organizations, talk about them with responsible oversight bodies, harvest information, share that information.

This is not like airplane crashes. These crashes occur one at a time. They are well hidden in our organizations. If you do the math, let us say there are 60,000 deaths a year and there are 6,000 hospitals. That is 10 crashes a year. If you talked to any hospital CEO in this country, I will bet you not one of them will tell you that they know of ten sentinel events in their organization in the past year and I believe them because this information is not even getting up inside organizations.

We have to create a very different environment and culture change has to happen but it is going to take a long time and I think we need to create a statutory framework that fosters that kind of culture change. Downstream I think we can talk about mandatory reporting systems. We can talk about public reporting but you have got to gain the confidence of providers that it is safe to talk about and safe to surface this information or it is simply not going to happen.

Mr. LANGBERG. Could I make a comment?

Mr. STEARNS. Yes, certainly.

Mr. LANGBERG. I just wanted to comment that right now without legislation that environment exists.

Mr. STEARNS. So you don't think we need legislation.

Mr. LANGBERG. Well, I am saying that right now we can do a lot of what Dr. O'Leary has outlined right now through the QIO system because that confidentiality now exists with the QIOs at the State level. And so many of the things that we have been talking about in similar testimony about the need to measure, the need to report and need to disseminate best practices can be done now in a confidential environment through working with the QIO system.

Mr. O'LEARY. If I might, I don't think that is actually clear where a hospital reports that information to you. The information you have may be protected but they may have waived their confidentiality protections. I don't think that has been tested actually.

Mr. STEARNS. Well, very quickly, sir. We don't want to get into——

Mr. GOLDEN. It is our understanding that it was tested in a case in Tennessee a few years back and it does have protection.

Mr. BILIRAKIS. Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman. I have a number of questions and I know I will run out of my 5 minutes. Ms. Foley, the Joint Commission's definition of a sentinel event includes some very serious errors, surgery on the wrong body part, abduction of an infant, a rape of a patient. Don't you think these type of serious adverse events should be subject to a mandatory public reporting system?

Ms. FOLEY. They certainly rise to the level of severity and probably merit stronger encouragement, perhaps mandatory. They are the most of the severe of the severe. I mean I support what the Sentinel Event Program has accomplished and did participate in a few root cause analyses myself as an administrator, but we also know that there are a lot of errors that occur well below the threshold of severe and permanent harm or death or rape or infant abduction that could be corrected in systems if we knew about them, talked about them, shared that information. So I don't want to evade the answer. I think we all need to figure out at some point there is a threshold from where it becomes so severe the potential for harm that there should be a mandatory nature.

Mr. GREEN. Again, those that I mentioned obviously should rate a little higher above just inadvertent error. Dr. Golden, you mentioned in your testimony that reporting information regarding medical errors should be mandatory. Many of our witnesses have focused on the voluntary reporting, and why do you think it should be mandatory?

Mr. GOLDEN. The errors I am talking about now are adverse events, certain specific categories of, if you will, accidents. Those are the kinds of issues that were discussed by the IOM as often complex interactions that resulted in consequences and events that were not foreseen by the participants, and I think that those are often very rare and we can identify them in certain categories.

And since they are fairly rare and sort of a random kind of process of system failures it is useful to report those so we can analyze them and allow institutions that hadn't seen that error yet to learn from that experience of others so we can raise the safety of the en-

tire system and not just one or two institutions that have that error.

Mr. GREEN. Do you think the idea is to get the data into a big system and run the analysis and then see what we find out, and the second approach is like that followed by the PROs where you go into the records and look at specific areas known to have problems and focus on improvement in those areas?

Mr. GOLDEN. I think that since some of these events are very small numbers and you have to go through lots of charts the mandatory reporting would help us identify those rare events. At the same time, we can focus on specific diseases and processes and through structured review find errors of omission and commission that basically can become disease focused sort of like Dr. Norwood said earlier about becoming focused on areas of improvement.

So it is a combination of factors there, one for rare events and one for systematic evaluation of diseases and processes that can be high yield and then bring about improvement.

Mr. GREEN. Can Congress focus on encouraging more of those focused studies like the PROs are doing and while we are still trying to understand how to create this large error data bank. Is there something we can do on a short-term basis?

Mr. GOLDEN. Yes, I think we can expand the current programs we have in place with the PROs. I think we can support AHRQ in terms of research to identify the performance measures. That is really what it comes down to. A lot of this is performance measurement, which we are very well adapted and many institutions now can do to get the data to look at the gaps and performance and then to educate and outreach.

And that is the other piece of what many of us are doing now especially at the local level is to work with institutions, give them technical assistance to work with the data, and then improve what they are doing. That is the last piece to make a difference in performance in response to data.

Mr. GREEN. Mr. Chairman, I have one other question of Ms. Foley here. Dr. Berwick, first on our panel and other experts in the study of medical errors, cite the need to develop best practice guidelines that are shown to reduce medical errors. At the moment there is already a good bit of information or knowledge about practices that can reduce medication errors. For example, physicians can electronically write prescriptions, hospitals can bar code medications. What is your opinion about such best practices for medication? How much are we going to help reduce medical errors by those using the technology we have heard from other panels?

Ms. FOLEY. I think it would be a tremendous asset and there have been a few demonstrations. I know some institutions have implemented pieces of this. I would support it wholeheartedly and be very realistic in saying that that will take a resource allocation both in terms of the research and development of the best devices and the mechanisms that would be supportive of that and then for the institutions to be able to bring that into their system and get that up and running there would also be an accompanying cost but it would be an incredible step forward.

Illegible handwriting, there is no secret that that is a major problem in our system and the number of people who have to read, in-

terpret and touch a prescription and order from the point it is ordered to the point it is administered is a chain of individuals who wish to be very responsible, and the more the systems can support their care the better the outcome will be. I think it would be a major reduction in those types of mistakes, not always that end up in the most adverse event but they can lead to them and they certainly count as the errors that we know are frequent.

Mr. GREEN. How would that compare to the concerns about staffing shortages?

Ms. FOLEY. Well, I think we need to do both. Very seriously.

Mr. BILIRAKIS. Dr. Ganske to inquire.

Mr. GANSKE. Thanks, Mr. Chairman, and thanks to the panel. So much in so little time, I guess. I guess I should start by saying, Mr. Chairman, that I think we should have some additional information on the validity of the incidence of significant medical errors. And one way that we could do that within the existing structure would be to instruct the National Institutes of Health to look at this problem and to look at particular disease treatment regimens, follow them, look at them, because as I pointed out in my opening statement before, you have to be careful about attributing a result to an error when it could be the result of the disease or the natural progression particularly if you are dealing with very complicated patients with a lot of different illnesses.

And there is a certain incidence, whatever is acceptable, regardless of how good your technique is. I would never claim to a patient that I was operating on that I had a 0 percent incidence of infection. I don't know how you can do that. So I think we need to look at very carefully how you define an error, the level of the error, and I think there is that expertise, for instance, at the NIH that we ought to look at.

Second, I would make a point, I do not think that this debate on errors should lead to an opening of the national practitioner data bank. That practitioner data bank was set up for another reason. The data in that data bank did not necessarily indicate errors. Some of that data is related to settlements. And, you know, a practitioner, be it a nurse or a physician, may not have made that decision. That is an insurance company decision as to whether that settlement was made or not.

In fact, the nurse or the doctor may feel very, very strongly that they want to take it to court because they know that they did not commit any malpractice. And yet it is reported in there as a settlement and if you would release that data the public wouldn't make that differentiation. I even heard some Members of Congress say that they think that this information ought to be posted on a doctor's office wall, for goodness sakes.

I want to ask this panel, why don't we just go down the line, yes or no, do you think that the national practitioner's data bank should be open?

Mr. PERRY. I don't think that is the best way to do it but I do believe in public awareness at least at the institutional level of medical errors.

Mr. O'LEARY. No.

Mr. GOLDEN. A little bit longer. I talked to physicians. They are interested in improving care. They are fearful of data banks because of what could happen to the data, so I would say no.

Mr. LANGBERG. No.

Ms. FOLEY. And no.

Mr. GANSKE. Okay, so pretty much unanimous no. This is what my fear about some of what we are talking about and that is when we are talking about errors of omission or commission these are decisions that are frequently medical judgments. Let me give you an example and this is where you have to be very careful when you use best practice guidelines. I was a hand surgeon and I took care of thousands of finger fractures. The vast majority of those finger fractures I could treat with splinting, a closed reduction splinting, and you get a good result.

But, you know, once in a while I might have a pianist come along or professional musician or a surgeon and instead of just getting 80 percent range of motion as your result you might need nearly normal range of motion. And so your decision, your judgment there might be to do an open reduction and an internal fixation type procedure. But when you are looking at best practice guidelines there is always inherently a value judgment that determines how you determine that and it almost always is on the basis of cost versus optimal outcome.

And so I, for instance, might have taken care of a patient that needs that operation. Maybe that patient was that one patient out of 200 that gets an infection because they had a dirty finger open fracture. Somebody looks at that and now they say, oh, you know, you shouldn't have treated it that way. That is where I think we need to have some very sophisticated analysis and I think that goes along with what you were alluding to, Dr. O'Leary, when we look at this question.

Two other things. Mr. Chairman, I am very glad we had this but you know what, if you really want to look at some egregious medical practices going on in this country, I would like to share with you some of the web sites on medical quackery. You would be amazed at what some people are being sold over the Internet as medical care and some of the really, really bad results that people are getting from unprofessional or really quack treatments. And this is something we ought to look at.

Finally, I want to say this about HMOs as it relates to your comments, Ms. Foley. It was 6 months or 12 months ago that either on Nightline or Front Line or PBS, some such program, there was a documentary on the effect of HMOs in the system, and I will never forget the segment where they interviewed an RN who was in charge of a floor. Dr. Langberg, you are shaking your head like you know what I mean. And I am not bashing hospitals on this because I know that hospitals are under that gun.

But this poor nurse just about—I think she broke down and cried on that interview about how frustrated she was with having to deal with the degree of medical complexity and being left with health aides. And they interviewed a health aide, what a good soul that lady was. She was doing her honest to God best to take care of patients and she just didn't have the training or the knowledge to do that.

And I think, Mr. Chairman, we need to look at the effect of HMOs on the medical errors that are occurring around the country, especially as it relates to nursing staffing in hospitals.

Mr. BILIRAKIS. I thank the gentleman. Dr. Snyder.

Mr. SNYDER. Thank you, Mr. Chairman. Dr. Golden, as the Arkansas representative here, I will aim my questions at you. This report that came out, there has been some discussion earlier today about how reliable we think the studies and the extrapolations were. Do you buy the numbers?

Mr. GOLDEN. I am not sure about the death rates, extrapolated death rates, but I looked at one of the studies, some of the data has not been published, but a study out of Utah and Colorado the other day, and they seemed reasonable. Certain percentages of the adverse events were deemed preventable or not preventable. And I thought the numbers in that paper and surgical literature was actually fairly reasonable.

Mr. SNYDER. Now if you all and the public and perhaps Congress and the State legislatures, if they are in the year 2010 and we are looking back and saying, well, how are we doing, do we have any base line numbers out there that we are going to be able to tell over the next few years how we are doing?

Mr. GOLDEN. We are increasingly developing those base line numbers but I think as you heard earlier I think from Dr. Norwood, I think you have to base it on individual disease states and surgeries and processes, and we have those numbers now. On certain kind of catastrophic problems it is more random and I think we have a harder time getting those base line numbers but the more specific we ask the question the better we will have the base line. So those numbers are available now and we can get numbers to compare our progress. We sure can.

Mr. SNYDER. As opposed to kind of the whole system wide——

Mr. GOLDEN. Well, that is correct. I mean we know now the drug time for treatment of MIs, for acute thrombolysis. We know how many people are getting aspirin. We know when people are getting Ace inhibitors for their congestive heart failure. We know the rates of mammography use. We have those numbers and we can use those numbers to assess our progress.

Mr. SNYDER. The last question I wanted to ask you with UMS and Little Rock that is just a bridge away across the street to the VA hospital, and we have talked a lot about the VA today and the work that they are doing, what is happening in the medical school or the nursing school curriculum, what changes have you seen recently or do you foresee happening with regard to patient safety?

Mr. GOLDEN. There are a number of things. I taught physical diagnosis for years at UNS and Dr. Jeanie Hurd came along with me. She became now the dean of graduate medical education. She and I worked together on these issues specifically and in fact will be a member of the QIO board I think this summer. She developed a whole program called Objective Structured Clinical Examinations where students can't just get an easy path. They have to go in a room. They have a standardized patient, a standardized set of clinical circumstances, and they can't hide. Somebody is watching that exam. And schools all over the country are developing these things.

It makes the students very nervous but if you go in a room and you ask the student, okay, here is a patient sitting there, tell me what you hear when you listen to the heart. They either hear the murmur or they don't. And you begin to get a sense of performance, of competency. The student gets immediate feedback of what they can or cannot do and that to me is a terrific improvement in medical education because it is a standardized event where the student either gets it or he doesn't or she doesn't and gets immediate feedback as to what they know and don't know.

Mr. SNYDER. That is a tremendous opportunity and I think we are going to have more and more education on these issues as well for quality improvement with the health staff. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank you, Dr. Snyder, and thank all the members of the subcommittee. We have been here for quite some time. Ms. Foley and gentlemen, thank you so very much for being here. I failed to make this point to the other panels, but I hope that any questions we may forward to you, you might respond to, if you would as soon as you possibly can. Thank you so much. Tough subject. I would like to think that you have helped us an awful lot in addressing it.

[Whereupon, at 2:20 p.m., the subcommittees were adjourned.]

[Additional material submitted for the record follows:]

PREPARED STATEMENT OF THE AMERICAN OSTEOPATHIC ASSOCIATION AND THE AMERICAN OSTEOPATHIC HEALTHCARE ASSOCIATION

This statement is presented on behalf of the American Osteopathic Association (AOA) and the American Osteopathic Healthcare Association (AOHA). The AOA represents the 44,000 osteopathic physicians throughout the United States who practice medicine and are committed to ensuring the highest standards of patient care. The AOA is the national professional organization for osteopathic physicians, and is the recognized accrediting authority for colleges of osteopathic medicine, osteopathic postdoctoral training programs and osteopathic continuing medical education. The AOHA represents the nation's hospitals and health systems that deliver osteopathic healthcare or osteopathic graduate medical education. Through a for-profit subsidiary, the AOHA provides its members with access to risk management assistance, among other products and services.

Osteopathic medicine is one of two distinct branches of medical practice in the United States. While allopathic physicians (MDs) comprise the majority of the nation's physician workforce, osteopathic physicians (DOs) comprise more than five percent of the physicians who practice in the United States. Significantly, D.O.s represent more than 15 percent of the physicians practicing in communities of less than 10,000 and 18 percent of physicians serving communities of 2,500 or less.

The AOA and the AOHA are deeply concerned about the frequency of adverse events cited by the Institute of Medicine in its recent study, "To Err is Human." The Institute reported that between 44,000 and 98,000 patients died or were injured in 1984 and 1992 as a result of these adverse events.

The members of the osteopathic medical profession have long supported efforts to improve patient care by drastically reducing medical errors. In 1945, the AOA's Healthcare Facilities Accreditation Program (HFAP) was established. The HFAP is authorized by the Health Care Financing Administration (HCFA) to accredit osteopathic and allopathic hospitals and healthcare systems for Medicare purposes. The HFAP assists hospitals and their staffs in reducing or eliminating medical errors by developing Quality Monitoring and Improvement programs that monitor patient safety. On January 27, the AOHA held its first seminar on improving patient safety and reducing medical errors. Additional seminars are planned for March 24, and will be held throughout the year.

The AOA and AOHA generally support the IOM's recommendations to bolster nationwide efforts to improve patient safety. We support forums that explore ways in which healthcare organizations can participate in the effort to reduce medical er-

rors. The healthcare community can, and should, expand current activities to identify and address system failures that lead to medical errors.

The osteopathic medical community will continue its efforts to strengthen existing quality improvement activities at every level, including the education and training of medical professionals and administrative personnel. We do not believe that the way to improve healthcare is to increase federal mandates, regulation, and administrative burdens, which could suppress reporting and inhibit open discussion of adverse events and medical errors.

The AOA and the AOHA agree with the IOM that it is important to have reliable information about adverse events that healthcare professionals can use to assess, analyze and correct systemic and other failures that lead to such events. There is potential for such information to enhance the understanding of medical errors, while preventing future errors. Unfortunately, there is scant proof among the approximately 20 states currently reporting such data that the healthcare systems are any safer in those states than in states that do not have such reporting.

We do believe, however, that state medical error reporting programs already in place may offer models for a federal effort to compile similar data. These should be closely reviewed and considered before federal action is taken. For instance, the data now being collected should be analyzed to determine whether or not the data used in the IOM study is reflective of the current state of affairs. Additionally, consideration ought to be given to the development of pilot projects designed to collect adverse event data. Finally, federal agencies should use the data compiled by states with mandatory reporting programs to determine whether their data is comparable with the IOM's data, which may be outdated.

Outdated data may have distorted the IOM's conclusions about the alleged epidemic of medical errors. Accurate data could help federal agencies determine which areas of healthcare experience the most errors and are most in need of restructuring. Accordingly, the AOA and AOHA would recommend a revised study using more current data than 1984 or 1992 as reported by the IOM.

Mandatory reporting of adverse events presents a number of serious problems. Healthcare facilities may be reluctant to cooperate with mandatory (or even voluntary) data reporting if they perceive that they will be disciplined. It will be difficult to learn from errors and to improve systems if facilities and individuals fear that the information will be used against them. Only after the IOM study and its supporting data have been analyzed fully and pilot projects established, should policymakers consider the establishment of a national database, with either voluntary or mandatory reporting.

If a national effort to gather and analyze adverse event data goes forward, the information should not be solely available to federal healthcare agencies. Stripped of its identifiers, it also must be available to healthcare facilities, researchers, accreditation organizations, and other healthcare entities that, in turn, could use the data to benchmark and monitor changes in the occurrence of medical errors. In this way, the database would serve as a tool to promote higher standards of patient care. Healthcare facilities and providers who report and assess medical errors can attempt to rectify particular problems by monitoring their data and comparing it with federal, state and local trends. Identifiable data is not necessary for this function to be met.

Identifiable data should not be available to the public because to do so would inhibit reporting due to a natural fear of punishment and litigation. Healthcare professions continuously work to correct medical errors. The AOA and the AOHA believe that the American healthcare system operates well on the whole. Public confidence in that system should not be undermined while healthcare providers seek to increase patient safety.

Another reason that the AOA and the AOHA recommend national data remain confidential and secure is that such data could be used as background information for litigation. Any national data that is gathered should be considered information only for peer review. Since peer review protections vary greatly from state to state, at a minimum, any federal data gathering initiative must provide protection from discoverability and use in malpractice litigation. The data must be used only for the purpose of improving the safety standards of American healthcare.

The AOA and the AOHA stand ready to support the IOM in improving patient safety in the United States. We welcome the opportunity to work with this committee and others dedicated to patient safety. Our members and staff are available to assist in the development of legislation that would lead to the continued improvement of the American healthcare system.

PREPARED STATEMENT OF NATIONAL MEDICAL CONCEPTS, INC.

New Medical Concepts, Inc. (NMC), a telecommunications and healthcare information company headquartered in Fort Lauderdale, FL is pleased to present this statement for the hearing record to the House Commerce Committee Subcommittees on Oversight and Health and Environment and the House Veterans Affairs' Subcommittee on Health as they examine medical errors. We believe the Institute of Medicine's Report To Err Is Human: Building A Safer Health System and the report to Congress issued last week by the General Accounting Office on Adverse Drug Errors provide a strong basis for Congressional action on one of the most serious problems in our healthcare system: the need to improve patient safety.

Our comments focus on problems associated with one of the most significant aspects of this problem in terms of impairment of quality of care and unnecessary costs: the need to assure safe prescription drug use by patients in the outpatient setting.

NEW MEDICAL CONCEPTS, INC.

NMC was founded in 1997 by a group of business, healthcare and telecommunications professionals with recognized expertise in innovative technology, medicine, pharmacy and healthcare operations. The firm has developed **RxAlerts**, a unique voice and text messaging alert system using automated, personalized wireless and wired communications, which has the potential for dramatically reducing patient medication non-compliance and fostering more effective communications between healthcare providers and their patients.

Most would acknowledge that drug therapy is often the most effective and cost-efficient way to achieve desired therapeutic outcomes in the treatment of patients. But drugs cannot work if they are not taken or are taken improperly. All drugs have side effects; some known, some unknown; some serious, some not. Because of the potential for harm and the increased significance of drug therapy as a treatment modality, safe medication use must be a priority objective in today's healthcare system. The problem of medication noncompliance is very real and demands practical solutions, the kind that foster integrated communication between patient and provider and which our company has developed.

Adverse Drug Events

An adverse drug event (ADE) would typically be defined as any undesired effect associated with drug therapy such as harmful reactions (adverse drug reactions or ADRs), treatment failure, medication errors, overdoses and non-compliance. Consequences range from ineffective treatment to injuries, at times resulting in death. The population that is most at risk because of these events are the chronically ill patients of all ages and the elderly. With an aging population, the use of prescription drugs will rise and likewise, the risk of medication misuse and ADEs will also increase.

Medication Non-compliance

We wish to emphasize to the Committee that the problems associated with medical errors and adverse drug events are just as significant (and probably more prevalent) in the outpatient setting as in the institutional setting. Certainly the overwhelming percentage of the several billion medications dispensed per year are to patients who are not in hospitals, nursing homes or other institutional settings, but who receive their drugs from community pharmacies. Safe medication use and the associated problem of medication non-compliance by patients in the ambulatory setting deserve this Committee's serious attention.

Indeed, the General Accounting Office report on "Adverse Drug Events" released last week identified patient non-compliance in the ambulatory setting as a major source of adverse drug events. The report also described medication non-compliance as a major source of emergency room and hospital admissions. For example, the GAO cites a report finding that 58 percent of adverse drug events in patients visiting an emergency room were caused by medication non-compliance. Another study it cites found that 11 percent of all elderly admissions to a hospital were related to medication non-compliance. Among the proposals the GAO makes for reducing adverse drug events is improving communication between patients and physicians about the risks and benefits of medication.

DEFINITION, REASONS, THOSE MOST SERIOUSLY AFFECTED

Medication non-compliance, or not taking a medicine as it was prescribed, is a worldwide health issue. Non-compliance includes taking too much medication, taking medication not prescribed, not taking medication prescribed, altering the pre-

scribed dosage, or altering the time between doses. The reasons for non-compliance vary and may include forgetfulness, confusion over generic and brand names, unclear information about how to take or how much to take of a medication, disappearing symptoms of an illness, no perceived improvement in a patient's condition or well-being and, for those with low income, the difficult choice of having to select food or heat over drug expenditures. As with ADEs generally, the elderly and the chronically ill are particularly susceptible to the problem of medication non-compliance. They usually take multiple prescriptions, and they are more susceptible to memory problems and confusion.

RELEVANT STATISTICS

- Thirty years ago (1970) only 650 medications were available; today the number approaches 10,000
- Over 2.7 billion retail prescriptions were dispensed in the U.S. in 1998. (GAO)
- 30-50 percent of all prescriptions are not taken correctly. (U.S. Food & Drug Administration)
- More than a billion prescriptions are taken incorrectly each year. (U.S. Chamber of Commerce)
- The estimated annual cost of medication non-compliance exceeds $100 billion. (National Pharmaceutical Council)
- Non-compliance kills 125,000 Americans each year. (National Pharmaceutical Council)

SOCIAL AND ECONOMIC CONSEQUENCES

Non-compliance with the taking of medication has significant implications not only in terms of poor health outcomes for the patient but for the healthcare system itself. Its full effect on morbidity, mortality, and the associated healthcare costs are only beginning to be recognized. One national study revealed more than $75 billion in direct annual costs (with variable assumptions, the range was from $31 to $137 billion) as a result of medication use problems in the United States. It based its findings on preventable treatment associated with increased admissions to hospitals and nursing homes and increased visits to physician offices and hospital emergency rooms which resulted from medication non-compliance.

The costs estimated in this study related only to the direct cost of first time events and did not address consequential adverse health events (i.e., new medical problems resulting from the primary illness) or the indirect cost of lost employee productivity/absenteeism and turnover. When indirect costs due to non-compliance are added to the direct cost figures, total economic costs exceed $150 billion (Johnson, Jeffrey A. and J. Lyle Bootman. "Drug-Related Morbidity and Mortality: A Cost-of-Illness Model," Archives of Internal Medicine 155:1949-56, Oct. 6, 1995). Drug-related morbidity and mortality costs are in the same range as diabetes, cardiovascular disease and obesity—leading some experts to suggest that drug-related problems should be considered a major category of disease.

FAILURE TO ADDRESS THE PROBLEM

Medication non-compliance has reached the forefront of the medical community's awareness, but efforts to focus on safe medication use and the problem of medication non-compliance have been limited. While there have been major efforts made in developing technologies to detect and minimize adverse drug reactions, essentially sophisticated computer systems utilized by pharmacies and hospitals, these innovations do not address the more complex and subtle causal factors associated with noncompliance, notably communications between patient and healthcare professionals. Patient counseling requirements, consumer information sheets that accompany prescriptions, public service announcements, educational brochures and the specialized educational programs that are part of "disease management" programs are all positive developments, but have not proven sufficient to assure appropriate and safe medication use by patients. There have been few efforts made, technological or otherwise, to develop programs or products to assist health professionals and individual patients in dealing comprehensively with the problem.

CONCLUSION: INNOVATION THAT ADDRESSES MEDICATION NON-COMPLIANCE MUST BE ENCOURAGED

The inescapable conclusion is that if patients are non-compliant with medication therapy, desired outcomes (whether it be a cure, relief of symptoms or improved quality of life) are impaired. Indeed, it is clear that many emergency room and physician office visits and hospital and nursing home admissions could be prevented

with interventions targeted at improving medication compliance. There can be little doubt that non-compliance is a significant health and economic burden on the healthcare system; that interventions directed at improving compliance will result in improved health outcomes; and that a significant cost savings will be realized through interventions directed at improving compliance.

NMC believes our product **RxAlerts** is an effective and practical tool which will assist the healthcare system in addressing the problem of medication non-compliance. **RxAlerts** is a comprehensive medication compliance and support product/program which uses sophisticated state-of-the-art software, utilizing proprietary computer time-clocking engines, to provide personal customized health-related information to patients from their health providers through wired and wireless communication media—alphanumeric and voice paging, facsimile transmission, cellular telephony, the internet, wired telephones and television (pending). The product applications have two-way communications capability and are encrypted to assure patient confidentiality. NMC is initially focusing its efforts on disease states like HIV, asthma, diabetes, post-organ transplants and certain pulmonary and heart conditions where medicine regimens are difficult, where there is a criticality of maintaining consistent medicine levels, where there is a need to modify or enhance behavior and where there is an overall need to communicate with patients on a regular basis.

New Medical Concepts is encouraged that the Committee is examining the issue of medical errors, and we pledge to work with Congress, federal and state health agencies and the healthcare community in finding real world "Patient Connectivity" solutions which will foster safe medication use and improve the quality of care patients receive.

PREPARED STATEMENT OF SHANDS HEALTHCARE

Dear Mr. Chairman, Members of the Committee: I am writing as CEO of Shands HealthCare, with its mission of providing excellent patient care, improving community health, and supporting education and research for the State of Florida. Shands HealthCare is an integrated clinical delivery system, which offers the most comprehensive range of services in North Central Florida. The not-for-profit enterprise encompasses six acute care hospitals, two specialty hospitals, a home care company, and manages the University of Florida clinic operations as well as an extensive physician network. Shands at the University of Florida, the system's flagship hospital, is the academic medical center for the University of Florida Health Science Center and is recognized as one of the Southeasts leading tertiary care centers, and as such receives the majority of its patients from every county of Florida and Southeast Georgia. Shands at the University of Florida is closely linked with the College of Medicine at the University of Florida resulting in the development and delivery of cutting edge technology for the delivery of patient care.

In addition, Shands HealthCare, the University of Florida, and University and Methodist Medical Centers have joined forces to form Shands Jacksonville, of which I am the Chairman of the Board of Directors.

I also have the honor of serving as Chairman of the Council of Teaching Hospitals (COTH), a division of the Association of American Medical Colleges (AAMC), representing over 400 teaching hospitals across the nation. In addition, I serve on the Boards of the American Hospital Association and the Florida Hospital Association, and was recently elected Chair of the Florida Statutory Teaching Hospital Council. As a member of the Board of the National Committee for Quality Health Care, I have been directly involved in the promotion of quality for health care teams.

We believe that we have a fundamental responsibility to continually improve the quality of care and services provided to our patients. As part of their mission, teaching hospitals provide a disproportionate share of the most complex health care services. This translates to patients entering the health system who are sicker and more complicated yielding health needs greater than those traditionally seen elsewhere.

Hospitals have long recognized their role in improving the care provided to patients. Initiatives already in place at teaching hospitals include, but are not limited to: leadership commitment to improving the care provided; internal reporting of incidents for the identification of possible opportunities for improvement; use of external benchmarking; proactive attention to improving processes through the use of quality improvement tools and techniques; and, sharing of information related to trends and successes.

Shands HealthCare participates in each of these, as well as required external reporting to the State of Florida for specified serious incidents. **These reporting processes have only been successful because of the protections put in place by the Florida Legislature to maintain the confidentiality of the informa-**

tion reported. This is a crucial step to ensure that the process remains non-punitive and successful.

One of the keys to success has been the focus of the Quality Committee of the Board of Directors on quality improvement, of which reducing efforts is but one component. Reporting of issues and involvement of the Board has reinforced the commitment at all levels of the organization to improving and maintaining the health of people in the State of Florida and the Southeastern United States.

Thank you for your consideration and response to our desire to work closely with Congress as it pursues ways to continue to improve the quality of health care services.

PREPARED STATEMENT OF AMERICAN COLLEGE OF PHYSICIANS—AMERICAN SOCIETY OF INTERNAL MEDICINE

The American College of Physicians-American Society of Internal Medicine (ACP-ASIM), representing over 115,000 physicians who specialize in internal medicine and medical students with an interest in internal medicine, appreciates the opportunity to comment on the report of the Institute of Medicine (IOM), *To Err is Human: Building a Safer Health System.* Our membership includes practicing physicians, teaching physicians, residents, students, researchers, and administrators who are dedicated to assuring high quality medical care.

The IOM report highlights unacceptable quality and safety problems in the nation's health care system. The report reveals that more people die each year as a result of medical errors than from motor vehicle accidents, breast cancer, or AIDS. It notes that medication errors alone account for over 7,000 deaths annually. This is a dismal record that exceeds the 6,000 deaths each year due to workplace injuries. Significantly, the IOM report finds that "the problem is that the system needs to be made safer" and indicates that the "problem is not bad people."

The IOM report concludes that the U.S. health care industry lacks a systematic way of identifying, analyzing, and correcting unsafe practices. In order to achieve this end, the report states: "Preventing errors means designing the health care system at all levels to make it safer. Building safety into processes of care is a more effective way to reduce errors than blaming individuals. The focus must shift from blaming individuals for past errors to a focus on preventing future errors by designing safety into the system." The report lays out a comprehensive strategy for addressing these problems. It challenges the profession to make significant changes to achieve a safer health care system. We accept this challenge.

ACP-ASIM offers the following comments regarding specific recommendations in the IOM report:

Creation of a Center for Patient Safety (IOM Recommendation 4.1):

ACP-ASIM agrees with the IOM recommendation that a highly visible center is needed with secure and adequate funding to set national goals, evaluate progress, and develop and coordinate a research agenda to achieve improvements in patient safety. We firmly believe that such an effort should involve the many private sector initiatives that are also now underway. We concur with the IOM that a coordinated national effort is needed and that adequate and stable funding must be assured. If the center is to be housed in a federal agency, it should be in a non-regulatory agency such as the Agency for Healthcare Research and Quality (AHRQ). A coordinated program for research and achievement of national goals for improvements in patient safety should be as objective as possible and should not be tied to a federal agency with regulatory responsibilities. AHRQ has the expertise and an existing infrastructure for funding research and coordinating activities concerning health care quality. ACP-ASIM, therefore, supports increased funding for AHRQ to accomplish these expanded functions.

Mandatory Reporting (IOM Recommendation 5.1):

The IOM report recognizes the need for both mandatory and voluntary error reporting systems. It explains that mandatory reporting systems are needed to hold providers accountable for their performance. It further advises that mandatory reporting should focus on the identification of serious adverse events (deaths or injuries resulting from medical interventions). The IOM notes that the focus of a mandatory reporting system should be narrowly defined. It recommends that the Forum for Health Quality Care Measurement and Reporting (The Quality Forum), a recently formed public/private partnership charged with developing a comprehensive quality measurement and public reporting strategy, should be responsible for promulgating and maintaining reporting standards.

The IOM report also calls for licensing and accreditation bodies to expand the scope and magnitude to which patient safety is reviewed and evaluated in rendering licensing/accreditation decisions.

ACP-ASIM agrees with the intent of this recommendation, but is concerned about its possible implementation. We strongly agree that physicians have a professional obligation to patients and society to report serious errors resulting in adverse events. It is appropriate that information on serious adverse events be reported to appropriate authorities and that a uniform, national reporting format be developed. We further agree that a public/private sector body, such as The Quality Forum, should be responsible for clearly defining what should be reported and developing the uniform reporting format. However, we are apprehensive about the possible role of the federal government in mandating what is to be reported and what will be done with the data. We urge Congress and federal agencies not to define reporting requirements too broadly or to be overly inclusive. We are concerned that mandatory reporting requirements could be excessively burdensome to institutions and individual physicians. We, therefore, agree with the IOM that a more narrowly defined program has a better chance of being successful.

We also wish to highlight that the IOM calls for devoting adequate attention and resources for analyzing reports of adverse outcomes to identify those attributable to error. The IOM notes that it is only after careful analysis that the subset of reports attributable to error can be identified and follow up action taken. We agree with the IOM that the results of the analyses, not all data that are required to be reported, should be made available to the public.

ACP-ASIM emphasizes that licensing and accreditation bodies considering patient safety issues in making licensing/accreditation decisions should not review every case patient record, but should review representative samples of patient care. Patient safety reviews should be completed within a reasonable time and with minimal disruption or additional administrative burdens for physicians or institutions.

Voluntary Reporting Systems (IOM Recommendation 5.2 and 6.1):

The IOM calls for voluntary reporting systems to collect information on errors that cause minimal or no harm. It notes that voluntary reporting of less serious errors can identify and remedy patterns of errors and systemic problems. It notes that the aim of voluntary systems is to lead to improvements in patient safety and that the cooperation of health care professionals is essential. The IOM clearly recommends that voluntary reporting systems must be protected from legal discovery. IOM further recommends that Congress pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality.

ACP-ASIM supports voluntary reporting of incidents that do not result in fatalities or major errors, but could be symptomatic of systemic problems. However, protection of the confidentiality of data is essential to ensure that events involving medical errors or other incidents adversely effecting patient safety are reported and acted upon. Physicians and other health professionals have a responsibility to patients and the public to assure that all actions adversely affecting the quality and safety of patient care are reported and acted upon through a system of continuous quality improvement. However, ACP-ASIM recommends that voluntary quality improvement systems must protect individual confidentiality. The confidentiality of reported data must be protected so that physicians and other health care professionals are encouraged to report all adverse incidents without fear that their cooperation will increase their exposure to law suits for professional liability or other sanctions. Any potential increased exposure to fines, loss of hospital privileges, or even possible loss of medical licensure will discourage physicians from voluntarily reporting "near misses" and other adverse incidents.

Consequently, we strongly suggest that any voluntary reporting system must be primarily educational rather than punitive.

Nevertheless, ACP-ASIM acknowledges that physicians have a professional obligation to disclose to patients information about procedural or judgment errors made in the course of care if such information is material to the patient's well-being. Errors do not necessarily constitute improper, negligent, or unethical behavior, but failure to disclose them may. (ACP-ASIM Ethics Manual, 1998, p.8-9)

The President's Executive Order

In response to the IOM report, President Clinton announced on December 7, 1999, that he had signed an executive order directing a task force to analyze the report and report back within 60 days about ways to implement its recommendations. He also directed the task force to evaluate the extent to which medical errors are

caused by misuse of medications or medical devices, and to develop additional strategies to reduce these errors. He further directed each of the more than 300 private health plans participating in the Federal Employee Health Benefits Program to institute quality improvement and patient safety initiatives. He also signed legislation reauthorizing the Agency for Healthcare Research and Quality and providing $25 million for research to improve health care quality and prevent medical errors. The AHRQ will convene a national conference with state health officials to promote best practices in preventing medical errors. In addition, the President announced that he was directing his budget and health care teams to develop quality and patient safety initiatives for next year's budget.

ACP-ASIM applauds all of these actions by the Executive branch to address the problems identified in the IOM report.

Issues for Further Review

The IOM report raises many questions that will require further examination. We urge Congress to consider the following:

- What should be required for mandatory reporting? Should reporting be required only for the most egregious errors involving death or serious injury? How will "serious errors" be distinguished from "less serious" errors? Will mandatory reporting be cumulative, by institutions or by individual physicians?
- To whom should data be reported? Should it be reported to state agencies only, to states and the federal government, or to private agencies?
- What data should be released to the public? For errors causing serious injury or death, what should be the extent of data released? Should everything be reported or just the final analysis? Does the public have a right to know the number of adverse incidents reported by a physician?
- What happens to the information that is reported? Will there be follow-up actions, and if so, will these be released to the public? Who will have access to the raw data, and will there be adequate protections of confidentiality?
- Should licensing bodies use data on errors to deny or revoke physician licenses? Should data on physicians be available to hospitals for consideration in granting or denying hospital privileges?
- How can reporting requirements avoid creating excessive costs and administrative burdens for physicians and health care organizations?

Conclusion

ACP-ASIM is strongly supportive of the recommendations of the IOM report, *To Err is Human: Building a Safer Health System.* The College agrees that far too many preventable errors are committed that do not get reported and that solutions are needed to improve the quality and safety of patient care. ACP-ASIM concurs with the IOM's conclusion that the focus must be the reform of the system, not the punishment of individuals. ACP-ASIM encourages the profession to take up the challenge raised by the IOM to improve the quality and safety of patient care. The College supports setting a national goal of reducing medical errors by 50% within five years. Such an achievement will require substantial commitment of resources and effort. Substantial financial costs will be involved, but these may be largely offset by benefits in improved patient care and better health outcomes. Regardless of the costs, the public has a right to expect health care that is safe and effective. The profession is responsible to individual patients and to the public to continuously seek to improve the quality of medical care and make sure that health care services are provided as safely as possible.

The College applauds the prompt initiatives instituted by the President and will look forward to working with Congress in addressing issues requiring legislative action. However, as we have indicated, there are many questions that need to be addressed before a national plan with mandatory and voluntary reporting requirements can be implemented. ACP-ASIM appreciates the deliberation that the Committee is giving to the IOM report and the opportunity to submit testimony. We are prepared to work with the Congress and the Administration to reduce the number of medical errors.

PREPARED STATEMENT OF HON. HELEN CHENOWETH-HAGE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF IDAHO

I would like to thank Chairman Bilirakis and Chairman Everett for holding today's hearing. I appreciate the subcommittees for holding a joint hearing to discuss ways to improve the quality of our nation's healthcare system. By working together we can reduce the frequency of medical errors.

When the Institute of Medicine released a report "To Err is Human: Building a Safer Health System", I was shocked to learn that as many as 98,000 preventable deaths occur each year.

If this is true, then the frightening thing is, no one knows the exact number of preventable deaths. Each year, an estimated 44,000 to 98,000 patients preventable deaths occur in our healthcare system. Forty-four thousand and 98,000 is an unacceptably high number. Why can't the Administration determine with more precision the actual number of preventable deaths? Why are so many preventable deaths occurring in the world's most advanced nation? The high number of preventable deaths is unacceptable. We can and must do more. People must have faith in the system.

As Congress works to improve the quality of medical care, we must also work to restore people's trust in the system. They are, after all, entrusting their precious lives in the hands of America's doctors. Patients must be assured that they are receiving high quality care at all times.

I look forward to hearing from our excellent panels of witnesses. We must take their recommendations to heart. After all, they are the ones who deal with the system on an everyday basis.

Chairman Bilirakis and Chairman Everett, I thank both of you for holding this hearing and I look forward to working with everyone on both committees to improve our nation's healthcare system.

CONSUMER COALITION FOR QUALITY HEALTH CARE
February 7, 2000

The Honorable MICHAEL BILIRAKIS, *Chairman*
Subcommittee on Health and Environment
Commerce Committee
U.S. House of Representatives
2125 Rayburn HOB
Washington, DC 20515

DEAR CHAIRMAN BILIRAKIS: I am writing in support of your efforts to examine ways that the federal government can address the issue of medical errors. As the Institute of Medicine (IOM) report released last fall revealed, medical errors are unnecessarily robbing our nation of valuable lives and resources. It is critical that Congress focus on ways to systematically attack this crisis in the health care industry and your hearing this week will help to move this public discussion forward.

As the Committee considers alternatives to identifying, measuring, and reducing medical errors in the health care system, I ask that you carefully consider the appropriate use of the quality monitoring and improvement infrastructure that already exists. Quality Improvement Organizations (QIOs), also known as Medicare Peer Review Organizations (PROs), offer a unique opportunity for Congress to quickly address some of the medical error issues outlined in the IoM study. PROs already evaluate and work to improve the quality of care provided to millions of Medicare beneficiaries.

QIOs are known to the consumer community for their work in community-based quality improvement projects and hospital discharge appeals. They have a strong track record in using multidisciplinary teams with the clinical expertise necessary to work with providers and purchasers in the private sector with the goal of reducing medical errors and improving the quality of care for Medicare and Medicaid patients.

Any national system to reduce medical errors must be perceived by consumers as objective and sufficiently independent. QIOs have the appropriate external independence necessary to carry out the difficult and often sensitive work of identifying and working to correct medical errors.

As the Committee weighs its options on public reporting of serious medical errors and a national approach to reduce medical errors and "near misses," please consider the value of those entities that can successfully identify the root-causes of errors, the best practices from across the country, and objectively assist hospitals in developing systems interventions. I believe that you will find there is great potential in using the PRO system. They are available to do this kind of work in every state without creating a new infrastructure—this would provide consistency and save valuable resources.

Thank you for your consideration of these important issues. I look forward to working with you on these and other concerns regarding medical errors in the future.

Sincerely,

BRIAN W. LINDBERG

CONSUMER COALITION FOR QUALITY HEALTH CARE
February 7, 2000

The Honorable SHERROD BROWN, *Ranking Minority Member*
Subcommittee on Health and Enviroment
Commerce Committee
U.S. House of Representatives
2125 Rayburn HOB
Washington, DC 20515

DEAR RANKING MINORITY MEMBER BROWN: I am writing in support of your efforts to examine ways that the federal government can address the issue of medical errors. As the Institute of Medicine (IOM) report released last fall revealed, medical errors are unnecessarily robbing our nation of valuable lives and resources. It is critical that Congress focus on ways to systematically attack this crisis in the health care industry and your hearing this week will help to move this public discussion forward.

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Sincerely,

BRIAN W. LINDBERG

PREPARED STATEMENT OF HON. CONSTANCE A. MORELLA, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MARYLAND

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to appear before you to heed the call for Congressional leadership in response to the recent report that as many as 98,000 Americans die unnecessarily every year from medical mistakes made by physicians, pharmacists and other health care professionals.

Before I read the November 29, 1999 report from the Institute of Medicine (IOM), I knew that the human cost of medical errors was high. However, I was surprised to read that medical errors kill between *44,000* and *98,000* people in U.S. hospitals each year. The IOM report estimates that the financial costs of these preventable

errors are between $17 billion and $29 billion each year. Medical errors afflict patients in a variety of health care settings, including hospitals, day-surgery and outpatient clinics, retail pharmacies, nursing homes, and even in home care. The magnitude of this loss of life is staggering because these numbers mean more people die from avoidable medical mistakes each year than from highway accidents, breast cancer, or AIDS. Yet while other areas of the U.S. economy have coordinated safety programs that collect and analyze accident trends, including those that track nuclear reactor accidents, highway crashes and airline disasters, there is no centralized system for keeping tabs on medical errors and using that information to prevent future mistakes.

According to the IOM report, the majority of medical errors do not result from individual recklessness, but from basic flaws in the way the health system is organized. For example, stocking patient-care units in hospitals with certain full-strength drugs—even though they are toxic unless diluted—has resulted in deadly mistakes. Also, illegible writing in medical records has resulted in the administration of a drug for which the patient has a known allergy. A May, 1999 report from the U.S. Pharmacopeia (a copy of which is attached) found that confusion over similarly named drugs, such as "Cefuroxime" versus "Cefotaxime," accounts for approximately one-quarter of all reports to the USP Medication Errors Reporting Program.

In addition to the preceding examples, other concerns stem from the increasing complexity of numerous health care specialists where, when a patient is treated by several practitioners, they often do not have complete information about the medicines prescribed by other practitioners or the patient's illnesses unrelated to the specific concern that practitioner is addressing.

Before the technological advances we've benefitted from over the past decades, scientific knowledge moved forward through the concept of "trial and error." Unfortunately, expecting each of the thousands of Americans hospitals to continue to rely on trial and error to improve patient care is not an acceptable solution when it comes to protecting the quality of human life. Mr. Chairman, we have the technology before us to remedy the lack of coordination resulting from our rapidly evolving health care system and to stop putting patients at risk as mistakes are repeated because one practitioner cannot learn from the mistakes of another.

One solution specifically suggested in the IOM report is the increased utilization of the voluntary reporting system called MedMARx. MedMARx is maintained by the U.S. Pharmacopoeia (USP), a not-for-profit, volunteer-based, private organization located in my district in Rockville, Maryland. The mission of the USP is to promote the public health by establishing and disseminating officially recognized standards of quality and authoritative information for the use of medicines and other health care technologies by health professionals, patients, and consumers.

The MedMARx program, launched in August 1998, is a national Internet-based, anonymous database designed to help prevent and reduce medication efforts in hospitals. MedMARx is based upon the premise that the sharing of field experiences and concerns among health care professionals is important to reducing medication errors and providing safer, better quality health care. MedMARx allows hospitals to anonymously report, track, and monitor their medication errors, and to identify trends and pinpoint problem areas. Users also can learn from the experiences of other hospitals. By using MedMARx, hospitals throughout the United States can learn from other hospitals and their experiences with proactive risk assessment and product processes. This revolutionary method of risk avoidance improves patient safety and the quality of patient care, while reducing the substantial financial and emotional costs associated with medication errors.

MedMARx now boasts 100 hospitals throughout the United States as participants, making it the first national program to help hospitals prevent medication errors. However, in order to make this system more successful, and with the encouragement of Dianne Cousins, R.Ph., Vice President for USP, I will soon introduce legislation to encourage the growth of MedMARx by giving hospitals and health care professionals the incentive to voluntarily report problems encountered during clinical practice. According to USP, it is "clear that a significant obstacle to the full implementation of any national medication error reporting program is the lack of disclosure of the reports in civil litigation and regulatory investigation." Therefore, my legislation will protect the confidentiality of MedMARx data on medical mistakes where the information is collected and analyzed solely for the purpose of improving safety and quality. The information covered by my legislation shall not be subject to subpoena or discovery in any administrative or civil proceeding, provided, however, that these materials are kept confidential. Further, the protection afforded by my legislation will not extend to the underlying fact that an error occurred, which would be otherwise discoverable by traditional means. Without the protection afforded by this simple but important legislation, hospitals and health care profes-

sionals fear that information reported to MedMARx might ultimately be subpoenaed and used in lawsuits against them, thereby discouraging their participation in MedMARx.

I am committed to working with my colleagues in Congress to promote the widespread use of MedMARx and allow the USP to build a comprehensive Internet-based information database to provide feedback to reporting professionals, product manufacturers, and regulatory agencies. Working together, Congress can ensure the success of MedMARx and begin improving patient safety and the quality of patient care, and as a result, reduce the substantial financial and emotional costs associated with medication errors.

USP Quality Review

Use Caution—Avoid Confusion

Confusion over the similarity of drug names, either written or spoken, accounts for approximately one-quarter of all reports to the USP Medication Errors Reporting (MER) Program. This issue involves confusion between similar brand names, between similar generic names, and between similar brand and generic names. Such confusion is compounded by illegible handwriting, incomplete knowledge of drug names, newly available products, similar packaging or labeling, and incorrect selection of a similar name from a computerized product list.

Below is a list of similar drug names reported to the USP MER Program. Remember that these names may not sound alike as you read them or look alike in print, but when handwritten or communicated verbally, these names have caused or could cause a mix-up. (Brand names are *italicized*.)

Accupril	*Accutane*
Accupril	*Monopril*
Accutane	*Accupril*
Acetazolamide	Acetohexamide
Acetohexamide	Acetazolamide
Acular	*Ocular*
Adderall	*Inderal*
Adenosine	Adenosine Phosphate
Adenosine Phosphate	Adenosine
Adriamycin	*Aredia*
Adriamycin	*Idamycin*
Akarpine	Atropine
Aldara	*Alora*
Allegra	*Viagra*
Allopurinol	*Apresoline*
Alora	*Aldara*
Alprazolam	Lorazepam
Altace	*Amaryl*
Altace	*Artane*
Alupent	*Atrovent*
Amantadine, Ranitidine	Rimantadine
Amaryl	*Altace*
Ambien	*Amen*
Amen	*Ambien*
Amicar	*Amikin*
Amikin	*Amicar*
Amiloride	Amlodipine
Amiodarone	Amrinone
Amlodipine	Amiloride
Amoxicillin	*Amoxil*
Amoxicillin	*Atarax*
Amoxil	Amoxicillin
Amrinone	Amiodarone
Anaspaz	*Antispas*
Ansaid	*Asacol*
Antispas	*Anaspaz*
Anusol	*Anusol-HC*
Anusol-HC	*Anusol*
Apresoline	Allopurinol
Aredia	*Adriamycin*
Artane	*Altace*
Asacol	*Ansaid*
Asacol	*Os-Cal*
Asparaginase	Pegaspargase
Atarax	Amoxicillin
Atarax	*Atixan*
Atixan	*Atarax*
Atropine	*Akarpine*
Atrovent	*Alupent*
Attenuvax	*Meruvax*
Azithromycin	Erythromycin
Benadryl	*Benylin*
Benylin	*Benadryl*
Benylin	*Ventolin*
Bepridil	*Prepidil*
Betagan	*Betagen*
Betagan	*Betoptic*
Betagen	*Betagan*
Betoptic	*Betagan*
Betoptic	*Betoptic S*
Betoptic S	*Betoptic*
Brevibloc	*Brevital*
Brevital	*Brevibloc*
Bumex	*Buprenex*
Bumex	*Permax*
Buprenex	*Bumex*
Buspirone	Bupropion
Bupropion	Buspirone
Cafergot	*Carafate*
Calan	*Colace*
Calciferol	Calcitriol
Calcitriol	*Calciferol*
Captopril	Carvedilol
Carafate	*Cafergot*
Carboplatin	Cisplatin
Cardene	*Cardizem*
Cardene	*Cardura*
Cardene	Codeine
Cardene SR	*Cardizem SR*
Cardiem	*Cardizem*
Cardizem	*Cardene*
Cardizem	*Cardiem*
Cardizem CD	*Cardizem SR*
Cardizem SR	*Cardene SR*
Cardizem SR	*Cardizem CD*
Cardura	*Cardene*
Cardura	*Coumadin*
Cardura	*Ridaura*
Carteolol	Carvedilol
Carvedilol	Captopril
Carvedilol	Carteolol
Cataflam	*Catapres*
Catapres	*Cataflam*
Cefaclor	Cephalexin
Cefazolin	Cefprozil
Cefol	*Cefzil*
Cefotan	*Ceftin*
Cefotaxime	Cefuroxime
Cefprozil	Cefazolin
Cefprozil	Cefuroxime
Ceftazidime	Ceftizoxime
Ceftin	*Cefotan*
Ceftin	*Cefzil*
Ceftin	*Cipro*
Ceftizoxime	Ceftazidime
Cefuroxime	Cefotaxime
Cefuroxime	Cefprozil
Cefuroxime	Deferoxamine
Cefzil	*Cefol*
Cefzil	*Ceftin*
Cefzil	*Kefzol*
Celebrex, *Celexa*	*Cerebyx*
Celexa, *Cerebyx*	*Celebrex*
Celexa	*Zyprexa*
Centaxin	*Cytoxan*
Cephalexin	Cefaclor
Cephalexin	Ciprofloxacin
Cerebyx, *Celebrex*	*Celexa*
Chlorpromazine	Chlorpropamide
Chlorpromazine	Prochlorperazine
Chlorpropamide	Chlorpromazine
Cipro	*Ceftin*
Ciprofloxacin	Cephalexin
Cisplatin	Carboplatin

Claritin-D	*Claritin-D 24-hour*
Claritin-D 24-hour	*Claritin-D*
Clinoril	*Clozaril*
Clinoril	*Orovail*
Clomiphene	Clomipramine
Clomipramine	Clomiphene
Clomipramine	Desipramine
Clonazepam	Clonidine *Klonopin*
Clonazepam	Clonazepate
Clonidine	*Klonopin*
Clonidine	*Klonopin* Clonazepam
Clonazepate	Clonazepam
Clozaril	*Clinoril*
Codeine	*Cardene*
Codeine	Iodine
Codeine	*Lodine*
Cognex	*Corgard*
Colace	*Calan*
Corgard	*Cognex*
Cortef	*Lortab*
Coumadin	*Cardura*
Covera	*Provera*
Cozaar	*Zocor*
Cyclobenzaprine	Cyproheptadine
Cyclophosphamide	Cyclosporine
Cycloserine	Cyclosporine
Cyclosporine	Cyclophosphamide
Cyclosporine	Cycloserine
Cyproheptadine	Cyclobenzaprine
Cytarabine	*Cytosar* *Cytoxan*
CytoGam	*Gammimune N*
Cytosar	*Cytovene*
Cytosar	*Cytoxan* Cytarabine
Cytosar-U	*Neosar*
Cytotec	*Cytoxan*
Cytovene	*Cytosar*
Cytoxan	*Centoxin*
Cytoxan	*Cytosar* Cytarabine
Cytoxan	*Cytotec*
Danazol	*Dantrium*
Dantrium	Danazol
Darvon	*Diovan*
Daunorubicin	Doxorubicin
Daypro	*Duopres*
Deferoxamine	Cefuroxime
Demerol	*Desyrel*
Denavir	Indinavir
Depakote	*Senokot*
Depo-Estradiol	*Depo-Testadiol*
Depo-Testadiol	*Depo-Estradiol*
Desferal	*DexFerrum*
Desipramine	Clomipramine
Desipramine	Imipramine
Desipramine	Nortriptyline
Desyrel	*Demerol*
DexFerrum	*Desferal*
DiaBeta	*Zebeta*
Diamox	*Dobutrex*
Diazepam	*Ditropan*
Diazepam	Lorazepam
Dicyclomine	Diphenhydramine
Diflucan	*Diprivan*
Diovan	*Darvon*
Diovan	*Dioval*
Diovan	*Zyban*
Dioval	*Diovan*

Diphenatol	Diphenidol
Diphenhydramine	Dicyclomine
Diphenidol	*Diphenatol*
Diprivan	*Diflucan*
Ditropan	Diazepam
Duopres	*Daypro*
Dobutamine	Dopamine
Dobutrex	*Diamox*
Dolobid	*Slo-Bid*
Dopamine	Dobutamine
Doxepin	Doxycycline
Doxorubicin	Daunorubicin
Doxorubicin	Doxorubicin Liposomal
Doxorubicin	Idarubicin
Doxorubicin Liposomal	Doxorubicin
Doxycycline	Doxepin
Dynabac	*DynaCirc*
Dynacin	*DynaCirc*
DynaCirc	*Dynabac*
DynaCirc	*Dynacin*
Edecrin	*Eulexin*
Efudex	*Eurax*
Elavil	*Orovail*
Elavil	*Plavix*
Eldepryl	Enalapril
Elmiron	*Imuran*
Enalapril	*Eldepryl*
Equagesic	*EquiGesic*
EquiGesic	*Equagesic*
Erex	*Urex*
Erythrocin	*Ethmozine*
Erythromycin	Azithromycin
Eskalith	Estratest
Estraderm	*Testoderm*
Estratab	*Estratest*
Estratest	*Eskalith*
Estratest	*Estratab*
Estratest	*Estratest HS*
Estratest HS	*Estratest*
Ethmozine	*Erythrocin*
Etidronate	Etomidate
Etidronate	Etretinate
Etomidate	Etidronate
Etretinate	Etidronate
Eulexin	*Edecrin*
Eurax	*Efudex*
Fam-Pren Forte	*Parafon Forte*
Fentanyl Citrate	Sufentanil Citrate
Fioricet	*Fiorinal*
Fiorinal	*Fioricet*
Flomax	*Fosamax*
Flomax	*Volmax*
Fluorouracil	Fluorouracil
Fludara	*FUDR*
Fludarabine	*Flumadine*
Flumadine	Fludarabine
Fluorouracil	Flucytosine
Flurazepam	Temazepam
Folic Acid	Folinic Acid
Folinic Acid	Folic Acid
Fosamax	*Flomax*
FUDR	*Fludara*
Furosemide	Torsemide
Gammimune N	*CytoGam*
Genzar	*Zinecard*
Glipizide	Glyburide

Glucophage	*Glutofac*
Glucotrol	*Glucotrol XL*
Glucotrol	Glyburide
Glucotrol XL	*Glucotrol*
Glutofac	*Glucophage*
Glyburide	Glipizide
Glyburide	*Glucotrol*
Granulex	*Regranex*
Haldol	*Stadol*
Haloperidol	Halotestin
Halotestin	Haloperidol
Hemoccult	*Seracult*
Heparin	*Hespan*
Hespan	Heparin
Humalog	*Humulin*
Humulin	*Humalog*
Hydralazine	Hydroxyzine
Hydrocodone	Hydrocortisone
Hydrocortisone	Hydrocodone
Hydromorphone	Morphine
Hydroxyzine	Hydralazine
Idamycin	*Adriamycin*
Idarubicin	Doxorubicin
IMDUR	*Imuran*
IMDUR	*Inderal LA*
IMDUR	*K-Dur*
Imipenem	*Omnipen*
Imipramine	Desipramine
Imovax	*Imovax I.D.*
Imovax I.D.	*Imovax*
Imuran	*Elmiron*
Imuran	*IMDUR*
Imuran	*Tenormin*
Inderal	*Adderall*
Inderal	*Isordil*
Inderal	*Toradol*
Inderal LA	*IMDUR*
Indinavir	*Denavir*
Iodine	Codeine
Iodine	*Lodine*
Isordil	*Inderal*
K-Dur	*IMDUR*
K-Phos Neutral	*Neutra-Phos-K*
Kefzol	*Cefzil*
Klonopin	Clonidine
Klonopin	Clonidine Clonazepam
Lamictal	*Lamisil*
Lamictal	*Lomotil*
Lamictal	*Ludiomil*
Lamisil	*Lamictal*
Lamisil	*Lomotil*
Lamivudine	Lamotrigine
Lamotrigine	Lamivudine
Lanoxin	*Lasix* *Lomotil*
Lanoxin	*Lonox*
Lanoxin	*Xanax*
Lasix	*Lomotil* *Lanoxin*
Lasix	*Luvox*
L-Dopa	Levodopa Methyldopa
Leucovorin	*Leukine* *Leukeran*
Leukeran	Leucovorin *Leukine*
Leukine	*Leukeran* Leucovorin
Levbid	*Lithobid*
Levbid	*Lopid*
Levbid	*Lorabid*
Levobunolol	Levocabastine
Levocabastine	Levobunolol

Levodopa	L-Dopa	Methyldopa
Levoxyl		*Luvox*
Librax		*Librium*
Librium		*Librax*
Lioresal		*Lotensin*
Lisinopril		*Risperdal*
Lithobid		*Levbid*
Lithobid		*Lithostat*
Lithostat		*Lithobid*
Lodine		Codeine
Lodine		Iodine
Lomotil		*Lamictal*
Lomotil		*Lamisil*
Lomotil	*Lanoxin*	*Lasix*
Loniten		*Lotensin*
Lonox		*Lanoxin*
Lopid		*Levbid*
Lopid	*Lorabid*	*Slo-Bid*
Lorabid		*Levbid*
Lorabid		*Lortab*
Lorabid	*Slo-Bid*	*Lopid*
Lorazepam		Alprazolam
Lorazepam		Diazepam
Lortab		*Cortef*
Lortab		*Lorabid*
Lortab		*Luride*
Losartan		Valsartan
Lotensin		*Lioresal*
Lotensin		*Loniten*
Lotensin		Lovastatin
Lotrimin		*Lotrisone*
Lotrisone		*Lotrimin*
Lovastatin		*Lotensin*
Loxitane		*Soriatane*
Ludiomil		*Lamictal*
Luride		*Lortab*
Luvox		*Lasix*
Luvox		*Levoxyl*
Medi-Gesic		*Medigesic*
Medigesic		*Medi-Gesic*
Medrol ADT		*Medrol Dosepak*
Medrol Dosepak		*Medrol ADT*
Medroxyprogesterone		Methylprednisolone
Megace		*Reglan*
Mepron (Atovaquone in U.S.)		*Mepron* (Meprobamate in Australia)
Meruvax		*Attenuvax*
Methadone		Methylphenidate
Methotrexate		Metolazone
Methyldopa	L-Dopa	Levodopa
Methylphenidate		Methadone
Methylprednisolone		Medroxyprogesterone
Methylprednisolone		Prednisone
Metoclopramide		Metolazone
Metolazone		Methotrexate
Metolazone		Metoclopramide
Metoprolol		Misoprostol
Micro-K		*Micronase*
Micronase		*Micro-K*
Minoxidil		*Monopril*
Misoprostol		Metoprolol
Mitomycin		Mitoxantrone
Mitoxantrone		Mitomycin
Monoket		*Monopril*
Monopril		*Accupril*
Monopril		Minoxidil
Monopril		*Monoket*

Morphine		Hydromorphone
Murocel		*Murocoll-2*
Murocoll-2		*Murocel*
Naprelan		*Naprosyn*
Naprosyn		*Naprelan*
Narcan		*Norcuron*
Nasalcrom		*Nasalide*
Nasalide		*Nasalcrom*
Nasarel		*Nizoral*
Navane		*Norvasc*
Nebcin		*Nubain*
Nelfinavir		Nevirapine
Neocare		*Neocate*
Neocate		*Neocare*
Neoral		*Nizoral*
Neosar		*Cytosar-U*
Nephrox		*Niferex*
Neumega		*Neupogen*
Neupogen		*Neumega*
Neurontin		*Norvasc*
Neutra-Phos-K		*K-Phos Neutral*
Nevirapine		Nelfinavir
Niacin		*Nispan*
Nicardipine	Nifedipine	Nimodipine
Nicoderm		*Nitroderm*
Nifedipine	Nicardipine	Nimodipine
Niferex		*Nephrox*
Nimbex		*Renex*
Nimodipine	Nicardipine	Nifedipine
Nispan		Niacin
Nitroderm		*Nicoderm*
Nizoral		*Nasarel*
Nizoral		*Neoral*
Norcuron		*Narcan*
Norflex	*Norroxin*	Norfloxacin
Norfloxacin	*Norflex*	*Norroxin*
Norroxin		*Neurontin*
Norroxin	*Norflex*	Norfloxacin
Norpramin		Nortriptyline
Nortriptyline		Desipramine
Nortriptyline		*Norpramin*
Norvasc		*Navane*
Nubain		*Nebcin*
Ocufen		*Ocuflox*
Ocufen		*Ocupress*
Ocuflox		*Ocufen*
Ocular		*Acular*
Ocu-Mycin		*Ocumycin*
Ocumycin		*Ocu-Mycin*
Ocupress		*Ocufen*
Omnipen		Imipenem
Ortho-Cept		*Ortho-Cyclen*
Ortho-Cyclen		*Ortho-Cept*
Orunil		*Clinoril*
Orunil		*Elavil*
Os-Cal		*Asacol*
Oxycodone		*OxyContin*
OxyContin		Oxycodone
Paclitaxel		Paroxetine
Paclitaxel		*Paxil*
Parafon Forte		*Fam-Pren Forte*
Paraplatin		*Platinol*
Parlodel		Pindolol
Paroxetine		Paclitaxel
Paxil		Paclitaxel
Paxil		*Taxol*
Pediapred		*Pediazole*

Pediazole		*Pediapred*
Pegaspargase		Asparaginase
Penicillamine		Penicillin
Penicillin		Penicillamine
Penicillin G Potassium		Penicillin G Procaine
Penicillin G Procaine		Penicillin G Potassium
Pentobarbital		Phenobarbital
Peratine		*Periactin*
Periactin		*Peratine*
Percocet		*Percodan*
Percodan		*Percocet*
Permax		*Bumex*
Phenobarbital		Pentobarbital
Pindolol		*Parlodel*
Pindolol		*Plendil*
Pitocin		*Pitressin*
Pitressin		*Pitocin*
Platinol		*Paraplatin*
Plavix		*Elavil*
Plendil		Pindolol
Plendil		*Prilosec*
Plendil		*Prinivil*
Pondimin		Prednisone
Potassium Phosphates		Sodium Phosphates
Pravachol		*Prevacid*
Pravachol		Propranolol
Precare		*Precose*
Precose		*Precare*
Prednisone		Methylprednisolone
Prednisone		*Pondimin*
Prednisone		*Prilosec*
Prednisone		Primidone
Premarin		*Primaxin*
Premarin		*Provera*
Prepidil		Beprridil
Prevacid		*Pravachol*
Prevacid		*Prinivil*
Prilosec		*Plendil*
Prilosec		Prednisone
Prilosec		*Prinivil*
Prilosec		*Prozac*
Primaxin		*Premarin*
Primidone		Prednisone
Prinivil		*Plendil*
Prinivil		*Prevacid*
Prinivil		*Prilosec*
Prinivil		*Proventil*
Prochlorperazine		Chlorpromazine
Proctocort		*Proctocream HC*
Proctocream HC		*Proctocort*
Profen	*Profen II*	*Profen LA*
Profen II	*Profen*	*Profen LA*
Profen LA	*Profen*	*Profen II*
Promethazine		Promethazine w/Codeine
Promethazine w/Codeine		Promethazine
Propranolol		*Pravachol*
Propranolol		*Propulsid*
Propulsid		Propranolol
Proscar		*ProSom*
Proscar	*ProSom*	*Prozac*
ProSom		*Proscar*
ProSom	*Prozac*	*Proscar*
Proventil		*Prinivil*
Provera		*Covera*
Provera		*Premarin*
Prozac		*Prilosec*

Prozac	*Proscar*	*ProSom*
Quinidine		Quinine
Quinine		Quinidine
Ranitidine	Amantadine	Rimantadine
ReFresh (breath drops)		*Refresh* (lubricant eye drops)
Refresh (lubricant eye drops)		*ReFresh* (breath drops)
Reglan		*Megace*
Regranex		*Granulex*
Relafen		*Rezulin*
Remeron		*Zemuron*
Reno-M-60		*Renografin-60*
Renografin-60		*Reno-M-60*
Reserpine	*Risperdal*	Risperidone
Retrovir		Ritonavir
Revex		*Nimbex*
Revex		*ReVia*
ReVia		*Revex*
Rezulin		*Relafen*
Ridaura		*Cartara*
Rifabutin		Rifampin
Rifampin		Rifabutin
Rimantadine	Amantadine	Ranitidine
Risperdal		Lisinopril
Risperdal	Reserpine	Risperidone
Risperidone	Reserpine	*Risperdal*
Ritonavir		*Retrovir*
Roxanol		*Roxicet*
Roxicet		*Roxanol*
Rynatan		*Rynatuss*
Rynatuss		*Rynatan*
Salbutamol		Salmeterol
Salmeterol		*Salbutamol*
Selegiline	*Serentil*	Sertraline	*Serzone*
Selegiline		Sertraline
Senokot		*Depakote*
Serandt		*Hemocult*
Serentil	Selegiline	Sertraline	*Serzone*
Serentil		*Serzone*
Serentil		*Sinequan*
Seroquel		*Serzone*
Serzone	Sertraline	Selegiline	*Serentil*
Serzone		*Seroquel*
Sinequan		*Serentil*
Slo-Bid		*Dolobid*
Slo-Bid	*Lopid*	*Lonbid*
Sodium Phosphates		Potassium Phosphates
Solu-Medrol		*Depo-Medrol*
Soma		*Soma Compound*
Soma Compound		*Soma*
Soriatane		*Luxiane*
Stadol		*Haldol*
Sufentanil Citrate		Fentanyl Citrate
Sulfadiazine		Sulfasalazne
Sulfasalazine		Sulfadiazine
Sulfasalazine		Sulfisoxazole
Sulfisoxazole		Sulfasalazine
Sumatriptan		Zolmitriptan
Symmetrel		*Synthroid*
Synagis		*Synvisc*
Synthroid		*Symmetrel*
Synvisc		*Synagis*
Taxol		*Paxil*
Tegretol		*Toradol*
Temazepam		Flurazepam
Tenormin		*Imuran*
Tenormin		Thiamine
Tenormin		*Trovan*
Testoderm		*Estraderm*
Tetracycline		Tetradecyl Sulfate
Tetradecyl Sulfate		Tetracycline
Thiamine		*Tenormin*
Tiagabine		Tizanidine
Tiazac		*Ziac*
Tizanidine		Tiagabine
Tobradex		*Tobrex*
Tobrex		*Tobradex*
Tolazamide		Tolbutamide
Tolbutamide		Tolazamide
Toradol		*Inderal*
Toradol		*Tegretol*
Toradol		*Torecan*
Toradol		Tramadol
Torecan		*Toradol*
Torsemide		*Furosemide*
Tramadol		*Toradol*
Tramadol		*Voltaren*
Trandate		*Tridrate*
Triad (Butalbital/ Acetaminophen/Caffeine)		*Triad* (topical)
Tridrate		*Trandate*
Trifluoperazine		Trihexyphenidyl
Trihexyphenidyl		Trifluoperazine
Tri-Norinyl		*Triphasil*
Triphasil		*Tri-Norinyl*
Trovan		*Tenormin*
Ultane		*Ultram*
Ultram		*Ultane*
Ultram		*Voltaren*
Urex		*Erex*
Uricit-K		*Urised*
Uridon		*Vicodin*
Urised		*Uricit-K*
Valsartan		Losartan
Vancenase		*Vanceril*
Vanceril		*Vancenase*
Vancomycin		Vecuronium
Vanxin		*Ventolin*
Vecuronium		Vancomycin
Ventolin		*Bengkin*
Ventolin		*Vanxin*
VePesid		*Versed*
Verapamil		*Verelan*
Verelan		Verapamil
Verelan		*Virilon*
Versed		*VePesid*
Versed		*Vistaril*
Vexol		*VoSol*
Viagra		*Allegra*
Vicodin		*Uridon*
Vinblastine		Vincristine
Vincristine		Vinblastine
Viracept		*Viramune*
Viramune		*Viracept*
Virilon		*Verelan*
Vistaril		*Versed*
Vistaril		*Zestril*
Volmax		*Flomax*
Voltaren		Tramadol
Voltaren		*Ultram*
VoSol		*Vexol*
Xanax		*Lanoxin*
Xanax		*Zantac*
Xanax	*Zantac*	*Zyrtec*
Yocon		*Zocor*
Zagam		*Zyban*
Zantac		*Xanax*
Zantac		*Zofran*
Zantac	*Xanax*	*Zyrtec*
Zebeta		*DiaBeta*
Zemuron		*Remeron*
Zestril		*Vistaril*
Ziac		*Tiazac*
Zinacef		*Zithromax*
Zinecard		*Genzar*
Zithromax		*Zinacef*
Zocor		*Cozaar*
Zocor		*Yocon*
Zocor		*Zoloft*
Zofran		*Zantac*
Zofran		*Zosyn*
Zoloft		*Zocor*
Zolomitriptan		Sumatriptan
Zonalon		*Zone A Forte*
Zone A Forte		*Zonalon*
Zosyn		*Zofran*
Zyban		*Zagam*
Zyrtec	*Xanax*	*Zantac*
Zyprexa		*Celexa*
Zyprexa		*Zyrtec*
Zyrtec		*Zyprexa*

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Statement of

The Health Care Liability Alliance

Before
the Joint Hearing of

The House Commerce Committee's
Health and Environment Subcommittee,
The Oversight and Investigations Subcommittee
and
The House Veterans' Affairs Health Subcommittee

on

"The Findings in a Report from the Institute of Medicine on Medical Errors"

February 9, 2000

Statement of the Health Care Liability Alliance
before
the Joint Hearing of the House Commerce Committee, Health and Environment Subcommittee, Oversight and Investigations Subcommittee and House Veterans' Affairs Committee Health Subcommittee
" Medical Errors"
February 9, 2000

The Health Care Liability Alliance (HCLA) is a coalition of more than 30 organizations committed to reform of the health care litigation system to enhance its fairness, timeliness, and cost-effectiveness. HCLA's members are organizations and associations of physicians, hospitals, blood banks, health device manufacturers, health care insurers, pharmaceutical manufacturers, and biotechnology companies.

HCLA applauds the Chairman's timely leadership in connection with the issue of patient safety. We appreciate the opportunity to submit our views regarding the report of the Institute of Medicine (IOM) entitled "To Err is Human: Building a Safer Health System." We look forward to working with the Chairman, members of the Committee, and their staff as Congress debates this important issue.

Because of its concern for the effect the tort system has on the quality of care, HCLA welcomes the IOM Report. The Report makes a significant contribution by recognizing that the tort system is a major barrier to improving the quality of care. That underlying conclusion provides the basis for meaningful tort reforms.

INTRODUCTION

The tort system as it now operates in this country increases health care costs by forcing providers to practice defensive medicine and by imposing inordinate litigation costs on the health care system. These costs are borne by patients, people with insurance, people who are trying to buy insurance, people who need care, and taxpayers--through higher health care costs, higher insurance premiums, higher taxes, and reduced access to care.

The tort system does not provide benefits that justify these costs. It does not carry out its intended functions. It does not establish a rational standard of care. Findings of liability, made in court with hindsight and with the benefit of leisurely contemplation that rarely are possible in the actual delivery of care, often do not provide an accurate standard of medical conduct. As one expert on the tort system has summarized this situation, "The fundamental problem of tort liability, especially in the areas of products liability and medical malpractice, stems from the unpredictability of its imposition."[1]

This retroactive, case-by-case, and arbitrary standard making has caused doctors to practice defensive medicine— to order medical procedures out of a perceived need to

have a defense available if there should be an adverse event. Cesarean delivery rates provide one example. Because juries awarded large recoveries for birth injuries where obstetricians did not perform a Cesarean section, doctors have performed them more often than they otherwise would have. Cesarean rates rose from 4.5 per 100 births in 1965 to 24.1 in 1986.[2]

The essentially unlimited power of juries to award non-economic damages results in verdicts that are not just and that when publicized whet the appetite of trial lawyers and traumatize providers. In many cases, (enough to engender disdain for the litigation system and fear on the part of the provider), there is no logical or medical connection between the provider's action and liability or between the injury and the amount of damages awarded.

The Harvard Study of hospital care in New York itself demonstrated that the filing of claims was not correlated to negligence.[3] In a follow-on study of claims of malpractice filed by patients in the Study, several of the authors concluded that "the severity of the patient's disability, not the occurrence of an adverse event or an adverse event due to negligence, was predictive of payment to the plaintiff."[4] In other words, the amount patients recovered through the tort system was a function of their health condition, not any negligence by the health care system. The authors concluded more generally, therefore, that "the standard of medical negligence performs poorly in malpractice litigation."[5]

The tort system thus presents a provider with the random risk of catastrophic financial injury. This causes some providers to quit practice and others to limit their practice, reducing patients' access to care, particularly in inner-city and rural areas. Most of those who continue to practice are forced to engage in defensive medicine. This results in more medical interventions for patients, as the increased rate of Cesarean deliveries demonstrates, thereby adding costs and putting patients at greater risk. It is estimated that defensive medicine costs at least $50 billion per year.[6]

At the same time, the litigation system does not provide fair and timely compensation for injured patients. They must wait on average 3 1/2 years for resolution of their claims by the litigation system. If they prevail, they typically must give 33-60% of any recovery to their lawyers in contingency fees. Only 28 percent of the amount spent to provide insurance coverage actually goes to victims; the rest is spent in transaction costs and in operating the tort litigation system.[7] The tort system imposes a 72% tax on patients and providers.

Because of the threatening and contentious climate it creates, the litigation system, rather than protecting patients, is actually impeding efforts to improve the quality of care. It makes it difficult for providers to acknowledge mistakes. It deters open discussion of possible errors. And it discourages providers from filing reports, seeking assistance, and collaborating with other providers and experts to improve quality.

The money spent on defensive medicine and litigation expenses could be better used to improve the quality of care and access to it. The energy and focus that the present system channels into litigation-related and litigation-induced actions should be redirected into developing better quality control systems and innovative ways of delivering care.

INSTITUTE OF MEDICINE REPORT

With one exception, the IOM Report avoids inflated rhetoric. The exception is its statement that as many as 98,000 people may die annually because of medical error. This figure is extrapolated in ways that are not explained from 71 deaths that the Harvard Study of the medical records of 31,429 patients discharged from 51 New York hospitals in 1984 said were attributable to negligence.[8] This extrapolation has no scientific basis, as the authors of the Study themselves have recognized.[9]

The Harvard Study, moreover, suffered from methodological flaws, and its results have not been duplicated. The reviewers who determined which records reflected negligence agreed in only 10% of the cases. In an effort to confirm findings that rest on this shaky foundation, a second set of reviewers examined a subset of 318 of the records. Apparently they did not reach the same conclusions on individual records that were attributed to the primary set of reviewers.[10]

The authors of the Harvard Study also applied their methodology to patients in Colorado and Utah hospitals in 1992. Extrapolating the results of this study, the authors concluded that 44,000 deaths were caused nationwide by medical error. The IOM Report finds this, and the unexplained figure of 98,000 deaths, to represent a range.[11] The more recent study, however, could equally be seen as an indication that health care improved in the 8 years after the New York study, that better care is provided in Colorado and Utah, or, since the results of the Harvard Study could not be duplicated, that the parameters of the Study are vague and the methodology is flawed.

It is not our purpose here to discuss the weaknesses of the Harvard Study or the exaggerated extrapolations that have been made from it. Patient safety and quality care should not be a numbers game. We should, as a health care system and as a society, endeavor to eliminate avoidable injuries. In doing so we must remember, as the Harvard Study reminds us,[12] medical intervention is inherently risky and is provided by people. People are only human, and the title chosen for the IOM report reflects the reality this presents; "To Err is Human." Because we are dealing with medical intervention by human beings, we must focus on what we can do together to reduce the number of unnecessary injuries suffered during the delivery of health care services.

The IOM Report makes a vital contribution to this effort by its recognition and discussion of the three interrelated factors that now impede efforts to improve patient safety.

First, it emphasizes that the problem is not "bad apples,"[13] although there are some "bad people" and they must be weeded out. Mistakes are often caused, or are not prevented, by system (both technical and organizational) failures. As the Report suggests, because providers are only human, they need systems to help them avoid mistakes; but we cannot let reliance on systems dull the special intelligence that humans posses or lull them into lethargic complacency.

The focus must be on developing systems that avoid future mistakes and not on attempting to pin blame for past conduct on an individual. This important observation leads the Report to balance public policy in favor of error prevention and away from faultfinding: "When an error occurs, blaming an individual does little to make the system safer and prevent someone else from committing the same error."[14] "Although a punitive response may be appropriate in some cases (e.g., deliberate malfeasance), it is not an effective way to prevent recurrence."[15]

Secondly, the Report emphasizes the need to report information about adverse events or potential adverse events in order to identify patterns of conduct that threaten safety and to assess the success of corrective actions. It correctly recognizes that reporting is essential to the primary goal of prevention. The Report provides a comprehensive summary of the numerous and varied reporting systems that are currently in effect.

Thirdly, and most importantly, the Report recognizes that there is a critical and common element or impediment that prevents all the reporting systems, regardless of how they are structured, from collecting the information they need. That impediment is the tort system.

Participants and witnesses to an adverse event are reluctant to report it (even if required by law to do so) out of fear that doing so will trigger or support a tort claim. The irrationality of the litigation system and the randomness of its results trigger a defensive reaction. Fear of being enmeshed in that system, even if one is ultimately found not to be liable, deters reporting.

As the Report concludes, "Patient safety is also hindered through the liability system and the threat of malpractice, which discourages the disclosure of errors. The discoverability of data under legal proceedings encourages silence about errors committed or observed."[16]

As a result, it finds "All reporting systems, whether mandatory or voluntary, are perceived to suffer from underreporting. Indeed, some experts assert that all reporting is fundamentally voluntary since even mandated reporting can be avoided....The volume of reporting is influenced by more factors than simply whether reporting is mandatory or voluntary....One factor is related to confidentiality."[17] "Thus," the Report concludes, "the prominence of litigation can be a substantial deterrent to the development and maintenance of the reporting systems discussed in this report."[18]

It is refreshing that the IOM Report recognizes this problem. It is important to the debate that it does so. The tort system impedes efforts to improve health care by deterring the reporting of data needed to make improvements in the health care system. Recognition of this fact by The IOM should provide the needed impetus for addressing this basic problem.

As the Report recognizes, the tort system deters reporting even where confidentiality is promised. There is concern that confidential data will leak. There is also fear that what is confidential today may not be protected tomorrow. The Report cites the powerful example of the continuing political pressure to "open up" the National Practitioner Data Bank.[19] Providers are concerned that the constant political pressure eventually will be successful, leading to a breach not only of a particular data source but also inserting the opening wedge for a more general release.

Confidentiality of adverse event reports, therefore, is necessary to develop an effective reporting system that will permit identification of safety problems and permit assessment of remedial actions. But there is on-going concern that even confidential reports will be fed into the litigation system—by leaks or by surrender to political pressure to remove the confidentiality protection. Confidentiality of reports is necessary to improve reporting, but it is not sufficient. The tort system also must be reformed.

TWO REFORMS THAT ARE NEEDED

The findings of the IOM Report, therefore, confirm the need for a combination of two reforms: confidential protection for adverse event reports and a reformed tort system.

Confidential reporting

It is important that Congress act on the findings of the Report by protecting the confidentiality of reports made of adverse events or of problems that could lead to adverse events.

The Report in several places emphasizes the need for reporting to be confidential. It appears, in fact, to call for Federal legislation to protect confidentiality of all reports although it also makes an inconsistent recommendation that would deny confidentiality to reports of adverse events leading to serious injury. The Report recommends Federal legislation to "extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality."[20]

As the Report's discussion of peer review protection reflects, the nature and the scope of the current protection varies widely from state to state.[21] Not only does the scope of the protection afforded by each state differ greatly, but in some instances the sharing of peer review materials with third parties engaged in health care quality efforts, such as The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), has been held to waive any confidentiality protection.[22] Moreover, the efficacy of these state

protections is further undermined by uncertainty surrounding the application of the peer review privilege should the parties be drawn into federal court. This occurs, for instance, in actions brought under a Federal statute with related medical malpractice claims under state law (i.e., pendent state claims).

As the Report recognizes, health care providers must have confidence that the peer review privilege will be applied with consistency and predictability if they are to come forward with information regarding medical errors.[23] The discussion in the Report focuses on immunity and protection of peer review materials and deliberations from discovery. In urging that the protection be expanded, the Report at a minimum recommends that quality and safety information derived from reports or from investigation (the main areas now protected in different ways by peer review statutes) be protected from use in litigation and from public dissemination. The information derived through the peer review process may involve the "most serious adverse events"; thus this recommendation calls for the appropriate confidential treatment of such information.

However, the Report also says that such information should be available for public consumption and that only reports of events other than the "most serious adverse events" should have confidentiality protection.[24] We discuss this misplaced, and internally inconsistent, position below. The important fact is that the Report finds that confidentiality is necessary for effective reporting and patient safety improvements and recommends in, at least one place, across-the-board confidentiality.

Tort reform

Even where confidentiality would be provided, but particularly where it would not, reporting and improvements in the health care system quality can best be advanced by reforming the tort system to protect providers from random and excessive judgments. HCLA urges Congress to enact the tort reforms embodied in its proposed legislation which is modeled on the MICRA reforms enacted in California in 1975.

These reforms would preserve the ability of injured patients to obtain compensation for their economic injury and to recover reasonable non-economic damages. They would: 1) encourage non-judicial resolution of claims and ensure that plantiffs' lawyers did not capture an excessive contingency fee from their clients; 2) prevent plaintiffs from obtaining double recovery (collateral source rule); 3) limit non-economic damages to a reasonable amount ($250,000); 4) require plaintiffs to bring any action in a reasonable time after the injury occurs or is recognized (statute of limitations and statute of repose); 5) protect any particular defendant from paying a larger percentage of any recovery than is warranted by his/her conduct (joint and several liability).

Passage of these measures will restore a measure of balance to the tort system, give providers more faith in the system, and therefore facilitate reporting—which ultimately will result in greater patient safety.

As the IOM Report recognizes, patient safety is not adequately served by the present system. If the tort system in its current state were adequately protecting patient safety, the Report would not have been necessary. The tort system is not only not the answer; it is the barrier to the enhanced quality systems that the Report correctly finds are the best way to improve safety. The underlying, if unarticulated, theme of the Report, therefore is that tort reform is necessary to improve the quality of health care in this country.

ACTIONS THAT SHOULD NOT BE TAKEN

The Report correctly concludes that the barrier to systems improvements in health care is not the lack of reporting mechanisms but the tort-induced reluctance of participants to provide data through the existing avenues. There is no indication that there are not enough reporting requirements. The Report describes them comprehensively. The need is to make the changes necessary to encourage more reporting, and for the agencies and institutions to which reports are made to analyze the information and act on them more vigorously.

HCLA questions, therefore, whether any purpose would be served by adding new reporting requirements or creating new agencies to collect or coordinate reports. In fact, adding new reporting requirements would only distract attention from the need to make the essential tort changes to support the existing reporting requirements.

No new reporting requirements without confidentiality

While recognizing that the barrier to existing reporting requirements is a lack of confidentiality and fear of the tort system, the Report does not address this barrier, except in its recommendation that peer review protections be expanded.

Instead it recommends that mandatory reporting of serious adverse events be expanded by federal statute, without corresponding confidentiality protection. Indeed, while it offers a gesture toward the states' role, it would make mandatory reporting a federal requirement in any state that did not on its own come to the conclusion that mandatory reporting is needed.[25] Although The Report recognizes that the absence of confidentiality is impeding compliance with existing reporting requirements, it would make mandatory reporting a national requirement while providing no confidentiality protection.

The Report would permit confidentiality protection only for voluntary reporting of events that are not serious—where it is least useful. If an event results in little or no harm, there may be less concern about tort litigation. The Report offers confidentiality protection here, where it is worth less, but would deny it in the serious cases, where it is important to elicit reporting. Recommending confidentiality for voluntary reports is not a sufficient response to the problem identified by the Report itself—that lack of confidentiality deters reporting.

Drawing a line, moreover, on when reporting is required and when it is confidential on the basis of whether the action resulted in "serious" harm will bog down the health care system in line-drawing and hair-splitting. What is serious harm? Who defines it? Suppose the event could have had a serious harm if it had not been caught? How long is serious? Is an extra day in a hospital serious? Is a false positive that leads to patient concern serious? Suppose the patient was not able to understand the test result; is a false positive serious in that case?[26]

Rather than trying to impose reporting by regulation and mandates, and varying the protection for different types of reports, Congress should provide protection for all safety and quality reports, and for consideration of them. This is the best way to advance patient safety efforts.

No centralization of safety efforts

It would be both unnecessary and harmful to create the new Federal Center proposed in the IOM Report. The Report envisages various roles for this new Center. HCLA believes these are unnecessary and would actually detract from efforts to improve patient safety.

The Report sees a need for the Center to establish a "national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety."[27] The premise that only the creation of a government Center can create a national focus and provide leadership is disturbing.

As the Report indicates, efforts to enhance patient safety are being undertaken in different ways by a variety of individuals and institutions: insurers, manufacturers, providers, academic institutions, trade associations, etc. It may look messy and confused, but the pursuit of knowledge often is, particularly in an area as complex and varied as the design and manufacture of health care products and the delivery of health care.

Commissions, meetings, and public awareness can all contribute to a national focus. So can efforts by political leaders, if conducted without demagogy and finger pointing. A new Center is not necessary to do this. This proposal is really symbolic; concern would be demonstrated by creating a new Center and spending more money.

An approach based on centrally developing and collecting safety-related data could in fact impair safety research and promotion of safety activities. A centralized agency for safety research could well become hitched to a particular view or approach, subordinating all others. It is more effective for different people to try different approaches.

Creating a "highly visible [governmental] center" is likely not only to diminish the diversity of research and views but to politicize patient safety. Once there is a "highly visible" government agency tasked to provide leadership and develop research and recommendations, every interest group will descend on it in an effort to gets its

agenda adopted. Congress will inevitably be drawn in. It would be far more effective, if more research is needed, to provide funding to a variety of researchers on a scientific, non-political basis.

The Report also has another role in mind for the new Federal safety Center. It would not be limited to research. It would receive and analyze reports (from the states)--apparently the mandatory reports of "serious adverse events" discussed above. The Center would become a national data bank for at least some kinds of reports. But it is unclear how the information would be used and who would have access to it. The Center apparently would "identify persistent safety issues that require more intensive analysis and/or a broader-based response."[28] In other words, it would use the data to do more studying. But would the agency act on the information? To whom would it give its findings?

What is needed is not central collection of information, nor more analysis and dissemination. Needed information should be given to those in a position, and with the most powerful incentive, to use it to improve patient safety. Instead of funneling data through a centralized, and possibly politicized, government agency, the focus should be on doing what is necessary to get the information to those who will actually use it to improve patient safety.

Hospitals need more information about errors that are made there. Licensing boards need more information about their licensees. It is far simpler, and more effective, to inform a device manufacturer that the labeling is confusing than to report this to Washington. With this information, manufacturers, providers, and insurers would have the greatest incentive and the best ability to use it to improve safety.

Instead of creating a centralized, nation-wide, government-led reporting system, we should focus on doing what is necessary to get more information to the people on the front lines of health care quality.

Compliance will be enhanced if reporters know they are reporting to an entity that will use the information effectively. A nurse is far more likely to report an error to her nursing supervisor or to report a problem with a device to its manufacturer than to file a form destined for a distant Federal bureaucracy. Health care providers are the people who are most concerned with quality of care and patient safety. They are more personally and directly concerned than is a distant government bureau. They strongly want to avoid adverse events. They want to provide good care.

There is another practical factor that must be considered. Providers function under conditions of considerable stress. They are quite astute in distinguishing between what is real and what is more government make-work. They are more likely to report when they believe it will do good (particularly if they have protections of confidentiality) than where they are told to fill out another government-imposed form that seems to bear little or no relation to their real world—patient care.

Providers, manufactures, suppliers, employers who sponsor health plans, and insurers, deal with each other and with various licensing and quality institutions on an on-going basis. They should be encouraged to report potential or existing problems and discuss improvements among themselves. This can best be achieved by protection of confidentiality for reports and discussions, and by reform of the tort system. Requirements that they file reports with a state agency for forwarding to Washington, D.C., will not encourage reporting or enhance collaborative efforts to improve the quality of care.

CONCLUSION

The IOM Report documents the obstacles to greater patient safety efforts: the difficulties in securing more reporting that result from the lack of confidentiality and the shadow cast by the litigation system. But rather than addressing these problems, it recommends more reporting (but without confidentiality) and centralizing the reporting system.

The problem, however, is not a lack of centralized reporting; it is the barriers to reporting and to safety-improvement measures posed by the tort system.

The problem is not a lack of reporting mechanisms, but a lack of assured confidentiality and fear on the part of the people who would report that they will be enmeshed in the litigation system.

The primary need is not more data and more studies; it is for those in the field attempting to improve patient safety to have confidence that cooperating in safety-improvement measures will not result in involvement in burdensome tort litigation.

The fears induced by the tort system cannot be resolved by expanding the already unsuccessful requirements to report. The problems of the tort system itself must be addressed.

The solution should not be centralized or governmental; it should be private and dispersed. Medical errors, when they occur, happen at the local level, and local solutions are best crafted to solve local problems.

The quality of health care, consequently, can best be improved by reforming the tort system to: 1) reduce the number of lawsuits, 2) make the system more fair and efficient, and 3) reduce its costs. Reforms in this direction would lessen the pressures to practice defensive medicine, lower health care costs, and increase access to care. At the same time, a fairer and less random tort system, and assurances of confidentiality, would reduce the barriers to reporting and enhance the ability of the field to identify problems and to make corrections.

[1] Jeffrey O'Connell, "Two-Tier Tort Law: Neo No-Fault & Quasi-Criminal Liability," 27 Wake Forest Law Review 871 (1992).
[2] Richard E. Anderson, "Billions for Defense," Archives of Internal Medicine. 1999; 159: 2401
[3] Paul Weiler et al., A Measure of Malpractice. Cambridge: Harvard University Press; 1993.
[4] Troyen A. Brennan et al, "Relation Between Negligent Adverse Events and the Outcomes of Medical-Malpractice Litigation," N Engl J Med 1996; 335:1963-7.
[5] Ibid.
[6] David Kessler and Mark McClellan, "Do Doctors Practice Defensive Medicine," QJ Econ. 1996; 111: 353-390.
[7] Jeffrey O'Connell and C. Brian Kelly, The Blame Game. Lexington Books; 1987:127.
[8] Berkeley Rice, "Do doctors kill 80,000 patients a year?" Medical Economics. November 21, 1994; 1(discussing extrapolation to 80,000 deaths).
[9] Troyen Brennan et al., "Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study," N Eng. J Med 1991; 324: 370-6.
[10] "Billions for Defense" at 2400. The second set of reviewers found the same incidence of adverse events and adverse events due to negligence, but not in the same charts. Rather than confirming the reliability of the methodology used, this provides further demonstration of the uncertainty of what is an adverse event and what is negligence.
[11] "To Err is Human" at 1, 22.
[12] A Measure of Malpractice at 138.
[13] "To Err is Human" at 42.
[14] Id. at 4.
[15] Id. at 47.
[16] Id. at 37.
[17] Id. at 85.
[18] Id. at 94.
[19] Id. at 105.
[20] Id. at 9.
[21] Id. at 103-104.
[22] As the Report recognizes, "One legal fear is that disclosure of internal quality data to outside reviewers not under a peer review statute will lead to discovery from JCAHO in lawsuits; indeed, many fear that disclosure to JCAHO would invalidate even the nondiscoverability protections each hospital enjoys for its own data under its state peer review statute." Id. at 108.
[23] Id. at 96.
[24] Id. at 9.
[25] Id. at 8.
[26] Unintentionally demonstrating the problem, the Report also refers to the kinds of acts that would fall under the voluntary (and confidential) reporting scheme as ones that resulted in "no harm...(near misses) or very minimal patient harm." (p. 74) What is supposed to be done with respect to injuries that fall between serious and minimal?
[27] "To Err is Human" at 5.
[28] Id. at 76.

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