HEALTH QUALITY AND MEDICAL ERRORS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES

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CONTENTS

Page

Advisory of February 27, 2002, announcing the hearing 2

WITNESSES

American Hospital Association, and Danbury Hospital, Matthew Miller, M.D . 12
American Nurses Association, Mary Foley 23
Institute for Healthcare Improvement, Donald M. Berwick, M.D 17
Michigan Department of Veterans' Affairs, Veterans Health Administration, James P. Bagian, M.D 7
Pittsburgh Regional Healthcare Initiative, and Jewish Healthcare Foundation of Pittsburgh, Karen Wolk Feinstein 28

SUBMISSION FOR THE RECORD

American Academy of Family Physicians, Leawood, KS, statement 43
American Academy of Orthopaedic Surgeons, statement and attachment 45
American Academy of Pediatrics, statement and attachment 48
American Health Quality Association, David G. Schulke, statement and attachment 54
American Society for Clinical Pathology, statement 57
American Society of Health-System Pharmacists, Bethesda, MD, statement 58
Cerner Corporation, Trace Devanny, Kansas City, MO, statement 62
College of American Pathologists, statement 63
eHealth Initiative, statement 65
Healthcare Leadership Council, Mark R. Grealy, statement 68
Premier, Inc., statement and attachment 70
Siemens Medical Solutions Health Services Corporation, Malvern, PA, Donald Rucker, M.D., statement and attachment 71

HEALTH QUALITY AND MEDICAL ERRORS

THURSDAY, MARCH 7, 2002

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 11:10 a.m., in room 1100 Longworth House Office Building, Hon. Nancy L. Johnson (Chairman of the Subcommittee) presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
February 27, 2002
No. HL–13

CONTACT: (202) 225–3943

Johnson Announces Hearing on Health Quality and Medical Errors

Congresswoman Nancy L. Johnson (R–CT), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee will hold a hearing on improving health quality. In addition, strategies to ensure patient safety and reduce medical errors will be discussed. **The hearing will take place on Thursday, March 7, 2002, in the main Committee hearing room, 1100 Longworth House Office Building, beginning at 11:00 a.m.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. Witnesses will include representatives from the U.S Department of Veterans' Affairs, the provider community and academia. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

According to the Institute of Medicine (IOM), fatalities from medical errors are estimated to be the eighth leading cause of death in the United States. In 1999, IOM's study *To Err is Human: Building a Safer Health System*, estimated annual deaths from medical errors are at least 44,000 and may be as high as 98,000. The number who are injured is higher.

More often than not medical errors occur because of endemic system problems, not lack of skill or imprudence. Seniors interact with the medical system more frequently than most because of the potential for accident, injury or death to Medicare beneficiaries is more prevalent. As the country's largest insurer of seniors, Medicare has the potential to create processes and adopt technological advances that decrease adverse medical events, thereby significantly improving the quality of patient care and reducing Medicare costs.

In announcing the hearing, Chairman Johnson stated, "Medicare patients are some of the most vulnerable in the health care system. We must take the opportunity presented by advances in patient care and technology to protect seniors from harmful errors and improve the quality of their care. There should be very little disagreement on such a goal, so a bipartisan approach is possible. Here is an area where we can revolutionize senior care."

FOCUS OF THE HEARING:

Thursday's hearing will focus on improving health quality through reductions in medical errors and enhanced patient safety.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please note: Due to the change in House mail policy, any person or organization wishing to submit a written statement for the printed record of the hearing should send it electronically to A *hearingclerks.waysandmeans@mail.house.gov*, along with a fax copy to 202/225–2610, by the close of business, Thursday, March 21, 2002. Those filing written statements who wish to have their statements distributed to the press and interested public at the hearing should deliver their 200 copies to the

Subcommittee on Health in room 1136 Longworth House Office Building, in an open and searchable package 48 hours before the hearing. The U.S. Capitol Police will refuse unopened and unsearchable deliveries to all House Office Buildings.

FORMATTING REQUIREMENTS:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. Due to the change in House mail policy, all statements and any accompanying exhibits for printing must be submitted electronically to *mailto:hearingclerks@mail.house.gov*, along with a fax copy to (202) 225–2610, in Word Perfect or MS Word format and MUST NOT exceed a total of 10 pages including attachments. Witnesses are advised that the Committee will rely on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. A witness appearing at a public hearing, or submitting a statement for the record of a public hearing, or submitting written comments in response to a published request for comments by the Committee, must include on his statement or submission a list of all clients, persons, or organizations on whose behalf the witness appears.

Note: All Committee advisories and news releases are available on the World Wide Web at *http://waysandmeans.house.gov/*.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call (202) 225–1721 or (202) 226–3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Chairman JOHNSON. Good morning, everyone. The hearing will come to order, and while there are a number of other Subcommittee hearings in progress, we are looking forward to a lot of our Members joining us over the course of the hearing.

Unfortunately, medical errors are an endemic problem that permeates our health system. According to the Institute of Medicine (IOM), preventable medical errors are the eighth leading cause of death in America, accounting for at least 44,000 and as many as 98,000 mortalities in hospitals each year. The number of injured is even greater. In addition, IOM also estimates that medical errors in hospitals cost between $17 and $29 billion each year.

This is shocking and unacceptable to care givers and to patients alike. As medicine has become more complex, systems have not developed commensurate with the caregiving challenge. Patients rely on the system to improve their lives, not endanger them. And health professionals work long and hard hours after years of intensive, costly training, to help people, not to hurt them.

Not only do avoidable patient errors harm patients, they drive up health costs by requiring expensive medical interventions to correct subsequent problems. For example, adverse drug events and interactions in hospitals are prevalent and costly. According to estimates from Cardinal Health, Inc., there were more than 625,000 preventable adverse drug events in hospitals in the year 2000, at a cost of $2.9 billion. Reducing just half of those errors through innovations such as electronic prescribing could save billions and patient lives.

I am hopeful that this Committee can produce bipartisan legislation soon that will address this problem in a thoughtful, effective

way, honestly recognizing the lack of malice that is causing such errors and the cost of the systems necessary to address them. Systemic approaches to reduce medical errors are endorsed by academicians and practitioners, and have the potential to dramatically improve health quality and patient safety while reducing costs.

The best way to reduce medical errors is to learn from our mistakes, and I would like to just share a short passage from the IOM study. One of the report's main conclusions is that the majority of medical errors do not result from individual recklessness or the actions of a particular group.

This is not a "bad apple" problem. More commonly, errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them. Thus, mistakes can best be prevented by designing the health system at all levels to make it safer, to make it harder for people do so something wrong and easier for them to do things right.

Reporting adverse events allows us to gain insight into those specific events and to identify patterns or common factors creating errors, changing practices, and preventing future errors. Individuals will not disclose their mistakes if they think they are going to be embarrassed or harmed. Appropriate legal and confidentiality protections are an essential element of a reporting system that works.

One common cause of errors is illegible prescriptions, because patients are often given the wrong prescription because the doctor's handwriting is misread. Electronic prescribing has the potential to dramatically improve patient compliance with drug regimens, reduce adverse drug interactions, and improve patient health and reduce costs.

Today we will hear from the Michigan Department of Veterans' Affairs (VA). They have adopted a successful reporting system that has improved patient safety. Also, the Pittsburgh Regional Health Care Initiative will discuss their success in implementing an ambitious zero tolerance policy for medical errors, and I might add that we do have testimony from Secretary O'Neill on this important system and issue, one that he has been very involved in in the past. Finally, we will hear from an academic and providers on their perspective to improve health outcomes and patient safety.

I look forward to the testimony. The solutions to this problem are not partisan. Working together, we have the opportunity to literally save lives. I look forward to working with my colleagues on the Committee to address this issue promptly.

With that, I would like to recognize Mr. Stark.

[The opening statement of Chairman Johnson follows:]

Opening Statement of the Hon. Nancy L. Johnson, a Representative in Congress from the State of Connecticut, and Chairman, Subcommittee on Health

Unfortunately, medical errors are an endemic problem that permeates our health system. According to the Institute of Medicine (IOM), preventable medical errors are the eighth leading cause of death in America, accounting for at least 44,000 and as many as 98,000 mortalities in hospitals each year. The number of injured is greater. In addition, the IOM also estimated that medical errors in hospitals cost between $17 and $29 billion each year. This is simply unacceptable. Patients interact with the health system to improve their lives, not endanger them.

Not only do avoidable patient errors harm patients, they drive up health costs by requiring expensive medical interventions to correct the subsequent medical prob-

lems. For example, adverse drug events and interactions in hospitals are prevalent and costly. According to estimates from Cardinal Health, Inc., there were more than 625,000 preventable adverse drug events in hospitals in 2000 at a cost of $2.9 billion. Reducing just half of those errors through innovations such as electronic prescribing could save billions.

It is equally unfortunate that Congress has not taken significant steps to address this problem. Many issues before this Committee are contentious. This is an issue, however, that can and should be dealt with in a nonpartisan manner this year. I am hopeful we can produce legislation soon that will take care of this problem in a thoughtful, collaborative way.

Systemic approaches to reduce medical errors are endorsed by academics and practitioners, and have the potential to dramatically improve health quality and patient safety while reducing costs.

One way to reduce medical errors is to learn from our mistakes. Reporting adverse events allows us to gain insight into how to prevent errors. But individuals will not disclose their mistakes if they are punished for doing so. Appropriate legal and confidentiality protections should be a part of any reporting system.

Often, patients are given the wrong prescription because of illegible scripts from doctors. Electronic prescribing has the potential to dramatically improve patient compliance with drug regimens, reduce adverse drug interactions. For example, transcription errors were eliminated and medication errors were cut in half after the Ohio State University Health system implemented electronic prescribing. As this Committee considers Medicare modernization and a prescription drug benefit, it is critical that the Medicare program is equipped with the necessary tools to ensure a reduction of medical errors and improved health outcomes.

Today we will hear from the Department of Veterans' Affairs, who has adopted a successful reporting system that has improved patient safety. Also, the Pittsburgh Regional Healthcare Initiative will discuss their success in implementing an ambitious zero tolerance policy for medical errors. Finally, we will hear from an academic and providers on their perspective to improve health outcomes and patient safety. I look forward to your testimony.

I would like to once again stress that the solutions to this problem are not partisan. Working together, Republicans and Democrats have the opportunity to literally save lives. I look forward to working with my colleagues to address this important issue.

Mr. STARK. Madam Chair, thank you, and I want to direct this commentary not across the aisle but at the Congress in general and certainly at the medical care delivery system in particular.

Once again we are having a hearing. The IOM report came out in 1999. We have had hearings. We had a similar hearing to this identical hearing in 2000. Here we are, 2 years later, another hearing. I have introduced a bill. I am not sure it is any good, but there have been bills introduced to begin the process of setting in place a system for systematically reviewing medical errors and setting up procedures to prevent them.

Now, you are going to hear from some people that we should have a voluntary industry effort. That is just crap. The Joint Commission on Accreditation of Healthcare Organizations or JCAHO isn't worth a pound of salt. They have never punished a hospital that I know of in the existence of their so-called inspections of the hospitals. They are paid by the hospital.

So, unless we are willing to sit down—we went through this same thing with needle sticks. The hospitals fought us on safe needles like Billy be-damned until some hospital got sued for $8 or $9 million and then they said, "Oh, maybe we should use safe needles." They won't move unless we move and make it a requirement.

Tort reform will come up. I think that is nonsense. If somebody cuts off the wrong leg, you don't need a system to tell you that you have been harmed, and you are going to sue. If you are too dumb

and don't know it is the wrong leg, maybe you have got other problems.

I mean, there are tort suits in the medical system—it is very dangerous going to the hospital, and it is one of the few industries in this Nation that doesn't have a systematic, detailed requirement for keeping records, for protecting whistle-blowers, for doing all these things. It is going to take a major mindset change that, if—in other words, you have got to get over, "You don't squeal on your buddies. That is not considered nice in the delivery of medical care."

Well, we have to make it very comfortable for people to do that. As you say, confidentiality is important. There is a whole host of things, but I just hope, Madam Chair, that you will get a bill out. We ought to be able to get a bill like this through on suspension if the hospitals don't fight us. All right? I mean, who would think, if we came under suspension with a bill that wanted to deal with quality of care, which is not mentioned much in Medicare, that we would have any resistance unless it comes from the very people who are committing errors?

Now, it is not pointing a finger and saying it is because they are not diligent. It is just, it is not required, and until we require it, I think this is one of the areas that we are going to have to say, I hope you will agree with me, that we can't just talk it into conformity. We have to mandate it, and that, I know it sounds like a regulation, but I hope we can move to begin to do it and put it in law, and we will have regular oversight perhaps.

So I thank you for getting the ball rolling, once again, and I hope that the next meeting we have will be a markup. Thank you.

Chairman JOHNSON. Thank you, Mr. Stark.

I do hope that this hearing will shed light on the two most difficult issues in this area, and particularly the first issue is what prevented legislative action following the hearing 2 years ago. There are two very difficult issues.

One is, how do you promote the kind of reporting that gives you a handle on all the little, tiny things that happen, that could have happened better? If you had known about them you would have seen a pattern or you would have seen an opportunity to put into place a system that would have prevented big errors. And how do you differentiate the need for protection in that system from the system that our malpractice laws serve? I think those are two different systems, and the rules in my estimation have to be different, but that is what we want you to talk about. Do they have to be different, and how different?

The second issue that wasn't as big an issue 2 years ago is, what is the cost of this? What do institutions have to be able to fund, to manage, and to invest permanently in? Not just the one-time cost. What are the ongoing, systemic costs of changing the system of health care delivery to enable us to put in place structural approaches that will minimize human error?

So those are the two issues. I hope we all approach this hearing with an open mind on them, because last time our inability to particularly resolve the issues around the reporters did prevent legislation. I hope that won't be the case this time, because there is simply too much opportunity for us to not only protect patients but

also to better serve people who come out of medical training with enormous debts, who are in this business to provide care for people who desperately need it.

Mr. STARK. How about tying it to updates in the Medicare reimbursement, Madam Chair? That might get some action.

Chairman JOHNSON. You and I have long disagreed on the value of mechanical Federal formulas, and if what is happening to physicians isn't evidence that mechanical formulas cause problems, I don't know what is.

Okay, let's start. Dr. Bagian, Director of the National Center of Patient Safety, the Michigan Department of Veterans' Affairs, from Ann Arbor. Thank you for being with us and for sharing your experience in these areas.

STATEMENT OF JAMES P. BAGIAN, M.D., P.E., DIRECTOR, NATIONAL CENTER FOR PATIENT SAFETY, VETERANS HEALTH ADMINISTRATION, MICHIGAN DEPARTMENT OF VETERANS' AFFAIRS, ANN ARBOR, MICHIGAN

Dr. BAGIAN. Thank you, Madam Chairwoman, for the opportunity to come here, and Members of the Committee. I thought I would share the experience of a little bit of the Michigan VA and try to answer some of the questions you just posed in the initial remarks here.

We certainly agree that safety is the foundation upon which quality is built. You can't begin to say you have a quality system if you don't provide safety to the patients. The Michigan VA has been very interested and active in patient safety since 1997, almost 2½ years before the IOM report you mentioned in your initial comments. We have worked very hard on that, and I will share some of those lessons.

My history is slightly different. I began as an engineer, became an astronaut, and spent much time in aviation as well as medicine, and then came to this, which I felt was a very good chance to bring systems thinking and prevention to medicine, which we hadn't always done in very systematic ways. I think there are several points we need to recognize here.

Though often people in shorthand talk about errors, medical errors, and in fact if you look at the patient safety handbook in the Michigan VA, we don't use the term "errors" at all. It doesn't appear, because errors are just one subset of things you want to prevent. There are many things that occur that people would not view as an error but yet cause harm to the patient, and it is harm to the patient we want to prevent.

They are human beings. Whenever there are human beings in play, there will be errors made. No one is perfect. If we require them to be perfect in order not to harm a patient, that is a losing bet, guaranteed.

In aviation, for example, you have more than one engine on a plane that flies across the ocean. The reason is not that we try to build engines that are unreliable, but we recognize one might fail and yet we don't want the plane to crash. In medicine, on the other hand, we have single-engine planes, and we figure they have got to be perfect, and we know they always aren't. So we think we need to look at that.

We have to understand that it is systems solutions. As you pointed out, people don't come to work to hurt a patient. That is not the issue. The issue is when people that are well-meaning make mistakes or don't use things appropriately. There is a whole number of things. It is not just errors.

How do we figure out how to prevent those things and put systems in place to really study the causes? It is not so simple as the typical line that you hear, for instance, on a medication problem: "Tell the nurse to be more careful." That is not really a Nobel Prize winning strategy. We have to wonder why did this happen.

I think we need to understand that the systems, there are a number of accountability systems that have been in place and still are, and they are appropriate. There is appropriate use of the accountability systems, but you need a learning system, one by which we can learn when there is a problem. We share it very quickly with others, so they can learn. If we don't do that, we cause everyone to pay the same price for their own individual learning, and they don't share, so each one of us learns from the injury of a patient. That is a terrible way to do this.

You talked about cost. I can tell you in the Michigan VA we have looked at this as we put the system in place which is in place in all our facilities. We see the cost in aggregate, in full time equivalents (FTE), if you want to look at it that way, is about 1.1 FTE a year to do full root cause analysis and corrective actions in a large-size hospital.

That is peanuts. That is really nothing when you look—and I can show you a number of examples, I won't waste the short time I have here right now—but just small corrections often cause avoidable, just in costs, operating costs alone, often $100,000 a year, which more than pay for the cost of that. So to say it is a cost, it really isn't. It is a cost avoidance strategy, but you have to pay some money to make some money.

It is not blame and shame. It is you really want to learn from these things and set up a way to do it, and that is understanding what is blameworthy and what is not. We don't say our system is a blame-free system. Please understand what I mean by this.

What we did is, we say there are some actions that are blameworthy, that is what we call intentionally unsafe acts, those acts that are criminal acts, acts that involve substance or alcohol abuse on the part of the care provider, or acts that were intentionally unsafe. That is, the person knew it was unsafe and did it anyway.

I think we all would agree they should be in a system that is discoverable, that is available to a plaintiff's attorney or anybody else who wants to look at it. On the other hand, innocent mistakes, if you will, do not deserve that same treatment. They should be confidential so people can feel free to share them locally and globally so people can learn, and we have that ability within the Michigan VA system. We think that is important.

Since we put this system in place, we have seen a 30-fold increase in reports, we have seen a 900-fold increase in close call reporting, 900-fold. That is 90,000 percent, which means close calls are those bad things that could have happened but didn't. You want to learn by those. You don't want to wait until somebody is hurt before we decide to do something different. Learn from the

close call. We do that, and I have numerous examples where concrete things that had global impact have been detected through that.

We also found in the old systems, 50 percent of the cases that would be looked at, people thought were not preventable because we didn't give them good systems tools to look at this, good human factors oriented tools. Now 100 percent come back with prevention, preventive strategies. That is huge. That means people are thinking differently. We think that is important.

To get there, though, we had to deal with certain barriers, and the barriers were, people were worried about punitive action, and that is from their perspective, not from the boss's perspective. That is not just, are you going to get fired, are you going to be suspended? That is are you going to be publicly humiliated, embarrassed?

All those things count. They are real roadblocks to sharing. We have to have protection so people understand that when they are not in the blameworthy category, that they can share, because the blameworthy ones won't tell you anyway. You know, if people did it deliberately, they are never going to tell you, so you have to have your other accountability mechanisms to deal with that.

Aviation learned this a long time ago with the Aviation Safety Reporting System (ASRS), because aviation had this problem. There was a crash not 40 miles from where we are sitting right now, where 92 souls perished, all because what was learned 6 weeks prior to that by another crew wasn't shared because of fear of punitive action. The Federal Aviation Administration, FAA, reacted decisively, started, had National Aeronautics and Space Administration (NASA) start the ASRS, and now they have a de-identified, that is not anonymous, reporting to NASA, which then shares those vulnerabilities with the community so they can be addressed.

We have an internal system at the Michigan VA, but we also have an external system we have set up that NASA actually runs for us, and it allows people to report. Now, I will say that that is something that can be used anywhere. We cannot right now, because of confidentiality issues, open it to outside Members, but Kaiser Permanente for instance has approached us and wants to be part of it. The U.S. Department of Defense, DOD, does. University of Michigan does, Vanderbilt, and on and on and on.

Until there is legislation which allows people to be able to share these things between institutions within a State, and more importantly, across States, they can't do that, because to share that means it is all discoverable, which means people will not report. So in the safety realm we need protection if you want people to truly be able to share nationally. The Patient Safety Reporting System, PSRS, that has already been put in place with NASA, what we have done, could easily be opened up to others with the stroke of a pen, but without confidentiality protection it cannot happen. So we think this is extremely important and necessary and would really put it forward so people can share and learn.

I guess I would leave you with, until now the way we have worked in medicine is experience is the best teacher, but it is also the most costly teacher, and the people who pay our tuition are the

patients. That is a terrible way to do business. We should really learn from each others' experience and not cause us to learn through harm done to others. Thank you.

[The prepared statement of Dr. Bagian follows:]

Statement of James P. Bagian, M.D., P.E., Director, National Center for Patient Safety, Veterans Health Administration, Michigan Department of Veterans' Affairs, Ann Arbor, Michigan

Mr. Chairman and Members of the Committee, I am pleased to be here today to discuss the significant challenge of improving the safety of health care delivery and particularly the approach that VA is taking to address this problem.

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

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

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

VA implemented nationwide internal and external reporting systems that supplement the many accountability systems we already had. The new systems' sole purpose was for organizational learning. They were constructed to encourage maximal reporting of even close calls and potential problems with non-punitive methods. This was essential because without the ability to identify system vulnerabilities and to analyze their root causes for common systematic problems our ability to achieve meaningful and sustainable patient safety improvement is limited. One method VA employed to better understand how to make these systems optimally function was to first do some surveys and focus groups of both VA and external healthcare workers to better understand their concerns and the characteristics that would help make our program effective. One point that was clear concerned the issue of punitive measures. Specifically, health care providers' view of punitive actions extended beyond typical administrative punishment to include factors such as shame, embarrassment, and professional reputation. Protection from these factors, was essential if we were to receive any reports from which we could then learn and proceed to undertake improvement and prevention efforts. This information convincingly demonstrated that confidentiality is pivotal to assuring the non-punitive intent and po-

tential of your learning system to the personnel from which you wish to receive reports.

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

Confidentiality is the common element that enables a safety system to be effective. It is important to recognize that making patient safety information confidential does not deprive any of the pre-existing internal or external accountability systems of information that they require. The two systems are mutually independent, that is, data reported and developed in the course of a patient safety activity is in addition to, separate, and apart from events identified to oversight reports. Voluntary reports on close calls and other problems would not otherwise exist were it not for a confidential system. Currently, the statutory protection for this type of information varies from state to state and does not permit the confidential and privileged sharing of information across state borders. Confidentiality for patient safety information, if uniformly available, will facilitate the sharing of information between institutions in a particular locale as well as on a national basis. Without it, the fear of shame, embarrassment, and other punitive measures stands in the way of dissemination of information that will improve the quality and safety of health care and benefit patients everywhere.

Experience in the VA system has shown that reporting of events and especially close calls increased dramatically after clear definitions were enacted as to what constituted a confidential patient safety issue. This has resulted in the identification and mitigation of system vulnerabilities not just within the VA system but globally. Without confidentiality the same results could not have been achieved.

Interest in improving patient safety is at an all time high. Very early, VA identified improved patient safety as a high priority. Our systems now serve as benchmarks to be emulated by others. We are proud of our accomplishments, however, there are numerous other methods and approaches that are currently in use, being developed, or are being contemplated. As more experience and data emerge from these activities it will be possible to identify safe practices that can be universally applied for patients' benefit. Uniform, unambiguous, and assured confidentiality of patient safety information is essential for these efforts to flourish. We must approach patient safety in a way that emphasizes and celebrates prevention, not punishment.

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

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

Chairman JOHNSON. Thanks very much, Dr. Bagian. We will be working closely with you as we use your experience, amongst others, to help guide us in making these difficult decisions. I thought the difference you drew between accountability and learning systems is really key here.

I am going to go slightly out of order for a variety of reasons. I would like to recognize Dr. Miller from Danbury Hospital. First of all, his testimony will put in perspective the other half of this problem at the very beginning of the hearing, and second, I am very

proud of his leadership, as I am of the Connecticut hospital system, and have worked very closely with the hospitals in my district because I have hospitals that are very small in rural areas, and hospitals that are superb teaching hospitals. Dr. Miller runs the Danbury Hospital, which is kind of a hybrid of both. It is a teaching hospital in a small city, surrounded by relatively small towns but on the border with New York and in the New York City environment.

So it is a pleasure to have you with us, Dr. Miller, and to have you share the experience of an institution in trying to grapple with these very problems.

STATEMENT OF MATTHEW MILLER, M.D., VICE PRESIDENT, MEDICAL AFFAIRS, DANBURY HOSPITAL, DANBURY, CONNECTICUT, ON BEHALF OF THE AMERICAN HOSPITAL ASSOCIATION

Dr. MILLER. Madam Chairman, I am the Vice President of Medical Affairs——

Chairman JOHNSON. You have to get very close to these microphones.

Dr. MILLER. I am the Vice President for Medical Affairs at Danbury Hospital, a community teaching hospital in Danbury, Connecticut. I have worked in health care for 30 years as a practicing physician, and for the last 10 years as a physician executive. I am here today on behalf of the American Hospital Association (AHA). We appreciate the opportunity to present our views on improving health care quality and safety.

We are extremely proud of the initiatives that hospitals and their staffs have adopted to improve patient safety. We are eager to work in furthering those efforts. I would like to talk about the importance of creating a culture of safety in health care, the role of medical error reporting, and the potential of technology to prevent adverse events.

We must create a system where medical errors are detected and analyzed so that we may learn how to reduce those errors in the future. To do this we must, one, provide a nonpunitive environment for reporting errors; recognize that most errors are failures of systems, not individuals; investigate errors thoroughly, using root cause analyses; and, four, collaborate with experts and peers on the lessons learned.

The AHA supports efforts underway in the Senate to create an improved confidential system for the voluntary reporting of patient safety information. We hope that this Subcommittee will take a similar approach.

We all agree that reducing medication errors is a critical goal for us improve health care safety. We must have systems in place to ensure that important clinical information is available to physicians at the time drugs are prescribed, so that orders can be complete and accurate. Effective medication management systems must ensure that the right patient is getting the right medication at the right time, the right dose.

New technology can be very helpful in reducing medication errors. Examples include computerized physician order entry, CPOE, and bar coding for drug and patient identification. We need to rec-

ognize, however, that these technologies do not provide a single silver bullet solution to these medication errors.

With CPOE, physician orders are entered directly into a computer. The computer provides real time patient data, including allergies and lab test results. It also provides pertinent formulary information, standard dosing protocols, and guidelines for care, all in one location. I do believe that CPOE systems, when fully implemented, have extraordinary potential to prevent errors.

We have begun implementing CPOE at Danbury Hospital, but the road will be long and arduous. We cannot discount a number of other very important considerations.

One, CPOE is expensive. We will need at least $2.5 million over the next 2 years, and we are getting off cheap because we had already purchased a system. Other comparably sized hospitals to mine will spend $5 to $10 million, and that doesn't include maintenance.

The CPOE is fairly new, not widely tested beyond large academic medical centers with homegrown systems.

Three, there is no off-the-shelf package ready to install. The CPOE requires substantial customization.

Four, CPOE systems must interface with other hospital information systems. We, for example, just discovered a problem with our pharmacy system. We will have to change that system entirely.

Five, staff support for implementation will be huge, involving physicians, pharmacy, nursing, information technology. Not all hospitals have those resources either for implementation or for maintenance, and ultimately, education of all the staff and major work redesign will be necessary to achieve all the planned goals.

We can't forget that there are multiple other medication management strategies that hospitals can and, in fact, must implement first, such as standardized orders, practice guidelines, formulary control, computerized access to clinical information. These strategies can accomplish a lot and they are actually much easier to implement.

Bar code technology is another tool to prevent medication errors. The AHA is very supportive of efforts underway at the Food and Drug Administration or FDA to promulgate bar code regulation that will enable information systems to verify correct patient medication and dose.

It is important to understand this issue against a backdrop of larger health care environment. Hospitals are facing unprecedented pressures, including a severe work force shortage, soaring pharmaceutical prices, and increased professional liability costs.

In conclusion, a third of all hospitals are operating in the red today and another third are teetering on the edge. It is vital that hospitals have adequate resources to meet the needs of their communities, and for this reason we are asking Congress to forego budget neutral provider payment adjustments; approve the full Medicare inpatient inflation update; protect Indirect Medical Education or IME payments; and help find a solution for the nearly 40 million uninsured. We look forward to working with Congress and others to help us cross what has been called a quality chasm.

I would be happy to answer any questions.

[The prepared statement of Dr. Miller follows:]

Statement of Matthew Miller, M.D., Vice President, Medical Affairs, Danbury Hospital, Danbury, Connecticut, on behalf of the American Hospital Association

Madame Chairman, I am Matthew Miller, M.D., Vice President for Medical Affairs at Danbury Hospital in Danbury, Connecticut. 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 today on an issue of critical importance for hospitals and the patients and communities they serve: improving health quality by developing strategies to ensure patient safety and reduce medical errors.

Danbury Hospital is the primary diagnostic and treatment center for approximately 361,000 residents in western Connecticut and adjacent counties in New York State. We are a major teaching facility with a highly skilled staff and state-of-the-art technological capabilities, which include: a Level II trauma center; magnetic resonance imaging (MRI); laser, laparoscopic, and endovascular surgery; two linear accelerators; interventional radiology; a neonatal Level II nursery; and a state-of-the-art cancer center. The hospital is recognized as a regional referral center and as the community health center for Danbury and the surrounding areas.

I have spent most of my 30-year career in health care as a practicing pulmonologist and physician executive. As Vice President for Medical Affairs I have administrative responsibility for clinical quality and safety, utilization of clinical resources, risk management, medical staff credentialing, regulatory compliance, and medical staff liaison functions. It is with this experience that I come before you today to discuss medical errors, how technology can help reduce those errors, and the role that hospitals play in improving patient safety through these initiatives.

Madame Chairman, I would like to state, on behalf of the entire hospital community, how proud we are of the initiatives that hospitals and our staffs have already adopted to improve patient safety. We look forward to working with you in the future as we continue to enhance our safety policies so that we minimize errors and continuously improve our care. This hearing gives all of us testifying before you today an opportunity to share our insights with you, and with each other, so that together we can reduce medical errors. As I'm sure my colleagues will agree, improving health quality and patient care is a team effort and we stand ready to do our part.

CREATING A CULTURE OF SAFETY

Hundreds of times a day, every day in today's hospitals, health care is provided through a complex system that involves people, technology, medical devices, and pharmaceuticals. This complexity has mushroomed in the past decade. Preventing and reducing errors is therefore a very complicated task that never ceases. Every medical error, whether or not it causes harm to a patient, must be detected and analyzed systematically in order to improve our ability to prevent these errors.

To prevent errors, we must create a culture of safety. Most of what has been learned in recent years about how to reduce errors and improve patient safety is based on two guiding principles. First, human beings, by their very nature, are vulnerable to error. Although the individuals involved are sometimes the focus after an error occurs, we know that errors most often occur because of failures in the systems in which individuals work. As a result, reducing medical errors will require us to develop and re-design the delivery of health care to build in error-resistant systems.

Second, we must create an environment in which we learn from our mistakes. As a first step, we have to develop effective mechanisms for candid discussion of errors, something that cannot be achieved in an environment of punishment or fear. Physicians, nurses, and other caregivers should not be penalized for stepping forward after a mistake has been made to report their error or an error they observed. We need to create supportive systems both within health care organizations and through specific legal reforms.

Today, when health care providers share confidential internal information with health care oversight agencies, other hospitals, or outside experts, they may jeopardize the protection that state laws provide to internal quality analysis discussions and expose the institution and caregivers to crushing legal liabilities. This legal "Catch 22" impedes efforts to share critical safety and quality information and analysis to prevent similar events from happening. It is essential that carefully constructed federal confidentiality and evidentiary legal protections be developed to encourage a culture of safety based on candor and learning. Further, reporting must be standardized and carefully defined.

The AHA continues to support federal legislation to address this issue. In the Senate, there is an effort underway to address how the Congress could create an improved system for the voluntary sharing of patient safety information both with external experts and across health care delivery sites with adequate confidentiality protections. We hope that this subcommittee will consider a similar approach in addressing health care safety issues. It is vital that the Congress enact legislation that protects the analysis and sharing of adverse event and other patient safety information so that caregivers can uncover, analyze, and share their experiences and learning, without fear of reprisal.

At Danbury Hospital, we are committed to creating a culture of safety. We have put in place a non-punitive reporting system that relies on intensive safety, education, and quality training. We scrutinize any adverse event to understand the cause so that we can change our systems to prevent similar occurrences. Further, we are committed to using new technologies that will improve patient care.

THE POTENTIAL OF NEW TECHNOLOGIES

Medication errors are a critical concern for health care. We know from the research that roughly two-thirds of medication errors, those that reach or don't reach the patient, occur in physician ordering and administration.[1] We must have systems in place to make sure that important clinical information is available to physicians and pharmacists at the time drugs are prescribed. Further, we must build systems that make sure the right patient is getting the right medication and dose at the right time.

There is extraordinary promise in reducing medication errors by using technology such as Computerized Physician Order Entry Systems (CPOE), bar-code technology, and drug administration systems, and through the development of standardized electronic medical records**.** However, there are very important issues surrounding their availability and implementation. Allow me to focus on CPOE and bar-coding as examples.

One way patient safety can be improved by information technology is through the use of machine-readable symbols such as bar-codes in a standardized format on all quantities of medication matching the right drug to a patient bar-coded identification. Bar-code technology can enhance patient safety by ensuring there is real-time verification of the correct patient, medication, dose, and time. The AHA is very supportive of efforts underway at the Food and Drug Administration (FDA) to promulgate regulations that would require human drug products and biologics to be bar-coded. This effort will promote code standardization, which will successfully enable information systems that rely on the availability of bar-coded drug information.

In the area of medication ordering, CPOE systems have great potential to reduce prescription-based errors. As you know, CPOE is a computerized system that allows physician orders to be entered directly into a computer, which simultaneously provides vital patient data and guidelines that give the physician valuable information as these orders are entered. CPOE centralizes critical information, such as: the patient's vulnerability to allergies, interaction with other drugs, standard dosing, recent pertinent laboratory data, prescribing tips, and standard or customized order sets.

At Danbury Hospital, I have spent considerable time carefully examining CPOE systems and, while I firmly believe that CPOE can reduce errors, reduce unnecessary variations in care, and improve staff efficiency, it is important to also recognize that these systems do not provide a single, "silver bullet" solution to drug prescribing errors. We are committed to implementing CPOE over the next two to three years, but it will be an expensive and arduous road. Let me share with you what I have learned about these systems.

The science of CPOE is still very new, except for the handful of larger academic institutions with home-grown systems developed over many years. While about a dozen commercial systems are available today, many of these systems have not been tested widely and have not been tested in what would be considered a prototypical community hospital. Although most of these health care organizations report significant quality and safety gains, in many instances, the cost savings are elusive, or at least difficult to quantify. Further, CPOE systems are not standardized—there is no off-the-shelf system that can be purchased tomorrow and operated immediately. It is important that the vendor community speed-up its efforts to create standardized systems that can be readily adopted so that hospitals can be assured that their investment will result in the care improvements anticipated. This is also

[1] Leape LL, Bates DW, Cullen DJ et all. Systems Analysis of Adverse Drug Events. JAMA 1995; 274:35–43.

an area where there may be a role for federal research through the Agency for Healthcare Research and Quality.

It is essential that CPOE systems effectively interface with other information systems in use at the hospital. Specifically, it is critical that these systems work with the pharmacy, laboratory, radiology, and medication administration systems already in place. At Danbury Hospital, we have identified a problem with the interface between our CPOE vendor's system and our current pharmacy computer system. As a result, we will have to completely replace the pharmacy system at an additional cost of $500,000, adding six to nine months to our implementation plan.

In addition, the cost to implement such systems can be overwhelming. For Danbury Hospital alone, we estimate putting in a CPOE system will cost $2.5 million over the next two-and-a-half years, a relatively low estimate because we have already purchased the software. Nor does this figure take into consideration annual maintenance costs of about $500,000. For other comparable hospitals starting from scratch, the literature estimates a cost from $5 to $10 million to fully implement an effective CPOE system

Hospitals face many challenges when it comes to implementing a CPOE system. This is a massive undertaking, which for Danbury Hospital will require a significant amount of clinical and technical manpower over the next two years to successfully achieve our objective. It is critical to the success of a CPOE system to have the commitment and active involvement of pharmacy, nursing, and medical staff. Without the buy-in and participation of physicians and others, CPOE systems will remain unused or misused, and potentially create new sources of error. This commitment means many hours of planning by key personnel, as well as massive education for the entire hospital staff.

In order to realize all of the goals of CPOE, be they reduced costs, improved quality, or most particularly improved safety, hospitals will need to redesign the work processes of their physicians, nurses, pharmacists, and technicians. Short of embarking on CPOE, there are multiple other medication management strategies that hospitals can, and must, implement first, such as standardized orders, practice guidelines, formulary control, and computerized access to clinical information. These strategies begin the consensus building process. Suffice it to say that although we are committed to CPOE, it has been a tough decision to proceed, carefully weighed, and one that will occupy a great deal of our time and resources over the next two years.

Hospitals must also "own" and manage the system, which requires hands-on, expert information technology (IT) staff. But it is important to understand the reality of hospitals' financial situation. Many smaller hospitals simply can't afford to make the large financial commitment that maintaining such a level of IT staff support. For hospitals that may have the available IT resources, many are currently overtaxed attempting to meet the obligations and deadlines set forth in the Health Insurance Portability and Accountability Act (HIPAA).

CPOE is just one example of a promising technology where stakeholders need to work together before widespread implementation is a reality. But in many cases, successful implementation of new technologies will require further scientific advancement of the technology, worker buy-in, and capital to purchase needed technologies. Hospitals are committed to using the best available technology within their resources to improve patient care and reduce medical errors. Overcoming these obstacles will be critical to realizing the substantial benefits CPOE has to offer hospitals and the health delivery system as a whole. We look forward to working with the Congress, the vendor community, and others to address these issues so that we may truly improve patient safety and save lives.

OTHER HOSPITAL CONSTRAINTS

While I know that the focus of today's hearing is on how to improve patient care and safety, it is important to understand this issue against the backdrop of the larger health care context. As this subcommittee is well aware, hospitals are facing unprecedented pressures that, when put together, threaten to erode the community hospital's foundation. Let me just touch on a few.

There is an alarming health care workforce shortage nationwide, with 168,000 open positions in hospitals alone. Critical shortages in nursing and pharmacy positions hurt hospitals' ability to successfully adopt new technologies, such as CPOE systems, which rely on the availability and expertise of pharmacy staff in particular.

Hospitals are also facing soaring pharmaceutical prices, with annual double-digit increases in cost. Further, changes taking place in the legal system mean that hospitals and caregivers face considerable increases in professional liability coverage costs. And, as you know, we are working to provide new equipment and training

so that our hospitals will be prepared for any emergency, including the threat of bioterrorism.

In Connecticut last year, only a minority of hospitals had a positive operating margin. Throughout the United States, one-third of all hospitals are operating in the red and another third are teetering on the edge financially. It is vital that hospitals have adequate resources to meet the needs of their communities. This means not allowing "budget-neutral" spending decisions to further reduce Medicare and Medicaid payments to hospitals. And it means making improvements, such as the full Medicare inpatient inflation update, which will help us continue to meet the soaring demands being placed on us.

Further, teaching hospitals, such as Danbury, are facing a significant cut in our graduate medical education funds. This scheduled cut must be eliminated if we are to continue providing sufficient resources to train the next generation of caregivers in the practices, and use of potential technologies, that can improve patient quality and safety for years to come.

Finally, there are nearly 40 million people living in the United States who do not have health insurance at all. Medical studies demonstrate that the uninsured live sicker and die younger because they are forced to go without the medical help they need. The men and women of America's hospitals see every day the devastation and pain that are caused when people do not have coverage, causing them to come to us much sicker than they should.

CLOSING

For thousands of years, healers have lived by the motto "primum non nocere"—first do no harm. The nurses, doctors, and others on the hospital patient care team strive every day to deliver safe, efficient, and compassionate care. But in today's complex, high-tech world of medicine, despite our best efforts, we can have unwanted and unintended consequences. As good as our systems are for preventing and reducing medical errors of all kinds, we can and must do better.

It is important that we continue to focus on what it means to promote a culture of safety. At AHA, and at Danbury Hospital, we are committed to these important issues.

You have heard testimony about creating a culture of safety at the Veterans' Administration (VA) and received a statement regarding the airline safety reporting system run by the National Aeronautic and Space Administration (NASA). There is much to learn from their successes in promoting a culture of safety, in particular through the creation of non-punitive systems for the reporting and sharing of adverse event information.

In our efforts to create a culture of safety, there is a role for technology, and in particular CPOE systems, to help prevent medical errors and improve care. But we must be cognizant of technological, cultural, financial, and other challenges as we strive to provide the best possible health care to every patient that comes through our doors. Again, it is important to remember that there is not one solution or one activity that will make our systems error proof.

We look forward to working with Congress, our colleagues, and the vendor community to address head-on the financial, technological, legal, and cultural issues that can help us cross what has been called a "quality chasm."

Chairman JOHNSON. Thank you very much, Dr. Miller.

I would like to recognize Dr. Berwick, the President and Chief Executive Officer (CEO) of the Institute for Health Care Improvements in Boston. Dr. Berwick.

STATEMENT OF DONALD M. BERWICK, M.D., PRESIDENT AND CHIEF EXECUTIVE OFFICER, INSTITUTE FOR HEALTHCARE IMPROVEMENT, BOSTON, MASSACHUSETTS

Dr. BERWICK. Thank you, Madam Chair. I have submitted my full remarks for the record.

Since the IOM report, there has been indeed a lot of progress in this country, and I want to acknowledge that. The issue is explicit and visible. Most consumers seem aware that there are safety challenges in the health care system. A lot of hospitals have begun to

promise to improve safety, and a small but important minority of them are becoming much more open about their own injury rates and measuring their frequency.

Some of the highlights include the work at Pittsburgh you will be hearing about. I am aware of community efforts in Whatcom County, Washington and in Florence, South Carolina, to improve safety at the community level. There is a consortium of children's hospitals that is focused on this as their primary agenda. I am aware of a collective of 57 hospitals working on substantial safety improvements, and other important progress is being made nationally.

The Federal leadership on this has been dramatically important. The work at the VA, DOD, the Health Resources and Services Administration (HRSA), and most importantly, the Agency for Healthcare Research and Quality (AHRQ) has actually been, I think, the catalytic work in this country. I want to personally thank Congress on behalf of my colleagues for your commitment and bipartisan support for this work, but there are obstacles. We are not going fast enough. Let me tell you what some of the obstacles are.

First, there is still denial in the industry. There are a lot of doctors and hospitals that still think this isn't a problem. We need congressional voice, Federal leadership to say it is a problem and it must change.

The second obstacle is capital costs. Some of the technologies to get safety systems into place are beyond the reach of small hospitals especially. There is a threshold to cross here. Last week the Advisory Board published a report saying that CPOE, which I thoroughly endorse, costs something like $7.5 million per facility.

We know CPOE, for example, saves money. There is a good study in JAMA, the Journal of the American Medical Association, that said there is a 13-percent reduction in the total cost of hospitalization in hospitals with CPOE introduced, 13 percent on the bottom line of costs. I believe it is there, but it is downstream, and we have got to get over this activation issue.

The third problem is, we are still paying for defects. I don't think hospitals intend to hurt anyone, but it still is true that hospitals that injure patients get paid for treating those injuries.

Fourth, there is lack of standardization. I will come back to that in a minute. The Federal government has a real opportunity to offer some standardization that would help the industry accelerate.

Finally, there is persistent fear. For a lot of reasons—lawsuits, embarrassment, loss of market share—organizations, individuals in health care are very frightened to discover and reveal and discuss openly their defects. We have got to get over this. Fear is incompatible with learning, and safety can't be achieved without learning. Safe systems are open, transparent systems. A frightened work force is not going to go there.

We have been distracted by the issue of public reporting. I have an opinion on this. I think we need to be committed to transparency, but we have a very frightened work force that needs some security to know that they can discuss safety issues safely, or we are not going to get further on this.

I think we have been stuck in a national debate about mandated reporting or not mandated reporting. I think we have to get over it. What we know is, safety has to be openly discussed, openly assessed, openly explored. The Centers for Medicare and Medicaid Services (CMS) should insist that health care organizations that it pays have to assess safety, they have to study it, they have to discuss it openly, they have to learn about their own injuries. That is for sure.

I have six suggestions for Congress about things you could do that would help us at this stage. It is not primarily a Federal problem, but let me tell you what I think would help.

First, please continue to support the investments that you are seeing in the VA, in HRSA, in DOD, and in AHRQ in this agenda. We are really getting some leadership out of these systems.

I want to editorialize. I am deeply concerned about proposed budget cuts this year in AHRQ's budget. If you proceed with the current budget, the Agency for Health Care Research and Quality will be unable to fund any new investigative research. It goes to zero, except in specific targeted areas.

Now, you have made safety a targeted area, but that doesn't solve the problem. Without investigator-initiated research, we are not going to get the learning we need in this field. If you do give AHRQ the funds it needs to support investigator-initiated research, it is a wise investment in how to manage a $1.5 trillion system, and I fear we are about to make a big mistake.

Second, ask CMS to sponsor some market area experiments to reward quality and safety. Right now a hospital or health system that reduces injuries to patients actually takes a financial loss often because it gets paid for treating the consequences of its own injuries. We have to figure out how to stop paying for defects in care and start putting the opposite incentives to work: grants, tax credits, low-interest loans. There is some current legislation on this, but right now we are paying for defects and we have got to stop doing it.

Third, I think we should, with all due respect to Mr. Stark, create a circumstance in which one, at least one State in this country can try a no-fault malpractice liability system. I think it will work. Here is the system we should try. It should have six properties:

Always let patients and families know when a patient is injured, extreme honesty, and you are not in the system if you don't adopt that.

Second, apologize. We have trouble saying we are sorry.

Third, compensate the victims of energy directly and fairly and promptly. Right now only 2 percent or 3 percent of the money that is being exchanged in the system is actually going to victims of injury.

Fourth, bear the responsibility at the entity level. Let the hospitals, the health systems, bear that responsibility. Don't go to the personal individual blame level, because that is going to increase the fear that is our problem in getting to safety cultures.

Fifth, learn from the events, continually reduce risks within and among organizations.

Sixth, deal differently with the criminal and grossly negligent. That has to be done promptly and severely, and that is 2 percent of the problem.

I think a test of this kind of system in one State or one region of the country would teach us, and we win either way. If it works, we learn that it worked; and if it doesn't work, we learn it doesn't work and can move the agenda on.

The fourth recommendation to Congress is, create some limited privilege for reporting on patient injuries for the individuals who make the reports. I think Jim has shown in the Michigan VA, we know from theory and practice in other industries, if there isn't some form of protection for the individual—I do not think it should extend to the entity, to the hospital or the health system, but at the individual level there has to be protection, or people are no fools, they won't talk about things when that talk is going to come back to hurt them.

Fifth, don't worry about constructing a large national database on errors or injuries. It will be a waste of time and money. We don't need it. We should fund AHRQ thoroughly, to have a research database on this, and you are about to make a mistake if you proceed with the current budget on that, but if we fund the research work, that is all the data we need. We don't need a massive national architecture on data on injuries.

Finally, ask CMS to adopt some simple information technology standards. We really are stuck. It is one of the reasons Danbury Hospital has to spend so much money. I can explain this in questions if you want, but there are a few decisions we could make about standard vocabularies for coding in this country.

If CMS said, "You must use these codes as a condition of participation," we are done. It would be behind us, and then we can have a national data backbone that would allow hospitals and health systems to talk to each other, that would have saved Danbury millions of dollars, and Congress is in a really important position here. The CMS could actually make the difference in getting us there.

We have made a great running start. I commend you for what has happened, and now we have a few more jobs to do and we can make it even better.

[The prepared statement of Dr. Berwick follows:]

Statement of Donald M. Berwick, M.D., President and Chief Executive Officer, Institute for Healthcare Improvement, Boston, Massachusetts

Since the IOM Report, *To Err Is Human*, released in November, 1999, the nation has made a great deal of progress in confronting the burden of injury from health care. We have made the issue explicit and visible. I think most consumers are now aware of the problem, which is a step toward building will for change. Some hospitals have promised to improve patient safety. A small, but significant, minority of hospitals have begun to look for injuries and to try to measure their frequency. Skillful experts, including some from other industries, have started to help us.

Let me give you just a few highlights:

- A consortium of all stakeholders in the Pittsburgh area has publicly announced that they will reduce medication injuries and post-operative staph infections to zero. Similar consortia in Whatcom County, Washington, and in Florence, South Carolina, have made plans to improve medication safety dramatically.
- The Children's Hospital Corporation of America, involving several dozen children's hospitals, has chosen patient safety as its major care improvement agenda.

- Fifty-seven hospitals from all over the US in a collaborative called "Quantum Leaps" are now openly measuring their medication injury rates, comparing them, learning from each other, and aiming for ten-fold reductions.
- A newly launched medical journal called "*Quality and Safety in Health Care*" is providing researchers and clinicians in the US and the UK with an outlet to publish their work.
- The National Academy of Engineering and the Institute of Medicine have launched a project to see how new engineering approaches can be applied rapidly and directly to safety in health care settings.
- The VA and NASA have begun a fascinating collaboration on reporting systems and on human factors engineering.

The Federal government has been in the lead in this sea change. I think you already know that the Veterans Health Administration, the Department of Defense, the Health Services and Resources Administration, and, above all, the Agency for Health Care Research and Quality have invested heavily in new care initiatives, technologies, and research to make patients safer. The Quality Interagency Coordinating Task Force (QuIC), which has bridged two administrations, is a wonderful example of cooperative learning and action among agencies that too often in the past have not worked closely together on common issues. We would be nowhere near as far along as we are without this Federal leadership, and I commend both Congress and the Executive Branch for your commitment and bipartisan constancy on this issue.

Along with this important progress, we have also now become aware of some obstacles. None of them are insurmountable, and in some cases, the Federal government can clearly help to accelerate change. Here are a few of the problems that have surfaced:

- First, **persistent denial**. Many clinicians and organization still seem to think, despite the evidence, that the problem of safety is not as large as we know it to be. This denial is fading fast, and I think we are well into a new era of recognition and aims for improvement. It remains important for Congress, Federal agencies, and other leaders to keep the pressure on, and to insist on improvements.
- Second, **capital costs**. Health care systems are facing—or at least say they are facing—investment barriers to adopting some important technologies that make care safer, most importantly computerized physician order entry—CPOE. Correctly adopted, CPOE can reduce medication errors by as much as 80%, but it requires a level of computerization that the health care industry largely lacks. The technologies cost hospitals a lot up front—millions of dollars—$7.5 million on average according to a recent estimate, and some hospitals say they lack sufficient sources of capital. CPOE in the long run saves money; one study said it reduces hospital costs 13%. The American Hospital Association has found that hospitals with good Information Technology support generally cost less and have better outcomes than others. The barrier is getting from here to there; it's a transitional problem.
- Third, **paying for defects, instead of for safety and quality**. Our system of financing still often pays well for poor care. A hospital that reduces patient injuries can today experience a significant decline in revenue, since it would often otherwise get paid for managing the consequences of those injuries. This is not a stopper for ethical hospitals, and most are ethical, but it is a problem.
- Fourth, **lack of standardization**. Facing high capital costs, health care organizations are nervous about the lack of standards for coding and procedures, fearing that they could invest today in systems that could rapidly become outmoded or incompatible in the future. Lack of standardization is an impediment to progress, and I see no force other than the Federal government able to create such standards rapidly and at a national scale.
- Fifth, and perhaps most important, **fear**. For many reasons—threats of lawsuits, embarrassment, loss of market share, and others—organizations and individuals in health care are frightened to discover, reveal, and openly address defects in their care. This fear is incompatible with learning and with safety, itself. Safe systems are open systems, and a frightened workforce cannot properly address safety improvement.

Along the way, we have all been a little distracted by the very contentious issue of public reporting of patient injuries. It is contentious because, on the one hand, it seems only right that the health care industry should be disclosing its performance to the people who depend on it and pay for it. I hope and believe that we are

emerging overall from the era of secrecy about performance of care systems, and the more recent IOM report, *Crossing the Quality Chasm*, called unequivocally for a whole new level of commitment to transparency, not just to inform consumers, but to allow health care systems, themselves, a better chance to learn from each other. Safety is important, and it is illogical to exempt it from the rule of transparency.

On the other hand, we do know that people in health care are running scared, and that a frightened workforce hides its defects instead of learning from them.

And so, we have gotten a little stuck since the IOM safety report. A few courageous health care organizations have just gone ahead and become open about measuring safety, and, I must say, they are none the worse for it. Most, however, are still pretty timid about it. They fight disclosure, and they fight CMS when they propose that safety should be openly measured and discussed.

In my opinion, it is high time to leap over our shadow on this one. I simply do not believe that a risky, complex, stressed industry will have the will or the knowledge it needs to move beyond traditional assumptions about achievable performance unless and until it faces facts and data on its own work. Safety should be a topic openly discussed, openly assessed, and openly explored, and I hope that CMS, like other important purchasers, will do what it can to assure that that open dialogue becomes more and more widespread. CMS should insist that the health care organizations it pays must assess, study, and learn about their own patient injuries, disclose those injuries to the patients who are harmed, and continually and demonstrably reduce the risks of injury.

Congress can help this maturation to occur by a few, simple, persistent steps:

1. **Continue to support the investments of the VA, HRSA, DoD, and, most crucially, AHRQ, in the agenda of learning and improvement of patient safety**, for the benefit of their patients, and for the instruction of all.

I am deeply concerned about this year's proposed reductions in the budget of AHRQ. It would be wise to expand, not to cut, our nation's meager investment in studying how our $1.5 trillion care system can be made better continually. Preserving line items for patient safety research is helpful, but not at all sufficient. Please understand that the proposed AHRQ budget would bring nearly to a standstill new investigator-initiated health services research proposals—bring them to zero—and that means a sudden slowing down of research and investment which ultimately has a major impact on the well-being of our patients. If you give AHRQ the funds it needs to support investigator-initiated research, even more than in the past, you can count on a high rate of return in health care quality improvement.

2. **Ask CMS to sponsor and allow several market-area experiments to reward quality and safety**. Try to adjust payment streams so that health care organizations that become safer thereby become more viable. Right now, a hospital or health system that reduces injuries to patients often actually loses financially, because it gets paid for defects. We have to figure out how to stop paying for defects in care, and to start putting exactly the opposite incentive to work. Pay hospitals more when they reduce their injury rates, and less when they don't. Grants, tax credits, or low-interest loans, as some currently proposed legislation would offer, may help some of the less wealthy hospitals move faster into modern information systems.

3. **Create the circumstance in which at least one state or area can test a no-fault malpractice liability system for a few years**, so that we can begin to put to rest the most commonly cited obstacle to openness. Either we will learn that that leads to much more openness, or that it doesn't, and, either way, we gain knowledge we badly need. The system we most badly need to test would have the following components: (a) always letting patients and families know when a patient is injured by care ("extreme honesty"); (b) apologizing; (c) compensating victims of injury fairly and promptly; (d) bearing this liability at the "entity" level (hospital, health care system), not at the personal level (physician, nurse); (e) learning from events, and continually reducing risks within and among organizations; (f) dealing differently and promptly with the small class of criminal and grossly negligent events.

4. **Create some limited privilege for reporting on patient injuries for the individuals who make those reports**. I am not asking for secrecy at the entity level, but rather for some protection for a doctor or nurse who sees something go wrong, or actually falls into some pattern of error, and who can and will talk about it, but only if that does not come back to hurt them.

5. **Do not worry about constructing some massive national database on errors or patient injuries**. We don't need it. It may help if AHRQ has a re-

search database of that type, but regional and statewide reporting systems will be quite enough if we also have ways for the people involved in those systems to meet and talk with each other and to share what they are learning.

6. **Ask CMS to adopt some information technology standards**, required of those organizations they pay, for coding of messaging, medications, laboratory tests, and diagnoses. It is important, and feasible, for CMS to select a single set of such standards from among several good available options, and then to build confidence in the health care system that these will remain stable for a considerable time, so that it becomes prudent and logical to invest in compatible data systems with confidence that they will work well into the future. That will make CPOE and other safety-enhancing computer technologies much more attractive and feasible. I also think CMS should join the Leapfrog Group in informing hospitals that, by some deadline, a hospital without either CPOE or a demonstrably better method for medication safety cannot be a Medicaid provider.

We really have a running start now on making health care safer. We need to keep the heat on the topic, invest in the research to know how to improve the situation, insist on openness and sharing, pay more for quality than for defects, and make it both important and safe for the wonderful people who work in health care to learn about their own errors, about the harm done to patients, and about how to reduce that harm continually.

Chairman JOHNSON. Thank you very much.

Ms. Foley, President of the American Nurses Association.

STATEMENT OF MARY FOLEY, PRESIDENT, AMERICAN NURSES ASSOCIATION

Ms. FOLEY. Thank you, and good morning. I really do appreciate the opportunity to be here and return to the table to talk about the importance of prevention of health care injuries.

As you know, there are more than 2.7 million registered nurses in the country right now, 2.2 million of us are still working in the field. We are very committed, and it has always been a cornerstone of our nursing profession to be worried about and try to attend to the issues of patient safety.

Of course, as you have mentioned, Congresswomen, the landmark report "To Err is Human" really brought this attention to the forefront. It was the most talked-about health care issue in the year 2000, and while I do also agree with our previous speakers, there has been some good work started, we need to continue to push on the issue of systems of care and systems of safety that protect our critically important patients.

I am here, however, to put a slightly different face on the discussion because the system of safety cannot overlook the people who provide the safety net and the monitors of safety, and for us nurses play that role in a very critically important manner.

We have long maintained, and we are beginning to get some significant research which validates the relationship between high quality, safe patient care and the amount and the skill of the nursing staff, and we applaud the research that has been supportive of those findings. The CMS and four U.S. Department of Health and Human Service agencies in the years 2000 and 2001 have reported correlations between safe staff and certainly the reduction of complications and injuries such as falls.

I support, as does nursing, the implementation of technology, for example, computer order entry, but the pursuit of technology should not be in a vacuum. it must consider the people who will

then be part of that system. I think Dr. Miller mentioned the training, but importantly as well the people who provide the care and do the actual monitoring and assessment are just as critical to a good computer order entry system, so the pharmacists and the nurses have to be present in adequate numbers and with qualifications that are commensurate.

We also know, as I have mentioned, that—well, so on the issue of staffing, I just want to reiterate that we are recommending then efforts to support valid and reliable staffing measurements that really address what are the needs or the acuity of our patients, and that that concept be integrated into Medicare and Medicaid programs as a form of condition of participation.

We very strongly applaud the efforts of the Veterans Administration. They are demonstrating the best practices, particularly in the area of early reporting and near miss analysis, and I think that is a field that needs to be further promoted and supported.

Additionally, we are very concerned about skilled nursing facilities. I have been very alarmed by the reports that we have heard. Nurses are not surprised, however, by some of the shocking findings that we are hearing about care in skilled nursing facilities. We continue to support adjustable minimum nurse-patient ratios in those settings.

Let's talk about the issue of mandatory overtime. Again, the system of care and the human factors involved in the safe delivery of care, there is inadequate research. It is beginning to be performed. We have one particular study, an AHRQ-funded study, to look at nurses and fatigue.

Over two-thirds of nurses in a survey last September told us that they are being asked to work unplanned overtime, and of course the epidemic of mandatory overtime has been both a very negative image for nurses, it is affecting our ability to recruit and retain, and we know we have a shortage coming. More importantly, we are very concerned about the safety of nurses who feel that they are too fatigued to provide safe care, and there are ample studies that show that fatigue has a correlation to injury and safety issues. So we do support Congress's continued discussion and support for the Safe Nursing and Patient Care Act of 2001, which we think is a balanced approach.

Let me just quickly mention the reporting, the role of the whistle-blowing. Mr. Stark, thank you for mentioning that, very much. The ability to safely report, in fact the enhancement of safe reporting mechanisms is very important to nursing. If we cannot speak out and let people know when we see care that is inadequate or unsafe or lax quality and there are negative repercussions, it will be difficult to be the full advocate that we believe we must be and that we should be.

So, in conclusion, I would like to just continue to support this system approach, but the people as part of that system must be considered. They have to be able to be there. All nurses want to do, and I have said this many times, all nurses want to do is give good care. We must attend to the people and the equipment and to the technology that makes that care possible.

I would have to say, very importantly, though, Congressman, you asked us about the cost. The alternative to a safe system with ade-

quate staff is the cost of untold numbers of injuries, errors, terrible patient satisfaction, and the cost of that type of system is unacceptable. I am a believer in prevention. I believe the investment in a safe environment with adequate staff who are well qualified and well cared for will indeed pay dividends over the many years to come.

Thank you.

[The prepared statement of Ms. Foley follows:]

Statement of Mary Foley, President, American Nurses Association

Good morning Madam Chair and Members of the Subcommittee, I am Mary Foley, MS, RN, president of the American Nurses Association. Thank you for the opportunity to discuss our concerns regarding patient safety and medical errors. ANA is the only full-service association representing the nation's registered nurses (RNs) through its 54 constituent nurse member associations. Our members include RNs working and teaching in every health care sector across the entire United States. I myself have more than 25 years experience as a staff nurse, a nurse executive and a clinical instructor in nursing.

Numbering more than 2.7 million, nurses are the largest health care workforce in the nation. From the nurse midwives who attend delivery, to geriatric nurse practitioners who manage end-of-life care, to staff nurses who care for us during times of acute injury or illness, nurses are integral to health care across the human lifespan. We touch patients and manage teams of medical professionals in hospitals, clinics, community health centers, offices, nursing homes and patient's homes. We are the ones who will ultimately implement and be impacted by new patient safety initiatives. Therefore, nurses have a substantial contribution to make to the developing debate on medical errors.

The issue of patient safety has always been the cornerstone of nursing. The Code of Ethics for Nurses clearly states that "as an advocate for the patient, the nurse must be alert to and take appropriate action regarding any instances of incompetent, unethical, illegal, or impaired practice by any member of the health care team or the health care system or any action on the part of others that places the rights or best interests of the patient in jeopardy." ANA has been active in the debate on medical errors, both prior to the release of the Institute of Medicine (IOM) study *To Err is Human* and since it publication. This statement provides a summary of our actions and positions, and our requests for future policy.

The Changing Health Care Delivery System

The landmark IOM report *To Err is Human* (1999) described a fractured health care system that is prone to errors and detrimental to safe patient care. This problem is readily apparent to the nurses who have been caught inside the topsy-turvy world of our rapidly changing health care delivery system. We have seen market forces, reimbursement changes, and new technologies revolutionalize health care. Unfortunately, these changes have not always resulted in better patient care.

In the past decade, the advent of managed care and changes in Medicare reimbursement have exerted downward pressure on provider margins. As a result, health care facilities have employed radical cost reduction programs. Throughout the 1990s, new models of health care delivery were implemented, and highly-trained, experienced—and therefore higher paid—personnel were eliminated or redeployed. As RNs typically represent the largest single expenditure for hospitals (averaging 20 percent of the budget), we were among the first to feel the pinch. Often lesser-skilled, lower-salaried assistive staff were hired as our replacements. Nationally, nurses wages were cut and RN employment in the hospital sector decreased. Accordingly, it was only five short years ago when nurses were being laid off in droves.

At the same time, recent advances in medical technology have resulted in truly amazing treatments and procedures. These advances are extending and improving the quality of our lives. They are also increasing the complexity of health care. Just think of premature infants in neonatal units or the burn victims from the recent terrorist attacks; these patients are able to survive and thrive when only a few years ago they could not. Nurses in these units manage patients who are supported by heart-lung bypass machines, ventilators, and constant drug infusers. Patients such as these require constant monitoring, as even minute changes can quickly lead to disaster. Thus, today's nurses are engaged in painstaking, complicated care more often, with fewer supports than ever before.

In sum, recent changes in health care delivery have increased the pressure placed on staff nurses who are now required to oversee unlicensed aides while caring for a larger number of sicker patients. At the same time, the elimination of nurse managers has decreased the support, advocacy and resources necessary to ensure that staff nurses can provide optimum care.

The Failures of the Culture of Blame

In addition to the changes described above, the recent increase in competition within and among health care providers, as well as the upswing in public concerns about the quality of health care, have lead institutions to focus on their marketability. ANA is concerned that many institutions have responded to this pressure by creating a punitive atmosphere that continues to assign and emphasize individual blame for errors, misjudgements and patient dissatisfaction. These facilities continue to assume that the appropriate way to deal with patient care problems is to increase the oversight and discipline of health care workers; as opposed to identifying and resolving central system problems.

Although a range of sanctions are available to punish providers held responsible for committing medical errors, these measures are rarely credited with much success. Professional licensing boards are often backlogged and sometimes criticized for failure to take appropriate disciplinary action. Legal avenues reach only a fraction of the injuries caused by health care error. Most importantly, regulatory and legal sanctions are only imposed after mistakes have been made and do very little to prevent them in the first place.

This is not to say that providers and practitioners who are negligent or incompetent should not be removed from clinical practice. Certainly, we must be able to deal with people who are unable to practice safely. ANA maintains that mechanisms for individual accountability should be maintained. We also contend that an over reliance on individual scrutiny has failed to address the burgeoning system problems that have fostered poor patient care.

The Role of Appropriate Suffering

ANA has long maintained that the safety and quality of care provided in the nation's health care facilities is directly related to the number and mix of direct care nursing staff. More than a decade of research shows that nurse staffing levels and skill mix make a difference in patient outcomes. Studies show that where there are more nurses, there are lower mortality rates, shorter lengths of stay, better care plans, lower costs, and fewer complications. In fact, four HHS agencies—the Health Resources and Services Administration (HRSA), Health Care Financing Administration (now the Centers for Medicare and Medicaid Services, or CMS), Agency for Healthcare Research and Quality (AHRQ), and the National Institute of Nursing Research (NINR) of the National Institutes of Health (NIH)—recently sponsored a study on this topic. The resulting report, released on April 20, 2001, found strong and consistent evidence that increased RN staffing is directly related to decreases in the incidence of urinary tract infections, pneumonia, shock, upper gastrointestinal bleeding, and decreased hospital length of stay.

CMS, the IOM, the General Accounting Office, and numerous professional and consumer organizations have found similar evidence regarding the relationship between nurse staffing and patient care in nursing facilities. An ongoing study commissioned by CMS has detailed the relationship between insufficient nurse staffing and increases in bed sores, urinary tract infections, sepsis, and weight loss in nursing home residents.

A recent ANA staffing survey, involving 7,300 RNs, reinforces the connection between adequate staffing and quality of care. This report shows that 75 percent of respondents felt that the quality of nursing care at their facility has declined over the past two years. More than 5,000 nurses (68 percent) cite inadequate staffing as a major contributing factor to the decline in quality of care. More than half believe that the time they have available for patient care has decreased. The public at large should be alarmed that *more than 40 percent of the respondents to the ANA survey state that they would not feel comfortable having a family member cared for in the facility in which they work.*

ANA maintains that something must be done to address staffing concerns. Adequate staffing levels allow nurses the time they need to make patient assessments, complete nursing tasks, respond to health care emergencies, and provide the level of care that these patients deserve. Adequate staffing also increases nurse satisfaction and reduces turnover. For these reasons, ANA supports efforts to require acute care facilities to implement and use valid and reliable staffing plans based on patient acuity as a condition of participation in the Medicare and Medicaid programs. We are excited about the advances that the Veteran's Administration has made in

patient safety, and we look forward to working with the Veteran's Health Administration officials as they develop a new national nurse staffing policy. In addition, we support efforts to enact upwardly adjustable, minimum nurse-to-patient staff ratios in skilled nursing facilities.

The Critical Problem of Mandatory Overtime

By far the riskiest result of understaffing is the abuse of mandatory overtime as a staffing tool. Nurses across the nation have told me their concerns about the dramatic increase in the use of mandatory overtime. ANA hears that employers are insisting that a nurse work an extra shift (or more) or face dismissal for insubordination, as well as being reported to the state board of nursing for patient abandonment.

The use of mandatory overtime is not as uncommon or isolated as some would have you believe. In fact, the term 'mandation' has been coined by the health care industry to describe this staffing tool. A recent ANA survey (sample size 4,826) revealed that two-thirds of nurses are being required to work some mandatory or unplanned overtime every month.

ANA's concerns about the use of mandatory overtime are directly related to patient safety. We know that sleep loss influences several aspects of performance, leading to slowed reaction time, failure to respond when appropriate, false responses, slowed thinking, and diminished memory. In fact, 1997 research by Dawson and Reid at the University of Australia showed that work performance is more likely to be impaired by moderate fatigue than by alcohol consumption. Their research shows that significant safety risks are posed by workers who stay awake for long periods. Thus, it only stands to reason that an exhausted nurse is more likely to commit a medical error than a nurse who is not forced to work overtime.

Nurses are placed in a unique situation when confronted by demands for overtime. Ethical nursing practice prohibits nurses from engaging in behavior that they know could harm patients. At the same time, RNs face the loss of their license—their careers and their livelihoods—when charged with patient abandonment. Absent legislation, nurses will continue to confront this dilemma. For this reason, ANA supports the Safe Nursing and Patient Care Act of 2001 (H.R. 3238, S. 1686) which would ban the use of mandatory overtime through Medicare provider agreements.

ANA supports working through the Medicare system because we believe that the abusive use of overtime promotes poor patient care and therefore is a matter of public health safety. Just as limits on work hours for airline pilots, flight attendants, and truck drivers are enacted through transportation law, we believe that this matter should be handled through health law. The Safe Nursing and Patient Care Act is a fair, measured response to the abuse of mandatory overtime. ANA strongly encourages all Members of this Committee to support its enactment.

Patient Advocacy and Whistleblower Protections

In addition, ANA maintains that nurses must be able to speak out about quality-of-care problems without fear of retaliation or the loss of their jobs. Patient advocacy is at heart of nurse's professional commitment. In turn, patients depend on nurses to ensure that they receive proper care. Patients must be assured that nurses and other health care professionals, acting within the scope of their expertise, will be able to speak for them without fear of reprisal.

Whistle blowing by nurses usually results from concern about issues that jeopardize the health or safety of patients, or occupational safety and health violations that place the employee at risk. Yet, even though we are responsible for patient care and well-being, nurses are often powerless when another health care provider performs unethical or life-threatening practices. Retribution and dismissal for whistle blowing are not uncommon. In fact, there have been a number of legal cases involving nurses who have been retaliated against for "blowing the whistle" on their employers.

Current whistle-blowing laws remain a patchwork of incomplete coverage. For example, the False Claims Act contains a whistleblower provision that applies only in cases of fraud or misuse of Federal funds. The Emergency Treatment and Labor Act (EMTALA) includes protections for patient advocacy, but only for personnel working in the emergency department of a hospital. The Whistleblower Protection Act of 1989 only applies to federal employees (e.g., VA nurses). This confusing, incomplete coverage leaves many nurses fearing reprisals such as dismissal, harassment, and blacklisting. This lack of a blame-free reporting system prevents many nurses from taking the risk of trying to protect their patient's health and safety. In order to allow nurses to function as successful patient advocates, effective whistleblower protections for nurses who report unsafe patient care must be enacted.

Where to Start?

A number of experts, including those sitting here with me today, have proposed valuable solutions to the problem of medical errors and patient safety. ANA supports many of these initiatives; however we insist that the central issues of staffing, overtime and whistleblower protections must not be lost in this debate.

Medication errors serve as a good example. The IOM estimates that medication errors increase hospital costs by about $2 billion per year. Disturbingly, the IOM also estimates that the number of lives lost to preventable medication errors alone represents over 7,000 deaths annually—more than the number of Americans injured in the workplace each year. The U.S. Pharmacopeia, which has tracked medication errors since 1991, recently reported on the first full year of an internet-based reporting mechanism for medication errors and near misses. The analysis of 6,224 reports revealed that most errors occur in the administration of medications—the delivery to the patient. U.S. Pharmacopeia reports that, "the primary contributing factor to medication errors were distractions and workload increases, many of which may be a result of today's environment of cost containment." ANA could not agree more. While we support innovations such as information technology designed to reduce medication errors, we understand that these efforts will not be successful if the broader system issues are not addressed as well. In the end, any system that requires a nurse to work a 16-hour shift, while caring for too many critically ill patients, in a ward where he or she is not supported by adequate staff is destined to failure.

Conclusion

Madam Chair, I have been a registered nurse for more than 25 years. I have been a staff nurse, a nurse executive, and a clinical instructor in nursing. I know something about nurses. We are called to the profession by a desire to provide compassionate care to people in need. Believe me, no one becomes a nurse for the money. We are driven by a desire to provide safe, high-quality health services. We will remain in patient care as long as this is possible.As long as unreasonable schedules, dangerous understaffing, and fears of institutional reprisal keep nurses from meeting this calling, many will continue to leave the bedside. Nurses do not want to be a part of a health system that fails to meet the needs of patients. Registered nurses, hospital administrators, other health care providers, health system planners, and consumers must come together in a meaningful way to create a system that supports both patients and health care providers. We should begin by improving the environment for nursing.

Chairman JOHNSON. Thank you very much.

Dr. Feinstein, Chair of the Pittsburgh Regional Health Initiative from Pittsburgh. Welcome.

STATEMENT OF KAREN WOLK FEINSTEIN, PH.D., PRESIDENT, JEWISH HEALTHCARE FOUNDATION OF PITTSBURGH, PENNSYLVANIA, AND CHAIR, PITTSBURGH REGIONAL HEALTHCARE INITIATIVE, PITTSBURGH, PENNSYLVANIA

Dr. FEINSTEIN. Thank you, Madam Chair. I also want to express the regrets of Secretary O'Neill, who is in Kuwait, who would be here to testify. His testimony is on the table. Secretary O'Neill and I, before he was Secretary, Co-chaired the initiative that you referred to, the Pittsburgh Regional Healthcare Initiative, which we view as a vast learning network involving the total collaboration of all the hospitals in our region to reduce medical error, hospital-acquired infection, and most importantly, Madam Chairman, to follow through on what you suggested, which is the critical systems redesign on all levels, so that people within health care can do things right.

That is so critical to us because getting to the root cause of patient safety issues really isn't another layered-on activity with all the other things we layer on at the hospital level, but it is part of

a total systems redesign, a new way of regarding the health care enterprise that is so critical to overall process improvement.

At the moment, we are the first region in the country where competing hospitals have come together in total collaboration, to count every medication error and infection, count them the same way, and share that information openly. Thirty hospitals, twenty corporations, four health plans, a small business purchasing coalition, hundreds of health professionals have all come together, many of whom have signed contracts pledging themselves to work toward zero perfection goal in medication errors and in hospital-acquired infections.

As I wanted to mention, even though we have come together, we have all installed the same databases and we are using and sharing information, I do want to assure you, because this issue has been raised, our hospitals are no less rancorous and competitive than any others. As I like to say, our health system is just as sick as any other community's. It is not because everybody gets along in Pittsburgh that we are able to collaborate.

The reason we have been able to come together is a collective awareness of the scale of the problem, of the errors that plague our hospitals and the overall system errors, not just medication and infection, that result in waste, overuse, inefficiency, and often a lack of applying the best practices even though there is good knowledge to suggest what we should be doing.

The core in our mind of what was wrong is that our systems have lost a collective focus on helping care teams deliver the right care every time for every patient, which leads to the inevitable imprecision, waste, and errors about which we have convened today. When we realized that the systems issues were the root of the problem, we wanted to look at a powerful model for process improvement, and we turned to Alcoa. We couldn't find anything as powerful.

We wanted to look at some organization, that had adopted a successful framework for quality and safety, so we went to Alcoa. Alcoa is headquartered in Pittsburgh, and it had the best safety record in the world. Think of this, it is 18 times safer to work in Alcoa with molten metal and sheaves of aluminum, all four edges are like knives, than it is to work in your average hospital.

So we were looking for something powerful in the way of process improvement that would move us to the kind of systems change that we had seen at Alcoa, engaging every professional at the point of care in becoming an improvement scientist, helping everyone look at each problem, each error, as an opportunity for learning, for the root cause analysis, experimentation, measurement, and shared learning you have heard here.

I would like to echo Don Berwick's comments. We really couldn't be doing what we are doing now in our collaboration, with our databases installed to capture our hospital acquired infection data and the shared learning that is going on, without the Centers for Disease Control Prevention (CDC)and their NNIS, the National Nosocomial Infectious Surveillance, system for measuring infection.

Obviously, good data entry, analysis, attempting solution and then sharing the learning, are essential. Believe me, the databases

alone, without the support in how to use them and how to gather learnings, wouldn't get us to where we are.

Let me quickly say, the kind of support that we would love to have, that we would need from the Federal government to get to this system of perfect patient care to which we aspire, is increased confidentiality protections. We can't deal with errors, we can't solve them to root cause, without confidentiality protection.

Second, we need support for an environment where these clinical data systems and other methods we are using to get better patient outcomes, where constraints are removed, rewards are introduced. Expanding a Federal partnership, working with CMS, AHRQ, CDC, and others to continue doing this is incredibly important to us.

One of our most powerful learning tools as well as our databases is observation. We want to engage the appropriate Federal agencies in direct learning and more collective observation at the point of care, to see where rules and regulations and other constraints impede our efforts to bring about the systems change.

We suggest Federal support for more demonstrations applying successful industrial models, such as the Toyota Production System model we are using, in local hospitals. We would also like to see training in safety, both worker and patient safety and systems improvement, a core component of the education of all health professionals.

We would also like to see more medical research and education funding dedicated to improving quality of care delivery at the point of care. We need new knowledge about how to deliver health care, and how to apply the knowledge we already have more perfectly. Along with that, of course, I would like to suggest we would benefit from experiments in methods of payment that provide incentives for doing the right thing at the right time. We have tried very hard to enlist the professionals at the point of care as the driving force in our initiative. I want to emphasize how important I think that has been to us, and the fact that they are allowed to experiment and come up with their own solutions is a critically important learning tool.

Thank you very much.

[The prepared statement of Dr. Feinstein follows:]

Statement of Karen Wolk Feinstein, Ph.D., President, Jewish Healthcare Foundation of Pittsburgh, Pennsylvania, and Chair, Pittsburgh Regional Healthcare Initiative, Pittsburgh, Pennsylvania

Chairman Johnson, Congressman Stark and distinguished Members of the Committee:

I am Karen Wolk Feinstein, Chair of the Pittsburgh Regional Healthcare Initiative (PRHI)—a community-wide effort to establish Southwest Pennsylvania as the world leader in patient outcomes—including perfect patient safety.

On behalf of the more than 30 hospitals, 20 corporations, four health plans, small business purchasing coalitions, unions, government officials, and hundreds of physicians, nurses pharmacists and other clinicians that constitute PRHI, it is an honor to be asked to testify today.

Two days ago, in downtown Pittsburgh, CEOs from the region's competing hospitals met to openly review patient safety incidents in their institutions and to discuss powerful leadership approaches to address those errors. Today, I'd like to tell you why this is happening in our community, describe help we have already received from federal partners, and note how federal policy can help efforts like ours, if the intention is to fix healthcare systems "from the bottom up."

For us, addressing safety issues is not adding another layer of activities for hospitals and other healthcare providers. Achieving safe practices is integrally connected to the entire process of restoring each patient to health as quickly as possible.

To err may be human, but failure to share those errors, learn from them, and prevent them from happening again is unforgivable. Cloaked in darkness, secrecy and fear of reprisal, medical mistakes are not used for learning, so they are repeated. Like Sisyphus, we err and err again because we do not fix our systems after each error to prevent future ones.

That is why, in American health care today, a hospital patient has a 7% chance of contracting a preventable hospital-acquired infection during their care, and a 2.3%–4.6% chance of being damaged by a medication error.

The scale of damage is stunning. Recent anthrax attacks took five innocent lives. Healthcare-acquired infections are associated with 88,000 deaths each and every year, and afflict more than two million Americans a year. The direct financial cost of caring for these infections in our region alone exceeds $110 million per year. In fact, our first data sharing efforts show that just one type of infection (blood stream infections) in intensive care units costs our region $15 million a year. As this Subcommittee knows, the story isn't any better for medication errors. They wound or kill approximately 770,000 Americans annually. But these aren't the only costs associated with errors.

The reason errors occur at shocking rates is also the reason why the American healthcare system is staggering on so many fronts, including escalating costs and rising dissatisfaction among all healthcare workers. What is that reason? We have lost our collective focus on helping care teams deliver the right care, every time, for every patient. Imprecision, waste, and errors are inevitable.

To regain our focus on the patient and to learn how to create a better performing healthcare system in our region, more than 30 hospitals and PRHI's other coalition members have formally committed to working together to eliminate medication errors and healthcare-acquired infections. (PRHI hospitals are also working to perfect patient care in six areas of clinical medicine).

In setting this framework for change, we drew our inspiration from Alcoa, which is based in Pittsburgh, and PRHI's founding Chair, now-Treasury Secretary Paul O'Neill. In 1987, when Secretary O'Neill became its CEO, Alcoa publicly committed to eliminating workplace injuries. Over the next 13 years, all of its employees worked together to learn how to do so, from the maintenance worker in Brazil to the CEO in Pittsburgh. Alcoa is now the safest workplace in the world. In 2002, Alcoa—a heavy manufacturing company with 140,000 employees in 37 countries—is 18 times safer to work in than the average hospital.

It is no coincidence that over the same period, Alcoa experienced dramatic overall gains in its business, becoming by far the world's largest, most efficient and most profitable aluminum producer.

To move decisively toward those kinds of results in our community's healthcare delivery system, we have become the first region in the country where competing hospitals have begun efforts to count every medication error and infection, count them in the same way, and share that information openly for the purposes of learning.

We have had extraordinary help from federal agencies and national resources. The Centers for Disease Control in Atlanta has been a generous strategic partner in attacking healthcare-acquired infections. Recognized as a world authority in infection control and public health, the CDC has been collecting hospital-acquired infection rates through the National Nosocomial Infection Surveillance System (NNIS) for 30 years. NNIS has, however, historically been available only to hospitals that meeting rigid criteria, due to funding and other constraints. CDC generously made a variant of its NNIS system available to each PRHI hospital. CDC also provides extensive on-site instruction and support for our efforts. Our first shared target for surveillance and improvement, initiated April 1, 2001 has been a catastrophic type of blood stream infection occurring in intensive care units. We are moving on to other critical infection types this year.

To report and learn from medication errors, PRHI's partner hospitals have all agreed to use U.S. Pharmacopoeia's MedMARx system, a web-based error reporting tool that allows healthcare workers to describe errors and their contributing causes according to the most credible national standards, and to learn from the experiences of other hospitals in the system. PRHI hospitals share their information regionally as well as nationally. Pittsburgh area hospitals constitute less than 5% of the hospitals contributing error reports to MedMARx, but have provided approximately 15% of the errors reported to MedMARx to date. This does not mean that Pittsburgh

hospitals have more medication errors. On the contrary, just that they are more committed to error reporting—the first critical step in error prevention.

In September, our patient safety efforts were given a critical dose of support from the Agency for Healthcare Policy and Research (AHRQ). Under a generous AHRQ grant for studying the implementation and use of patient safety reporting systems to the University of Pittsburgh, PRHI, and a number of local and national research partners, including Carnegie Mellon University, RAND and Purdue University, we will accelerate the pace of our patient safety programs by refining how to translate the information contained in patient safety reports into knowledge in front-line healthcare workers that actually protects patients. With AHRQ support, we can also generate insights to share with the rest of the country regarding effective and less effective strategies. AHRQ has constructed a national learning network for grantees that will be an important resource for us.

The direct support of these federal agencies, together with a generous grant from the Robert Wood Johnson Foundation and a strong base of funding support from local corporations and foundations, has been indispensable.

We believe that federal health care policy can further aid efforts like ours, if it addresses the root cause of under performing health delivery systems and supports strategies for reducing error and improving performance at the point at which patients are cared for.

Enlightened federal policy can succeed where previous "quick fixes" have failed if it relies less on mandates, regulation and punishment, and more on helping health care teams get care right by creating learning networks. Here are some key steps:

- **Increasing confidentiality protections for reporting and learning from medical errors** without lessening a patient's right to information about their own medical care. We cannot stress how important an expanded zone of protection beyond today's loophole-filled state peer review statutes for discussion about medical errors will be to future progress. When punishment, ridicule and legal exposure drive reporting underground, learning does not occur. Like aviation, nuclear energy and other high-risk industries, the government must act decisively to protect the reporting, analysis and sharing of information about errors and near misses. Extending the confidentiality protections of Medicare's Peer Review Organizations (now called QIOs) to reporting on all of an institution's patients would be welcome, but healthcare institutions will respond most powerfully if protection is extended to other major error reporting systems, such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and MedMARx, particularly if the hospital is required to participate.
- **Increasing support for the quality improvement efforts of clinicians and institutions**. The federal government, together with allied organizations such as JCAHO and the National Committee on Quality Assurance (NCQA), can and should expand technical assistance efforts to support quality improvement efforts within institutions and communities. Government can also provide financial incentives for healthcare institutions to install and use error reporting and prevention systems, as well as clinical data systems that link processes of care with patient outcomes. Helping to set universal standards and definitions for these measurement systems would also be a critical government contribution. The CDC and other federal agencies are poised to help more institutions and communities establish these kinds of critical learning infrastructures, if resources can be made available.
- **Expanding federal partnership with local communities and rewarding local initiative.** Just as government can increase its investment in quality improvement efforts within individual institutions, it can add enormous energy to community-wide efforts like PRHI by participating in learning partnerships with coalitions like ours. The problems in health care are too complex to untangle from Washington. Only by getting out to where care is delivered, and observing how we can help care teams learn to deliver the best care precisely, will the path to addressing America's continuing health care crisis become clear. We are working with other like-minded health systems improvement efforts around the country to establish just such a grassroots learning network, and would welcome participation by federal agencies.

We also recommend the following federal policy steps:

- Invest in demonstrations applying successful industrial models, such as the Toyota Production System, to health care. (We have such experiments underway at five local hospitals).

- Make training in safety and systems improvement a core component of medical education.
- Increase medical research funding dedicated to encouraging academic physicians and institutions to become more deeply involved in measuring and improving quality of care.
- Accelerate experiments in methods of payment that might better reward "the right care at the right time." And provide relief for federal/community partnerships where it becomes clear that specific regulations impair patient outcomes or efficient care delivery.

In exchange, individual healthcare institutions and communities like ours are obligated to create the kind of learning network I have described, to create regional healthcare delivery systems fundamentally committed to and capable of performing at the highest levels.

The partners of PRHI are committed to this framework for change. We are honored by your interest in our work. I look forward to your questions and comments.

Chairman JOHNSON. Thank you. I thank the panel for their thoughtful remarks.

I want to ask two questions. The first one is, some of you have had very direct experience in creating what one of you referred to as a culture of safety. Many of you mentioned openness, transparency, that you have to be able to let people and encourage people to say whatever is on their mind, if they observed something they thought was odd, and so on and so forth, so that there is free and open communication. What is the relationship to creating that kind of system and also having whistle-blower protection? Dr. Bagian?

Dr. BAGIAN. This is Jim Bagian.

Chairman JOHNSON. Am I saying that right?

Dr. BAGIAN. Bagian. That's fine.

Let me tell you experience we have had, you know, because we have had to deal with this, certainly. The big issue is that the care giver doesn't view it as punitive when they go to do it, and we don't have whistle-blower protection per se, though there is some that exists.

Within our system, if you submit data or there is data in the safety or quality system, you may not divulge that to anyone, and there actually is a criminal penalty of, I think it is like a $10,000 fine and 6 months in jail, for disclosure of anything in there. So people understand when they submit into the quality system that it is to be used for quality and safety improvement and nothing else. That has always been very clear, and from a leadership standpoint we have always been very aggressive to enforce that.

The other thing is, as I mentioned before, the whole definition of getting people to even want to trust the system, that they have to see it will do good. That is where we saw a ramp-up over the first 10 months of the new system, that they saw reports of the same type of incidents that had been reported in the past. There is like nothing new under the sun, pretty much. The problems that occur today have occurred for eons, certainly decades.

When they saw the results were more systems-oriented, that made a huge difference to the culture change, and that is why we saw the dramatic increase in reporting and as far as actual really meaningful solutions that actually prevented problems, rather than just document problems, which really doesn't do much at all. So I think it is people have to understand how it will be used, and then

you must demonstrate it, and leadership, and I can't emphasize this enough.

One of the things we did is at every facility, the facility chief executive officer has to actually concur or not concur with each line item of a recommendation that a team—this is a team of nurses, physicians, pharmacists—says this is what needs to be done. If they nonconcur, they have to put in writing, in the record, why they don't concur, and then it goes back for revision, but they can't just say, "I don't like to do this."

That has caused tremendous better communication within the hospital in general, and actions taken, because where the accountability, if there is any, resides, if you want to look at it that way, is with the chief executive officer of the hospital, that they take responsibility that these improvements will be made. I think when people—and we have gotten reports from the field that people can't believe that problems that were dealt with in a punitive manner before actually are dealt with in a constructive manner, that they actually see improvement, and that kind of primes the pump and it builds on itself.

Chairman JOHNSON. Thank you. Anyone else wish to comment? Mary? Ms. Foley?

Ms. FOLEY. Yes, thank you. I think it is an excellent question. I think it is consistent with the environment of both the blame-free and the non-disciplinary approach. I mean, the ultimate, not the ultimate sacrifice but a severe sacrifice for someone who believes it is imperative for them to professionally report an incident or a practitioner is the loss of a job, and that indeed is what we are attempting to prevent by passing the whistle-blower protection.

So, it is an extreme type of discipline or intervention that really just puts a, casts a pall over people's belief that it is the right thing, it is the necessary thing to do. It is not the only approach. I think there are many levels of just that stimulating the reporting in an environment in which it is safe, that it is protected, that it is promoted. The whistle-blower is an extension of that same type of protection for that more severe action, and we see it connected because that whole attitude, that there are costs to doing the right thing, has to be eliminated or people will be repressed, and that is unfortunate.

Chairman JOHNSON. Dr. Miller?

Dr. MILLER. I certainly agree with what has been said already. I would just add that within an organization, often you want to promote the culture of reporting but you also want to make that easy to do, and it is not always so easy. It takes time to report. The reporting can be confidential or not confidential.

In terms of whistle-blower kinds of things, we certainly have those things in place in our organization, but we actually tie it to a little bit of what Dr. Bagian was talking about. If someone wants to report an error, they can do it confidentially, they can do it by phone, they can do it in writing, but we have a policy that within 5 days we get back to them.

Whoever, if they say who they were, we not only protect them for reporting it and encourage it—and my report card internally is to have more errors reported this year, not fewer—but that we have an obligation to get back to whoever blew that whistle, if you

will, and tell them what our action was. Sometimes there is no action that can be taken, but they deserve a response, and I think that takes care a lot of the disgruntled employee, or nurse or pharmacist or doctor that says, you know, "I can't bother complaining anymore. Either they will go after me or they won't do anything about it anyway."

Dr. FEINSTEIN. Madam Chairman?

Chairman JOHNSON. Dr. Feinstein?

Dr. FEINSTEIN. Can I say one thing, too? I would de-emphasize issues of whistle-blower protection and focus on developing a positive reward system, with incentives that a chief executive officer who is really committed to solving problems and having an error-free environment would endorse. Certainly that is something we learned when we observed Alcoa. If there is a passion for this, if the person at the top says, "This is a learning environment, we are here to learn, we are not here to hurt anybody," it creates an environment and culture that is so important to error reduction.

Anything that can be done to support that should be encouraged. We do have an example of a hospital among all of our hospitals who is doing the most reporting on medication error. I would say it is the culture at the hospital and the support of the chief executive officer that is bringing forth so many errors. They report many times, multiple times the number of errors that any other hospital does. They have the same protections, and we have great belief in protections. They have no more, no less than anyone else, but they have a chief executive officer who really supports this.

Chairman JOHNSON. Dr. Berwick?

Dr. BERWICK. One quick word on that. If a system needs whistle-blower protection, it isn't going to get safe, because it means there is fear in the system. I think you should have the protections, but don't expect—that is not culture change. That is just good police work.

Let me explain for a second what happens in a hospital where the culture change exists. You just get the other image in your mind, is what Karen said. Take Luther-Middleford Hospital in Eau Clare, Wisconsin, a great place. The chief executive officer there did what Karen said, she said, "We can't be safe if we don't know what's going on. I will be behind you. Tell us what's going on." Nursing reports of injuries to patients went up 40fold within 3 months.

The local newspaper got hold of it and ran a headline, said "Hospital Injuries Increase 40-Fold." They got it completely wrong. All that happened was, it became a transparent system and finally they could get to work on it. The courage it took on the part of that executive and the board to do it, and then to go to the community and say, "No, let us explain what happened," that is what culture change and leadership looks like. So do whistle-blowers, but we are after a different phenomenon in the industry, which is a different kind of courage at the executive and board level.

Chairman JOHNSON. Thank you. I do think that leadership is key, and nothing will happen without it, and no amount of law or whistle-blower protection will change the culture if there isn't leadership.

You might all think about, how can we hold the top executive more accountable for that leadership, as opposed to providing whistle-blower protection? Because in the end culture change can't be done negatively, it has to be done positively.

Now, I separate this entirely in my mind, although I know they're not entirely separate, from this issue of mandatory overtime which I think is a very serious development in our system, and will carry with it enormous potential for errors if we don't do something about it. So, you know, I want to recognize that, because I have had some terrible examples come to my attention of the abuse of mandatory overtime. I think nonetheless cultural change cannot be legislated from Washington, so the question is, how do we change the way we hold our systems accountable and look at you?

Then I want to just get back to this issue of cost. You have given us some very good information about the initial cost. It is clearly multi-million. Why is it that our capital payment system isn't sufficient, or is it?

We no longer make you prove that you made capital expenditures in order for us to give you capital payments. There is sort of an automatic capital payment system now that gives you money, assuming all of the kind of technology change and the various things you have to do to upgrade your operating rooms and so on. So, why isn't that sufficient to focus on this issue, or is it? Dr. Miller?

Dr. MILLER. Unfortunately, it is not. I can give you an example from Danbury. We do run in the black, and we have dollars that are available for capital purchases every year, and the price tag on those purchases, capital purchases or renovations, goes up annually. Pharmacy costs are going up double-digit annually. New technologies that we need to have in order to provide quality care to our patients, I don't mean something esoteric or to compete, I mean quality care for patients, those things cost more money.

Very specifically, we talked about the dollars for computerized physician order entry. A single example, one 371-bed hospital. This fiscal year, our clinical leaders for capital equipment purchase requests was $50 million. I had $20 million to spend. That means $30 million that was requested, not for frivolous things but for replacement items, renovations, fix this, the physical plants that weren't as sturdy as they once were, they were built 25 years ago, new technologies that a new surgeon wants in the operating room, all those things cost money. I don't have enough money for this year's requests. New technologies like physician order entry, and I had to get the budget to approve that, meant there were $2 million worth of things that I couldn't buy instead.

Chairman JOHNSON. Thank you very much. Dr. Berwick?

Dr. BERWICK. Thank you, Madam Chair. I want to divide the capital question into several categories because it is not one problem.

First problem, wiring physician offices. Five years from now there is no reason in this country we should have handwritten prescriptions. There is no reason any physician shouldn't have access to a hospital medical record for one of his patients. There is no reason we shouldn't have a master drug list.

For an average doctor, it is a small amount of capital, $10,000, $20,000 to get into that world, but a lot of physician practices are having a lot of trouble getting there. We need some solution. I think it should be a public default system available to anyone, out of the VA or somewhere, where we just say, "You can have this if you want it. If you want something better, you can invest in it."

Second, small hospitals, small and rural. I don't know how big Danbury is, but there is a whole—there are thousands of hospitals that can't spend the $3 million it will take them to get CPOE. We have got to help them out.

The third, the big systems I am frankly not worried about. We have lots of investment going on, and big capital investments in enormous multi-hospital systems, they are going to make those investments. There is a little problem here on return on investment, because once you get into the world of safety and quality improvement, money is saved by the system but it may well be lost to the hospital.

I was just in Bellingham, Washington, where the hospital is supporting a community effort to improve diabetes care. They know it is going to end up reducing their revenues by $2.5 million a year because diabetics aren't going to be in the hospital, and it is a system saving that doesn't go to the hospital. We have got to solve that problem. We have to get—that is what payment for quality would look like, that creative circumstance in which, when the money is harvested out of the system, it goes back into the system in a more creative way.

The last issue is a cost-reduction thing. It is kind of how could you reduce the cost of capital? The standardization problem is very serious. Right now, investing capital for some facilities is a very risky game, because they could capitalize a system with one language and tomorrow we could end up with a different language structure and they will have wasted a lot of money or have a lot of adaptation to do.

That is why I think the safety issue is related to a national move to say, "Here are the standard languages. We promise you this is going to be here. For laboratories it will be Loink. For diagnoses it will be Snomed." Whatever we decide, let's just make a decision and say to the Nation, "Now you can be safe in investing."

Chairman JOHNSON. Just briefly, do we know enough to establish a single standard language?

Dr. BERWICK. There are six standards we need, in my opinion; four we do, two we don't.

Chairman JOHNSON. Okay.

Dr. BERWICK. Laboratories, everyone agrees that Loink is the right system. If CMS said tomorrow, "That's the system, everyone code now or we won't pay your bills in 3 years," that will get that solved.

For diagnoses I think Snomed is the right answer. It is currently owned in a proprietary way, but negotiations are underway for the government to make those public domain. We should get that done. That has been going on 18 months. It doesn't make any sense.

There is a system for dialog called HL7 which you have invested in. It could be the national standard. Everyone kind of agrees it is better than anything else.

There is the DICOM, the Digital Imaging and Communications in Medicine system.

We don't know quite yet nationally how to code drugs, medications, and we really need to. We need to have a standard medications coding system in the country.

We don't know how to code procedures yet, although there are several options. Within 6 months, if you told CMS, "Let's establish, let's have the backbone, let's say these are the systems, they're not going to change," you will save millions of capital for hospitals like Danbury, and we will get on with the job. I think it will require Federal leadership. We don't have another structure to get that job done.

Chairman JOHNSON. Thank you very much. I am going to turn to Mr. Stark, and yield the Chair to Mr. Camp of Michigan. Thank you.

Mr. STARK. Thank you, Madam Chair.

Let me just take one more crack here at EMTALA, the Emergency Medical Treatment and Active Labor Act, and the Patients' Bill of Rights bill, which has been passed in both Houses, and a section which I think has no quarrel from either side of the aisle or in either House. Is there anybody who would object to either of those standards being used?

Now, the American Hospital Association has, but tell them to get with it, Dr. Miller. I mean, I think we can find and take care of that, and I think everybody understands that it is the issue of the subordinate who reports to their supervisor, who ignores them, and then the subordinate goes elsewhere. Arguably that is not desirable, but it probably is more desirable than having a subordinate who will suborn those issues. I think we could get that one taken care of pretty quickly.

The issue of capital and getting the system working just may very well be a problem in the system. When you allow or encourage, depending on what State you are in, a lot of competition and oversupply, when you are running less than 60 percent of staff-bed occupancy, then you have got to say, "Well, wait a minute." Or when you have got to make the case that you want to buy a computer system for a 20-bed rural hospital. It would probably cost almost as much as it would for your hospital, Dr. Miller, but you have got 20 times more people that you are serving.

That politically, you know, you can't get any of my colleagues who want to close the hospital, as small as it may be, on their watch. Nobody builds statues to us in our home district for closing a hospital or a post office. So we have got to find some way for the communities to get off stage, to perhaps consolidate, to share equipment. I don't know, we aren't going to be able to do that, and that is part, I think has got to be part of this.

In the costing, one of the things that occurs to me is that you all in the hospital business don't take your recalls. I take my car in to get it tuned up and they do something, the dealer has to fix it for free if they screwed up, right? I go to the hospital and something happens subsequently, poor Blue Cross has got to pay again to send me back.

Now, if we changed the system and you had to do your own recalls, that is either a loss of revenue or an increase of cost, you

slice it either way you want, and I suppose you ought to be compensated for that. I mean, I think if that is part of what is having people drag their heels on this, and I don't know whether they are so harsh that they are willing to say, "We won't do it because it's going to cost us more to correct our mistakes," I hope that people aren't thinking that way, but they may. I think that would be a valid issue for us to say, "Okay, if we are creating more procedures, then we're going to pay for it."

We are going to have to come to that same issue, I suppose, with pharmaceuticals. They are costing more. They are costing you more on the one hand, and they are probably, if they do what they say they are going to do, my Zocor, which is very expensive, means you are less likely to get me into some heart program where you make a lot of money on me.

The next thing is, what are we going to do about boutiques? As we balkanize your hospital, so all the cardiologists in Danbury say, "Uh-uh, we're going to create our own heart hospital," they are going to thumb their nose at you and pull a lot of your good revenue, high-margin revenue, out.

All of these things face you. It doesn't happen in the veterans' hospitals, I don't suppose, now, but I hope that you will work with us to address that. I don't think it does us any good. I mean, I think the balkanization thing hurts teaching hospitals, in which I have a lot of faith, and managed care plans, they aren't going to teaching hospitals if they can avoid it because it costs them more.

I think that in this overall review of safety we have to help you, but you have got to be willing to work with us. I mean, we can't just say no, we are not going to have regulation, because then we are not going to get a universal computer language.

I mean, you have to be willing to trust us that we won't impact too much, and we have to trust you that you are not going to just come and hit us all the time for more capital. When I will tell you, you ought to be thankful that Danbury is not in California, because retrofitting California hospitals for Earthquakes, we are looking at $8 or $9 billion. Our hospitals, they are doing pretty well but not that well.

So, I mean, there is a shared responsibility here, and I assure you that while some of us may be more skeptical than others about absolute tort reform, I have no quarrel with the idea of no-fault. I mean, I wrote the original bill for the District of Columbia, and driving in this city with no-fault auto insurance, and you would wonder about what we were doing those many years ago. It can work, as long as you leave the outlier for the gross negligence, because I think that threat has a salutary effect on those chief executive officers who may not just completely want to do this out of the goodness of their heart.

So, thank you for being here. Please push us, because this, we can talk this to death. There are some bills. Tell the Hospital Association to give us their bill. I mean, the Secretary can get to the drafters of legislation more quickly than I can. Let Secretary O'Neill draft a bill for us and send it over. I will introduce it for him, but we have got to get going.

I mean, this process, we won't please everybody, so I will just shut up and say that the secret is when all of you are frowning,

Ms. Foley, Dr. Miller, Dr. Berwick. Then we have got the right bill. If anybody is smiling, somebody got away with something. So let's get you all frowning, drop the gavel and say, "Go forward with a bill." I really hope we could do it. Thank you very much.

Thank you.

Mr. CAMP. [Presiding.] Thank you. I just have a couple of questions.

Dr. Berwick, you were the author of this groundbreaking study on this issue which said that preventable medical errors are the eighth leading cause of death in America, accounting for as many as 98,000 mortalities in hospitals each year, and I think this only gives us a window on hospital deaths and does not really include the number of patients injured. Do you have an estimate of the number of patients that are harmed or killed as a result of medical errors in America each year?

Dr. BERWICK. I don't have it, nor does any such estimate exist that I know of. The eighth leading cause of death figure is attached to the estimate of 44,000. If it is 98,000, it is the fourth leading cause of death, just hospital injuries. What we do know is that certain forms of ambulatory surgery centers are quite unsafe. We know there are injuries in nursing homes.

The other calculation that would be great to see would be deaths and injuries due to quality failures beyond safety hazards, for example, the failure to use the best-known medication or the failure to use the proper diagnostic procedure. That is not called an error in the errors report. That is a different kind of failure, and my own estimate is that there are many times that number of people who are suffering unnecessarily because of quality failures as there are of the more confined area of just errors.

Mr. CAMP. So, then how serious would you say this problem is?

Dr. BERWICK. The biggest opportunity for improving the health status of Americans, beyond prevention of disease, is to improve the quality of health care.

Mr. CAMP. Dr. Feinstein, you mentioned that obviously if Federal policy doesn't have quick fixes, in your testimony, and relies less on mandates and punishment and more on what you called learning networks, what would be the ideal components, just to summarize, of an error reporting system?

Dr. FEINSTEIN. Well, error reporting systems and new technologies are tools that become part of a general quality and process improvement framework. I don't want to in any way miss the opportunity to say that databases are very important. Protections so that someone can enter data on problems, all problems is critical. It is how Alcoa became the best in the world. Even more important is to embed all of these into a process improvement framework. This is what I would encourage the Federal government to do. We need to create in health care the same total safety environment that you have in aviation and the nuclear power industry.

That involves research and education efforts directed at understanding, for everybody involved in a health enterprise, how to create a quality and a safety-focused environment. Systems need to keep learning how to move continuously toward improved safety, and more application of what we know to be good practice. The partnerships we have had with CMS, AHRQ, CDC, to date have

helped us to build this improvement framework, to understand what works, and also how you are continually, as you introduce new technologies and as you gather more data, you are continually coming up with new problems.

Mr. CAMP. All right. You have mentioned that you believe State peer review statutes are inadequate, and why do you think that is so, and is that why you think we need a single national standard?

Dr. FEINSTEIN. I will speak from our own example—our Pennsylvania State peer review statutes are good. The Medicare protections through our Quality Improvement Organization, QIO, are very good, but involves only the Medicare population. Hospitals are treating a very broad base of patients. We want to learn from all our errors, all our problems. Every one is significant, even the ones that are minor, even the ones that don't hurt people.

Mr. CAMP. Thank you. The gentlewoman from Florida.

Ms. THURMAN. Thank you, Mr. Camp. I apologize for not being here for all the testimony, but we have this little stimulus package on the Floor today that we seem to all be concerned about and want to see something done with.

Beyond that, I probably just want to get some ideas from all of you. I don't know if you are familiar with a piece of legislation that Mr. Houghton and I have introduced on medication errors. It is actually—and it is being done by Senator Graham from Florida and Olympia Snowe in Maine, and there are a few differences but not much of a difference.

I am curious because we think, at least looking at the numbers, medication errors seems to be a very high part of any of this system that we are concerned about. Some of the numbers we have seen, that there have been approximately 7,000 deaths, some 250,000 nonfatal injuries. What I also find interesting about it is that by doing some of this, and I think you all have alluded to this, that because of this that it costs about $4,700 per patient admission because of these issues.

So, we put a piece of legislation together specifically to look at technology, the kinds of things we can do with technology. Jim, I know that you all have done much of this at the Michigan VA, and DOD has similar technology. I happen to have had the experience of my mother being at Walter Reed. They have a wonderful system going on out there. It is all computerized. Doctors know what is going on. Everything goes into the computer, the patient's information, what medicines and all those kinds of things. I was fascinated by what had happened out there, and certainly the VA hospital in Gainesville and others have implemented some of that.

What we are trying to do is actually give about $1 billion over a 10-year period of time to help hospitals and nursing homes, because we think skilled nursing facilities have got to be in this mix, and we also have taken a part of these dollars and we have carved out about 20 percent of those dollars going to rural health areas, because that too is something we think is absolutely necessary.

Then we have actually tried to work on a board that would be called the Medical Information Technology Advisory Board, specifically because we also think that as we get this information, as we are using with the patients, as it is working, we also know that we want to be able to transmit this information so in case somebody

needs the information for follow-up on somebody. We also recognize there is information, privacy issues come up, privacy issues that become a concern, and so the difference between Senator Graham's and our bill basically is that issue.

There will be some criticism of this bill because funding comes out of the Medicare Trust Fund. I don't want that to be where it comes. That just seems right now the best place that we can look for the dollars. We think it is a good investment, potentially saves money, and certainly would like to work with any of you on this issue. Certainly, based on your comments, there is not money in these hospitals. There is not anything to be able to be done with capital improvements. That is going to create a problem.

Just based on my explanation of what we have done here, can you give me a little bit of feedback on whether you think that this might be something that could work, would be helpful, and what we can do to get this moving?

Dr. BERWICK. I will start. I am sorry, I was aware of it as the Graham-Snowe bill. I think it is a good idea. I think it would at least get some acceleration into the system.

Here are two ideas. One is, continue as you are to make sure the money goes where the need is. Industry ought to be obligated to obligate capital to this when it can afford it. So as long as you are targeting rural, small areas, hospitals that are in underserved communities, I am happier that we are not offering money where it won't make a difference.

The second is an idea I have got. I have no way to know how to put it in the legislation, but I think it is a good idea. Why reinvent the wheel over and over and over again for a thousand rural hospitals, or if you want to go to physician offices, for 20,000 physician offices?

Could it be a government task to fund and create a single national default option which is available at extremely low cost as the basic system, so we could say to rural hospitals or to physicians' offices, "You can have this one. The VA built it. They put the money in. It's your money. It's your tax dollars." Or if not VA, someone else. "It's yours. You can have it for free. If you want to buy something with higher end or higher functionality, of course feel free to invest money further."

No one is going to do that, and it would really accelerate the action a lot. We have spent public dollars on wonderful systems that, with some adjustment and some investment, perhaps under your legislation, could become a national gift, I guess, to the system that is having trouble getting over this capital threshold. It would save in aggregate nationally lots of money, because then we won't have a thousand places doing a thousand different things. We will have one system that everyone can use.

Mr. CAMP. Just quickly, we do have a recorded vote with 8 minutes left, so if you could just quickly sum up.

Dr. MILLER. A couple of quick points. I am interested in the legislation. I don't know all of its details. I am a little anxious about designation of dollars more to rural hospitals. I would want to make sure we are putting the dollars where they need to be.

Ms. THURMAN. It is 20 percent. It just carves it out of 20 percent, so they don't get left out of the system.

Dr. MILLER. They shouldn't be, but the middle-size community hospital is often the one that should have more complicated systems in place, because it is big enough and may not have the resources.

The source of dollars is always problematic. We talked earlier aboutsources. Taking it out of Medicare funds is just going to take it out of one pocket and put it in the other. It is not going to solve my problem.

The third, I will be brief, but it is an issue. The whole business of cost savings with new technologies, I believe in it, I believe in that $4,000 figure. I have read the studies. I think those savings are way down the line, and they are illusive. The Advisory Board has published four stars for quality for physician order entry, and that is why we should do it; one star for cost savings. That will be hard to achieve.

Ms. FOLEY. I will sum very quickly, as well. Thank you. I haven't looked at the bill, but it sounds good, because the most difficult position that good administrators are put in is to choose where to spend their money. If they have to choose between technology and adequate staff, that is a terrible position to put good people in, so additional incentives for the pursuit of the technology while we also provide the adequate funding for the people.

The U.S. Pharcacopeia, USP, study showed that primary contributing factors to medication errors were distractions and work load increases. So, though we know there are some savings and error prevention to be achieved, we don't want to just go off in one direction. That is why that system approach, which is what we are all about, is very good. It sounds very exciting. Thank you.

Ms. THURMAN. Thank you all very much.

Mr. CAMP. All right. I want to thank you all for your very helpful testimony, and this Health Subcommittee hearing on health quality and medical errors is now adjourned.

[Whereupon, at 12:31 p.m., the hearing was adjourned.]

[Submissions for the record follow:]

Statement of the American Academy of Family Physicians, Leawood, Kansas

Introduction

This statement, submitted to the Ways and Means Health Subcommittee regarding patient safety and health care quality is offered on behalf of the 93,500 members of the American Academy of Family Physicians (AAFP).

The Academy Finds the Creation of a Non-Punitive Environment a Mandate for Safety Reporting

The Institute of Medicine's report, *To Err is Human,* released in December 1999, highlighted the unacceptable frequency of health care errors. All patients need to know they can rely on their physicians to do the utmost to bring about the best possible medical outcome. Such assurance requires that patients are as free as possible from harm due to medical errors, regardless of the setting. Unfortunately, the IOM study makes clear that adverse events occur with unacceptable frequency. It is timely and appropriate for this aspect of quality in the delivery of health care to become the focus of nationwide attention and efforts for improvement. Today's hearing focuses on how Congress can help initiate a patient safety reporting system to promote quality health care.

In the US, most healthcare contacts are made in office settings; most office-based care is primary healthcare; and family physicians provide more primary healthcare than any other specialty. In 1998 in the US, there were 39 million hospital discharges and 829 million outpatient visits, suggesting that ambulatory care may hold

an even more important opportunity for improving patient safety. A recent study of the ecology of medical care confirms this large, relative difference in exposure to outpatient and inpatient care. This study, based on data from the Medical Expenditure Panel Survey (a nationally representative, longitudinal survey sponsored by the Agency for Healthcare Research and Quality), found that for every one thousand patients in a month, 217 would be seen for a medical condition in the outpatient setting and only eight to nine individuals would be hospitalized.

Three years ago, the AAFP made a $13 million commitment to improving the research infrastructure for primary care ($7.7 million for three Centers, and $5.3 million for the Robert Graham Center for Policy Studies in Family Practice and Primary Care). In the last year, that investment contributed the first US study of errors in ambulatory care. The Robert Graham Center and the AAFP National Research Network learned from 43 practices across this country what physician-reported errors look like. These findings are currently in peer-review at the international journal, *Quality and Safety in Health Care.* The Academy recently launched a six-country study to look at errors in similar clinical settings in the U.S., New Zealand, Canada, the Netherlands, Australia and England so that patient safety and quality improvement projects could benefit from comparison with other countries.

The Academy has been awarded an innovation grant from the Agency for Healthcare Research and Quality (AHRQ) to develop a Center of Excellence that will identify, test, and disseminate strategies for making primary health care safer. One strategy already in use is a computer web-based anonymous error reporting system that has so far proved effective not only in identifying threats to patient safety but also in improving more general aspects of primary health care quality. The success of the Academy's error reporting system beyond initial testing stages will depend upon Congressional efforts to ensure that information reported remains confidential, is protected from use in legal actions and will not be used in separate punitive actions as a result of a report having been filed.

Finally, the Academy believes that there is a need for error-reporting systems that are "open, discussible and without blame," in the words of Dr. Donald Berwick, one of the IOM study authors, and an invited guest of the Subcommittee. Only by researching the underlying cause of medical errors, creating effective interventions and addressing future prevention, can the IOM's call for a 50 percent reduction in the rate of medical errors over the next five years be realized.

Additional Principles That Need to Be Incorporated into Patient Safety Legislation

The Academy supports the following principles as integral to creating a learning culture that actively seeks to improve the delivery of health care.

Analysis and Feedback

Reporting systems cannot become warehouses of data. Information submitted to reporting systems must be the basis for conducting analysis that results in changes being made to practice. When effective procedures are developed to respond to the underlying cause of patient safety events, they should be compiled and widelydisseminated to all healthcare professionals and organizations.

Confidentiality

Confidentiality protections are absolutely necessary for both healthcare professionals and healthcare organizations to trust that reported information will not be used in a punitive fashion. Without such an assurance, individuals will continue to make independent assessments about the utility of reporting their observations to outside entities. Reporting systems should protect the identity of individual patients and abide by all relevant confidentiality laws and regulations. The identities of healthcare professionals and organizations involved in errors should not be disclosed outside a reporting system without consent. This vital protection ensures that reporting systems, such as the ground-breaking system developed by the Academy, have a far greater likelihood of being successful facilitators for improving patient safety.

Information Sharing

While maintaining the confidentiality measures highlighted above, sharing information is fundamental to a reporting system's ability to achieve widespread improvements in patient safety and to instill a confidence in the public that safety issues are being addressed. The causes of errors and their solutions must be widely shared so that all healthcare organizations can learn from the experiences of others.

Legal Status of Reporting System Information

Congress should create new federal protections for information submitted to patient safety reporting systems. Informationdeveloped in connection with reporting systems should be privileged for purposes of federal and state judicial proceedings in civil matters, and for purposes of federal and state administrative proceedings, including with respect to discovery, subpoenas, testimony, or any other form of disclosure. This new privilege should not interfere with the availability of records that would be otherwise attainable, including patient access to their own medical record.

Conclusion

The Academy appreciates this opportunity to submit a statement to the subcommittee and looks forward to working with Congress to develop effective patient safety legislation. This is a matter of continued interest to AAFP and we thank the Ways and Means Health Subcommittee for its interest in the topic.

Statement of the American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons (AAOS), representing 18,000 board-certified orthopaedic surgeons, appreciates Chairman Johnson's efforts to hold a hearing to address health quality and patient safety. AAOS has long supported initiatives to reduce medical errors and improve the quality of health care not only for Medicare patients, but for all health care recipients.

AAOS shares the concerns of the Subcommittee on Health that medical adverse events must be decreased, especially in light of the recent report by the Institute of Medicine: *To Err is Human: Building a Safer Health System.* We agree that there is a need to create a culture of safety in reporting, and that we must embrace efforts that continuously strive to improve the quality of patient care.

AAOS has designated the elimination of medical errors as a high priority in our policies and practices, and, as a result, has committed significant financial and clinical resources to educate our members in the practice of safe care. We are pleased to share highlights of our work over the past several years to reduce or eliminate specific types of surgical errors.

In 1997, we launched the "Sign Your Site" initiative, an education program that urges surgeons of all surgical specialties to mark the operative site, in consultation with the patient, as part of their pre-surgery routine. This protocol has the overwhelming support of our members, who believe this program will prevent wrong-site surgery. Numerous hospitals throughout the country have responded positively to this campaign, and mandatory "Sign Your Site" programs have been initiated at an increasing number of hospitals. AAOS supports the "Sign Your Site" initiative as a required protocol for every hospital seeking certification by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). We also believe that a unified effort among surgeons, hospitals and other health care providers to initiate pre-operative and other procedures will help to prevent surgical error.

Since 1990, the AAOS Committee on Professional Liability has conducted a series of closed-claim professional liability insurance studies, through on-site retrospective review of the records of insurance companies across the country, in order to assist orthopaedic surgeons in providing optimum patient care. Several orthopaedic diagnoses and procedures have been reviewed, including foot and ankle surgery, spine surgery and spine fusion, total hip and knee replacement, knee arthroscopy, fractures of the hip, femur and tibia, and pediatric problems, and have resulted in the publication of two books and numerous articles that have identified trends in unexpected outcomes and medical errors and provided risk management. From these studies, we have been able to establish or clarify appropriate treatment protocols and methods of operation, enabling us to promote safe and appropriate surgical practice. This guidance emphasizes thorough patient consent discussions about treatment options and alternatives, risks of treatment, non-treatment, and patient expectations regarding eventual functional ability after treatment.

The AAOS Board of Directors recently created a "Patient Safety Committee" within the organization to promote safe practices and to reduce and prevent adverse events that could occur in orthopaedic practice. This permanent committee will undertake several initiatives over the next few years to enhance member and patient knowledge about safe medical practices. A few of the Committee's goals include the development of educational programs and communication publications that will alert our members to potential medical product and drug interaction complications; development of a curriculum on patient safety for adoption into residency and fellowship programs; and development of working relationships with other professional

societies and federal agencies that will focus on community based and national collaborative initiatives for implementation of patient safety improvements. A major charge to the Committee will be the continued education of AAOS members to achieve a culture of safety within their practice and to incorporate patient safety considerations into practice guidelines.

AAOS also remains a recognized leader in the process of Continuous Quality Improvement (CQI), an important cornerstone of our strategic plan that helps us provide "Best Care" to our patients. We have developed a comprehensive patient education program that will empower patients by encouraging them to take control of managing their own health care and increased communications to the public about the AAOS' own commitment to this effort. The AAOS Committee on Evidence Based Medicine remains focused on developing clinical practice guidelines and performance measures to improve quality and efficiency of care, which can be used to assist physicians in diagnosis and treatment decisions.

In addition to our internal education efforts, we continue to look beyond our own organization to work with Federal agencies and other health care organizations that support efforts to reduce medical errors. The Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ) dedicated itself under the leadership of Director John Eisenberg, MD, to conduct and disseminate research in order to improve the outcomes, quality, access, cost and utilization of health care services. We have maintained a dialogue with key AHRQ staff to continue to provide input into their research efforts and medical error projects, and AAOS Fellows have participated in discussions surrounding the formation of a key AHRQ initiative, the Patient Safety Task Force. This Task Force has begun to evaluate and explore ways to minimize the burden of reporting adverse events and errors and to explore the development of a single, coordinated system for collecting data that would be easy to use and would provide reliable, valid information.

We are active participants in the National Quality Forum (NQF), a not-for-profit public-private membership organization established to develop and implement a national strategy for health care quality measurement and reporting. AAOS remains committed to participating in the Ambulatory Surgical Care Consensus Project of the National Patient Safety Foundation, a broad-based partnership of health care clinicians, consumer advocates, health product manufacturers, public and private employers and payers, researchers, regulators, and policymakers.

AAOS, as part of a large group of national health care organizations, developed a set of key principles and safeguards that we believe should be incorporated into voluntary patient safety reporting systems.

These principles call for: the creation of a non-punitive environment for safety reporting that focuses on preventing and correcting systems as opposed to laying blame on individuals or organizations, a comprehensive analysis of data to identify where improvements can be made and new protocols should be developed, assurance of confidentiality protections for patients, healthcare professionals and organizations, the ability to disseminate and share patient safety information to facilitate positive improvements, and federal protection for reporting system information. We believe it is critical that data collected and shared for the purposes of improving patient safety be privileged, or use of patient safety reporting systems may ultimately be discouraged. (*Please see attached listing of principles*.)

As the Subcommittee evaluates appropriate responses to prevent patient harm and minimize health systems errors, policies should encourage a constructive partnership between the federal government, hospitals, physicians, and other medical providers and personnel. These public and private initiatives should be encouraged through a non-punitive, cooperative environment, and should take a system-wide approach that ensures patient confidentiality and appropriate legal protection of all information involved in patient safety reporting systems. Before instituting new reporting systems, AAOS encourages federal and state governments to determine through initial, scientifically sound research whether and how existing reporting programs have led to a reduction in medical errors.

AAOS thanks Chairman Johnson, and the members of the Subcommittee for holding this important hearing. We stand ready to work with the Subcommittee and other Members of Congress to ensure safe practices in our health care system.

General Principles for Patient Safety Reporting Systems

1. Creating an Environment for Safety. *There should be a nonpunitive culture for reporting healthcare errors that focuses on preventing and correcting systems failures and not on individual or organization culpability.*

- Healthcare professionals and organizations should foster a positive atmosphere that encourages the submission of healthcare error reports to public or private oversight organizations, accrediting bodies, an official compendial body, or other generally recognized patient safety reporting systems. The existence of a reporting system does not relieve healthcare professionals and organizations of their responsibility to maintain professionally recognized standards of care.

2. Data Analysis. *Information submitted to reporting systems must be comprehensively analyzed to identify actions that would minimize the risk that reported events recur.*

- Systems within organizations should be scrutinized to identify weaknesses and processes that make healthcare errors possible or likely to occur, and to identify actions to prevent future errors. Effective procedures and/or protocols developed through reporting systems should be compiled and widely disseminated to all healthcare professionals and organizations.

3. Confidentiality. *Confidentiality protections for patients, healthcare professionals, and healthcare organizations are essential to the ability of any reporting system to learn about errors and effect their reduction.*

- Reporting systems should protect the identity of individual patients and abide by all relevant confidentiality laws and regulations. The identities of healthcare professionals and organizations involved in errors should not be disclosed outside a reporting system without consent.

4. Information Sharing. *Reporting systems should facilitate the sharing of patient safety information among healthcare organizations and foster confidential collaboration with other healthcare reporting systems.*

- Sharing information is fundamental to a reporting system's ability to achieve widespread improvements in patient safety and to instill a confidence in the public that safety issues are being addressed. Sharing of error-related information is subject to the confidentiality principle.
- The causes of errors and their solutions must be widely shared so that all healthcare organizations can learn from the experiences of others.
- In some circumstances, it will be desirable to share reports of errors among reporting systems, and with other appropriate quality improvement entities, in order to accomplish root cause analyses, to construct action plans, and to engage in other efforts to enhance patient safety.

5. Legal Status of Reporting System Information. *The absence of federal protection for information submitted to patient safety reporting systems discourages the use of such systems, which reduces the opportunity to identify trends and implement corrective measures. Information developed in connection with reporting systems should be privileged for purposes of federal and state judicial proceedings in civil matters, and for purposes of federal and state administrative proceedings, including with respect to discovery, subpoenas, testimony, or any other form of disclosure.*

(a) Scope. The privilege for the information prepared for a reporting system should extend to any data, report, memorandum, analysis, statement, or other communication developed for the purposes of the system. This privilege should not interfere with the disclosure of information that is otherwise available, including the right of individuals to access their own medical records.

(b) No Waiver. The submission of healthcare error information to a reporting system, or the sharing of information by healthcare organizations or reporting systems with third parties in accordance with these principles, should not be construed as waiving this privilege or any other privilege under federal or state law that exists with respect to the information.

(c) Freedom of Information Act. Healthcare error information received by and from reporting systems should be exempt from the Freedom of Information Act and other similar state laws. Such an exemption is necessary to preserve the privilege discussed in this principle.

(d) Impact on State Law. A federal law is necessary to assure protection of information submitted to national reporting systems, but the federal protection should not preempt state evidentiary laws that provide greater protection than federal law. Providing such information to reporting systems should not constitute a waiver of any state law privilege.

Statement of the American Academy of Pediatrics

The American Academy of Pediatrics is pleased to provide a statement to the Subcommittee on Health of the Committee on Ways and Means on issues of great importance to pediatricians—Health Quality and Medical Errors.

Pediatricians provide the highest quality care to infants, children, and adolescents but the Academy acknowledges that there are opportunities for improvement. Our goal is to minimize errors and maximize quality. The June 2001 policy of the Academy "Principles of Patient Safety in Pediatrics" provides direction on setting up processes to identify and learn from errors, developing performance standards and expectations for safety, and promoting leadership and knowledge (attached).

Patient safety may be broadly defined as including medication use (medication errors and adverse drug events [ADEs]), wrong or delayed diagnosis, surgical errors, birth injury or nosocomial infection. Infants and children are at increased risk for harm because of their limited reserves and the increased opportunities for error entailed by weight-based dosing for virtually all pediatric medications. Because there is very little published research about pediatric patient safety issues, it is imperative that the Agency establishes a specific research agenda focusing on patient safety issues in the pediatric population.

Background: Medication Errors in Pediatrics

An important component of patient safety is medication error. The Institute of Medicine report, "To Err is Human," suggests that medication errors are the most frequent type of patient safety error. Little research has addressed the problem of medication errors and adverse drug events in pediatric settings. The lack of pediatric studies is unfortunate because children pose unique challenges, including increased opportunities for error entailed by weight-based dosing for virtually all medications, and the potential for more serious consequences of drug errors due to the limited reserves of smaller children.

Hospital Settings for Pediatric Care

In a study of complex errors in hospital prescribing, one researcher demonstrated that the likelihood of drug error is an exponential function of the number of drugs administered. A hospitalized pediatric patient receives an average of seven medications. The errors most frequently recognized in association with hospital pediatric drug therapy include computation errors of dosage and dosing interval, errors in drug orders (including written instructions and interpretation), and errors in drug preparation or conflicts with prescribed dosages. Children are at particular risk for these types of errors, as the broad range of patient age and size requires dosage individualization, most often using dosage equations.

Drug dosages for children are calculated on a per weight basis that is significantly different from calculating dosages for adults. A computation error can result in a significant under or over-dosage. One medication safety issue especially harmful in pediatrics is commonly referred to as the 'ten-fold' error (e.g., a misplaced decimal point can mean a ten-fold change in the appropriate dosage of medication). One example dramatically illustrates this type of error. Jose Eric Martinez was an ill two-month-old who exhibited early signs of congestive heart failure. In order to ameliorate his condition, the physician ordered intravenous Digoxin over aseveral day stay. However, because of a decimal point error in determining the appropriate dosage, the infant was given a dose that was 10 times what was intended and died.

In order to better structure appropriate interventions, it is critical to understand which pediatric age groups experience adverse events most frequently. The Harvard Risk Management Foundation, with significant experience in children's hospital settings, suggests that there may be particular drug distribution and administration challenges in patients weighing less than 5 kilograms (personal communication, Frank Federico). Research is needed to confirm these findings and to support the development of interventions that focus on clinical decision-making and the use of alternate medications to improve care and decrease errors.

In the only study documenting the epidemiology of medication errors in a children's hospital setting, Rainu Kaushal, MD and her colleagues found that serious pediatric medication errors (potential adverse drug events and preventable adverse drug events) occurred at a three-fold higher rate than in adults. This study provided important confirmation of the unique epidemiology of medication errors in pediatric inpatient populations and suggests that hospitalized children are at a greater risk of serious medication errors than adults are. This finding gives additional emphasis to the need for study of appropriate interventions in the pediatric population.

In a review characterizing the nature and potential consequences of actual prescribing errors involving dosage equations at a tertiary care hospital, Timothy

Lesar, PharmD, discovered that errors most commonly involved children (69.5%) and antibiotics (53.5%). Forty-two percent of errors were considered to put the patient at risk for serious or preventable adverse outcome. Errors in decimal point placement, mathematical calculation, or expression of dosage regimen accounted for 59.5% of dosage errors. Moreover, the dosage equation was wrong in 29.5% of dosage errors. The study analyzed the characteristics of 200 consecutive prescribing errors with potentially adverse outcomes involving dosage equations.

In addition, research is needed to ensure the safe administration of intravenous medications in the inpatient setting. Because the administration of intravenous medications in a pediatric patient often necessitates the use of a precise delivery system (e.g., an electronic pump), this technology presents both an additional opportunity for error as well as a potential safety check. Research could help determine whether partnership with industry to improve pediatric medication usage (e.g. explicit labeling for pediatric safety/dosing, small volume infusion devices, etc.) can help reduce the rate of medication errors for infants and children.

Because children depend on others to advocate for them, research on the role families play in reducing medical errors in inpatient settings would also be useful.

In the only published evaluation of an intervention to improve safety in hospitalized children, Folli and colleagues demonstrated that a pharmacy review of medication orders could prevent erroneous orders from being implemented at a rate of 14–18 per 1000 patients days. Dr. Kaushal and his colleagues are presently evaluating two other interventions to reduce serious medication errors in pediatrics: computerized physician order entry and clinical ward-based pharmacists with continuous quality improvement teams.

Ambulatory Settings for Pediatric Care

With ambulatory settings providing an increasing proportion of care, patients in inpatient care settings represent only a small part of the population at risk for ADEs. It is estimated that 70 percent of pediatric care takes places in ambulatory settings. This involves well-child, acute, and chronic illness care. Furthermore, although prior studies in adult outpatient populations have demonstrated that ADEs are common, costly, expensive and often serious or fatal, what is known about the prevalence and type of medication errors in pediatric ambulatory settings is extremely limited.

Pediatricians in ambulatory settings prescribe medications in more than half of patient encounters. In a recent survey of a random sample of 1,600 of its members, researchers at the American Academy of Pediatrics found that prescriptions are written for 52.9% of the patients a pediatrician sees during an average workweek. Among those prescriptions, 73.2% are for short-term acute illnesses and 29.2% are for chronic long-term illnesses. Data from National Ambulatory Care Medical Surveys (NACMS) also support this claim. Between 1993 and 1998 the number of office visits where a medication was ordered or provided increased 13.8%, from 109.1 million to 124. 3 million. These data illustrate the opportunity for medication error in children seen in ambulatory settings, yet no research has been conducted to identify common errors, develop a feasible system to report errors, or better understand practices to decrease error in these settings.

Home health care settings also pose additional challenges. Not only are there opportunities for errors in the intravenous administration of medications (e.g., prepackaged medications, preparing and disposing of syringes) but also in the management of children on ventilators and other forms of medical equipment. As in other ambulatory settings, little or no research has been conducted to identify and analyze the types of medical errors in pediatric home care settings. This is critical research given the interest in containing healthcare costs through early discharge to the home.

Types of errors occurring in pediatric ambulatory or home health care settings may include errors in physician drug prescribing (e.g. wrong dose, wrong medication, wrong route, prescribing a medication despite a known allergy, etc), pharmacy dispensing, and parental administration. Outpatient drug complications, which can be a result of a medication error, are not well studied in either adults or children. In a study by Tejal Gandhi, MD and colleagues of adult patients followed in urban clinics, drug complications in the ambulatory setting were common, although most were not documented in the medical record. No studies have been done to evaluate adverse drug events in pediatric ambulatory settings. It is imperative that epidemiologic studies document the type, frequency, and severity of errors in pediatric ambulatory settings.

Significant numbers of medications are given to children every day in schools, preschools and many child daycare settings. In fact, after the home, schools and preschools are the most common locations for medication administration to children

to occur. Systems of medication delivery at such institutions are too often sub-optimal or do not exist at all. The presence of school nurses increases the likelihood that a school district has a medication-delivery and recording protocol; however, the presence of school nurses is highly variable. In addition, childcare settings for infants and toddlers rarely have any support for health matters and little monitoring by the state agencies. Research on errors in these settings should be a priority. In addition, research is needed to design, promote, and implement standardized protocols for medication delivery in schools, preschools, child care centers, and family-based child day care homes.

Information Technology

Information technology has great potential to minimize medication errors. Computerized order entry has been shown to decrease errors. In addition, this technology offers the opportunity to coordinate care given by multiple individuals to a single pediatric patient. It is imperative that research examine the many uses of information technology in improving patient safety as well as how to influence clinician acceptance of information technology in both the ambulatory and inpatient settings.

Safe and Appropriate Use of Medications in Children

The safety of medication use in the pediatric population represents an important area of research need. This knowledge could minimize the risk and maximize the quality of care that children receive. The following are important topics for research:

Psychotropic drug use in children.

To determine the prevalence of psychotropic medication use in preschool-aged children, JM Zito, MD and colleagues analyzed ambulatory care prescription records from two state Medicaid programs and a salaried group model health maintenance organization (HMO). It was discovered that the number of psychotropic medications prescribed for preschoolers increased dramatically from 1991 to 1995. The use of stimulants, the most common class of drugs prescribed, increased three-fold in this age group during the early 1990s. These findings are especially remarkable due to the limited data on the efficacy and safety of psychotropic medication use in children. Epidemiologic studies are needed to evaluate clinical and treatment outcomes. Clinical trials are necessary to evaluate dosages, efficacy, and safety of certain drugs not approved for a pediatric age group.

Inappropriate use/overuse of antibiotics for otitis media (ear infections).

Antimicrobials are the second leading therapeutic category of drugs prescribed by office-based physicians in the United States each year. According to the 1996 NACMS, antibiotic prescriptions reached 128 millions doses compared to 86 million in 1980. From 1990 to 1992, almost one in six physician office visits resulted in antimicrobial prescription. In 1992, more than 6.5 million prescriptions were written for children with a cold or upper respiratory infection.

Otitis media is the leading indication for outpatient antimicrobial use in the United States. Overdiagnosis of and unnecessary prescribing for otitis media has contributed to the spread of antimicrobial resistance. In a recent prospective study, antimicrobial treatment of otitis media accounted for more than 90% of all antimicrobial use during the first two years of life. These data again underscore the increased risk children's health and safety when they are needlessly exposed to drugs.Research is needed to help physicians better identify which children need antimicrobials, and how to most effectively change clinicians' prescribing behavior for otitis media. Studies also have demonstrated that parents influence the physician's decision to prescribe antimicrobials. Based on this fact, it is essential that research identify effective approaches to change parents' expectations about the indications for antibiotics as well as how to improve physician-parent communication on this topic.

Reporting Systems

Based on the recommendations in the IOM report, state and national policy makers have begun to examine the role reporting systems play in reducing medical errors. However, there are significant external barriers to implementing effective reporting systems. The blame and punish philosophy and the search for individual culpability still persists. This is an obstacle to openly discussing or reporting errors. Reporting programs should be aimed at ensuring that health systems are safe for children. To do so, the reporting systems should be non-punitive, ensure anonymity, focus on system failures, recognize that adverse events may or may not be caused

by errors, and support the key role that organizational leadership plays in systems improvement.

To promote effective reporting systems that are designed to maximize patient safety, the Academy recommends AHRQ support research that will provide information to guide decision-making on the following issues:

- Understanding the relationship between organizational culture and reductions in medical error, specifically contrasting punitive versus non-punitive environments and different institutional approaches to creating cultures of safety in pediatrics.
- Determining the effectiveness of interdisciplinary safety teams with leadership sanctions in improving either rates of medical error reporting or changes in patient care systems.
- Examining the effectiveness of state reporting systems on reducing medical errors in pediatrics, including determining whether states that require mandatory board reports with disciplinary action have lower rates of medical error reporting.
- Exploring whether active error identification systems improve the yield of reported medication errors Ascertaining whether signal/trigger systems are as effective as spontaneous reporting systems for medication error.
- Exploring best ways to encourage reporting. Defining the impact of the error debate on families' satisfaction with health services.

Summary

In summary, the American Academy of Pediatrics urges the Congress to work with the medical community to address the following patient safety issues in the pediatric community:

- Testing and refining the methods for determining medication error, potential adverse drug effects, potential adverse drug effects, and adverse drug detection and analysis in both in-patient and ambulatory settings.
- Documenting the epidemiology of pediatric medication errors in both inpatient and ambulatory settings as a major step towards designing interventions to intercept errors and prevent ADEs in children.
- Documenting the epidemiology of pediatric medication errors in childcare and school settings.
- Developing and testing interventions to improve medication systems in both inpatient and ambulatory settings.
- Designing, promoting, and implementing standardized protocols for medication delivery in schools, preschools, childcare centers, and family-based child day care homes.
- Developing and testing effective reporting systems. Researching how to influence clinician acceptance of computerized order entry systems in both the ambulatory and inpatient settings.
- Studying the use of computer technologies as tools to minimize drug errors or as aids in coordinating care provided by multiple individuals.

REFERENCES AVAILABLE UPON REQUEST.

Attachment: *Principles of Patient Safety in Pediatrics*, AAP Policy statement:

Policy Statement

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Principles of Patient Safety in Pediatrics (RE060027)

AMERICAN ACADEMY OF PEDIATRICS

National Initiative for Children's Health Care Quality Project Advisory Committee

ABSTRACT. The American Academy of Pediatrics and its members are committed to improving the health care system to provide the best and safest health care for infants, children, adolescents, and young adults. In response to a 1999 Institute of Medicine report on building a safer health system, a set of principles was established to guide the profession in designing a health care system that maximizes quality of care and minimizes medical errors through identification and resolution. This set of principles provides direction on setting up processes to identify and learn from er-

rors, developing performance standards and expectations for safety, and promoting leadership and knowledge.

INTRODUCTION

The 1999 report of the Institute of Medicine, *To Err Is Human: Building a Safer Health System*, notes that errors in health care are a leading cause of death and injury.[1] Between 3% and 4% of hospitalized patients are harmed by the care that is supposed to help them. On average, of 100 hospitalized patients, 7 are exposed to a serious medication error that harms or could have harmed them. It is estimated that between 44,000 and 98,000 Americans die in hospitals each year as a result of errors in their care.[2] Although these figures have been challenged, there is no disagreement as to the importance of the topic or the existence of substantial safety concerns in health care. In response to the report, Congress and various states are proposing legislation and programs to improve patient safety.

The increasing complexity in patient care in addition to the public's increased scrutiny of the health care system underscores the need to make patient safety an issue of high priority. The American Academy of Pediatrics and its members are committed to improving the health care system to ensure that infants, children, adolescents, and young adults receive the best and safest health care.

All health care systems should be designed to prevent errors. The first step in designing these systems is to identify errors and study their pattern of occurrence within delivery systems to reduce the likelihood of adverse events. A specific concern in pediatrics is the lack of information on errors in the pediatric population and the strategies needed to minimize errors and maximize care in both the ambulatory (including schools and child care settings) and inpatient sectors. If the Academy is going to implement an effective and far-reaching agenda to address the public policy and research components of the patient safety debate, the set of principles listed below should serve as its guide.

RECOMMENDATIONS FOR IDENTIFYING AND LEARNING FROM ERRORS

1. Pediatricians are committed to bringing about the best possible health outcomes for children and their families. Because all medical interventions involve known and unknown risks, pediatricians should work with health care teams to create safe patient care environments and prevent medical errors.
2. Efforts to improve patient safety and prevent errors should focus on a systems approach. Existing research on hospital-based care reveals that medical errors rarely represent the failure of an individual caregiver. Most errors in medical care are systems errors related to equipment, complex processes, fragmented care, and lack of standardized procedures.
3. Systems should be developed to identify and learn from errors. These error learning systems should be open, promote discussion of errors without blame, and provide contextual data about the error. The Institute of Medicine has called for a 50% decrease in the rate of medical errors over the next 5 years, which can be realized only by researching the underlying causes of medical errors, creating effective interventions, and addressing future prevention.[1] These efforts must be completely separate from punitive strategies. Peer review protections should be extended to encourage participation in efforts to decrease the rate of medical errors. Currently, state and federal laws provide legal protection so health professionals can be candid during peer review without fear of legal action. This should also apply to situations in which a medical error occurs.

Error reporting systems are one part of an error learning system. We can identify and learn from errors through reporting programs aimed at ensuring the systems are safe for patients. To do so, reporting systems should:

- Be nonpunitive;

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[1] Committee on Quality Health Care in America, Institute of Medicine. In: Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err Is Human: Building a Safer Health System.* Washington, DC: Institute of Medicine; 1999.

[2] Hearings before the Subcommittee on Health Care of the House Committee on Veterans' Affairs and the Subcommittee on Health and the Environment and the Subcommittee on Oversight and Investigations of the House Committee on Commerce, 106th Cong, 1st Sess (2000) (testimony of Donald Berwick, MD, member Committee on Quality of Health Care in America, Institute of Medicine).

- Require that only the most critical events be subject to mandatory reporting;
- Require that information reported to internal and external patient safety review groups should not be discoverable in civil or criminal legal action;
- Allow individuals involved in the events to remain anonymous whether or not error is involved;
- Recognize that adverse events may or may not be caused by errors;
- Focus on systems failures; and
- Support the key role that organizational leadership plays in systems improvement.

3. Most research on medical errors is hospital based. It may not be appropriate to extrapolate the number or types of errors found in hospitals to the number or types of errors that might be found in ambulatory health care settings. Because most health care is delivered in ambulatory care settings, and in pediatrics, many medications are taken outside of the home (in schools and child care settings), research on errors in ambulatory care settings should be a priority, particularly for unique patient populations, such as infants, children, adolescents, young adults, and children with special needs. The problem of drug dose calculation errors for pediatric patients, in particular, should be explored.

RECOMMENDATIONS FOR DEVELOPING PERFORMANCE STANDARDS AND EXPECTATIONS FOR SAFETY

1. Patient safety guidelines should be developed through the coordinated actions of oversight organizations, group purchasers, and professional groups. These guidelines should be reasonable and based on a true assessment of the risk level associated with the specific patient safety intervention. In addition, recommended safety strategies should be flexible enough to allow health care providers to adapt them to varied delivery settings and to pediatric patients' needs.
2. Health care organizations should take into account unique pediatric safety issues. These include particular attention to the potential for errors in care attributable to changes in patient weight and physiologic maturation, limited capacity for cooperation in young children and high levels of dependency on others, and the relative rarity of most pediatric illnesses and accordant lack of widespread familiarity with their care. As uniform regulations and guidelines are developed, they should encompass the service delivery systems and their variations. The goal of pediatric patient safety systems inside health care organizations should be the implementation of safe practices.
3. Information technology has great potential to minimize medication errors. Computerized order entry has been shown to decrease errors and coordinate care given by many individuals to a single pediatric patient.[3] It is imperative that research examine the many uses of information technology to improve patient safety and ways to facilitate clinician acceptance of information technology in ambulatory and inpatient settings.
4. All individuals involved in providing health care to children should work together to:

   - Develop and enforce standards for the design of drug packaging and labeling that will maximize safety in use;
   - Require pharmaceutical companies to test proposed drug names to identify and remedy potential "sound-alike" and "look-alike" confusions with existing drug names;
   - Establish appropriate responses to problems identified through postmarketing surveillance, especially for concerns that are perceived to require immediate response to protect the safety of patients; and
   - Support expanded efforts to include children in new drug trials.

RECOMMENDATIONS FOR LEADERSHIP AND KNOWLEDGE

1. The Academy supports the creation of a Research Center for Patient Safety within the Agency for Healthcare Research and Quality. The Academy urges that this center be adequately funded to address the protection of all patients.

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[3] Kaushal R, Bates DW, Landrigan C, et al. Medication errors and adverse drug events. *Pediatr Res.* 2000;47:201. Abstract 1188.

2. Health care organizations should demonstrate their commitment to pediatric patient safety by establishing patient safety programs with defined executive responsibility in all settings where medications are delivered or care is provided to children and by developing a culture of improvement. Patient safety programs should:
   - Provide strong, clear, and visible attention to safety;
   - Represent a collaborative effort of physicians, nurses, allied health personnel, and administrative staff who have experience with and knowledge of patient safety;
   - Incorporate well-understood safety principles, such as standardizing and simplifying equipment, supplies, and processes;
   - Implement proven medication safety practices;
   - Establish interdisciplinary learning programs; and Address the special needs of inpatient and ambulatory care environments.
3. Research that explores the effect the error debate has on families' satisfaction with health care services should be conducted.

Promoting safety requires changing the culture of medicine to recognize that the potential for errors exists and that teamwork and communication are the basis to guarantee change. The promotion of patient safety and the decrease in the rate of errors should become one of the major goals of the Academy. Safety should be viewed as one component of a broader commitment to providing optimal health care for children—a goal that the membership embraces and that unites pediatricians with the families they serve.

NATIONAL INITIATIVE FOR CHILDREN'S HEALTH CARE QUALITY PROJECT ADVISORY COMMITTEE
(NICHQ PAC), 2000–2001

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The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

Statement of David G. Schulke, American Health Quality Association

The American Health Quality Association represents independent private organizations—known as Quality Improvement Organizations (QIOs)—that hold contracts with the Centers for Medicare and Medicaid Services (CMS) to improve the quality of care for Medicare beneficiaries in all 50 states and U.S. territories.

Congress created the QIO network to monitor and improve the quality of care delivered to Medicare beneficiaries and supports the work of the QIOs with about $300 million annually from the Medicare Trust Fund. In the early years of the program, QIOs were known as Peer Review Organizations and focused on oversight—on catching "bad" doctors and hospitals. However, over the past decade QIOs have dramatically changed their approach.

QIOs today work directly and cooperatively with hospitals and medical professionals across the country to implement quality improvement projects that address the root causes of medical errors. QIOs today are working to accomplish what this committee—in its announcement of this hearing—suggests should be a major bipartisan goal: resolving endemic problems that result from failing systems of care.

QIOs are improving the quality of health care not only by targeting errors of "commission"—medical errors that make the headlines—but also by systematically working with medical professionals to reduce errors of "omission" that result in care that falls short of evidence-based medicine. Examples of errors of omission include

failure to administer antibiotics prior to major surgery, or failure to prescribe ACE inhibitor drugs to appropriate heart failure patients.

Why The QIO Approach Works

QIOs are local organizations, employing local professionals, with a national mandate to improve systems of care. As such, QIOs act as catalysts for change trusted by both beneficiaries and providers. QIOs educate beneficiaries about preventive care and encourage hospitals and doctors to adopt and build into daily routines "best practices" for treating seniors with common and serious medical conditions.

Medical professionals work voluntarily and often enthusiastically with QIOs because QIO projectsreduce duplication of effort and burden on doctors participating in multiple hospitals and health plans. These projects also reduce the burden on hospitals that participate in multiple health plans, by bringing the parties together to work on the same urgent clinical priorities, using the same measures, the same abstraction tools, the same key messages. Even the best consultants working for individual hospitals cannot have this effect—and many providers cannot afford costly consultants. In short, QIOsaccelerate diffusion of evidence-based medicine to all providers—small, large, urban and rural.

What QIOs Have Accomplished

QIOs use data to track progress towards eliminating errors and improving treatment processes. They use data to measure hospital and provider performance on a list of clinical indicators over the course of a QIO project, and then compare results to baseline data to document change.

From 1996–1999, QIOs worked on local projects to improve clinical indicators in care for diseases and conditions that broadly afflict seniors—heart attack, congestive heart failure, stroke, pneumonia, diabetes, and breast cancer. Results from these projects show that QIOs have already made a significant difference. The latest available national data (1996–1998) show QIO projects resulted, for example, in:

- 34% more patients getting medications to prevent a second heart attack;
- 23% more stroke patients receiving drugs that prevent subsequent strokes;
- 12% more heart failure patients getting treatment needed to extend their active lives;
- 20% more patients hospitalized with pneumonia receiving rapid antibiotic therapy.

In 1999, CMS launched a national campaign for QIOs to improve care for cardiovascular conditions, pneumonia, diabetes, and breast cancer. The campaign began with creation of the first national quality portrait for Medicare. This baseline data showed considerable room for improvement in standard care in the six targeted clinical areas.

The baseline data for heart attack treatment, for example, shows the following percentages of patients (by state) receiving evidence-based care:

Clinical Process	Best State	Worst State
Prompt aspirin administration	97%	67%
Aspirin at discharge	97%	60%
Prompt beta blocker administration	79%	33%
Beta blocker at discharge	93%	47%

Recent re-measurement of a significant segment of this national data (for 19 states) indicates that QIO interventions are having substantial impact. For example, initial re-measurement data on reducing system failures in the treatment of heart attacks and pneumonia show:

Heart Attack Clinical Process	Median State Improvement
Prompt aspirin administration	16%
Aspirin at discharge	18%
Prompt beta blocker administration	26%
Beta blocker at discharge	26%

Pneumonia Clinical Process	Median State Improvement
Antibiotic within 8 hours	8%
Appropriate antibiotic administration	18%
Pneumococcal vaccination	15%

Besides participating in the national campaign to improve care in these six critical areas, QIOs are working to improve care in rural areas, to improve care for minority and ethnic populations, and to cooperate more closely with community-based groups that focus on better health care. QIOs are also working with nursing homes on the prevention of pressure sores, fall prevention, pain management, development of quality measures for rehabilitation services, improving diabetes outcomes, improving anticoagulant use, and conducting state-wide immunization campaigns.

Looking Ahead

CMS recently announced new directions for QIO efforts over the 2002–2004 contract period. National QIO quality improvement efforts will be expanded beyond the six original clinical areas to include care provided by nursing homes and home health agencies, reduction of surgical site infections in hospitals, and work with physicians offices on improving care for chronic diseases and preventive services such as cancer screening and adult immunizations.

QIOs will also be deeply engaged in a new CMS initiative to educate consumers with quality information to help them choose higher quality providers and motivate poor performers to improve. While CMS will be publishing the data, QIO efforts will be critical to public comprehension and use of the data. Nursing homes motivated to improve performance will receive QIO technical assistance to implement strategies that have worked in similar settings.

Recommendation

We urge the Committee to take closer note of what this program has accomplished and to verify its value through discussions with leaders of the medical community. We look forward to working with the Committee as it considers legislation to improve the quality and safety of Medicare.

Confidentiality Requirements for Medicare Quality Improvement Organizations

The confidentiality of information collected or developed by a Medicare Quality Improvement Organization (QIO) is assured by Section 1160 of the Social Security Act. It was the intent of Congress in drafting this provision to provide safeguards for information identifying a specific patient, practitioner or reviewer. These safeguards foster an environment that is conducive to quality improvement efforts and learning from errors.

Generally, the disclosure of data or information collected or developed by a QIO in carrying out its functions for Medicare is strictly prohibited. This information is not subject to subpoena or discovery for the purposes of an administrative or civil action. Further, the law states that any individual who violates the prohibition is subject to criminal fines and/or imprisonment.

The law does provide exceptions for QIOs to disclose to specific individuals or entities information that may identify providers or practitioners. Under certain circumstances, QIOs may provide such information to the practitioner or the institution where the practitioner works, State licensure and certification agencies, fraud and abuse or public health officials. These entities may only disclose information obtained from a QIO in the context of a judicial, administrative or other formal legal proceeding resulting from an investigation conducted by the agency. All of these exceptions are for the intended purpose of identifying and protecting the public from substandard care, fraud or abuse.

The confidentiality of QIO quality improvement efforts has helped establish a relationship of trust with providers. Currently, nearly 80% of Medicare hospitals nationwide are working with QIOs on one or more quality improvement projects. QIOs have also had some success working with outpatient physician offices, nursing homes and home health agencies. Efforts in the non-hospital settings will increase dramatically over the next few years.

The QIO approach to improving care is voluntary, educational, collaborative and non-punitive. Through this approach, QIOs have assisted providers and practi-

tioners in identifying quality issues and instituting appropriate changes to bring about measurable improvement. This process has achieved significant improvements in the quality of care for Medicare beneficiaries—and improving systems of care with Medicare participating practitioners and providers improves care for all patients.

March 2002

Statement of the American Society for Clinical Pathology

The American Society for Clinical Pathology appreciates this opportunity to comment on patient safety, an issue of great importance to the pathology and laboratory community. This statement focuses on patient safety initiatives within the pathology and laboratory medicine field, and shows how health care quality may improve as a result.

The American Society for Clinical Pathology (ASCP) is a nonprofit medical specialty society representing 151,000 board certified pathologists, other physicians, clinical scientists (PhDs), medical technologists and technicians. It is the world's largest organization representing pathology and laboratory medicine. As the leading provider of continuing education for medical laboratory personnel, the ASCP enhances the quality of the profession through comprehensive educational programs and materials.

The purpose of the ASCP is to improve public health by advancing the science and practice of pathology and laboratory medicine. Patient safety is an important part of this principle. To continue its leadership role in advancing patient safety, ASCP has developed a Patient Safety Initiative, which encompasses every part of the laboratory.

Transfusion Medicine Protocols

Transfusion medicine laboratory professionals have a long tradition for error detection and prevention systems by following standard operating procedures and conducting audits. While the proper application of these complex processes is critical to transfusion safety, dependency on numerous, diverse human interactions makes these processes prone to accidents and errors. Blood administration-related accidents and errors—which occur outside the confines of blood bank/transfusion service laboratory—represent a significant cause of transfusion morbidity and mortality. In the ongoing quest for improved transfusion safety, it is imperative that blood transfusion process safety be accorded the same emphasis as blood component safety.

To address this issue, ASCP joined with the American Organization of Nurse Executives in a Patient Safety Transfusion Medicine Project Team to identify seven essential components of the blood transfusion process. The joint project team developed flow charts and standard operating procedure checklists to assist hospital personnel in assessing the status of their own processes and procedures and take necessary actions to close gaps that may compromise blood transfusion safety. The preliminary results of this joint patient safety project were unveiled last month at a workshop sponsored by the Food and Drug Administration and the Agency for Healthcare Research and Quality.

Minimum Standards Necessary

The Centers for Medicare and Medicaid Services (CMS) found in a recent survey that 32% of waived laboratories failed to have current manufacturer's instructions, 16% didn't follow the manufacturer's instructions, 9% didn't follow manufacturer's storage and handling instructions, and 6% were using expired reagents and kits. This preliminary information is based on a survey conducted by CMS from October 2000 to January 2001. The results showed overall that a substantial 48% of waived laboratories surveyed had quality testing problems. The survey results were produced from an expanded pilot project undertaken by the agency of 270 certificate of waiver laboratories and 190 provider-performed microscopy laboratories surveyed in eight states.

Standards for clinical laboratory testing such as quality control, quality assurance, personnel standards, proficiency testing, and site neutrality should not be eroded as they have helped to raise the standard by which all laboratories operate. Problems that are identified can and are being corrected with the help and guidance of federal and private inspectors.

Use of the Autopsy

The autopsy is an important quality control vehicle. For example, a study published in the August 1998 issue of the *American Journal of Clinical Pathology* found that of 176 autopsies examined in a major tertiary care transplantation referral center, 79 autopsies, or 44.9%, revealed one or more undiagnosed causes of death. There were 123 undiagnosed causes of death in the 79 cases. Of the 123 undiagnosed causes of death, 13 were sole immediate causes of death, 72 were one of multiple immediate causes, 22 were intervening causes, and 16 were underlying causes of death. Low-technology autopsies frequently discover diagnoses that go undetected by modern high-technology medicine. Through the autopsy, problems in diagnosis may be recognized and ultimately assist in finding solutions to similar medical problems in future patients.

To accommodate better the needs and concerns of family members, hospitals should develop a coherent set of policies that explain the usefulness of an autopsy. ASCP suggests that these policies may include: developing an informational pamphlet that is made available to the patient's family, describing the autopsy procedure and its values; creating an office of decedent affairs within the hospital organization to assist dying patients, families and involved members of the medical staff to understand the details surrounding dying and death in the hospital environment; and creating in-service programs to ensure that nurses and social workers provide assistance in facilitating any efforts to obtain an autopsy consent.

The ASCP firmly believes that the autopsy is necessary to monitor the clinical judgment in the medical community. For quality assurance purposes alone, the autopsy is a critical service. Any condition of participation addressing the autopsy should also assure appropriate compensation for this service.

Second Opinions in Diagnostic Anatomic Pathology

As part of its Patient Safety Initiative, ASCP hosted the "Consensus Conference on Second Opinions in Diagnostic Anatomic Pathology: Who, What and When" on June 21, 2000, in Washington, DC. The conference, which was open to the public, convened with pathology experts of various disciplines, surgical representation, and a patient advocate. The conferees worked to reach a consensus on what specimens should be reviewed under second opinions, whose opinion prevails upon a second review, when a second opinion should occur, and to develop general guidelines for second opinions in diagnostic anatomic pathology.

The conference determined that second opinion is an important component of total quality assurance programs in diagnostic surgical pathology and cytopathology and is a key aspect in the assurance of patient safety for tissue and cytology based diagnoses. The conference urged the implementation of educational programs to inform clinicians and patients regarding the value of second opinion; the turn around time delays which second opinion will produce, and the legitimate differences of opinion that can exist in difficult cases.

It was recommended that all insurers provide a fair reimbursement structure for second opinion services, and that funding agencies support research into the detailed analysis of second opinion as a patient safety mechanism and that academic pathology centers should engage in such research. Overall, the effective use of second opinion in diagnostic anatomic pathology is a subject that needs to be better communicated to clinicians and patients.

Conclusion

Pathology and laboratory medicine have developed and continue to support the use of quality processes for the systematic detection and prevention of errors. These efforts concentrate on building safety into the delivery of health care, similar to the recommendations of the Institute of Medicine Committee on Quality of Health Care in America. Many patient safety initiatives, such as those recognized in donor blood testing and autopsies, have been absorbed by the laboratory profession in the interest of maintaining and improving quality. As new efforts are disseminated, it will be important that custodians of those efforts receive the resources they need to accomplish the task.

Thank you for the opportunity to provide this statement to the subcommittee.

Statement of the American Society of Health-System Pharmacists, Bethesda, Maryland

The American Society of Health-System Pharmacists (ASHP) is pleased to submit this statement for the record of the Subcommittee on Health's hearing on health

quality and medical errors. ASHP is the 31,000-member national professional association that represents pharmacists who practice in hospitals, long-term care facilities, home care, hospice, health maintenance organizations, and other components of health care systems. ASHP believes that the mission of pharmacists is to help people make the best use of medicines. Assisting pharmacists in fulfilling this mission is ASHP's primary objective.

The Institute of Medicine (IOM) report, "To Err is Human: Building a Safer Health System," states that since it isn't possible for nurses or doctors to keep up with all the information necessary for safe medication use, "the pharmacist has become an essential resource in modern hospital practice," and access to the pharmacist's expertise must be possible at all times. For decades, ASHP has been actively involved in promoting a fail-safe medication use system for hospitals and other components of our nation's health system, and ASHP agrees with the IOM that the active participation of pharmacy practitioners is essential to the creation of that fail-safe system. ASHP stands ready to assist the Subcommittee in developing meaningful recommendations to implement error reduction techniques.

In general, ASHP applauds the analysis and recommendations in the IOM report. Of particular interest to ASHP are recommendations dealing with mandatory and voluntary reporting systems, extension of peer review protections to data about patient safety and quality improvement as well as initiatives to improve the medication use process through the appropriate application of technology and the proper utilization of pharmacists as health care providers.

The Creation of a Non-Punitive Environment For Reporting is Essential

In order to achieve the IOM's call for a 50% reduction in the rate of medical errors over the next five years, it is essential to create a confidential, non-threatening, nonpunitive environment where errors can be reported, the underlying cause studied, and effective interventions devised and implemented. To do so, Congress must work with states and the private sector to create a single, nationwide error reporting program.

In June 2000, ASHP's House of Delegates approved the following statement regarding the development of an error reporting system:

Policy

The incidence of death and serious harm caused by mistakes and accidents in health care is unacceptable. This serious public health problem merits top-priority national attention. Addressing this issue will require major reforms and sizable investment of resources throughout the health care system, including the medication use process, which is a particular focus of the American Society of Health-System Pharmacists (ASHP).

ASHP believes that the following steps should be taken as part of a comprehensive national solution to the problem: (1) The establishment of a standardized, uniform nationwide system (with the characteristics noted below) of mandatory reporting of adverse medical events that cause death or serious harm, (2) continued development and strengthening of systems for voluntary reporting of medical errors, and (3) strengthening efforts to implement process changes that reduce the risk of future errors and improve patient care.

The fundamental purpose of reporting systems for medical errors is to learn how to improve the health care delivery process to prevent these errors. Reporting of medical errors must become culturally accepted throughout health care. A major investment of resources will be required in the health care system to apply the lessons derived from the reporting of medical errors. Marshaling those resources is an urgent issue for the governing boards of health care institutions, health care administrators, health professionals, purchasers of health care (including federal and state governments), third party payers, public policy makers, credentialing organizations, the legal profession, and consumers.

Requirements

The primary goal of *mandatory reporting* of adverse medical events that cause death or serious harm should be to foster accountability for health care delivery process changes to prevent errors or adverse medical events. If a patient dies or is seriously harmed because of a mistake or accident in the health care system, the practitioner or institution responsible for the patient's care should report the incident to a designated state health body. Further, states should be obligated to share information based on these reports promptly with a national coordinating body and with national programs that are designed to improve the quality and enhance the safety of patient care.

ASHP's support of a mandatory reporting system is contingent upon the system having the following characteristics:

1. An overall focus on improving the processes used in health care, with the proper application of technical expertise to analyze and learn from reports,
2. Legal protection of confidentiality of patients, health care workers, and the information submitted to the extent feasible while preserving the interest of public accountability,
3. Nonpunitive in the sense that the submission of a report, per se, does not engender a penalty on the reporting institution or practitioner or others involved in the incident,
4. A definition of "serious harm" that concentrates on long-term or irreversible patient harm, so as not to overburden the reporting system,
5. National coordination and strong federal efforts to ensure compliance with standardized methods of reporting, analysis, and follow up, that emphasize process improvement and avoid a culture of blame,
6. Adequate resources devoted to report analysis, timely dissemination of advisories based on report analysis, and development of appropriate quality improvement efforts, and
7. Periodic assessment of the system to ensure that it is meeting its intent and not having serious undesired consequences.

Experience associated with current mandatory state reporting of adverse medical events and mandatory public health reporting of certain infectious diseases should be assessed, and the best practices of such programs should be applied to the new system of mandatory reporting of adverse medical events that cause death or serious harm.

The primary goals of *voluntary reporting* of medical errors should be quality improvement and enhancement of patient safety. Reports by frontline practitioners of errors and "near misses" are a strength of such programs when report analysis and communication lead to prevention of similar occurrences. The public interest will be served if protection is granted to individuals who submit reports to voluntary reporting programs. The Medication Errors Reporting Program operated by the United States Pharmacopeia in cooperation with the Institute for Safe Medication Practices is an important initiative that merits strengthening; this program may be a model for voluntary reporting of other types of medical error.

It is important to emphasize the necessity of nationwide peer review protections to the successful implementation of any error reporting program. ASHP supports "federal legislative and regulatory initiatives that provide liability protection for the reporting of actual and potential medication errors by individuals and health care providers." Further, ASHP supports "federal liability protection for medication-error reporting that is similar in concept to that which applies to reporting safety incidents and accidents in the aviation industry."

Since current legal protection for medication error reporting (both actual and potential as defined in ASHP's "Guidelines on Preventing Medication Errors in Hospitals") is based primarily on state peer-review protection statutes or on case law, the extent of protection varies substantially throughout the country. For example, some states may limit protection to records prepared by peer-review committees and do not protect records provided to these committees. Given the state-to-state variance, medication errors may not be reported in a consistent and uniform manner, making trend analysis and subsequent corrective measures difficult.

Individual practitioners and health care entities may be hesitant to report medication errors for fear that the information could be used in civil liability lawsuits against them. There is no federal protection for individuals and entities reporting medication errors to national reporting programs. This lack of protection, and the consequent incomplete reporting, means that individual practitioners, health systems, pharmaceutical manufacturers, and other public and private organizations cannot learn of the component parts of a system error and develop corrective measures to enable a fail-safe medication-use system.

Such protection would only cover the information submitted to a designated national reporting entity. Individual practitioners and healthcare entities still would remain susceptible to liability action as a result of underlying incidents that form the basis of the report if the incident resulted in harm to an individual.

Federal legislation providing liability protection for the reporting of actual and potential medication errors would neither help nor harm individual patients who are injured, but it should help patients collectively because the reported data could be used to reduce the incidence of avoidable errors. Individual patients would still be able to seek a legal remedy for their injuries. Seeking this limited federal protection is preferred over attempting to obtain uniform protection from all 50 states.

ASHP and its members have a great deal of experience with existing reporting systems and will participate in the further development of mandatory or voluntary reporting programs.

Appropriate Application of Technology Improves the Medication Use Process

Everyone agrees that the number of medication-related errors is too high. Handwritten clinical data, incomplete, outdated or improperly implemented information technology increases the likelihood that this number will remain unnecessarily high. Research demonstrates that patient-safety geared information technology, when used appropriately and under the leadership of health-system pharmacists, who are responsible for the appropriate, accurate, and timely distribution of medications, can improve quality of care and reduce medication-related errors.

The biggest obstacle for hospitals when it comes to implementing information technology enhancements is the enormous cost of researching these systems, purchasing the necessary hardware and software, as well as training staff to use the technology properly.

The March 2001 IOM report, "Crossing the Quality Chasm: A New Health-System for the 21st Century," urges a significant national investment in information technology geared toward improving the quality of health care delivery.

ASHP supports a voluntary grant program that would provide funding for early adopters of new technology to meet the high price tag of this new technology as well as the necessary and important expense associated with properly educating and training staff on the correct use of the information system. The Medical Error Reduction Act (H.R. 3292), introduced last year by Ways and Means Committee members Amo Houghton (R–NY) and Karen Thurman (D–FL), would go a long way toward achieving this goal. Senators Bob Graham (D–FL) and Olympia Snowe (R–ME) have introduced similar bipartisan legislation (S. 824) in the Senate.

Recognizing Pharmacists as Health Care Providers Under Medicare Improves Quality of Care, Reduces Errors

Our nation's health care system relies heavily on thousands of powerful new prescription medicines to treat all sorts of diseases and conditions. Many patients, especially those over the age of 65, find themselves taking a bewildering array of medications. As medication use rises, so to does the risk of medication-related complications. Yet, despite being among our nation's highest risk patients, Medicare beneficiaries often have limited access to the valuable services of pharmacists.

As the IOM and others have recognized, pharmacists play an important role in improving the quality of patient care and reducing the risk of dangerous (and costly) medication-related complications. Working closely and collaboratively with physicians, the pharmacist is a trusted counselor who helps to streamline drug therapies prescribed by a number of specialists, matching effective therapies with patients' unique needs. Pharmacists also play vital roles in follow-up care, monitoring patient response and advising physicians on changes in dosage, medicine, or delivery method.

Currently, Medicare does not compensate pharmacists for these important patient care services. Because pharmacists are not considered "health care providers" under Medicare, their experience is underutilized, patient care is diminished, and reductions in unnecessary expenditures are not realized. Simply put, Medicare payment policies have not advanced to match the pharmacist's critical role in health care.

ASHP supports the passage of legislation to update Medicare statutes to recognize pharmacists as health care providers in a similar manner as other non-physician practitioners, including registered dieticians, nurse practitioners, physician assistants, certified nurse midwives, and clinical social workers, are recognized. Legislation, the Medicare Pharmacist Services Coverage Act (H.R. 2799/S. 974), has been introduced in both the House and Senate to achieve this goal. This important legislation will ensure that the entire health care team is able to properly utilize the pharmacist's expertise in drug therapy management.

Conclusion

ASHP thanks Chairwoman Johnson, and members of the Subcommittee for holding this important hearing. We appreciate the opportunity to submit a statement for the record and look forward to working with the Subcommittee and other members of Congress to develop effective patient safety legislation.

Statement of Trace Devanny, Cerner Corporation, Kansas City, Missouri

Madam Chairman and members of this committee, thank you for the opportunity to submit testimony outlining our views on the role of technology in improving healthcare quality and patient safety in the U.S.

My name is Trace Devanny and I am the president of Cerner Corporation. We are a $543 million company with our headquarters located in Kansas City, Missouri. We are considered by many to be the world's leading developer of clinical information systems software for the healthcare industry and our mission as a company is to transform healthcare through the implementation of information systems that improve healthcare quality and patient safety in the U.S. and around the world.

I would like to take a moment to thank the members of this committee for focusing attention on this important issue in healthcare. Your commitment will prove to be critical as we move forward to improve quality and safety for patients in the U.S. healthcare system.

Healthcare Problems

As this committee has no doubt learned by now, the U.S. healthcare industry is beset with serious problems—especially the 19th century approach of our healthcare with respect to technology. Nearly every other major U.S. industry has already moved to automate its systems. Try to imagine the banking and finance industry without computers. The airline industry is almost completely reliant upon its automated systems. Even your local car dealer has computers to track your service record when you go in for a repair.

Yet the healthcare industry, one of the largest industries in the U.S., continues to do business primarily the same way that it has for more than 150 years—with paper and pen. We have a saying at Cerner that the pen is the most dangerous medical device in healthcare today.

This Committee is obviously familiar with the December 1999 Institute of Medicine (IOM) study that estimated as many as 98,000 people die each year as a result of medical errors. But there are more storm clouds on the horizon for the healthcare industry. The graying of the baby boomer generation is about to create an unprecedented stress on our healthcare system—a system that is already overutilized and undercapitalized. And the baby boomers are going to peak during a critical workforce shortage. There is also enormous variance in treating patients while redundant and wasteful procedures eat up enormous costs.

Perhaps just as important, the follow-up March 2001 IOM study states that technology and clinical automation is one of the critical solutions to reduce the number of deadly medical errors. The value proposition for using technology in healthcare is relatively straightforward—20–40 percent cost reductions, the elimination of most medical errors, and the empowerment of consumers to better manage their own health. The IOM report tells us "automation of clinical, financial and administrative transactions is essential to improving quality, preventing errors, enhancing consumer confidence in the health system and improving efficiency." The IOM goes on to suggest $1 billion as a reasonable starting point to assist the healthcare industry in adopting needed technologies.

I should point out here that we believe $1 billion is a positive first step but that it will actually require far more than $1 billion to impact today's healthcare industry significantly. There is little question that the financial health of the current healthcare system will not support the large-scale investments necessary to address the current safety problems in healthcare.

An enormous transformation needs to occur—and quickly. Today's situation might be compared to the critical 'access' issues facing this country after World War II. At that time, as you may recall, Congress responded by passing the Hospital Survey & Construction Act— better known as "Hill-Burton." It was a massive infrastructure program providing the funding to build many of the nation's hospitals. But today's congressional imperative is not to build more facilities. Rather, it's to help establish a higher-quality, safer health system. A massive congressional effort needs to coalesce around funding for technology systems that provide demonstrated return on investment (ROI) and elimination of medical errors on a very large scale.

A Solution

Given the current state of the economy, however, and the limited resources of Congress, it is not realistic to think this enormous investment will take place immediately. Until there is support for a movement to fund a large-scale effort for technology infrastructure in healthcare, Congress should provide incentive funding for providers to help with the expense of automating systems that improve quality and

patient safety. Capital reimbursement methods within Medicare or Medicare competitive grants are two possible ways to move provider systems towards automating their systems—and we believe these "seed funds" would provide a greater return than the original investment.

A terrific first step in this evolution is the introduction of H.R. 3292. Cerner strongly supports this legislation and applauds Congress for taking this important first step in moving healthcare towards better quality and patient safety.

THE VALUE OF INFORMATION TECHNOLOGY IN HEALTHCARE

At Cerner, we believe deeply that the value proposition of information technology in healthcare is relatively straightforward. Technology will:

- *eliminate the majority of the avoidable medical errors;*
- *reduce the cost of healthcare by 20–40 percent;*
- *reduce the enormous variance* that currently exists around how physicians diagnose and treat the same medical problem;
- *empower the consumers* to better manage their own health by giving them access and control of their own medical records; and
- *improve workforce retention.*

There are several provider systems that have shown value through the use of healthcare IT systems. For example:

- A peer-reviewed study conducted by officials at the Banner-Samaritan health system in Phoenix was published in the Journal of the American Medical Association (JAMA) in 1998. The study measured the results of an adverse drug event warning system that had been implemented at the Banner Samaritan 650-bed site. **The study concluded that Banner-Samaritan saved $3 million and 36 lives annually through the use of its healthcare information system.** And the results today would be even more dramatic because of the rapid advances made in healthcare IT systems at Cerner.
- Detroit Medical Center saved $30 million in 2000 and projected savings of $50 million in 2001 due to improved charge capture and a reduction in redundant procedures.
- The INTEGRIS Health system, which operates 15 hospitals across Oklahoma, is saving approximately $5 million annually by reducing inappropriate or redundant medical procedures through the use of advanced information software.
- Through the use of electronic medical records, physicians at the University of Illinois Medical Center at Chicago (UIC) are spending 30 percent less time looking for charts and five hours a week less reviewing resident orders.
- Also at UIC, radiologists are saving one hour per day, and $1.3 million in nursing time has been reallocated away from administrative tasks by using technology patient safety information systems.

Should Congress provide incentive funding, it would find itself with more proof points across the U.S. that show better quality and safety in healthcare. By allowing visionary sites around the country access to compete for funding for IT implementation, Congress will almost immediately begin to make the business case for the industry through reduced costs, improved quality and better patient safety. There will also be real, measurable savings in the Medicare system.

Companies like Cerner cannot help to bring about this massive transformation alone. It will require a unifying force of leadership on a grand scale—and Congress must lead the way. By providing this leadership, Congress will help to save lives and address many of the overwhelming issues facing healthcare in the U.S. today.

Once again, I appreciate the opportunity to provide input into this committee's efforts to improve patient safety and our healthcare system. Cerner looks forward to working with this committee to improve the quality and safety of our healthcare system. I am available to answer any questions the committee may have now or in the months ahead. Thank you.

Statement of the College of American Pathologists

The College of American Pathologists (CAP) is pleased to submit this statement for the record of the Subcommittee on Health's hearing on health quality and medical errors. The College is a medical specialty society representing more than 16,000

board-certified physicians who practice clinical or anatomic pathology, or both, in community hospitals, independent clinical laboratories, academic medical centers and federal and state health facilities. The CAP thanks subcommittee Chair Nancy Johnson and the subcommittee's members for their interest in improving health care quality and patient safety.

The CAP is the leading advocate for quality medical testing for patients. The College accredits more than 6,000 laboratories, provides proficiency testing for more than 20,000, and offers various other quality improvement programs. Further, the College has developed the Systematized Nomenclature of Medicine (SNOMED), the world's most comprehensive international and multilingual clinical reference terminology with broad applications in patient safety and error reduction efforts.

As you may know, the College, in partnership with the Centers for Medicare and Medicaid Services and other agencies, works to ensure Medicare beneficiaries and patients nationwide receive quality care in the laboratory. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) recognize CAP accreditation as an acceptable substitute for federal laboratory inspections. Also, the College has worked closely with the Department of Health and Human Services on cancer screening, laboratory standards, genetic testing and other issues.

CAP Laboratory Accreditation Program (LAP) inspections and Proficiency Testing form the foundation of College quality improvement activities. The LAP has long led efforts to improve the accuracy and reliability of laboratory testing, thereby reducing errors and helping to ensure safer patient outcomes. Dovetailing with LAP is the College's Proficiency Testing program, which allows laboratories worldwide to compare their performance with that of peers and improve outcomes within the laboratory.

Two other CAP quality improvement programs of particular note are the Cancer Protocols and Patient Outcomes Templates. Cancer Protocols, co-developed with clinicians, standardize the evaluation and reporting of cancer specimens and help ensure all relevant information is consistently documented and available to best treat cancer patients. Complete pathology reports written in a clear format help protect patients from improper treatment by eliminating physician confusion about or misunderstanding of pathologic findings. The College's Patient Outcomes Templates respond to an emerging need in the marketplace for tools to improve communication and foster outcomes quality improvement. Pathologists and clinicians use this program to accurately evaluate and report specific conditions within their institution to determine the need for improvement. Both the Cancer Protocols and Patient Outcomes Templates are peer-developed and peer-reviewed, and made available at no charge to all CAP members.

Other College offerings targeted at quality improvement and error reduction include the Q–Probes and Q–Tracks programs, which allow laboratories to assess the quality of their clinical and anatomic pathology services by benchmarking their performance against other participating laboratories in the programs. Also of note is that several of the Q–Probes programs deal specifically with detecting errors.

SNOMED

The College's concern for quality extends beyond the laboratory walls. Accurate, comprehensive and efficient communication among physicians, laboratories, hospitals and other providers is essential to ensuring quality. A common language understood by all health professionals improves the coordination of patient care and can reduce the occurrence of medical errors.

The College's Systematized Nomenclature of Medicine, or SNOMED, is such a language. SNOMED is the most comprehensive international and multilingual clinical reference terminology available in the world. Its unparalleled scope delivers to the entire health care community unprecedented uniformity for medical communications that spans languages, clinical specialties and geographic borders.

SNOMED Clinical Terminology, for example, contains approximately 325,000 concepts linked to clinical knowledge to enable accurate recording of data without ambiguity. The terminology's content also includes more than 800,000 descriptions or synonyms relating to clinical concepts, as well as more than 950,000 links, known as semantic relationships, between clinical concepts. This structure ensures the proper relationships of diseases, treatments, etiologies, clinical findings, therapies, procedures and outcomes.

The possible applications of SNOMED are nearly limitless. The terminology is highly flexible, allowing its use by a wide variety of health care enterprises—from the individual clinician to major pharmaceutical companies, government agencies and nationwide provider organizations. The terminology will help users reduce administrative costs related to the delivery of health care worldwide by supporting the electronic patient record. It can be used to standardize surgical records, to code pa-

tient problem and diagnoses lists, to support computerized physician order-entry, to facilitate consistent tracking of infectious diseases, to report the incidence of cancer cases, to facilitate bioterrorism surveillance or to encode health-related literature, among many other possible uses.

When used in software applications, SNOMED serves as the common index or "dictionary" against which data is encoded, stored and referenced. This provides greater compatibility across software applications as computer codes used to capture medical concepts in one system can be interpreted and linked to terms with the same meaning in another. The terminology allows clinicians to precisely capture information about a patient's history, illnesses, treatments and outcomes in a consistent and computer-readable manner. More important, SNOMED is designed in a way that allows reuse of coded information for evidence-based medicine, outcomes studies, clinical research and administrative reporting.

By enabling consistent coding of clinical concepts, with clear relationships between terms and concepts, SNOMED helps ensure comparability of data recorded by multiple practitioners across diverse and often incompatible platforms and systems. For example, an internist in New York can communicate SNOMED-encoded patient data to a radiologist in France, and the radiologist can immediately understand and apply the information, even if using a completely different language and software system.

Whether data is retrieved from a single patient, a group of patients or an entire population, SNOMED improves the coordination of patient care, provides data crucial to quality improvement efforts and can reduce medical errors. Specifically, SNOMED:

- Provides clarity—and reduces the chance of misinterpretation—in the coding of patient information and improves understanding of a patient's condition through access to more complete clinical documentation.
- Allows health care providers to retrieve important information that might otherwise be buried among paper records.
- Provides better, more complete access to important patient information that can be linked to clinical alerts, knowledge databases and health education tools.
- Allows the systematic collection and analysis of data on errors, which provides access to important information necessary for statistical reporting that might otherwise be lost among paper records.
- Provides greater clinical specificity to support problem lists, outcomes research, performance measurement and quality improvement.
- Shifts investment from gathering and integrating data for population-based studies to understanding and interpreting the results and their implications on cost and quality of care.

While the extensive features of SNOMED are appropriately complex, its bottom-line benefit is simple: It helps health care professionals deliver the best possible patient care. In doing so, SNOMED improves quality and can reduce the likelihood that medical errors will occur.

The CAP thanks the subcommittee for the opportunity to present its views on this important issue and offers its support and continued assistance as Congress considers steps to improve the quality of care for all Americans.

Statement of eHealth Initiative

Introduction

The old adage is true: the American health care system is the best in the world but as we now know, in terms of reducing medical errors and increasing health care quality, our Nation could do much better. One of the keys to building a health care system that is safer and more effective and efficient in terms of cost, quality, and timeliness is the increased use of information technology. Such technology can improve and streamline clinical health care communications, data-sharing, and interconnectivity within and across health care-related institutions, patients, and public health agencies.

Many information technology tools that hold promise for improving the price and process of health care exist. However, a multitude of barriers— including inadequate reimbursement and lack of data standardization and connectivity issues, prevent these tools from being widely utilized by health care providers.

eHealth Initiative Undertakes Multi-Stakeholder Efforts to Create Safer, More Cost-Effective, Higher Quality Health Care System

Driving improvement in the quality, safety, and cost-effectiveness of health care through information technology is the mission of the eHealth Initiative (eHI), a non-profit organization with over 70 members representing many of the stakeholders in the health care industry. Through its collaborative projects and education and awareness-building activities, eHI brings health care decision-makers from the public and private sectors to examine the role of information technology in driving greater quality and safety as well as reducing health care costs and undertake projects which clarify how information technology can do just that. The organization also seeks to address two critical barriers to a better health care system enabled by information technology, the lack of economic incentives for better quality care enabled by information technology and the need for greater data standardization and connectivity within the health care system.

eHealth Initiative efforts relevant to today's hearing that relate to how information technology can increase health care quality, safety and cost-effectiveness fall into four key categories:

- **Economic Incentives**—eHI promotes economic incentives for better quality care through information technology.
- **Medical Errors Legislation—**eHI advocated for the passage of the "Medication Errors Reduction Act of 2001."
- **Clinical Data Standardization**—eHI is focused on driving greater clinical data standardization through the public-private collaboration to improve public health.
- **Connectivity**—eHI is working to increase connectivity between various stakeholders in the health care system.

eHI believes that each of the above endeavors is vital because they provide impetus to the proliferation of information technologies and encourage the coordinated, real-time health care communications network our Nation needs to address medical errors and health care quality issues.

Economic Incentives for Better Quality Care through Information Technology Needed

One of the most important steps that Congress can take to reduce medical errors and improve health care quality is to draft and pass legislation that provides economic incentives for better quality care enabled by information technology within the health care setting. Information technology has the power to improve the process and price of health care when properly integrated and implemented with workflow in clinical and administrative settings. Such technology can: (1) streamline the care process; (2) result in better patient health, productivity, and quality of life; and (3) reduce health care-related costs.

It is commonly understood that in the face of increasing reimbursement cuts and mounting clinical and administrative responsibilities, health care providers want to implement information technology solutions that decrease medical errors, lower costs, ease office practice burden, and enhance patient health. Unfortunately, the current health care business model does not support broad and effective use of such solutions.

It is problematic that currently, public and private health care incentives and reimbursements are largely based on the traditional doctor or hospital visit model where a consultation occurs and information is dispensed during a face-to-face interaction between provider and patient. As medical and information technology evolves, new care models which include the use of data from disparate clinical and administrative information systems to support better quality care or from remote interactions will become more prominent. Therefore, economic incentives that fund the purchase and adoption of new information technology to handle these functions must be implemented. Without these incentives, the purchase of new and enhanced information technology tools will be low on the priority list given tightened hospital and physician budgets, high administrative costs, and valid competing purchase and staffing priorities.

Many employers, health plans, and hospitals believe that they have squeezed all of the possible costs out of the system through the implementation of what many saw as the "answer to the reduction in health care costs"—managed care. Despite those changes, health care costs are continuing to spiral upward. This, combined with the aging of the baby-boomers is forcing the health care system to look for new answers. Ironically, there is little cashflow left within these organizations to fund the very infrastructure that will drive the next wave of much-needed cost reduction and improvement in quality—the strategic use of information technology.

As it has with the building of other infrastructure in the United States over the years (such as the hospitals with the Hill-Burton Act and the Interstate Highway

System), the federal government must play an important role in providing economic incentives for the building of the core of this information technology infrastructure. The government has successfully provided economic incentives for beneficial cardiac imaging, kidney dialysis, and laparoscopic surgery, which encouraged these technologies to flourish. eHI believes it should now provide similar incentives in the larger realm of information technology tools.

Such incentives or reimbursements should be designed and implemented as either add-ons to current federal reimbursement vehicles (through programs such as Medicare, which pay for approximately one-half of the health care in the United States) to defray the costs related to information technology infrastructure or funded through a variety of federally funded direct grant programs to health care institutions and physicians' offices.

Passage of "Medical Errors Reduction Act of 2001" Supports Medical Error Reduction and Health Care Quality

A second crucial step that Congress can take to reduce medical errors and improve health care quality is to pass the "Medication Errors Reduction Act of 2001" (S.824, H.R. 3292) introduced in the Senate by Senators Bob Graham (D–FL) and Olympia Snowe (R–ME) and in the House by Representatives Amo Houghton (R–NY) and Karen Thurman (D–FL). These House and Senate bills are important and will improve the basic care process by: (1) providing informatics and technology-focused grants to hospitals and nursing homes; (2) establishing a Medical Information Technology Advisory Board to develop, disseminating standards for electronic sharing of information; and (3) removing one of the major barriers to implementation of such information technology ¾ financing ¾ by providing over $1 billion of funding to hospitals and nursing homes to implement medication error-related tools and systems.

Information Standardization and Connectivity Critical to Boosting Quality, Safety and Cost-Effectiveness of Health Care

The nation is in need of an interconnected health care system, to drive further improvements in the quality, safety, and cost-effectiveness of care. As noted in the recent NCVHS report *Information for Health: A Strategy for Building the National Health Information Infrastructure* [1], we as a Nation have a timely opportunity and an urgent need to build a 21st century health support system—a comprehensive, knowledge-based system capable of providing information to all who need it to make sound decisions about health. This report calls for an *interconnected set* of technologies, practices, relationships, standards, and applications that support the many facets of health and health care.

According to the President's Information Technology Advisory Committee and Panel on Transforming Healthcare, the Nation's growing information and communications capabilities already facilitate some information flow to and communication among health decision makers. But the health sector is lagging far behind others (banking and entertainment, for example) in adapting and using information technology for its own purposes.[2] According to NCVHS, use of information technology in the health sector has been evolving, but without a plan.

As is noted above, one of the key components of a national health information infrastructure is the sharing of clinical information within and across health care-related institutions, patients, and public health agencies.

The amount of clinical data generated today in our Nation's hospitals, physician offices, labs, and pharmacies, continues to grow. Although there is an abundance of health care information and a pressing need for its use, clinical information often can not be utilized or combined effectively because data formats and transmission standards are not uniform. The development and widespread adoption of clinical data standards and the connectivity of such data is critical to the quality, safety, and cost-effectiveness of care delivered in our health care system.

HIPAA has provided the platform for the exchange of financial, clinical, and administrative information on health care transactions. These regulations will serve as a catalyst for moving the health care industry towards efficient and standardized electronic methods for communicating health claims, enrollment, eligibility, remittances, and related transactions. HIPAA includes not only standards for financial

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[1] U.S. Department of Health and Human Services National Committee on Vital and Health Statistics. November 15, 2001. *Information for health: a strategy for building the national health information infrastructure.*

[2] President's Information Technology Advisory Committee, Panel on Transforming Health Care. February 2001. *Transforming health care through information technology.* National Coordination Office for Information Technology Research and Development.

and administrative transactions, but also standards for privacy and security. The next step, however, lies in the development and broad adoption of clinical transaction standards.

Through the Foundation for eHealth, the eHealth Initiative is working with the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services, several state and local health partners, national standards organizations, and key leaders in the private sector in a public-private collaboration to transmit clinical data of public health importance from existing health information systems and data sources for public health surveillance purposes, using CDC's National Electronic Disease Surveillance System (NEDSS), which is a broad initiative designed to use national data and information systems standards for the development of efficient, integrated, and interoperable surveillance systems at the state and local levels. This initiative represents a critical next step towards accelerating greater data standardization, enhancing information systems interoperability, and facilitating broad adoption of supporting policies and technologies. The power of combining a national need for interoperable systems with data and architectural standards through CDC's NEDSS with the expertise and leadership of government and health care industry leaders, as well as national standards organizations, is extraordinary and will provide the catalyst that is needed to drive greater data standardization, connectivity and compliance with privacy and security policies—all of which serve as critical barriers to a national health information infrastructure which is greatly needed to drive greater quality health care.

Conclusion

In conclusion, there are a number of action steps this Subcommittee and Congress as a whole, can take to reduce medical errors, and increase cost-effectiveness, quality, and safety within the health care system. First, work must begin to construct and pass federally-funded economic incentives for better health care through information technology. Second, comprehensive medical errors legislation such as the "Medication Errors Reduction Act of 2001" must become law. And lastly, the public and private sectors must work collectively to increase data standardization and connectivity within and across health care-related institutions, patients, and public health agencies. eHI and our members stand ready to lend our voice and private-sector expertise in these endeavors.

Statement of Mark R. Grealy, Healthcare Leadership Council

The Healthcare Leadership Council (HLC) is a coalition of chief executives of the nation's leading health care companies and organizations representing all sectors of health care. Our members are committed to advancing a market-based health care system that values innovation and provides affordable, high-quality health care. HLC would like to thank the committee for focusing today on health quality and patient safety and for the opportunity to submit this statement.

While Congress considers how to enhance the safety of the nation's health care system through legislation, we ask you to consider also the numerous steps the health care industry has initiated to reduce error rates and to continually increase the quality of the care it delivers. Many health care providers are reducing human error by upgrading their systems technologies through the use of computerized physician-order entry, computerized on-floor pharmacies, and scanning bar-codes at the patient bedside. Manufacturers are changing their packaging to dose-by-dose packages, improving dosage and interaction instructions, and eliminating look-alike packages and names. Hospitals are removing high-error medicines from patient floors. Many hospitals are also voluntarily submitting error data to organizations like the Joint Commission on Accreditation of Health Organizations and U.S. Pharmacopia, where they receive analysis and feedback of how to avoid similar errors in the future. These are just a few of the many examples of some of the activities underway within our membership.

In an effort to increase safe practices and to cross-educate health organizations, HLC has launched its own effort and formed a Chief Executive Task Force on Patient Safety. Our goal is for the various sectors of the health care industry to work together to help elevate public confidence in the safety of the nation's health care system. We are accomplishing this by uniting behind a self-initiated protocol for addressing patient safety in the health care system responsibly, positively, and tangibly.

The HLC task force is guided by the following eight principles which we offer for the committee's consideration as it evaluates potential patient safety legislation:

1. ***Solutions should be developed collaboratively and with executive responsibility and leadership.*** A zero error medical environment will require devoted, thoughtful and creative collaboration of ALL STAKEHOLDERS. For example, all care givers must increase awareness of the potential for errors, administrators must facilitate systems of improvement, patients must be committed to complying with treatment programs, industry executives must make patient safety improvement a declared and serious aim by establishing programs with defined executive responsibility, and lawmakers and regulators must resist mandates that could stifle innovative problem solving.
2. ***A holistic quality assessment system must be developed and adopted for use in health care.*** Individuals are not the true source of errors in health care or any other industry. Systemic review of processes, practices and policies to uncover sources of error so the source of those errors can be eliminated is essential for improving safety in the health system. The health care system should incorporate the lessons learned in other industries that have greatly reduced their error rates.
3. ***Safe practice standards should be evidence-based, flexible and feasible.*** Nationally recognized safe-practice standards should be developed only through analysis of conclusive data on broad-based effectiveness and feasibility, and should consider evolving science. In addition to recognizing broad-based safe practices, health care organizations should be encouraged to and should be recognized for adopting tailored safe practice programs unique to their specific risk points, specialties, and patient populations.
4. ***Healthcare organizations, lawmakers, and other policy officials should support the automation of patient safety systems to the greatest extent possible.*** The Institute of Medicine is urging a new generation of patient safety systems that are automated, information system-based, and technologically driven. A voluntary health system information technology infrastructure should be encouraged and facilitated as broadly and rapidly as possible to help reduce incidence of human error in the practice of medicine.
5. ***Establish a culture of awareness—NOT blame—to drive health care errors into the open.*** Improving patient safety depends heavily on the ability to collect and analyze patient safety data, and to use that information to develop safer systems. Laws that perpetuate litigation are antithetical to the goal of transforming medical adverse events and "near misses" to permanent and pervasive systems improvements. Lawmakers should carefully consider any new laws or regulations that could actually do damage to the current health care system by making errors and "near misses" even harder to identify. Peer review protections should be instituted to protect organizations from the fear of litigation which will prevent the sharing of information.
6. ***A system of incentives is the key to patient safety.*** Using positive incentives to encourage health care organizations and all care providers to swiftly report health care delivery problems and to develop processes and procedures to prevent further errors in the area is the key to improving the safety of health care system.
7. ***Focus on prevention instead of errors.*** Instead of devoting major efforts to medical errors after the fact, develop a system focused on studying near misses, to prevent adverse events in the first place. This focus should be firmly impressed early on in graduate medical education programs as well as training programs for all types of health care professionals.
8. ***Consider the larger context.*** The cause of—and solutions for—adverse medical events must be considered in full context beyond the individual incidents that result in medical errors:
   - A hyper-regulated health care environment is not conducive to patient safety. Coping with more than 111,000 pages of complex Medicare rules, guidelines and instructions reduces the amount of time and attention left for providers to focus on their patients.
   - A litigious health care environment is not conducive to the promotion of awareness and information sharing necessary to understand and avoid medical errors.
   - A price-controlled health care environment reduces the ability for health care organizations and systems to implement the necessary technology that can positively affect patient safety.

There is no question that the health care industry as a whole must continue working toward a zero-error environment. Such an environment will require the devoted, thoughtful collaboration of *everyone*, including lawmakers, providers, health systems and patients. Numerous solutions should be considered before implementing any

that could hinder the creation of a safer health care environment. HLC is committed to working with Congress to ensure the highest standards for health care for all Americans. We look forward to working on this important health policy issue in the coming months.

Statement of Premier, Inc.

Premier, Inc., an alliance of leading not-for-profit hospitals and health systems, appreciates this opportunity to share our perspectives on healthcare quality, patient safety, and adverse medical events. There is, perhaps, no issue of greater import in the healthcare arena than the sustained improvement of care quality and reduction of systemic error. We thank the House Ways and Means Health Subcommittee Chairwoman Nancy Johnson (R–CT) and Ranking Member Pete Stark (D–CA) for holding today's hearing.

Public policy debate in the immediate wake of the 1999 Institute of Medicine (IOM) report, *To Err is Human: Building a Safer Health System*, coalesced around the controversial notion of mandatory versus voluntary reporting of medical errors and adverse drug events. Subsequent discussion was diverted from rhetorical, litigious finger-pointing and individual blame in favor of more pointed analysis of systemic shortcomings and cultural reform.

As much testimony offered today has echoed, Premier strongly believes that caregivers ought to be encouraged to share medical error and patient safety information without reprisal in a voluntary, non-punitive environment that puts a premium on information sharing. In the drive for sustained adverse medical event reduction, the importance of education and lessons learned cannot be overstated.

Numerous public and private organizations have engaged in campaigns, programs, and initiatives to foster these changes. The National Quality Forum (NQF), of which Premier is a member, is a public-private partnership charged with developing and implementing a national strategy for healthcare quality measurement and reporting. A current NQF project is aimed at generating consensus on a core set of patient safety measurements, with respect to avoidable adverse events in hospital care. The core measure set will enable standardized data collection and event reporting within and across states.

The Department of Health and Human Services' Agency for Health Care Research and Quality (AHRQ), with which Premier collaborates, supports medical error reporting demonstration projects, and the deployment of new and emerging information and patient safety technologies for the reduction of adverse events.

Premier supports legislative remedies to provide hospitals with the financial assistance necessary to offset the prohibitively high costs of acquiring and deploying patient safety and information technologies. By doing just that, the **Medical Error Reduction Act** (HR. 3292), introduced last year by Ways and Means Committee Members Amo Houghton (R–NY) and Karen Thurman (D–FL), would go a long way toward the achievement of a much-shared goal—the sustained improvement of healthcare quality and safety. We would note that similar bipartisan legislation (S. 824) has been introduced by Sens. Bob Graham (D–FL) and Olympia Snowe (R–ME).

HR. 3292 would authorize grants to facilitate hospitals' and nursing homes' purchase and development of technologies designed to reduce medication-related injury. The legislation is supported by a wide array of businesses, healthcare companies, labor organizations, and hospital groups (listed below). In addition, HR. 3292 emphasizes the value of health informatics programs, and encourages hospitals and other providers to establish health information technology advisory boards. A minimum of twenty percent of the grant funding in HR. 3292 would benefit rural providers.

Legislation is but one piece of the healthcare quality and patient safety puzzle. Premier and its member health systems have developed and continue to expand upon comparative databases of clinical, financial, and operational metrics at the provider level. Such databases allow hospitals to compare their performance against that of others, and to determine areas for measured improvement. The 1999 Institute of Medicine (IOM) report concludes that the core problem in healthcare service delivery is *not* that the individuals within those settings are not working hard enough. Rather, the report argued, we must develop systems to facilitate improvement. Premier's informatics databases were built with such solutions in mind.

The Premier Safety Institute, meanwhile, an alliance-wide initiative, integrates the safety-related activities of members, service units, business partners, and communities. These include the identification of safety-focused products, equipment, and

services; the provision of training, educational resources, and clinical and technical information; and the fostering of opportunities for networking and collaboration. Premier's on-going medication management clinical performance initiative (CPI), for example, integrates new and existing projects to improve patient outcomes by measurably reducing adverse drug events (ADEs) and supporting drug utilization improvements. The aim of this collaborative is to improve patient safety by reducing the average number of preventable ADEs at participating hospitals by 50 percent by June 2004.

Premier also champions industry adoption of the Universal Product Number (UPN) and accompanying bar code technology for the standard identification and tracking of hospital-administered drugs, biologicals and devices, as yet another innovative strategy for improving patient safety. HHS Secretary Tommy Thompson echoed this sentiment at a Senate hearing last year, telling lawmakers that "much like grocers use barcodes, caregivers can use UPNs to track and dispense medications and reduce simple human errors."

Attached to this document, please find the commentary of Premier President and CEO Richard Norling, as published in the Feb. 18, 2002 edition of *Modern Healthcare*. It offers additional insight into Premier's quality and safety improvement philosophy, and details about its initiatives. Again, we appreciate this opportunity to offer a statement for the record on an issue of such paramount importance.

Supporters of HR. 3292, the Medical Error Reduction Act

IBM
Daimler Chrysler
Siemens Vanderbilt University Medical Center
AFL–CIO
McKesson
Newt Gingrich
Aetna
National Rural Health Association
Premier
New York Presbyterian
Federation of American Hospitals
Joint Commission on Accreditation of Healthcare Organizations
VHA Inc.
eHealth Initiative
Verizon
Greater New York Hospital Association
National Association of Children's Hospitals
Florida Hospital Association
Cerner Corporation
David W. Bates, M.D.
BD
3M
EDS

Statement of Donald Rucker, M.D., Siemens Medical Solutions Health Services Corporation, Malvern, Pennsylvania

I am pleased to submit this testimony on behalf of Siemens Medical Solutions Health Services Corporation(Siemens) to the Subcommittee on Health, House Committee on Ways and Means, on the subject of improving health quality through reductions in medical errors and enhanced patient safety. Siemens is the leading provider of information systems and services to the healthcare industry and is the also the industry's leading application service provider, hosting applications for over 1,000 healthcare institutions from our Malvern, PA—based center, the largest data processing center for healthcare

The impact of medication errors and their associated costs is stunning, and by now well documented. The Institute of Medicine (IOM) study, *To Err is Human*,[1] compares the death of 6,000 Americans annually from workplace inquiries with the impact of medication errors that account for over 7,000 deaths annually. According to a study conducted by Bates, et al, at two prestigious medical centers, two out of

[1] To Err is Human—Building a Safer Health System, Kohn, et al, p. 1, 1999.

100 admissions experienced a preventable drug event that resulted in average increased hospital costs of $4,700 per admission[2] This is equivalent to $2.8 million annually for a 700-bed teaching hospital. The IOM study provides an extrapolation associating this volume with $2 billion in increased hospital costs from adverse drug events alone, even without considering other patient safety concerns such as nosocomial infections, surgical misadventures, patient falls, and myriad costly events that pose risk.

The IOM's second report, *Crossing the Quality Chasm,* provided a call to action to providers, government, consumers, employers and payers, and accrediting bodies to make changes to the health system to improve efficiency, quality and safety.[3]

Technology has been recommended as one of the solutions to the problem of too many medical errors. The Leapfrog Group has led the charge to implement computerized physician order entry for the intent purpose of reducing medication errors.[4] While computerized physician order entry can be used to address medication errors, we believe that physician order entry is most effectively deployed when being used to address the quality, efficiency, and effectiveness of all care, not just medications. This approach allows the health system to benefit from the computer-based patient record or CPR.

For addressing the full spectrum of medication errors, Siemens recommends addressing the entire medication use process. According to data compiled by Agency for Healthcare Research and Quality (AHRQ), 39–49% of the medication errors occur while ordering medications, and 26–38% occur during administration.[5] Siemens customers have achieved favorable results with technology that addresses both the ordering and administration of medications. Each system provides another layer of double checks. While the technology provides an important role in aiding the performance of the doctors, nurses and pharmacists, it does not replace these clinicians. In fact, the true benefits of the technology comes from the ability of the clinicians to re-engineer or re-structure their workflow, improve communication, streamline processes, facilitate care, and to focus on clinical decisions.

Siemens customers have experienced and measured significant reductions in errors and costs through the use of its clinical information systems. The benefits range from clearly quantifiable financial measures to other benefits that have a softer cost relationship.

Reductions in errors

Danville Regional Health System (Danville, VA) provides an example of how medication errors are prevented using bar code scanning and an electronic medication administration record that is integrated into the CPR. Danville presented data at the Siemens user group meeting September 9–12, 2001 and during a vendor showcase presentation at the American Society of Health-system Pharmacists meeting in December 2001 about their outcomes using Siemens Med Administration Check. This system uses bar code scanning at the point of care to help ensure that the right patient receives the right drug at the right dose, via the right route, at the right time. The system alerts nurses whenever a drug is past due, or that the nurse is attempting to administer a drug that does not match the order, or that the patient is not the intended patient. The hospital has been preventing on average 12 errors per month. Mary Washington Hospital, part of Medicorp (Fredericksburg, VA) also presented data at the September and December meetings. They indicated, using their language, that they were making on average 71 saves per week with the system. They defined a save as any of the following activities; scanning the wrong drug or patient, a drug that was scanned too early, or when nursing used the send message function to alert pharmacy to a problem with either the order or the drugs delivered. This averaged out to be 22 wrong medications scanned, 13 drugs scanned early, and 30 messages sent to pharmacy per week.

When looking at medication errors, transcription errors are accountable for 11%–12% of the mishaps.[6] The Ohio State University Health System has documented that using computerized physician order entry they have eliminated transcription

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[2] Bates D., et.al. JAMA, The Costs of Adverse Drug Events in Hospitalized Patients, 277:307–311, 1997.

[3] Institute of Medicine. Crosssing the Quality Chasm: a new health system for the 21st century. Washington, D.C. National Academy Press, 2001.

[4] Leapfroggroup.org

[5] Reducing and Preventing Adverse Drug Events to Decrease Hospital Costs. Research in Action, Issue 1. AHRQ Publication Number 01–0020, March 2001. Rockville, MD, USA.

[6] Reducing and Preventing Adverse Drug Events to Decrease Hospital Costs. Research in Action, Issue 1. AHRQ Publication Number 01–0020, March 2001. Rockville, MD, USA.

errors.[7] With 100% of all orders being entered into the computer system directly by physicians, there is no more illegible handwriting for nurses and clerks to decipher. Kingsbrook Jewish Medical Center in Brooklyn New York is another facility that has 100% of all orders placed directly by physicians into the computerized physician order entry system. Kingsbrook has also eliminated all verbal orders and telephone orders.[8]

Siemens is actively involved in furthering research into the effectiveness of information technology in reducing medical errors, not only in the inpatient setting, but in the ambulatory setting as well. Along with Denver Health and Micromedex, Siemens is conducting one of the first outpatient studies examining the feasibility of technology to improve patient safety when healthcare providers order medications. Denver Health's study of Medical Logic Modules (MLM) content and CPOE technology will focus on preventing drug-induced hyper—and hypokalemia, drug-induced nephrotoxicity, and drug-induced thrombocytopenia. The 18-month study began January 1, 2002 and is being funded by a grant from AHRQ.

Reduction in order cycle time

The order cycle time is the time from when an order is placed by the physician to the time that the patient receives the prescribed treatment or test. The order cycle time in a manual process can be many hours and involve many administrative tasks. From the time the physician writes the order to the time that the patient receives the ordered service, the paper order will have gone through many hands and transformations over several hours. Steps in the process would typically include transcription to the chart, delivery to the department that needs to perform the service, transcription into a departmental information system (such as a laboratory or pharmacy information system), calling the physician for clarifications or corrections, scheduling the test or procedure, processing, and documenting the results, and sending the results back to the patient's chart. With computerized physician order entry the physician enters the order directly into the computer system. This eliminates the need for transcription. Clinical decision support within the application provides alerts and reminders to the physician helping ensure that the order does not have any clinical conflicts and will not need future correction by the pharmacy or laboratory. This helps to reduce the number of times clinicians have to search for the physician to get clarification or signature for changes. Electronic interfaces eliminate the need for couriers or pneumatics tubes to transport the orders to the departments. The time from the physician placing the order to the time that the order is received in the department is seconds not hours. When the tests are complete, the results are then entered into the computer system and immediately available for the physician. Too often the test is finished but the physician does not have the necessary information because the results have not made their way back to the chart, or the physician is not where the chart is located. Electronic access provides physicians instant access from anywhere.

The shorter the order cycle time, the faster the patient can start receiving the desired therapeutic benefits. If an antibiotic is to be given once every six hours, and the drug takes six hours to get to the patient, then the patient would have missed one dose. This can be a significant delay in treatment, which in some cases can be significant in allowing the underlying illness to progress further prolonging treatment. The longer a patient is in the hospital the chances of them experiencing a nosocomial infection or other adverse event increases. Thus reducing cycle time reduces this risk. The reduced cycle time also facilitates the reduction in patient length of stay.

Several Siemens customers have documented significant reductions in order cycle time. The Ohio State University Health System showed reductions of 25% for laboratory orders, 43% for radiology orders, and 64% for pharmacy orders.[9] The pharmacy cycle times went from 5:28 hours down to 1:51 hours. Radiology procedures were finished almost 3 hours faster from 7:37 hours pre-computerized physician order entry to 4:21 hours with computerized physician order entry (CPOE). The reduction in laboratory cycle time ranged from 31 to 23 minutes. Rush-Presbyterian St. Lukes Medical Center in Chicago IL reported an average pre-CPOE medication

[7] Mekhjian HS, et. al. Immediate Benefits Realized Following the Implementation of Physician Order Entry at an Academic Medical center. JAMIA (In Publication for 2002)

[8] HIMSS 2002 Session 127 Can Physician Order Entry and Physician Alignment / Satisfaction Coexist?

[9] Mekhjian HS, et. al. Immediate benefits realized following the implementation of physician order entry at an academic medical center. JAMIA (In Publication for 2002)

order cycle time of 3:49 hours and post-CPOE time of 1:23 hours.[10] This is a 64% reduction.

Reduction in cost and length of stay

Computerized physician order entry has the potential to reduce the cost of care through many mechanisms, while at the same time improving quality. The reduced cycle time previously referenced helps to reduce length of stay and, therefore, reduces risk of complications associated with prolonged hospital stays. CPOE also can help by enabling the practice of evidence-based guideline driven care. Through the use of order sets and clinical decision support algorithms, the technology helps reduce the variance in the care processes. Reducing variance means that recommended treatments or tests are not forgotten. It means that pre-procedure or post-procedure processes are conducted in a consistent manner. This reduces the risk of errors and complications associated with not following the evidence-based best practice.

The Ohio State University Health System has studied the direct impact of computerized-physician order entry on cost of care for a period of 10–12 months pre and post implementation of CPOE.[11] This study showed significant reductions in the severity adjusted cost of care in three out of six care units studied. These reductions were a 7.46% reduction in the Heart unit and a 8.0% reduction in the Transplant unit of the University Hospital. The James Cancer Hospital's Surgical Oncology unit had a significant decrease in costs of 7.5%. These reductions represented savings of between $300 to $600 per stay. Only one of the six study units had a statistically significant increase in case mix index adjusted costs, which was 5% in the Hematology/Oncology unit of the James Cancer Hospital.

This same study also looked at the effects on average length of stay. When all of the services studied were combined for the University Hospital, there was a statistically significant decrease in the severity adjusted length of stay from 3.91 days to 3.71 days, and a reduction from 3.68 days to 3.61 days in the James Cancer Hospital.[12]

Other hospitals have shown savings in costs from the use of clinical decision support systems to direct physicians to less costly plans of care, but that are equally or more clinically effective. Kingsbrook Jewish Medical Center is saving $100,000 a year by restricting the use of high cost antibiotics to only those patients that have had a consult by an infectious disease specialist.[13] The computer system helps to enforce and track the policy. Not only does this save the hospital in direct costs, it also saves in the reduction of the over-use of antibiotics. In an unpublished study by Siemens customer Meridian Health, they were able to identify savings of $160,000 annually with a reminder that alerted physicians to the ability to change an intravenous medication to an oral medication when the patient resumes an oral diet. While they did not address a direct cost, Rush Presbyterian St. Lukes documented a reduction in Imipenem resistant bacteria strains in the hospital through their use of clinical reminders to reduce the over use of antibiotics.[14] The spread of antibiotic resistant bacteria adversely affect patient well-being and the effectiveness of the drug choices available to physicians. As more powerful drugs are needed to combat resistive strains, the cost of care increases.

In addition to the direct care costs, some hospitals have identified other cost savings or re-allocations. Rush Presbyetrian St. Lukes was able to reduce the amount of expensive multi-part forms that they purchase and store, as well as reduce clerical staff.[15] The Ohio State University Health System was able to re-allocate clerks used for chart pulls to become medical records coders.[16]

Compliance with documentation and best practice guidelines

Rush Presbyterian St. Lukes has documented that 100% of all physician-entered orders are now complete and legible when entered. All of the orders are dated, timed, signed, and most importantly are legible. This has helped reduce questions

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[10] Skarulis P, Brill J., Lehman M. HIMSS 2002 Session 126 Rush Physician Order Entry: From Physician Resistors to Physician Champions.

[11] Mekhjian HS, et. al.

[12] Mekhjian HS, et. al.

[13] Eisenberg, F., Krusch, D., Meindel, N., HIMSS 2002 Session 127 Can Physician Order Entry and Physician Alignment / Satisfaction Coexist?

[14] Skarulis P, Brill J., Lehman M HIMSS 2002 Session 126 Rush Physician Order Entry: From Physician Resistors to Physician Champions.

[15] Skarulis P, Brill J., Lehman M HIMSS 2002 Session 126 Rush Physician Order Entry: From Physician resistors to Physician Champions.

[16] Ahmad, A. POE Enterprise Roadmap Strategies and Benefits Realization, presented at Physician Order Entry "Best Practice" Planning and Implementation Strategies. February 28, 2002. Columbus OH

about the plan of care for patients in the hospital. Rush has also used Siemens INVISION® health information system to ensure that physicians properly document the specific reasons that certain tests are ordered. For radiology tests, the system makes it easier for the physician to enter the specific reason for a study rather than entering a generic "rule/out" comment. Without a more specific reason documented, the hospital needs to go through extra steps to locate the physician and obtain the reason. Insurance claims with non-specific reasons are rejected. By collecting the specific reason at the time of ordering, claims become more accurate, and redundant work is eliminated. The results observed at Rush were a reduction in "rule/out" reasons from 30% of all radiology orders down to 8%.[17]

Rush Presbyterian also demonstrated the ability of the CPOE system to positively affect the physician's ordering behavior to follow best practice clinical guidelines. Blood culture results are more accurate when two or three cultures are run within a 24-hour period instead of just one. The ability to get a more accurate result in the long run enables the physician to diagnose the patient more accurately and quickly. Through a simple on screen reminder, Rush changed their double culture orders from 39.8% to 57%.[18] Other forms of education were unsuccessful in changing physician behavior as evidenced by a lack of ordering practice change in physicians that were not entering orders directly into the computer system.

Other Benefits

When FDA recalled Rezulin in March 2000, Kingsbrook Jewish Medical Center was able to search the orders of 800 active patients and remove Rezulin use from those taking it within hours of the announcement.[19] The speed in being able to identify affected patients, take action, and minimally impact staff was only possible from the use of the computerized system.

Conclusion

Again, we appreciate the opportunity to submit testimony on this important topic. Expanding hospitals' use of use of computerized patient records will further help to improve the quality of care and reduce errors. Siemens customers have been able to show that these systems meet the objectives of improving efficiency, effectiveness, and safety. Further gains will be achieved as care models move to evidence-based best care practices. The computer-based patient record helps to facilitate these process changes. Technologies such as computerized physician order entry, point-of-care bar code scanning for medication quality checking, and clinical decision support systems enable clinicians to concentrate on making the right decisions instead of searching for the right information.

Attachment 1 Summary of Siemens Customer Realized Computerized Physician Order Entry Benefits

POE Outcome	Siemens Solution	Proven Outcomes
Reduction in Turn Around Time	• Electronic transmission of orders to departments. • Orders complete when written • Process standardization • Improved access to patient information	The Ohio State University Health System 25% reduction in Lab order cycle time 43% reduction in Radiology cycle time 64% reduction in medication cycle time Rush Presbyterian St. Lukes 64% reduction in medication cycle time Meridian Health System 84% reduction in medication cycle time
Reduction in Cost Reduction of variance in care	• Order sets • Process standardization	The Ohio State University Health System 7.5% to 8% reductions for several services Rush Presbyterian St. Lukes Reduction in multi-part forms Elimination of Unit Clerks

[17] Skarulis P, Brill J., Lehman M HIMSS 2002 Session 126 Rush Physician Order Entry: From Physician Resistors to Physician Champions.

[18] Skarulis P, Brill J., Lehman M HIMSS 2002 Session 126 Rush Physician Order Entry: From Physician Resistors to Physician Champions

[19] Meindel N. User Summit 2001, Washington DC

Attachment 1 Summary of Siemens Customer Realized Computerized Physician Order Entry Benefits—Continued

POE Outcome	Siemens Solution	Proven Outcomes
Reduction in Length of Stay	• Order sets • Process standardization	The Ohio State University Health System 1.9% to 5.1% reduction in length of stay
Increase compliance with best practice protocols	• Alerts and reminders	Rush Presbyterian St. Lukes Increase compliance with blood culture order procedure up from 39.8% to 57%. (Physicians using paper at same time did not change)
Reduction in errors	• Forcing functions • Ability to enforce policy through log-ons	The Ohio State University Health System 100% elimination of transcription errors 50% reduction of medication errors Kingsbrook Jewish Medical Center 100% eliminated verbal and telephone orders
Improve documentation compliance	• Forcing functions within workflow	The Ohio State University Health System Verbal order cosignature compliance rate up from 72.8% to 98.95% Rush Presbyterian St. Lukes 100% of orders entered directly by physician are dated, timed, signed, and legible
Reduce insurance claims rejections	• Provide alerts • Drop down selections make it easy to complete documentation.	Rush Presbyterian St. Lukes Radilogy order reason, made it easier to provide an accurate exam reason, instead of "rule/out", the rate of stated reasons of "rule/out" dropped from 30% of all radiology orders to only 8%.
Speed patient notification of recalls	• Search and report against enterprise patient list	Kingsbrook Jewish Medical Center Within hours of FDA recall notice, searched 800 active patients and discontinued affected drug.
Reduced use of overused antibiotics	• Online clinical alerts	Rush Presbyterian St. Lukes Imipenem resistance dropped from 50% to 15%
Resource re-allocation		The Ohio State University Health System FTE directed to chart reviews per-POE was promoted to a coder Rush Presbyterian St. Lukes Eliminated unit clerk positions

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