REDUCING MEDICAL ERRORS: A REVIEW OF INNOVATIVE STRATEGIES TO IMPROVE PATIENT SAFETY

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

MAY 8, 2002

Serial No. 107–112

Printed for the use of the Committee on Energy and Commerce

Available via the World Wide Web: http://www.access.gpo.gov/congress/house

U.S. GOVERNMENT PRINTING OFFICE

79–468CC WASHINGTON : 2002

For sale by the Superintendent of Documents, U.S. Government Printing Office
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REDUCING MEDICAL ERRORS: A REVIEW OF INNOVATIVE STRATEGIES TO IMPROVE PATIENT SAFETY

WEDNESDAY, MAY 8, 2002

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

The subcommittee met, pursuant to notice, at 10 a.m., in room 2123, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Deal, Ganske, Cubin, Wilson, Shadegg, Brown, Barrett, Capps, Eshoo, Wynn, and Green.

Staff present: Patrick Morrisey, deputy staff director and majority counsel; Steve Tilton, health policy coordinator; Cheryl Jaeger, majority professional staff; Eugenia Edwards, legislative clerk; John Ford, minority counsel; Karen Folk, minority counsel; and Jessica McNiece, minority staff assistant.

Mr. BILIRAKIS. I call this hearing to order. I appreciate the patience of the panelists and the audience. I would like to thank our witnesses for taking the time to appear before the subcommittee.

The Institute of Medicine's 1999 report, "To Err is Human," brought the frequency and devastating effects of medical errors into public scrutiny. In the report the Institute of Medicine estimates that an unbelievably high number, between 44,000 and 98,000, of Americans die each year as a direct result of potentially preventable mistakes.

During the 106th Congress, the American Nurses Association, the Joint Commission on Accreditation of Health Care Organizations, and U.S. Pharmacopeia testified before our subcommittee about strategies for reducing medical errors. Once again, we have the opportunity to hear from these organizations.

Today's hearing provides our committee with evidence about the successes the private sector has achieved in addressing this issue. I am also pleased that the administration has taken an active role in addressing patient safety. Last year Secretary Tommy Thompson announced the release of $50 million to fund 94 new research grants, contracts, and other projects to reduce medical errors and improve patient safety.

In addition, President Bush's fiscal year 2003 budget proposal includes a $10 million increase for patient safety activities at the Food and Drug Administration and the Agency for Health Care Re-

search and Quality. The information presented will be invaluable as we determine Congress's role, if any, in addressing this problem.

I have always believed that not every problem in our country requires action by the Federal Government. This hearing will play an important role as we consider legislative alternatives.

Again, I would like to thank our witnesses for appearing before the subcommittee today, and I would ask at this point unanimous consent that certain members of the panel who would like to supplement their verbal or oral testimony with visual presentations be allowed to do so, and that their time be extended accordingly. Hearing no objection, that will be the case, and I will yield to the ranking member, my friend, Mr. Brown, for an opening statement.

Mr. BROWN. Thank you, Mr. Chairman, for holding today's, I hope, informative hearing. I would like to thank our distinguished witnesses for joining us. Cardinal Health, Quest Labs, JACO, Pharmacopeia have been working to reduce medical mistakes, and they have important successes to share with the subcommittee today, and we thank you for that.

I want to extend a special welcome to Jim Hethcox, Vice President of Pharmacy Practice at Cardinal Health, and in my home State of Ohio and in Dublin, Ohio. Cardinal has developed a bar code technology to help ensure that patients receive the proper dosage at the correct time. They have also developed innovative packaging to help patients comply with their prescribing instructions.

I am looking forward, too, to the testimony of Bonnie Westra, a registered nurse. With the current critical shortage of nurses, they have a unique perspective of how error reduction programs are actually working.

The statistics, as we know, on medical errors are alarming. Medical errors are the eighth leading cause of death in the United States. Each year 90-some-thousand deaths are attributed to these errors. Medical errors drain an estimated $29 billion from the health care system every year, with 44 million Americans uninsured. There is a gaping hole in Medicare, where prescription drug coverage should be. There are unjustifiable and unconscionable disparities in the health of minorities. We don't have a cure for cancer and AIDS and heart disease, and on and on. We don't have $1, let alone $29 billion, to burn.

According to an IOM report published 3 years ago, medical errors are more often the result of systemic flaws, not negligence on the part of individual health care providers. The current system all too often leads to numerous errors that are unique: Infections resulting from lapses in hand washing, medication errors resulting from prescriptions difficult to read, missed diagnoses, improper treatments, contaminated blood products. Each of these types of errors calls for a different solution.

It is considered an error if patients have difficulty taking their multiple prescriptions, some with food, some without, some every few hours, some only at night, and then those patients are admitted into a hospital for failing to comply with the medications' directions. These examples highlight the flaws of the health care delivery system more than they do the failures of an individual.

Two years ago, the Commerce Committee held a hearing to examine the medical error problem highlighted in a report from the

Institutes of Medicine. At that time it was clear there were no quick fixes to the problem of medical errors, but since then both the private and the public sectors have made remarkable progress in the development of products and services aimed at reducing medical errors, as we have mentioned Cardinal's a moment ago.

While the private sector is here today to share their findings, I am disappointed that the administration is not here to share how, for instance, the Agency for Health Care Quality and Research at HHS is addressing this issue. They should be here to share their findings.

Aside from that, Mr. Chairman, I am pleased again to hear from our panelists. I hope this hearing adds to the momentum that has been building and the apparent successes in reducing medical errors. I thank the chairman.

Mr. BILIRAKIS. I thank the gentleman. Dr. Ganske, for an opening statement.

Mr. GANSKE. Thank you, Mr. Chairman. I think it is really important to have this hearing. I appreciate the effort you and the staff have put into this important issue. Prior to coming to Congress, I was a reconstructive surgeon. So I am intimately aware of the issue that we are talking about today.

I think it is important to start out by making a distinction between a good result and a bad result and an error, because it is inherent in human activity that sometimes not everything goes perfect. Let me give you an example.

If a patient gets an infection, now that is a bad result. Something unfortunate has happened, but was it an error? Maybe, and maybe not, because infections can happen, despite the best sterile technique. I mean, the skin is not a sterile organism, for example. No matter how much you scrub it, there are still going to be bacteria there.

Some operations take a long time, because they are very complicated. We know, for example, that the longer an operation goes on and you have an open wound, the higher the chance that you may have an infection. So what is an acceptable infection rate? Maybe it is half a percent or 1 percent for certain procedures. Maybe if you are operating on the gut in an emergency situation, doing everything right would still result in a higher infection rate than that.

So I think it is important for the public to make a distinction between a complication and an error. That is a very, very important distinction. There are errors of commission where you may do something wrong. There are errors of omission where you haven't done something that you should. There are errors in diagnosis, errors in treatment. There are errors in process, errors in evaluation and management.

In the operating room, an error in process would be, for instance, operating on the wrong extremity. So it will be interesting to hear some ideas from our panelists on how we can create processes and techniques to reduce the chance of those errors occurring.

A simple way might be that in the operating room, or in the preop area where the patient is awake, the surgeon is talking to him, you pick up the hand that you are going to operate on and you put

an X in the palm, or there is a procedure to put a red wrist band on the extremity that is going to be operated on.

Another thing I always thought was important in terms of making sure there weren't errors in the operating room was to reduce the sort of pandemonium and chaos that can sometimes occur. Operating rooms—I'm not saying that you can't have music in the operating room. Sometimes some quiet, soothing music is helpful, but sometimes some rock music and a lot of people talking can be distracting.

So there are different things that you can, practically speaking, do to reduce the chance of an error occurring. It will be interesting to hear the comments of the different panelists on this, but this is something that we should all be concerned about.

In every human endeavor there are errors, but in every human endeavor we strive to reduce the incidence of those errors, and I am looking forward to the testimony today, and I thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank you, Dr. Ganske. You have been a terrific addition to this committee because of the practical, real world experience that you have, and I appreciate your being here this morning. Ms. Capps for an opening statement.

Ms. CAPPS. Thank you, Mr. Chairman. I appreciate this opportunity to review the progress that has been made in reducing medical errors. After the 1999 Institute of Medicine report was published, this committee held hearings to consider its findings, and it is only appropriate that we now return to the subject to find out what has changed.

I am looking forward to hearing the opinions of our witnesses today regarding this important subject, and understand that they will be focusing on the technologies and the systems that health care providers can use to avoid medical errors. I am eager to hear what they have to say, but I also want us to be sure to look at the role of proper staffing in avoiding medical errors.

I have been very pleased to work with Chairman Bilirakis, ranking members Brown and Dingell, and several other members of this committee to address the growing shortage of registered nurses as one piece of this staffing issue. Five months ago, we passed a version of my bill, the Nurse Reinvestment Act, and the Senate has passed their own version of the same bill, and since then we have been working to develop a final bill that could be sent to the President's desk. This, I am convinced, will at least help to address the topic of shortages, which can be seen as a part of the issue around errors.

The nursing shortage is an increasing threat to patient safety, and it is one of the causes for the medical errors we are trying to address. We clearly have a shortage of nurses, and the number of patients is not going down. In fact, we can anticipate greater shortages and more and more patients in the future.

This means that nurses, and other staff people as well, but I am focusing now on nurses, are overworked and overstressed. They are forced to do the work of two or three nurses on a regular basis, and sometimes nurses are placed into jobs that they do not have the training for, because there isn't a properly trained nurse available

to do that work. These are conditions that are guaranteed to create serious medical errors.

When nurses and other health professionals are tired and frustrated, they are more apt to make mistakes. They are human. We are all human, and the low morale that comes from these mistakes and the workplace frustrations contribute to other mistakes.

Unfortunately, we cannot just flip a switch and suddenly have staffing where we need it. It takes a few years for a nurse to complete training and enter the workforce. For some in specialty positions, advanced clinical practices, it takes longer than that, and that is why it is imperative to pass nurse shortage legislation and get it signed by the President and out into the communities soon.

A bill that provides better training through scholarships, internships, and residencies and helps to foster better management practices can help us to ease the shortage and also to reduce medical errors. There are many steps we can take to avoid more medical errors, perhaps limiting residents' work hours, for example, but passing the Nurse Reinvestment Act soon and getting it onto the President's desk is a good first step to address these issues.

I have been pleased to work with you on this, Mr. Chairman. As you know, we have talked about it incessantly, and I do look forward to wrapping up this bill quickly. I yield back the balance of my time.

Mr. BILIRAKIS. Amen to your comments. You and I met last night on the nursing bill, and we plan to meet during this hearing as soon as we can get somebody to come here to replace us. Ms. Wilson for an opening statement.

Ms. WILSON. Thank you, Mr. Chairman. I look forward to listening to the testimony and reviewing the testimony, and I have no opening statement. Thank you.

Mr. BILIRAKIS. Ms. Eshoo for an opening statement.

Ms. ESHOO. Thank you, Mr. Chairman. Good morning to you and to our ranking member, Sherrod Brown. This is an important hearing, and I welcome it taking place.

I am concerned, because it has been a long time since the Institute of Medicine released its report on this issue, and Congress has yet to take steps to help reduce the number of medical errors occurring in our country. So we have some work to do.

Certainly, the report takes us, points us, in the direction of—It gives us the information from which we need to take action. The numbers from the 1999 report are really astonishing. More than 44,000 Americans are dying every year from medical errors, many of which could be prevented. We are all familiar with the term "the practice of medicine," and we know that there isn't a human being, regardless of where they hold their degree and how brilliant they are, that things can, obviously, go wrong. It is the mark of humanity, but there are many steps that can be taken by the Congress to help prevent what the report tells us.

So that is why I welcome this hearing, and to the distinguished panel that is here today, because obviously, we can't act in a vacuum.

One of the key elements of any proposal is to reduce medical errors. To reduce them, we have to have the access to the technologies that are specifically designed for specific purposes. Car-

dinal Health, represented here today, has a number of companies and products that are dedicated to helping hospitals and providers reduce their error rates.

I also think, and I am going to slide something in here, Mr. Chairman, that they are not—hospitals are not going to be able to afford to buy these technologies unless we do something that helps them, because they are in a vise, hospitals across the country, certainly in rural America but all over the country. Hospitals are in a vise between the public reimbursement systems and the private reimbursement systems.

So when the BBA Fix bill comes up, we need to keep—All of these issues are linked with one another. They are not just separate standing smokestacks. We really have to address them as a whole. Automated dispensing and health care worker identification are just two advanced mechanisms that can help hospitals and providers safeguard against improper or mistaken use of drugs or supplies.

As we rely more and more on a multitude of pharmaceuticals and devices to treat diseases, it is important that we also advance our ability to monitor the correct use of the products. Lifesaving products such as drugs and devices should be just that, lifesaving, not threatening.

Let us hear from our expert witnesses, and I am looking forward to hearing from them today. Then I hope this committee, which has distinguished itself in the past in so many different areas to make a difference for our country, will take action on the essence of the report and bring something forward to the full committee and to the full House so that we can bring these numbers down and really score a victory for the American people.

Thank you, Mr. Chairman. I yield back.

Mr. BILIRAKIS. I thank the gentlelady.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. CHIP PICKERING, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MISSISSIPPI

Mr. Chairman, thank you for holding this hearing today regarding medical errors. I look forward to the testimony from our panel of witnesses. When one looks at the number of individuals that are affected each year due to medical errors they find it astonishing. Studies have shown that there are at least 44,000 Americans that die each year due to medical errors and the number may be as high as 98,000. This is a problem that must be addressed.

In 1999, Congress reauthorized the Agency for Healthcare Quality and Research within the Department of Health and Human Services as the lead agency to improve healthcare quality, improve patient safety and to expand access. We also gave the AHRQ the authority to conduct research that will help us to better understand medical errors.

While Congress has not mandated a federal reporting system of medical errors, there are already some voluntary and mandatory systems in place. The Center for Disease Control in Atlanta operates a voluntary reporting system known as the National Nosocomial Infections Surveillance System. This system compiles data that reports on medical errors that occur through hospital-associated infections. The CDC also coordinates the National Immunization Program Vaccine Adverse Events Reports System. This system is designed to report the rare adverse effects that are associated with vaccinations.

At the Food and Drug Administration, healthcare professionals report any adverse events that involve medical products to MedWatch. MedWatch is a voluntary program that reports on the errors of medical products. The FDA also administers the Biological Product Deviation Reporting System. This system was developed in order

for reports to be given from licensed manufacturers of all biological products and unlicensed registered blood establishments on deviations in manufacturing.

Also, several private non-profit organizations have created reporting systems that are committed to reducing the number of medical errors. The Joint Commission on the Accreditation of Healthcare Organizations encourages companies to maintain a process for identifying, reporting, and analyzing medical errors.

There is no doubt that great strides have been taken among all in the healthcare community to reduce the number medical errors. Again, Mr. Chairman, I look forward to the discussion we are going to have this morning and commend you once again for your efforts and commitment to the quality of healthcare in our nation.

PREPARED STATEMENT OF HON. W.J. "BILLY" TAUZIN, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Thank you, Mr. Chairman for holding this important hearing to discuss medical errors.

Patient safety is, and should always be, an important concern for our committee. Government policies should always promote and encourage America's companies to produce products and services that reduce the incidents of consumer harm or error. This is not only sound public policy, but good business sense. Competition drives innovation, and it is this impetus that has made America the world leader in new solutions to help people live longer and better.

Two years ago, the House Commerce Committee held a joint hearing with the Committee on Veterans Affairs to focus on the problem of medical errors. This hearing followed the release of the Institute of Medicine's November 1999 report, *To Err Is Human.* In that report, the IOM estimated that at least 44,000 Americans die each year as a result of medical errors, and that the number may be as high as 98,000. If accurate, medical errors cause a greater number of deaths than motor vehicle accidents, breast cancer, or AIDS. Even more alarming, we may or may not be properly accounting for all of the medical errors that occur on a minute-to-minute basis or taking the appropriate steps to reduce their occurrence.

Human error is, by definition, unavoidable. We may not be able to achieve perfection, but we must strive to ensure that when a medical error occurs, the harm it causes to a patient is minimized. Today, we have an outstanding panel of witnesses who understand clearly that patient safety is the bottom line for their businesses. They represent companies which have a broad range of approaches to addressing the medical error problem. What is most exciting is that these witnesses represent merely a glimpse of some of the incredible collaborative efforts underway within the health care community that are creating new technologies and improving the delivery of services for patient safety.

Today, we have an opportunity to learn from the witnesses about the steps their businesses and non-profit organizations have taken since the publication of the IOM report. Though the recommendations of the Institute of Medicine were numerous, they certainly gave both the public and private sector a clear starting point for some serious discussion of how to comprehensively achieve better patient safety. Three of our five witnesses represent organizations that originally testified before this committee two years ago. I am most interested to hear from you all about the advances that have been made since then.

The federal government is an important player in our efforts to improve patient safety. Our public policies directly affect the ability of the private sector to conduct their business. The federal government currently maintains and operates numerous reporting systems and databases to help track medical errors and prevent their reoccurrence. The federal government also champions research to evaluate and determine the options available to address health care improvement. We must constantly examine these programs to enhance their efficiency and ensure that we are not trampling on the private sector's ability to innovate. The private sector represents our best opportunity to reduce the occurrence of medical error. We should ensure that any legislation we advance emphasizes that point.

Today, I would also like to take a moment to recognize a true leader in this field, John Eisenberg, former Director of the Agency for Health Care Research and Quality who recently passed away. His tireless determination and dedication to this issue will be sorely missed.

Thank you, again, Mr. Chairman for holding this hearing. It's nice to take a break—albeit temporarily—from our work on Medicare and focus on another important issue. We have so many priorities at this Committee. I'm excited that we are addressing such an important issue.

PREPARED STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Thank you Mr. Chairman for holding this hearing today on strategies for reducing medical errors.

In November of 1999, the Institute of Medicine released its eye-opening report on medical errors.

In its groundbreaking report, To Err is Human, the IOM made us painfully aware of the shortcomings in the area of patient safety.

According to some estimates, as many as 98,000 people die in any given year from medical errors that occur in hospitals. That's more than die from motor vehicle accidents, breast cancer, or AIDS.

The costs of preventable adverse events are staggering. The direct and indirect costs of medical errors range from $17 billion to $29 billion. By any standard, that is far too much.

At a time when other industries are finding more efficient ways to do things, the health care industry lags far behind.

As the IOM study points out, between 1990 and 1994, the U.S. airline fatality rate was less than one-third the rate experienced in mid century. In 1998, there were no deaths in the United States in commercial aviation.

In health care, however, preventable injuries have been estimated to affect between three to four percent of hospital patients.

We would never tolerate these statistics in any industry, be it air travel or food safety, and there is no reason we should excuse the health care industry.

Mr. Chairman, I am not condemning the hard-working health care professionals who serve this nation every day. I know they are committed, skilled individuals who do their best.

But it is abundantly clear that we can and should do better in this area.

The Institute of Medicine recommended a number of options to help reduce medical errors, such as the creation of a Center for Patient Safety within the Agency for Health Quality and Research.

They also suggested a new system of reporting, and better use of technological advancements.

And we certainly have seen, and will hear testimony, about how these methods can improve patient safety.

Technological advances in recent years can help us substantially reduce the number of medical errors.

For example, adverse drug events account for approximately $5.1 billion in costs each year. Almost one-third of these events are entirely preventable.

Better utilization of existing technologies could help us reduce these adverse drug events significantly.

I am happy to see a witness here from Cardinal Health Care.

I recently had the opportunity to learn more about Cardinal's Pixys (Pick-sus) system at a demonstration in the Cannon Caucus Room, and I was impressed by their product and the potential it has to reduce errors.

I am also interested in the bedside verification and bar code technology.

Those of us who remember the good-old-days when cashiers actually keyed in the cost of groceries, know how much more efficient bar code scanning is.

These are the kinds of time-tested technologies that could and should be adapted on the larger scale throughout our health care system.

I am also interested in the other witnesses testimony about their approaches to improving patient safety.

I realize there is no single solution to our patient safety problems, but I think we should consider all of our options, and am pleased that we will have the opportunity to do that today.

Thank you Mr. Chairman, and I yield back the balance of my time.

PREPARED STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Chairman Bilirakis, thank you for convening this hearing on strategies to reduce medical errors and improve the quality of care for all of America's patients. Two years ago, a report published by the Institute of Medicine (IoM) changed the way we think about medical errors. The report concluded that, most often, medical errors are caused by flaws in the health care delivery system, and less often are the fault of individual doctors, nurses, or other practitioners in the health care industry. And the report said that medical errors can be reduced or even eliminated by designing better systems.

Both the government and the private sector have embraced the conclusion of the IoM report and begun to examine in earnest the systems that lead to inadvertent mistakes. I would particularly like to commend the late Dr. John Eisenberg in his role as head of the Agency for Health Research and Quality. Dr. Eisenberg recognized that quality health care is not just an abstract ideal, but an attainable goal that can be reached through application of the best available science. Through his vision and dedication, the agency became the Nation's leader in the science of medical error reduction.

Today's witnesses will describe patient safety initiatives in the private sector. Several will highlight how new technology can dramatically decrease medical errors. Others will describe how management philosophies from manufacturing industries can be applied to health care. Finally, some will comment on how providers on the front lines of the health care delivery system can translate these new technologies and management philosophies into practice.

I would like to acknowledge the work of one additional organization who is not a witness today, but has been highly instrumental in mobilizing large purchasers of health care to promote patient safety. General Motors, in conjunction with the "Leapfrog Group," pioneered the practice of rewarding health care providers that demonstrate quality results. As the largest purchaser of health care in the country, the Federal government should carefully study this example.

I look forward to the testimony of our distinguished panel and to working with the Chairman on this important topic.

Mr. BILIRAKIS. We will now go to the panel of witnesses. Your written statements are a part of the record, and we would hope that you would supplement and complement them. I have already asked for unanimous consent as far as the videos are concerned. I understand that Mr. Hethcox has one. So why don't we start off with you, sir.

Mr. James Hethcox is Vice President of Pharmacy Practice, Cardinal Health, Inc. out of Dublin, Ohio, Mr. Brown's area, and I would turn the clock on to 5 minutes at this point in time. Please try to complete your oral statement within that 5 minute period of time, but then we will give you additional time on the video. Thank you, sir.

STATEMENTS OF JAMES M. HETHCOX, VICE PRESIDENT, PHARMACY PRACTICE, CARDINAL HEALTH, INC.; KENNETH W. FREEMAN, CHAIRMAN AND CEO, QUEST DIAGNOSTICS INCORPORATED ON BEHALF OF THE HEALTHCARE LEADERSHIP COUNCIL; DENNIS S. O'LEARY, PRESIDENT, JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS; ROGER L. WILLIAMS, U.S. PHARMACOPEIA; AND BONNIE WESTRA, AMERICAN NURSES ASSOCIATION

Mr. HETHCOX. Mr. Chairman, Congressman Brown, and members of the subcommittee. As stated, I am Jim Hethcox, Vice President for Pharmacy Practice for Cardinal Health. Prior to joining Cardinal, I was a pharmacy practitioner for 25 years in hospitals ranging in bed size from 200 to 1,000 beds.

I want to thank the subcommittee for the opportunity to testify regarding the products and services being developed by the private sector to assist in reducing medication errors as well as the obstacles the industry faces in broader adoption of patient safety tools.

Cardinal Health is a comprehensive provider of health care products and services. We provide product development, manufacturing and packaging, as well as distribution, operations and clinical improvement services. I am pleased to have the opportunity to comment on two of our cutting edge products that improve patient safety, specifically compliance packaging for the outpatient setting

and automated bedside verification of medication administration in the inpatient setting.

First, compliance packaging. Medication noncompliance—that is, a patient failing to take his or her medication as prescribed—is a major health problem and has been described as America's "other" drug problem. In the general population, rates of medication noncompliance range from 20 to 70 percent.

The issue is exacerbated among the elderly, as they take an increased number of prescriptions and may have increasingly compromised physiology. The average elderly patient takes 17 to 24 prescriptions a year. An AARP survey showed that 58 percent of the elderly population makes errors when taking medications, and nearly 10 percent of all Medicare hospital admissions are the result of medication noncompliance. Furthermore, the cost impact of noncompliance exceeds $100 billion per year.

Cardinal Health, a leader in pharmaceutical packaging promotes compliance packaging to help reduce such medication errors. Compliance packaging is a pre-packaged, ready to dispense system used for a treatment cycle of a medication that provides day and time reminders as well as patient education information to help patients take their medications correctly.

We believe that compliance packaging can help reduce errors in the outpatient setting, thus enhancing the probability of positive outcomes. Moreover, compliance packaging could save up to 1,700 hours a year in a busy retail pharmacy; this is an important benefit, given the shortage of pharmacists now facing this country.

The elderly are especially at risk of medication noncompliance. In 1999, the Congress directed the Department of Health and Human Services to award a grant to study the benefits of compliance packaging and improving seniors' ability to take their drugs as prescribed. That study will commence next month.

Turning to automated medication dispensing and bedside verification: Up to 30 percent of all hospitalized patients experience an adverse drug event, and research suggests that up to one-third of these are preventable. Patients who experience in-hospital medication related errors often require 2 to 5 additional days of hospitalization at a cost of $2,000 to $5,000 per admission.

Most errors are the result of breakdowns in the system of care. With approximately 3.75 billion drug administrations made annually to patients in hospitals, with an average of 20 steps per admission, the opportunity for things to go wrong are significant.

Pyxis, a Cardinal Health company, has revolutionized medication distribution within hospitals through development of an automated medication dispensing systems. These systems have greatly decreased the steps in the medication use process, and thus have improved safety.

A next step is to move medication related patient safety technologies directly to the patient's bedside. Such technology, specifically bedside verification, uses barcode scanning at the point of administration to ensure that the right patient receives the right medication in the right dose by the right route at the right time.

With the permission of the chairman, I have a short video of the Pyxis Veri5 system that I would like to show at the end of my testimony to demonstrate this technology.

The most significant obstacle inhibiting adoption of this exciting technology is the lack of barcodes on medication. Approximately 30 percent of unit dose medications bear manufacturer printed barcodes. We are encouraged that the FDA has indicated intent to publish a notice of proposed rulemaking on this issue. We believe standards developed in this area must be done in a thoughtful and cost effective manner, ensuring patients have timely access to this important patient safety technology.

Knowing that we share a common commitment to improve patient safety, I would like to leave you with three concluding thoughts.

One, the provision of patient care is indeed complex. There is no simple silver bullet or quick fix. Two, nor there is a cookie cutter solution for all organizations. Each environment has a unique set of needs, challenges, and capabilities. Finally, the road to patient safety will be an ongoing work in progress. Given health care's resource constraints, a logical and planned progression in which the work of each tomorrow will build upon a solid foundation built by each preceding today should serve us well.

Now I would like to let you hear directly from the practitioners currently using our bedside verification technology, and I thank you for your interest and attention.

[The prepared statement of James M. Hethcox follows:]

PREPARED STATEMENT OF JIM HETHCOX, VICE PRESIDENT, PHARMACY PRACTICE, CARDINAL HEALTH, INC.

Mr. Chairman and Members of the Subcommittee: I am Jim Hethcox, Vice President of Pharmacy Practice at Cardinal Health. I want to thank the Subcommittee for holding this very important hearing on medical errors and for receiving testimony on products and services developed by the private sector to assist in reducing these errors and obstacles the industry faces in broader adoption of these and other patient safety tools.

Cardinal Health is a comprehensive provider of products and services supporting the health care industry. The company has over 50,000 employees serving the hospital, retail pharmacy, and manufacturing segments of healthcare. Our purpose is to provide essential support that helps our customers succeed in their respective roles within patient care. The company's mission is to be an integral partner in the delivery and improvement of healthcare. We act as a vital link between manufacturers and providers of patient care, providing product development, manufacturing, and packaging services as well as distribution, operations, and clinical improvement services. Our products and services span the continuum of care, which includes acute, subacute, long-term, and outpatient care settings as well as the home. Cardinal Health is a leader in the health care industry in developing and delivering an unparalleled array of cutting-edge products and services that focus on improving medication safety.

Cardinal Health is committed to helping improve patient safety, and I am pleased to have the opportunity to comment on two of the many products and services provided by various companies within Cardinal Health that help to improve patient safety and reduce medical errors. The first is compliance packaging for the outpatient setting, and the other is automated bedside verification of medication administration in the inpatient setting.

COMPLIANCE PACKAGING

Medication non-compliance is simply a patient failing to take his/her medications as prescribed and represents a major health problem. In fact, it is such a common occurrence that the National Council on Patient Information and Education designated non-compliance as "America's other drug problem." In the general population, rates of medication non-compliance range from 20 to 70 percent. Most of the Members of this Committee as well as the other people in this room are probably personally familiar with the challenges of taking prescription medications correctly.

This issue is exacerbated among the elderly, as they take an increased number of prescriptions and may have increasingly compromised physiology.

It is estimated that the average elderly person takes 17-24 prescriptions a year.[1] An American Association for Retired Persons survey showed that 58 per cent of the elderly population makes errors when taking their medications.[2] Nearly 10 per cent of all Medicare hospital admissions are reported to be the result of medication non-compliance.[3] Furthermore, it has been estimated that the annual economic cost of non-compliance exceeds $100 billion per year.[4]

Cardinal Health is a leading provider of diversified pharmaceutical packaging services and promotes the use of compliance packaging to help reduce medication errors among consumers. Compliance packaging is a prepackaged, ready-to-dispense system that is used for a treatment cycle of a medication and that provides day and time reminders as well as patient education information to facilitate and motivate patients to take their medications correctly. Such packaging provides for the day and time for administration to be clearly identified on the package directly beside each dose. For example, a patient "punches out" the tablet from a blister package and takes the *correct dose* on the *correct day* at the *correct time.* An example of this type of compliance packaging is the packaging commonly used for birth control pills.

This type of compliance packaging encourages a patient to continue to take a medication to the end of the originally prescribed regimen and eliminates the need for patients to transfer their medications to other compliance containers. It aids patients in remembering when to take their medication and readily identifies when they have already taken a particular dose.

We believe that compliance packaging can help reduce errors of under- and over-consumption in the outpatient setting. When patients take prescription medications correctly at home, they are more likely to experience positive therapeutic outcomes. Studies have shown that compliance-improving programs have a cost-benefit ratio as high as 1:14.[5] When properly used, compliance packaging can help physicians and pharmacists provide standardized medication instructions in a minimum amount of time. A study conducted at Michigan State University estimated that compliance packaging could save up to 1,700 hours a year in a busy retail pharmacy.[6] This is especially important given the pharmacist shortage now facing this country.

We believe that compliance packaging can help decrease or eliminate the following types of non-compliance issues:

- Patients taking incorrect doses
- Patients taking medication at the wrong time
- Patients forgetting one or more doses
- Patients receiving unclear or small, unreadable instructions

As discussed previously, the elderly are especially at risk from medication non-compliance because of the number of prescription and over-the-counter medications taken in a day and the complexity resulting from different instructions on how to take each medication. In 1999, the Congress recognized the need to address this very important issue by directing the Department of Health and Human Services to award a grant to perform a study to determine the benefits of compliance packaging. The formal study will commence next month led by The Ohio State University, The University of Arizona, and Brigham and Women's Hospital to further research the issue of compliance and how packaging can improve seniors' ability to take their drugs as prescribed.

The study will monitor 300 Medicare patients for one full year, half receiving their medication in traditional prescription vials and half receiving their medication in a new, innovative "pill calendar" compliance package. Both compliance and clinical indicators will be monitored.

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[1] Kreling, David H., Mott, David A., Wiederholt, Joseph B. of the University of Wisconsin School of Pharmacy and Lundy, Janet, Levitt, Larry of The Kaiser Family Foundation, *Prescription Drug Trends: A Chartbook Update.* November 2001.

[2] *Prescription Drugs: A Survey of Consumer Use, Attitudes and Behavior.* American Association of Retired Persons, Washington, D.C., 1984.

[3] *A Study of Long-Term Care in Oregon with Emphasis on the Elderly.* Oregon Department of Human Resources, March 1981.

[4] *Noncompliance with Medications: An Economic Tragedy with Important Implications for Health Care Reform.* The Task Force for Compliance, April 1994.

[5] Smith, M. *The Cost of Non-Compliance and the Capacity of Improved Health Care Costs.* In Improving Medication Compliance, Proceedings of a Symposium. N&I Pharmaceutical Council, 1984.

[6] Lockhart, Hugh E., Twede, Diana, Thomas, Dena Briggs, Kokikar, Manisha P. *Comparative Cost Study: Packaging of Solid Oral Pharmaceutical Dosage Forms in Bulk and in Unit Dose Blisters.* Michigan State University School of Packaging, April 1994.

AUTOMATED MEDICATION DISPENSING AND BEDSIDE VERIFICATION

Cardinal Health recognizes that many medication errors that occur in inpatient settings are indeed preventable. Results from several studies suggest that the incidence of adverse drug events (ADEs) ranges from 1 to 30 percent of all hospitalized patients, depending on the broadness of the ADE definition used. Research shows that up to one-third of these adverse drug events are preventable.[7] Many of these preventable events are associated with significant rates of morbidity and mortality and have a significant impact on hospital costs. Patients who experience in-hospital, medication-related errors often require 2-5 additional days of hospitalization at an additional cost of $2,000-$5,000 per admission.[8]

Most errors are the result of one or more breakdowns in the system of care. It has been estimated that there are on average 20 steps involved in the medication-use process.[9] When you consider that approximately 3.75 billion drug administrations are made annually to patients in hospitals, with 20 steps per administration, the opportunities for things to go wrong are significant.

Errors in the medication-use process also can occur in long-term care settings. Indeed, the risks might be greater in these settings because the patients usually receive a greater number of drugs, and there is a limited presence of on-site physicians and pharmacists to help clarify medication orders.

Pyxis, a Cardinal Health company, is the leading provider of automated medication- and supply-dispensing systems for hospitals and other healthcare facilities. Pyxis has revolutionized the way medications are distributed within these facilities. Resembling a network of ATM machines, the technology is a point-of-care, computerized system that automates the distribution, management, and control of medications within hospitals and other facilities. It allows a pharmacist to perform safety and quality checks and approve medication orders electronically. Nurses gain immediate access to drugs from the point-of-care cabinets on the nursing unit. The drugs in these cabinets are packaged as unit-dose packages (i.e., a single dose per package) and are placed in individual compartments in the cabinet. In order to access medications, the nurse must first authenticate his or her identity.

While this technology has greatly decreased the number of steps in the medication-use process in the hospital and thus has significantly improved safety, our hospital customers have been clamoring for even more patient protections in the medication-use process. They want to ensure that the *right patient* is getting the *right medication* in the *right dose* by the *right route* at the *right time.*

This can be accomplished by utilizing bar code-scanning technology at the point of administration, i.e., at the patient's bedside, to verify administration of the proper medication. This verification is accomplished through the use of bar codes on medication packages, the patient's hospital identification bracelet, and the nurse's name badge. Once the nurse obtains the medication for a patient, a bar code on the unit-dose medication package is scanned with a hand-held device. The nurse then scans the bar code on the patient's bracelet and the bar code on his or her name badge. A rules-driven software program hosted on a computer verifies that the right patient is receiving the appropriate medication. If there are any safety concerns such as a wrong drug, dosage, etc., an alert is presented immediately notifying the nurse of the problem and thus helping to prevent an error.

This new technology is important to patients as well as healthcare providers. If the Chairman would allow, I have a short video of the Pyxis Veri5SM system that I would like to play at the end of my testimony to demonstrate how this technology works.

Such bedside, medication-verification products have only been on the market as a complete system for approximately two years. Hospitals choosing to implement this technology must invest in the technology itself as well as a radio-frequency infrastructure and then train their staff. However, the most significant obstacle that inhibits the adoption rate for this exciting technology is the lack of bar codes on unit-dose medications. Presently, approximately 30 percent of the unit-dose medications have manufacturer-printed bar codes. This means that hospitals must either pay a third-party vendor to repackage their unit-dose medications with bar code la-

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[7] Bates, DW, Cullen, DJ, Laird, N, et al. *Incidence of Adverse Drug Events and Potential Adverse Drug Events: Implications for Prevention. Journal of the American Medical Association,* 1995; 274(1):29-34.

[8] Bates, DW, Spell, N, Cullen, DJ, et al. *The Costs of Adverse Drug Events in Hospitalized Patients.* Adverse Drug Events Prevention Study Group. *Journal of the American Medical Association,* 1997; 277(4):307-11.

[9] Leape, LL. *The Health Profession's Responsibility for Reducing Adverse Drug Events: Improving the Quality of the Medication Use Process.* Escovitz, A, Pathak, DS, Schneider, PJ (eds). New York: Pharmaceutical Products Press. 1998:109-134.

beling or invest in capital equipment to repackage and bar code the unit-dose medications within the hospital. The first of these alternatives drives additional operating costs while the second alternative requires a capital investment plus the expense of precious staff time to operate the equipment. Further, current Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) regulations place constraints on repackaging and relabeling of unit-dose medications. More specifically, third-party vendors as well as hospital systems are constrained in packaging unit-dose medications at one facility for transfer to other hospitals, even to hospitals within the same system. This further impedes efficient use of both capital and human resources.

We were very encouraged to see that the FDA has indicated an intent to publish a notice of proposed rulemaking on the issue of bar coding of pharmaceuticals. Development of a uniform standard for the bar coding of unit-dose medications used within the institutional setting would be extremely helpful. However, this must be done in the most cost-effective manner possible for both providers and pharmaceutical manufacturers. Cardinal Health recognizes that health care costs continue to increase, and if the regulations are too complex or rigid, we may not only increase costs inappropriately but also unintentionally delay the implementation of this important safety initiative.

Cardinal Health also sees a tremendous potential for utilizing automated medication dispensing equipment and bedside verification tools in nursing homes. Given the elderly population and the high use of pharmaceuticals in this setting, the patient safety advantages could be most significant. However, the DEA currently prohibits "floor stock" in nursing homes, instead requiring that drugs be prepackaged for each patient for one month at a time. While this site of care closely mirrors a hospital setting, it is treated through regulations as an outpatient setting. The current distribution system has some advantages, but it also creates a great deal of waste and inefficiencies. The DEA published a concept paper on the issue of automated dispensing equipment in nursing homes over a year ago. We would encourage additional attention to this issue. Technology has advanced greatly over the past several years and could now accurately inventory and distribute medications in a safe and effective manner so as to improve the administration of medications within the nursing home setting.

Again, I appreciate the opportunity to testify about just two of the innovative patient safety tools that Cardinal Health provides to help ensure medications are used safely and appropriately. I would be pleased to answer any questions the Committee Members may have regarding my testimony. Thank you.

Mr. BILIRAKIS. Thank you, sir. Let's see. We will dim the lights and hope that everything works.

[Video shown.]

Video VOICE. What Veri5 affords us is the ability to take barcoding to the bedside, whereby the nurse, the drug and the patient all——

Mr. BILIRAKIS. Volume? Okay, we have a problem.

Video VOICE. Very quickly, they recognized the benefit of being able to feel more assured that that drug that they were given was, in fact, the drug intended for that patient.

Mr. PASQUE. One of the reasons that we chose this product was Pyxis' history of support in these types of products, and Veri5 has not failed to meet our expectations in this area.

Ms. JEWELL. The Pyxis Veri5 is a plus to have on your nursing unit in the hospital, I believe, because it shows the nurses that the hospital has taken an initiative to move forward.

Ms. BOVIE. I think the single most important benefit that this has brought to the patients at East Jefferson as well as our nursing staff is patient safety.

Ms. APRIL. We have had several near misses that really made nurses say, wow, if I did not have this piece of machinery, Pyxis Veri5, I would have given this medication, and it would have been an error.

Ms. BOVIE. On this post-partal unit where we have the device working, we have seen a total reduction from—I think our numbers were like five and six medication errors a month, now down to nothing. In the area of quality control, Pyxis Veri5 is the manager's dream. It certainly takes an awful lot of time off my plate in being able to have the pharmacist and his staff generate reports for us.

Mr. PASQUE. One of the advantages that we can see, having brought Veri5 live on our initial unit, is the assistance that it will give us in meeting the regulatory agencies such as Joint Commission, those requirements and regulations.

Ms. BOVIE. We can track everything from what we are now calling near misses in our medication process team, house-wide medication process team, those times when you go to a bedside and you go, oops, that medicine is not for you or, oops, yes, you do have an allergy to that. This device prints out a report. They go into the Pyxis med station and are able to vend that medication, and then take that from that point to a higher safety level. Now they can actually take that to the bedside when they are in a hurry and trying to accomplish all of those other things that nursing wants us to do. In the end, it saves time, because now you don't have nurses chasing down medication errors.

Ms. APRIL. I think this would be an excellent marketing tool to retain and recruit new nurses.

Ms. JEWELL. I would have to say, short sentence, Pyxis Veri5 improves patient safety.

Ms. BOVIE. It is patient safety, and you either want your patients to be safe or not, your choice.

Mr. HETHCOX. Thank you.

Mr. BILIRAKIS. Thank you. Does that complete your presentation?

Mr. HETHCOX. Yes, sir.

Mr. BILIRAKIS. Thank you very much.

Ken Freeman is the Chairman and CEO of Quest Diagnostics Incorporated. He is here on behalf of the Healthcare Leadership Council. Mr. Freeman, please proceed, sir.

STATEMENT OF KENNETH W. FREEMAN

Mr. FREEMAN. Mr. Chairman, thank you for the opportunity to speak with you this morning about a subject near and dear to my heart, improving patient safety in America.

I am Chairman and Chief Executive Officer of Quest Diagnostics, the Nation's leading provider of diagnostic testing, information, and services. We operate 30 full-service laboratories across the country and in Mexico and the U.K., as well as more than 1,350 conveniently located patient service centers where doctors send patients to have specimens collected, employing more than 30,000 people.

Today I am testifying on behalf of Quest Diagnostics as well as the Healthcare Leadership Council, or HLC. HLC is a coalition of chief executives from all disciplines within the health care system that meets to jointly develop policies, plans and programs to achieve our vision of an effective 21st century health care system. I will briefly describe the HLC's patient safety initiative and then describe what my company, Quest Diagnostics, is doing to reduce errors, thereby improving quality and safety.

The Healthcare Leadership Council's Chief Executive Task Force on Patient Safety was created so that all sectors of the health care industry could work together to help elevate public confidence in the safety of the Nation's health care system. HLC members have been active in seeking to improve safety for a long time, and their efforts represent a broad range of ongoing programs. I have attached to my statement a brief description of some of these programs, which I would like to submit for the record.

Mr. BILIRAKIS. Without objection.

Mr. FREEMAN. Thank you. Coming from all facets of health care, each HLC member company is addressing different safety needs in the health care system, while adhering to a common set of guiding principles. For example, we believe that solutions should be developed collaboratively and with senior executive responsibility and leadership. If the CEO isn't the most passionate advocate of a patient safety initiative, it simply will not happen.

We believe that a holistic quality assessment system must be developed and adopted for use in health care, because errors are caused by bad processes, not bad individuals. Improving quality requires that we improve processes, based on facts and data that are not always easy to collect. Safe practice standards should be evidence based and appropriately flexible.

Again, we must analyze the data to identify ways to improve practice standards, the processes, that are causing the errors themselves. Finally, HLC members strive to establish a culture of awareness, not blame, to drive sharing information about health care errors in an open manner. It all starts with acknowledging the opportunity for improvement.

At my own company, Quest Diagnostics, we have incorporated these concepts into our own "Six Sigma" initiative to help take us to the next level in improving quality and safety. The Six Sigma approach has paid dividends for countless manufacturing companies during the past 20 or more years, including General Electric, Texas Instruments, and Motorola.

We are the first major company in health care services to pursue Six Sigma and have been underway for more than 2 years. Six Sigma is already changing Quest Diagnostics, and I am absolutely convinced that it will ultimately change the world of health care quality and safety for the better, forever.

During today's hearing, you will learn about many fascinating and important technology solutions that will reduce errors and improve safety, but technology can only be as effective as the processes that employ it. The Six Sigma approach is a philosophy and a type of analytic thinking that can permeate an organization and drive behavioral change. Quality, safety, effectiveness and efficiency go hand in hand. Improving quality and safety is not only a moral imperative for us. It also makes solid business sense.

We have made a significant investment to provide foundation training for virtually all of our employees. We have extensively trained almost 200 Six Sigma experts that are called "Black Belts." These experts are leading more than 200 distinct defect reduction projects, with several dozen having been completed.

Six Sigma is a statistical measure representing virtual perfection, defined as 99.9997 percent quality, or no more than 3.4 errors

per million opportunities. Our pursuit of Six Sigma quality is in its early stages, and we also have much more to achieve, but we are making great progress.

One of our most successful Six Sigma projects has focused on improving the effectiveness of our specimen handling process to reduce the number of misplaced specimens for testing. When we started, this process already reflected a high level of quality. Now, in our business units that have implemented the new process, it nears perfection.

In another Six Sigma project we collaborated with hospital customers to reduce specimen collection errors that were causing nurses to re-draw blood from premature infants in neonatal intensive care units. These errors delayed diagnoses and subjected fragile, tiny patients to needless trauma. The root cause or reason was that the ICU nurses had never been properly trained in sample collection. Designing and implementing a simple training course to standardize the best procedures for drawing specimens made an enormous difference for premature infants and their families.

In another Six Sigma project we developed a new standardized medical report using the Six Sigma process, starting by listening to the voices of our physician clients. The report is easier to read, lets a doctor identify abnormal results more readily, and shortens the time required to review reports, reducing the likelihood that a doctor will misinterpret a test result.

We provide a critical health care service. Diagnostic test results drive more than 70 percent of health care decisions, but represent only about 4 percent of total health care spending in the U.S. Every day, doctors and hospitals order diagnostic tests to diagnose, treat or monitor the treatment of millions of patients; tests that are performed by the Nation's 10,000-plus independent and hospital laboratories. Early detection not only saves lives, it also saves money.

There is no looking back. The patient quality movement is gaining momentum among health care services providers. More companies and institutions are starting to discuss quality improvement in health care, and it is about time. This is the mega-trend that we collectively must act on, for the sake of patients.

In closing, I am confident that together the health care industry, including my fellow members of the Healthcare Leadership Council, is rising to the challenge, recognizing the opportunity to drive quality improvement, and taking action by measuring defects and analyzing and improving the many processes that cause them. This is the right thing to do for patients and their families, and it is also good business practice.

Once again, Mr. Chairman, thank you for the opportunity to speak with you this morning.

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

PREPARED STATEMENT OF KENNETH W. FREEMAN, CHAIRMAN AND CEO, QUEST DIAGNOSTICS INCORPORATED ON BEHALF OF HEALTHCARE LEADERSHIP COUNCIL

Mr. Chairman, thank you for the opportunity to speak with you this morning about a subject near and dear to my heart—improving patient safety in America.

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1,350 conveniently located patient service centers, where doctors send patients to have specimens collected, employing more than 30,000 people.

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The Healthcare Leadership Council's Chief Executive Task Force on Patient Safety was created so that all sectors of the healthcare industry could work together to help elevate public confidence in the safety of the nation's healthcare system. HLC members have been active in seeking to improve safety for a long time and their efforts represent a broad range of ongoing programs. I have attached to my statement a brief description of some of these programs, as well as HLC's principles on patient safety, which I would like to submit for the record.

Coming from all facets of healthcare, each HLC member company is addressing different safety needs in the healthcare system, while adhering to a common set of guiding principles. For example, we believe that solutions should be developed collaboratively and with senior executive responsibility and leadership. If the CEO isn't the most passionate advocate of a patient safety initiative, it simply will not happen.

We believe that a holistic quality assessment system must be developed and adopted for use in healthcare, because errors are caused by bad processes, not bad individuals. Improving quality requires that we improve processes, based on facts and data that are not always easy to collect. Safe practice standards should be evidence-based, and appropriately flexible. Again, we must analyze the data to identify ways to improve practice standards—the "processes"—that are causing the errors. Finally, HLC members strive to establish a culture of awareness—NOT blame—to drive sharing information about healthcare errors in an open manner. It all starts with acknowledging the opportunity for improvement.

At my own company, Quest Diagnostics, we have incorporated these concepts into our own Six Sigma initiative to help take us to the next level in improving quality and safety. The Six Sigma approach has paid dividends for countless manufacturing companies during the past twenty or more years, including General Electric, Texas Instruments, and Motorola.

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During today's hearing, you will learn about many fascinating and important technology solutions that will reduce errors and improve safety. But technology can only be as effective as the processes that employ it. The Six Sigma approach is a philosophy and a type of analytic thinking that can permeate an organization and drive behavioral change. Quality, safety, effectiveness and efficiency go hand-in-hand. Improving quality and safety is not only a moral imperative for us, it also makes solid business sense.

We have made a significant investment to provide foundation training for virtually all of our employees, and we have extensively trained almost 200 Six Sigma experts called Black Belts. These experts are leading more than 200 distinct defect-reduction projects, with several dozen having been completed. Six Sigma is a statistical measure representing virtual perfection, defined as 99.9997% quality, or no more than 3.4 errors per million opportunities. Our pursuit of Six Sigma quality is in its early stages and we also have much more to achieve. But we are making great progress.

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There is no looking back. The patient quality movement is gaining momentum among healthcare services providers. More companies and institutions are starting to discuss quality improvement in healthcare. And it's about time—this is the megatrend that we collectively must act on—for the sake of patients.

In closing, I am confident that *together* the healthcare industry, including my fellow members of the Healthcare Leadership Council, is rising to the challenge, recognizing the opportunity to drive quality improvement, and taking action by measuring defects and analyzing and improving the many processes that cause them. This is the right thing to do for patients and their families, and it is also good business practice.

Once again, thank you for the opportunity to speak with you this morning.

PATIENT SAFETY IN THE HEALTH CARE SYSTEM

HLC STATEMENT OF PRINCIPLES

The Healthcare Leadership Council's Chief Executive Task Force on Patient Safety was created so that all sectors of the health care industry could 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 principles:

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: 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 im-

provements. 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.

Members of the Healthcare Leadership Council have been leaders in developing innovations to improve safety within the health care system. The following illustrates a subset of patient safety initiatives underway at a few HLC member companies and organizations.

ABBOTT LABORATORIES

Abbott is helping to reduce medication errors through continued innovation in drug products. Abbott helped pioneer the availability of premixed solutions and prefilled syringes to minimize mixing and handling errors. Abbott also has developed numerous design and safety improvements for medication administration, including a pre-filled bar-coded syringe which automatically programs infusion pumps, helping to avoid medication errors caused by manual programming. Abbott also develops and continually improves products that protect against needlestick injuries.

In addition, Abbott has a error-reducing label enhancement program that includes color coding to help differentiate between products, printing on the backside of IV containers to ensure clinicians see all appropriate information, and machine readable industry standard bar codes on unit-of-use products.

Using Abbott's own clinical nurse consultants and partnerships with independent third parties, Abbott's support has made it possible for hundreds of health care professionals to complete continuing medical education programs developed by Abbott in cooperation with the Institute for Safe Medication Practices.

ASCENSION HEALTH

Ascension Health, the nation's largest non-profit hospital system, has numerous hospitals nation-wide which have implemented patient safety programs unique to their specific needs. Examples include:

Columbia-St. Mary's Hospital of Milwaukee, Wisconsin asked all clinical staff to complete a survey on medical errors. Over 400 responses offered many narrative comments on areas where the hospital excels in safety as well as areas in need of improvement. The survey prompted increased organizational communication with all clinical staff which is providing valuable information on how to improve the hospital's culture of safety. One project resulting from the survey is a leadership patient safety rounds pilot program to assess safety throughout the hospital.

St. Vincent's Medical Center of Bridgeport, Connecticut conducts a similar leadership rounds program to speak with front-line staff in a non-punitive way to discover "near misses" and to rapidly initiate changes to prevent recurrences.

Western Maryland Health System of Cumberland, Maryland has adopted several new medication-related programs, which include a non-punitive computerized medication event-reporting system, a computerized adverse drug reaction surveillance system, a patient Warfarin education program conducted by pharmacists, and com-

puterized, patient-specific physician alerts for "black box" and other FDA-related drug warnings.

St. Agnes Hospital of Baltimore, Maryland has established the MICROMEDEX system on their Intranet which provides detailed monographs on drugs, alternative medicines, toxicological management, reproductive risks, and interactions, among others. This system is used extensively by medical and pharmacy staff to reduce medication errors. In addition, St. Agnes invested $1 million in state-of-the-art patient beds which have alarms to prevent patients from falling, allow patients to sit up in bed to avoid bed sores, and allow patients to be weighed in bed by built-in scales.

BAXTER INTERNATIONAL, INC.

The AUTROS Point of Care System, developed by Baxter, is the first automated medication management system that combines medication bar-coding and wireless technology to link physicians, pharmacy and nursing at the point of care. This solution set integrates drug delivery products with the information required to ensure safe and effective delivery of medication. The clinical decision supports and accompanying alerts and warnings of the system is delivered through a wireless network, which supplies data in a way that improves clinician workflow, as it supports the clinicians as they deliver patient care under increasing time and cost pressures.

This integrated patient management solution provides instantaneous decision support at the bedside to ensure the five rights of patient safety: the right patient, the right medication, the right dose, the right time, and the right route; together, these facilitate the right outcome.

BD

BD (Becton, Dickinson and Company) is well known for its health care worker safety initiatives designed to reduce the incidence of sharps injuries. In addition to these initiatives, BD takes a systems approach to two key and highly interrelated processes that directly impact patient safety: the pre-analytical laboratory specimen process and the medication administration process.

Accurate Lab Specimens: The majority of erroneous laboratory results—which can lead to the prescribing and administration of inappropriate and perhaps harmful treatments—are caused by mis-identification of specimens at the point of collection. BD helps eliminate these errors by providing an affordable and comprehensive system that includes process analysis and redesign, root cause error analysis, a unique line of bar coded specimen containers, hand-held and bar code enabled computer technology, and management reports that allow hospitals to track and measure the results achieved with the system. These components have demonstrated specimen error reduction by an average of 79 percent, and have improved safety through the reduction of medication, transfusion, and other errors.

Bedside Identification: The last opportunity to halt medication errors is at the point of administration, or the patient's bedside. Designed to halt medication errors at the point of administration, the BD Rx System uses hand-held and bar code enabled computer technology to identify the system user, the patient, and the drug prior to administration. This ensures compliance with the clinician's order and safe medical practice.

CLEVELAND CLINIC FOUNDATION

The Cleveland Clinic's widely acclaimed "POEMs" (Prevention of Errors in Medicine) Initiative is based on the premise that each specialty and practice group understands error-prone links in its own clinical work better than any administrative body. The Cleveland Clinic's POEMs task force has had each component within the Clinic contemplate medical errors encountered in that specialty's duties, or "near misses" experienced or heard about in its specialty. As part of this process, each department chairman was directed to discuss the issue and the project at all staff meetings and to encourage the solicitation of specific activities and procedures that represent potential error-prone processes germane to that department or specialty.

Each department determined and ranked its top 2-3 specific error-prone processes. An internal departmental working group then developed appropriate interventions and strategies to mitigate potential errors.

FRANCISCAN MISSIONARIES OF OUR LADY HEALTH SYSTEM, INC.

A group of hospitalists at Our Lady of the Lake Regional Medical Center in Baton Rouge, Louisiana, led by Dr. Richard Slataper, has developed a tracking and reporting tool to promote evidence-based treatment. This is a hybrid system of paper and computer technology. It uses a customized data collection program from Pendragon Forms written for hand-held computers. This tool has already been successful in improving the use of ACE inhibitor therapy in patients with chronic heart failure. Cur-

rent plans are to expand to other areas such as coronary artery disease, stroke, diabetes, hypertension, vaccinations, code status and living wills, pain assessment, restraint use, smoking cessation, and deep venous thrombosis prophylaxis.

MERCK & COMPANY, INC.

Merck has undertaken several initiatives to reduce medication errors in both the inpatient and outpatient settings. Examples include:

Inpatient: Merck has introduced color-coded unit dose blisters to aid clinicians in distinguishing different doses of the same medication and to minimize dispensing errors. Merck also has voluntarily placed National Drug Code bar codes on virtually all hospital unit-of-use products to aid hospitals choosing to use drug identification technologies.

Outpatient: Because patient under- or over-dosing is an important source of medication errors, Merck has developed innovative packaging for some products that includes a simple calendar that can be personalized to help patients remember when they should take their next dose. The special pack also contains a user-friendly patient leaflet (in addition to the more technical leaflet for pharmacists and doctors) to help inform patients about their medicine and their condition to improve compliance with treatment.

PREMIER, INC.

Premier's Clinical Performance Initiatives (CPI) seek to improve the quality and safety of health care and reduce costs at its more than 1,800-member nonprofit hospitals. This is done through the use of evidence-based best practices that are implemented for widespread use. Each year-long collaborative effort between the CPI staff and representatives from Premier hospitals includes: face-to-face meetings and conference calls with CPI project directors, medical experts, and statistical analysts who guide Premier hospitals through clinical improvement processes; site visits by Premier's CPI staff to learn the specific needs of hospitals; networking among hospitals to overcome barriers and share successes; and analysis of data submitted by each hospital to Premier's Perspective™ database, a national warehouse of clinical data. Premier experts analyze this data to help hospitals identify ways to improve health services while reducing costs.

VHA INC.

VHA offers its member hospitals Patient Safety Team Training, a product focused on improving patient safety, patient satisfaction, and performance in the emergency or labor delivery departments. VHA's Patient Safety Team Training uses proven methods based on aviation crew resource management techniques employed in that industry. Grounded in two decades of research and development, this training process was evaluated at 12 leading health care organizations over two years. Effectiveness results included fewer observed clinical errors, minimized litigation costs, and enhanced ability to achieve compliance with patient safety standards of the Joint Commission for Accreditation of Healthcare Organizations as well as with the IOM's 1999 patient safety recommendations.

Under this program, a VHA physician and nurse who have expertise in team training implementation in the high-performance, high-stress care environment first conduct an on-site assessment of an organization's readiness. They then conduct "train the trainer" sessions where select physicians and nurses in the organization learn to present the core curriculum to all staff members, bring about a culture change in their department, and reinforce team work behaviors using facilitated leadership and coaching.

Mr. BILIRAKIS. Thank you very much, Mr. Freeman.

Dr. Dennis S. O'Leary is President of the Joint Commission on Accreditation of Healthcare Organizations, and he, too, will show a video after his remarks.

Dr. O'Leary, please proceed.

STATEMENT OF DENNIS S. O'LEARY

Mr. O'LEARY. Thank you. The Joint Commission very much appreciates the opportunity to testify today on the important contributions of the private sector toward improving patient safety in health care organizations.

The Joint Commission is the Nation's predominant health care standards setting and accrediting body. Founded in 1951, the Joint

Commission accredits almost 18,000 organizations across the mainstream of the health care delivery system. The scope of its activities and its focus on the safety and quality of health care services has long placed the Joint Commission in a unique position both to set and leverage expectations for patient safety across the full spectrum of provider services.

In 1995, patient safety issues assumed an even more prominent role in the Joint Commission's priorities. Having just introduced a new standards framework that emphasized attention to risk points in delivering health care services, we were faced with an apparent outbreak of unanticipated injuries and deaths in a variety of settings, including some of the Nation's most prestigious hospitals.

These sentinel events became a clarion call to the Joint Commission and to others that more needed to be done to improve the safety of health care in this country. To this end, the Joint Commission committed itself to a major national leadership role in helping health care organizations understand how and why health care errors occur, and in providing guidance and direction in efforts to reduce health care errors and adverse events.

First, we launched the Sentinel Event Program to encourage the identification, reporting, and analysis of adverse events inside health care organizations. Organizations were also asked to report these events and the results of their analyses to the Joint Commission's Sentinel Event data base.

We discovered that most serious adverse events were not being made known, even to organization leaders, principally because health care professionals involved in such occurrences are deeply shamed and, at the same time, deeply fearful of the humiliation and punishment that all too often has been the knee jerk response to human error.

Joint Commission standards now require organizations to develop internal processes that facilitate the identification and thorough evaluation of adverse events and to take actions to reduce or eliminate the possibility of such events in the future.

Second, we have made a major investment in the development and refinement of the tools necessary for in depth analyses of these events. This has lent great credence to our iron clad requirement that a root cause analysis be performed following each sentinel event. Development of the root cause analysis template for sentinel events is one of the most important contributions that the Joint Commission has made to the patient safety movement.

Third, the Joint Commission has introduced engineering principles into its standards requirements to promote the identification, analysis, and redesign of vulnerable organization systems. Vulnerable systems increase the risk that inevitable human errors will actually affect patients. The new requirement for the conduct of failure mode and effects analyses should create learning and preventive opportunities without the actual experience of adverse events.

Fourth, the Joint Commission has worked aggressively to share lessons learned with accredited organizations. By early 1998, the Sentinel Event data base had accumulated sufficient data to identify significant groupings of sentinel events and their underlying causes. With this information in hand, the Joint Commission launched "Sentinel Event Alert" as a brief periodical bulletin that

would focus upon specific types of sentinel events, describe lessons learned from the root cause analyses of that group of sentinel events, and suggest measures that health care organizations could take to avoid the occurrence of such events in their own settings.

To date, the Joint Commission has issued 25 "Sentinel Event Alerts" to its accredited organizations that address such topics as patient suicide, infant abductions, wrong-site surgery, transfusion reactions, and patient falls, amongst others.

We have several new initiatives on the horizon. This coming summer the Joint Commission will begin to focus the attention of accredited organizations on a series of national patient safety goals. Beginning next January, organizations will be expected to be in compliance with specific high priority recommendations associated with these goals.

Finally, the Joint Commission will convene a national invitational conference on the business case for patient safety. This conference is being co-funded with the Agency for Healthcare Research and Quality. The purpose of this initiative is to convince health care organization leaders that financial investments in patient safety will indeed serve the bottom line priorities that necessarily drive many of these organizations.

The road to patient safety is a never ending journey. This is because the continuing evolution of this Nation's health care capabilities make achievement of our patient safety goals a moving target, but it is also because long standing change will require counterintuitive strategies, culture change, and radical alterations in the way health care professionals are trained.

The patient safety challenges are neither small in number nor small in magnitude, but progress is being made by the private sector, by the public sector, and importantly, by both working together. We should take great heart in this progress as we continue our journey.

I would now like to conclude these remarks with the presentation of one of the public service announcements we have developed to encourage patients to also become involved in reducing medical errors. Thank you.

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

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

I am Dr. Dennis O'Leary, President of the Joint Commission on Accreditation of Healthcare Organizations. Our organization very much appreciates the opportunity to testify today on the important contributions of the private sector towards improving patient safety in health care organizations.

For those of you who are not familiar with the Joint Commission, we are the nation's predominant health care standard-setting and accrediting body. Founded in 1951, the Joint Commission is a not-for-profit, private sector entity that is dedicated to improving the safety and quality of care provided to the public. Its participating member organizations include the American College of Surgeons; the American Medical Association; the American Hospital Association; the American College of Physicians-American Society of Internal Medicine; and the American Dental Association. In addition to representation from these organizations, the 28-member Board of Commissioners provides seats for the field of nursing, and for public members whose expertise covers such diverse areas as medical ethics, public policy, and health insurance.

The Joint Commission accredits approximately 18,000 health care organizations. In addition to accrediting the substantial majority of hospitals in this country, the Joint Commission's accreditation programs evaluate the quality of care provided by

home care agencies; ambulatory care centers and offices whose services range from primary care to outpatient surgery; behavioral health care programs; nursing homes; hospices; assisted living residencies; clinical laboratories; and managed care entities. The Joint Commission is also active internationally and, in fact, has provided leadership in promoting attention to patient safety in other countries.

The scope and nature of the Joint Commission's involvement in the health care delivery system places it in a unique position to both set expectations for patient safety across the entire spectrum of provider services and to measure adherence to those expectations.

HISTORY OF THE JOINT COMMISSION'S INVOLVEMENT WITH ERROR REDUCTION

During the late 1980s, the Joint Commission initiated a complete re-engineering of the accreditation process. The new standards framework that was finally introduced in 1994 focused on identified "risk points" in health care delivery processes and substantially strengthened the Joint Commission's emphasis on patient safety.

In 1995, patient safety assumed an even more prominent role among the Joint Commission's priorities. The intensified focus on the occurrences of serious adverse events in health care organizations—which we call "sentinel events"—grew out of an apparent "outbreak" of widely publicized, unanticipated serious injuries and deaths in a variety of settings, including some of the nation's most highly-regarded hospitals. While not necessarily unique, as later studies would show, these sentinel events became a clarion call to the Joint Commission and to others that more needed to be done to improve the safety and quality of health care in this country.

We understood early on the critical importance of learning more about the epidemiology of these serious events, including the types of occurrences, their incidence, and their underlying causes. Only through amassing such information could we develop the capacity to share knowledge with and provide guidance to health care organizations, towards the objective of reducing future health care errors and sentinel events. Such information would also prove to be essential to future refinements of the Joint Commission's standards. The Joint Commission, therefore, committed itself to a major national leadership role in facilitating the identification of health care errors and adverse events; in working with individual organizations to reduce the risk of future adverse occurrences; and in sharing "lessons learned" with all accredited organizations. To these ends, the Joint Commission launched its Sentinel Event Program in 1996.

The Joint Commission's experience with its Sentinel Event Program provides us the unique perspectives we wish to share with you today. Our odyssey has been both an enlightening and sobering experience. The risk of errors in health care is high—an inevitable correlate of the intense human effort involved in patient care; the complexity of the services provided; the expectations as a matter of public policy, that care be provided with fewer resources; and the progressive introduction of new procedures, new technologies, and powerful new drugs, each with their potential great benefits and their potential for leading to patient harm. But we are dealing with more than the complexity and humanity of patient care. Most health care errors and even serious adverse events are not made known to organization leaders. This is principally because health care professionals involved in such occurrences are deeply shamed and, at the same time deeply fearful of the humiliation and punishment that all too often has been the knee-jerk response to human error by organization leaders as well as by professional licensure boards and state and federal quality oversight bodies.

In truth, if responsibilities are to be assigned, they have lain, and continue to lie, with organization leaders in assuring that safety is prospectively (and today retrospectively) built into all vulnerable organization systems and processes that have the potential to impact patient care. Humans, including health care professionals, will always make errors. The goal, we now understand, is to prevent those errors from reaching or affecting the patient. And the continuing challenge for all of us is to leverage and incent health care organizations and health care professionals to invest in these preventive efforts.

The Joint Commission's odyssey has involved the gathering of information, the sharing of knowledge, and the setting and application of state-of-the-art standards. However, as reflected in the Joint Commission's Sentinel Event Database [1], we are far closer to the beginning of the journey than we are to the end.

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[1] The Joint Commission's Sentinel Event Database contains information on nineteen types of serious adverse events in ten different settings. The database has been used to inform the development of recommended practices and available to other organizations who are working on patient safety initiatives.

THE JOINT COMMISSION'S APPROACH TO ERROR-REDUCTION

From the outset of its intensified focus on patient safety in 1995, the Joint Commission has required the performance of an in-depth analysis ("root cause analysis") of underlying causes for any sentinel event made known to the Joint Commission either through self-reporting (currently 80% of known occurrences) or through other sources such as the media (currently 20%.) The Joint Commission defines a reportable sentinel event as an unanticipated death or permanent loss of function. The definition also encompasses certain other serious occurrences such as transfusion reactions, infant abductions, and patient rape, among others. Joint Commission standards now require organizations to adopt a definition of sentinel event that is at least as encompassing as that of the Joint Commission, to establish internal processes for reporting sentinel events, to conduct root cause analyses of all such occurrences, and to make appropriate changes in organization systems based on the root cause analysis findings.

Current policy also encourages the voluntary reporting of sentinel events and the associated root cause analysis results to the Joint Commission's Sentinel Event Database. The root cause analysis is in essence a retrospective evaluation of what went wrong. Almost all of these analyses identify multiple contributory factors ("latencies"), which can be addressed through systems improvement. The value in gathering and sharing this information lies in the reality that these are in fact rare events with which most organizations have had little or no first hand experience. The preventative efforts that they are able to undertake based on this information have the potential to reduce the overall frequency of future sentinel events.

Development of the root cause analysis template by the Joint Commission is probably one of the most important contributions that it has made to patient safety. This tool has been made available to the field through numerous publications that provide step-by-step descriptions for completing these analyses. The Joint Commission places such a premium on the effective conduct of these analyses that failure to perform a satisfactory root cause analysis after a known sentinel event places the organization at risk for loss of its accreditation.

While root cause analyses play a vital role in efforts to reduce health care errors and adverse events, they are by definition reactive in nature. For this reason, the Joint Commission—in collaboration with widely-recognized patient safety experts—has now developed and recently implemented additional patient safety standards that place the onus on organization leaders to "create a culture of patient safety." The standards delineate expectations for the organization's patient safety program that draw particular attention to the needs for teamwork and effective communications among responsible care-givers. These latter priorities are based both upon the well-known experiences of the aviation industry and upon findings from the Sentinel Event Database which identify communication breakdowns as the most common underlying factor across all types of sentinel events.

These standards also create new requirements for the prospective analysis and where appropriate, re-design of systems identified as having the potential to contribute to the occurrence of a sentinel event. These "failure mode and effects analyses" (FMEA) are expected to create learning and preventive opportunities without the actual experience of an adverse event. Because there are today multiple vulnerable systems in health care organizations, each organization is expected to set FMEA priorities based either upon its own risk management experience or upon external sources such as the Joint Commission's Sentinel Event Database.

The new patient safety standards finally create the expectation that unanticipated outcomes will be communicated to patients and/or their families. Here again, the Joint Commission has taken a leadership role in addressing the public's patient safety interests.

By early 1998, the Sentinel Event Database had accumulated sufficient data to identify significant groupings of sentinel events and their underlying causes. With this information in hand, the Joint Commission launched Sentinel Event Alert as a brief periodic bulletin that would focus upon specific types of sentinel events, describe lessons learned from the root cause analyses of that group of sentinel events, and suggest measures that health care organizations could take to avoid the occurrence of such events in their own settings.

The first *Sentinel Event Alert* issue dealt with the then common practice of storing concentrated potassium chloride on nursing units. This liquid concentrate is used in the preparation of intravenous solutions but is deadly when administered in an undiluted form. The *Alert* suggested that concentrated potassium chloride not be available outside the pharmacy unless specific safeguards were in place. By all reports, this *Alert* and the attention placed on it by Joint Commission surveyors has been instrumental in virtually eliminating deaths due to the unintended adminis-

tration of concentrated potassium chloride to patients. Since 1998, the Joint Commission has issued 25 *Sentinel Event Alerts* to its accredited organizations. These *Alerts* include over 50 evidence or expert-based recommendations for preventing adverse events of various types. The topics addressed cover a wide range of issues—inpatient suicide, infant abductions, wrong site surgery, transfusion reactions, and patient falls, to name a few.

During an onsite survey, Joint Commission surveyors typically assess the organization's familiarity with and use of *Sentinel Event Alert* information. Each accredited organization is expected to consider for its own adoption information in the *Sentinel Event Alerts* that is relevant to its services. This coming summer, the Joint Commission will focus attention of accredited organizations on a series of National Patient Safety Goals. Beginning in January 2003, organizations will be expected to be in compliance with specific recommendations associated with these Goals that have previously been published in *Sentinel Event Alerts* or show that they are using alternative approaches that are just as effective. The National Patient Safety Goals will be recommended to the Joint Commission's Board of Commissioners by an expert panel that was appointed earlier this year.

Last month the Joint Commission, with the active support of the Centers for Medicare and Medicaid Services, launched its consumer-oriented **Speak Up** campaign. This program seeks to actively engage patients as members of the health care team and as active participants in their own care by "speaking up." The key messages of the Speak Up campaign, which are delineated in greater detail in its eye-catching brochure, include the following:

- **Speak up** if you have questions or concerns.
- **P**ay attention to the care you are receiving. Make sure you are receiving the right treatment. Don't assume anything.
- **E**ducate yourself about your diagnosis and the medical tests you are undergoing and your treatment plan.
- **A**sk a trusted family member or friend to be your advocate if you can not advocate for yourself.
- **K**now what medications you take and why you take them.
- **U**se a hospital, clinic, surgery center or other type of health care organization that has undergone rigorous on-site evaluation.
- **P**articipate in all decisions about your treatment.

This campaign acknowledges that physicians, health care executives, nurses and other health care workers are working hard to address the problem of health care errors. This campaign reinforces their efforts. The Joint Commission has already provided thousands of brochures and Speak Up buttons to accredited organizations. The brochures, now available in English and Spanish, are tailored to specific types of organizations such as hospitals or nursing homes, and contain a blank panel that allows the individual organization to add its own patient safety message to the brochure. The response to the campaign has thus far been very positive. Other groups—such as pharmaceutical companies, business coalitions, advocacy groups, and church groups—are also now expressing interest in using the brochures with their employees/constituents.

The next Joint Commission patient safety initiative, also of recent vintage is the core component of a Patient Safety Taxonomy. It is no small irony that the progressively expanding national discussions on patient safety over the past several years are not based on a common language. For example, there are no agreed upon definitions of medical error or adverse event. This critical missing element has hindered our collective ability to collect patient safety data in a consistent fashion, analyze of process failures, mine data (e.g., trends, pattern analysis), and disseminate new knowledge about patient safety.

The Joint Commission has now created the framework of a comprehensive Patient Safety Taxonomy and is working with the Agency for Healthcare Research and Quality and others to finalized a communication tool that will have broad potential utility for consumers, provider organizations, health care practitioners, purchasers, researchers and other audiences. The framework of the Taxonomy has recently been shared with the Institute of Medicine for consideration by its newly established committee on patient safety data standards.

Finally, as the creator (in 1996) of the highly regarded Annenberg Conferences on patient safety, the Joint Commission will branch-out over the next nine months to serve as the convener of four diverse national conferences on topics whose common underlying theme is patient safety. The most significant of these—an invitational conference on the Business Case for Patient Safety that is being co-funded through the Agency for Healthcare Research and Quality—will seek to convince health care organization leaders that financial investments in patient safety will indeed serve the bottom-line priorities that necessarily drive many of these organizations. Fol-

lowing the identification of a persuasive business case, the conference will frame a research agenda that has the potential to support a future business case for safety.

The remaining three conferences will bring together both recognized experts and disparate interests to address the issues of Nurse Staffing, Emergency Preparedness, and Emergency Unit Overcrowding. The confluence of factual information across these three sets of issues already suggests that a progressively under-girded delivery system is unable to either meet public expectations nor the provision of state-of-the-art or to assure the public of the safety of the care that is delivered to those able to access service. Significant public policy recommendations are expected to emerge from each of these conferences.

In still other collaborative efforts, the Joint Commission is working with the Centers for Medicare and Medicaid Services, the Agency for Healthcare Research and Quality, the National Quality Forum, purchaser-led Leapfrog Group, and others to further these patient safety initiatives.

THE CHALLENGES AHEAD

The road to patient safety is a never-ending journey this is because the continuing rapid evolution of this nation's health care capabilities make achievement of our patient safety goals a moving target. But it is also because long-standing change will require counter-intuitive strategies, culture change, and radical alterations in the way health care professionals are trained.

- Counter-intuitive strategies must meet the need to protect and support caregivers who make errors rather than punish them. When caregivers feel safe, patients are more likely to be safe because such strategies create the opportunities to truly learn from identified errors.
- If we cannot change the blame and punishment culture of our society, we must incent and promote counter-cultures of safety in our nation's health care organizations. This is a non-delegatable responsibility of organization leaders; those having the courage to rise to this challenge should be rewarded.
- This country has trained generation after generation of outstanding individual clinicians—physicians, nurses, and other professionals who make important, even life-and-death decisions for and with patients every day. Now we need to expand the applied knowledge base of future generations to include systems thinking and analysis, and we need to train this new advance guard of health care professionals as interdisciplinary teams.

The patient safety challenges are neither small in number nor small in magnitude. But progress is being made by the private sector, by the public sector, and importantly, by both working together. We should take great heart in this progress as we continue our journey.

Mr. BILIRAKIS. Okay, go ahead. Please proceed, Dr. O'Leary.

Video NARRATOR. Hospitals: One place patients hope nothing will go wrong, but sometimes things do go wrong with potentially life threatening consequences. Reported cases of wrong-site surgery are on the rise, according to an alert just issued by the Joint Commission on Accreditation of Healthcare Organizations.

The problems include surgery performed on the wrong body part or site, the wrong patient, or even the wrong surgical procedure altogether.

Mr. O'LEARY. These cases leave patients and their families incredulous and undermine their confidence in doctors and hospitals. They should never happen, but unfortunately, they still do. That is why we are enlisting patients and their families to help eliminate these tragic mistakes.

Video NARRATOR. Patient Mark Deedan who had knee surgery made himself part of the health care team, learning all he could about the procedure before being wheeled into the operating room.

Mr. DEEDAN. I was the one being operated on, and I felt it was my responsibility to make sure that things went well in the operating room and to become part of the health care team.

Video NARRATOR. Here are some tips for patients to prevent wrong-site surgery. Ask to have the surgical site marked with a

permanent marker to avoid any confusion. Make sure there is total agreement between you and your surgeon about exactly what will be done and where. Finally, don't be intimidated. Bring in a list of any and all questions to the surgeon before the procedure.

Video VOICE. The team, consisting of the surgeon, the anesthesiologist and the nursing staff, must work together and, if there is an issue and there is some concern about a process, they need to stop and regroup so that we understand what the optimal thing to do is for the patient.

Video NARRATOR. The warning about surgical mistakes is the latest alert issued by the Joint Commission, a group dedicated to making patient safety the top priority among accredited health care organizations. This is Sarah Vedor reporting.

Mr. BILIRAKIS. Thank you, Doctor. Does that complete your presentation?

Mr. O'LEARY. It does. Thank you.

Mr. BILIRAKIS. Thank you very much, sir.

Dr. Roger L. Williams is with U.S. Pharmacopeia. Dr. Williams also has a demonstration after his oral statement. Please proceed, sir.

STATEMENT OF ROGER L. WILLIAMS

Mr. WILLIAMS. Thank you, Mr. Chairman. It is an honor to be here speaking on this important topic. I will speak briefly about the United States Pharmacopeia, and then about our innovative programs to promote patient safety, after which Ms. Diane Cousins who presented before this subcommittee approximately 1½ years ago, will give a demonstration of one of our reporting programs termed MedMARx.

USP was begun in 1820 and, as such, is only slightly younger than the U.S. Congress. Physicians published the first pharmacopeia in the United States in 1820 as a means of listing the best medicines, giving them useful names, and providing standard recipes for their preparation. Even then, practitioners wanted their patients to receive carefully prepared medicines and use them correctly.

Over the years, Congress has relied on USP on many occasions. In 1848, Congress passed the Drug Import Act which requires drugs entering the United States to conform to USP standards. In 1906, in the Pure Food and Drug Act Congress recognized USP standards for manufactured drugs.

In 1938, Congress stated that FDA can legally enforce USP standards, including its packaging and labeling requirements. This policy represented an early attempt by Congress itself to address patient safety. Deaths at the time were occurring in the United States, because bichloride of mercury tablets, which is a highly poisonous disinfectant, were being confused with mercurous chloride tables, a therapeutic product. I am sure the committee can see how easy that confusion would occur.

In the last 30 years, USP has been in the forefront of innovative efforts to promote patient safety. This focus arose because of USP's historic concern with the quality of therapeutic products. In 1971 USP created a quality defect reporting program, and in 1991 USP moved to medication errors, based on the understanding that medi-

cation errors are multi-disciplinary and multi-factorial, not just related to product defects.

From this early experience, USP developed a new program for medication errors, termed MedMARx. MedMARx is innovative in many ways. First, it uses a standard terminology and classification for medical errors, thus facilitating reporting. Second, MedMARx captures extensive information beyond just the facts of the errors. It looks at factors within a hospital system that contributes to the error. Third, MedMARx allows anonymous reporting. Finally, MedMARx embraces the latest in information technology by receiving reports into USP's national data base electronically over the Internet.

The success of MedMARx has been impressive. Over 500 of the Nation's hospitals currently utilize MedMARx. In 1999, there were 6,000 reports to the data base. The next year there were 40,000 reports. Last year, there were over 100,000 reports, and this year we are expecting 200,000 reports from practitioners all across the country to the USP data base. That will total approximately 400,000 error reports to our data base.

MedMARx has already provided highly useful information. We have learned that, obviously, the practitioners are willing to report errors if a useful reporting tool is available and if reporting is protected from disclosure. Hospitals in the program for more than 1 year also report more frequently.

We have learned that the vast majority of errors do not, in fact, cause patient harm. Only a small fraction, 5 percent, of total reports are associated with patient harm, and this finding corresponds with other industries. In the aviation industry, it is well known that most errors do not result in plane crashes. This information is critical to understanding how to implement system improvements.

We have learned that certain drugs are especially error prone, insulin, anticoagulants, and the opiates, which is not surprising considering their narrow dose range. And we have gathered important information about medications in children and the elderly, because MedMARx captures both gender and age information.

Here we have learned some specific things, and here are two examples. Deaths have been reported due to inadvertent mix-up of neuromuscular blocking agents which paralyze the respiratory system and are highly useful in anesthesiology. USP, by its standards setting activities, responded with proposed warnings and color differentiation on packaging and labeling of these products.

Another example: Deaths have been reported due to the direct injection of an anti-cancer drug, Vincristine sulfate, into the spine instead of into the vein. It is highly toxic when given into the spine. USP responded again with changes in packaging and product labeling requirements that have reduced the error.

USP is excited about MedMARx, and we have many plans for the future. It can be expanded to other points of care. It can include adverse events and medical errors. The data base enhances research efforts to determine best practices for reducing errors, and it supports USP standard setting activities that approve packaging and labeling of therapeutic products.

We are interested in setting standards for computer based physician order entry systems and other support tools for practitioners, and USP wants to work collaboratively with all stakeholders in this effort.

As the Institute of Medicine recommended in its landmark 1999 report, Congress can strengthen MedMARx and other reporting programs by enacting a Federal medical error reporting privilege approach. For example, USP has worked closely with Congresswoman Morella in preparing a bill she first introduced last Congress and which she introduced yesterday to provide a privilege for information reported to USP. We believe that such legal protection would enhance reporting even beyond the assurance of anonymity.

In closing, I would like to make the following reports. A national data base for error reporting is highly desirable. USP is building that data base and will work collaboratively with Congress and all other stakeholders in its use.

Standard nomenclature and report formats, coupled with cutting edge information technology approaches, promote error reporting at points of care. The national error reporting data base should be extended to all points of care and all types of health care errors.

Thank you for the opportunity, and I will now turn the presentation over to Ms. Cousins who will demonstrate MedMARx.

[The prepared statement of Roger L. Williams follows:]

PREPARED STATEMENT OF ROGER L. WILLIAMS, EXECUTIVE VICE-PRESIDENT AND CHIEF EXECUTIVE OFFICER, UNITED STATES PHARMACOPEIA

On behalf of the United States Pharmacopeia (USP), I appreciate the opportunity to testify before the Health Subcommittee of the House Energy and Commerce Committee regarding innovative strategies to improve patient safety.

In recent years, USP has been in the forefront of innovative efforts to promote patient safety. Patient safety depends on the availability of methods and procedures to understand patient risk at the point of care. USP's primary effort in this regard has been to develop reporting programs that capture medication error risk and lead to the implementation of systems to prevent errors.

USP's patient safety efforts have culminated in the development of MedMARx SM, an interactive, anonymous, Internet-based medication error reporting program. MedMARx compiles medication error reports from participating hospitals in order to analyze patient safety trends, develop best practices and disseminate this information to participating hospitals. Approximately ten percent of the nation's hospitals participate in the program.

In the three full years since its inception, MedMARx has captured over 200,000 reports of errors from participating institutions. USP has already issued an annual report based on 1999 data and is preparing another report for the year 2000 data. Our annual reports are provided to Congress and other stakeholders, and data from the MedMARx program can be shared in anonymous form with relevant Federal and State agencies.

MedMARx is based on the premise that patient safety can more effectively be enhanced in a culture that emphasizes systemic change rather than blame. Early results support this view. We are encouraged, for example, by a marked increase in the number of second year reports from hospitals that participated in the first and second consecutive years of MedMARx availability.

The core innovation of MedMARx lies not just in a software program, but more broadly through engagement of frontline practitioners who, at the end of the day, are critical to any effort to promote patient safety. Whatever success MedMARx achieves rests on these practitioners and their commitment to good patient care.

Based on its experience, USP strongly supports congressional efforts to reduce preventable mistakes that occur throughout the continuum of prescribing, dispensing, administration and use of medicines. Specifically, USP supports enactment of a federal medical error reporting privilege to enable health care providers to report errors to systems like MedMARx without fear of adverse legal consequences. USP further believes that federal policies should encourage public and private ini-

tiatives at the national, state, and local levels to enhance patient safety and reduce the medical mistakes that cost the health care system billions of dollars each year.

I. BACKGROUND ON USP

Founded in 1820, USP is a private not-for-profit organization whose mission is to promote the public health by establishing and disseminating officially recognized standards of quality and authoritative information for the use of medicines and related articles for professionals, patients, and consumers. USP's governing bodies include its Convention, which meets every five years, and a Board of Trustees, which provides direction to staff in the years between Convention meetings. Standards-setting activities are conducted by the USP Council of Experts.

Membership in the Convention (representing approximately 400 associations), on the Board (11 members representing Convention constituencies), and on the Council and its Expert Committees (approximately 800 members) is entirely voluntary. To support the activities of these bodies, USP maintains a paid staff of approximately 320 in its Rockville offices. USP derives its income from the sale of its publications and reference standards materials. USP's expertise as a standards-setting body has been recognized in numerous federal laws.

USP standards are published in the *United States Pharmacopeia and National Formulary (USP-NF).* These standards are officially recognized in the Food, Drug and Cosmetic Act and are enforceable by the Food and Drug Administration. Thus, USP's primary publications are official compendia of the United States. More recently, Congress named *USP and NF* as the official compendia for dietary supplements.

Key components of USP's legal authority derive from efforts to improve patient safety. For example, prior to 1938 only USP standards for determining the identity, strength, quality, and purity of articles used in medical practice were legally enforceable, but that year Congress recognized and made legally enforceable USP packaging and labeling requirements in response to numerous fatalities resulting from the accidental ingestion of bichloride of mercury tablets. At that time, compendial packaging and labeling standards for bichloride of mercury tablets (a disinfectant), which was frequently and mistakenly taken for mercurous chloride tablets (a cathartic), recommended the following:

> "[t]ablets of an angular shape having the word 'poison' and skull and crossbones design distinctly stamped upon it. The tablets are to be colored blue. They are to be dispensed in securely stoppered glass containers on the exterior of which is placed a red label bearing the word 'poison'."

Even today, many of our monographs (e.g., potassium chloride for injection concentrate) incorporate legally enforceable packaging and labeling requirements for the purposes of reducing medication errors.

II. USP REPORTING PROGRAMS

In 1971, USP's historical concern with the quality of drug products led it to collaborate with the FDA and the American Society of Health System Pharmacists to create the Drug Product Problem Reporting Program—a national program in which health professionals were asked to voluntarily report problems experienced with drug products on the market. These defects often related to inadequate packaging or labeling such similarity in color or design of the label, or similar sounding drug names.

USP's focus today is on both the product and on the system in which the product is prescribed, dispensed, administered, and used. USP does not set practice standards per se, but as a practical matter, many of USP's standards indirectly affect professional practice and many practice standards are based on USP standards.

(a) Medication Errors Reporting Program

In 1991, USP began working with the Institute for Safe Medication Practices to coordinate the Medication Errors Reporting (MER) Program. Since then, the MER Program has received more than 7,000 reports of actual and potential medication errors. These reports have identified errors in various health care delivery environments, including hospitals, nursing homes, physicians' office, pharmacies, emergency response vehicles, and home care.

Through these reports, USP has come to understand that errors are multi-disciplinary and multi-factorial. They can be committed by experienced or inexperienced staff, by health professionals, support personnel, students, and even patients and their care givers. Medication errors can occur anywhere along the continuum from prescribing to transcribing to dispensing and administration. The causes of errors may be attributed to human error, to product names or designs, or to the medication

handling and delivery systems in which the products are used and in which individuals operate and interact.

As each MER report is received, it is shared with the product manufacturer and with the Food and Drug Administration. USP does not require that the name of the reporter, patient identity, or facility be reported. When such information is provided, however, USP respects the confidentiality of the report and will purge the identity of the institutions and individuals named in the report upon request. Reporters are advised of any corrective actions resulting from their report. Such actions are disseminated to all individuals who have reported to the MER Program and are publicly available on the USP web site.

In 1995, USP helped form the National Coordinating Council for Medication Error Reporting and Prevention. The Council, for which USP serves as secretariat, brings together 23 national organizations and agencies to promote the reporting, understanding and prevention of medication errors. The Council has developed a standardized definition of medication error, a taxonomy for error reporting and a newly revised index for categorizing medication error severity.

(b) MedMARx

Through USP's work with the MER Program and other collaborative efforts, USP realized the need for national standardization of medication error reporting, especially in hospitals. Hospitals were eager to submit reports to USP in an anonymous and standardized format that would allow them to compare their errors to those in other participating facilities. USP set out to develop and refine such a model for hospitals, and then broaden the model to include other health care settings and other types of reporting such as adverse drug reactions.

On July 27, 1998, USP made MedMARx available to hospitals nationwide. MedMARx is an internet-accessible, anonymous reporting program that enables hospitals to voluntarily report, track and trend data incorporating nationally standardized data elements (i.e., definitions and taxonomy). MedMARx is structured to support an interdisciplinary systems approach to medication error reduction and foster a non-punitive environment for reporting.

Hospitals use the program as part of the organization's internal quality improvement process. Hospitals can review errors entered by other institutions in "real time" and can also view any reported action taken by other institutions in response to the error. This feature affords institutions the opportunity to examine errors in a proactive manner. For example, the institution can review the error profile of a drug or class of drugs before a product is added to the institution's formulary to determine whether risk prevention measures or training programs should be instituted or, if the error profile is so serious, whether the decision to stock the drug should be rejected. MedMARx also supports the performance improvement standards of the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), which requires institutions to learn from the experiences of others in order to reduce risk.

Currently, over 500 hospitals have enrolled in the MedMARx program and other hospitals and health systems are joining rapidly. Hospitals of various types and sizes spanning fewer than 50 beds to approximately 1000 beds are enrolled. Participating hospitals include some operated by the U.S. Departments of Veterans Affairs and Defense (which includes hospitals around the world), as well as state-owned facilities.

Since 1998, more than 210,000 records have been submitted to the MedMARx database. USP has issued a summary of MedMARx data collected in 1999. In that first calendar year, 6224 reports were submitted by 56 facilities. The 2000 data report will be released on May 20th. During the second year of the program, participation strengthened to 184 hospitals submitting 41,296 reports.

The data show that the most common products involved in errors—Insulin, Heparin, Warfarin, and Opiate analgesics—require careful dosing, close monitoring, and adherence to protocol where established. The most common types of errors are omission, wrong dose, and unauthorized/wrong drug. With the aforementioned drugs, the outcome of such errors could be serious to fatal.

Yet another key finding is that most errors do not reach the patient—only 3% of errors reported to MedMARx caused patient harm. USP continues to gather reports of "near misses" because, as the experience with aviation has shown, all errors are critical to an understanding of patient risk.

MedMARx is readily expandable to other points of care in addition to hospitals and can collect information about medical errors beyond medication errors—in fact, USP is moving in this direction at the time of this report.

III. POST-REPORTING ACTIVITIES

Reporting is not a goal in itself. Rather, the purpose of reporting systems is to analyze the information provided and to implement effective, sustainable interventions that will prevent errors from recurring. Ideally, these interventions will be replicated throughout health care settings. Data received through USP reporting systems have led to changes in individual hospitals, across health systems, and have even led to changes in USP-NF packaging, labeling and nomenclature standards for health care systems nationwide.

(a) Actions by Hospitals and Health Systems

By compiling and trending errors in a standardized way, USP's reporting systems can lead to innovative strategies to address errors. For example:

- *Patient Misidentification*—A health system identified a trend of "wrong patient" errors and determined that nurses were not verifying the patient's identification (*i.e.*, checking the patient's wrist band) before administering medications. A thorough review of the cases found that wrist bands were often coming off or being removed for various reasons. This finding resulted in a reevaluation of all wrist band materials and procedures that will likely impact the entire system. A program is also being developed to encourage patients to ask questions and be informed about the medication administration process.
- *Prescription Writing Abbreviations*—A health system noted an unexpected increase in medication errors due to the use of abbreviations in prescription writing. The health system was puzzled since it had banned the use of error-prone abbreviations in prescription writing procedures. A closer look at MedMARx data revealed that the health system had acquired a hospital in the region, but newly privileged physicians had not been apprised of the no-abbreviations rule. Educational programs were immediately implemented for physicians from the newly-acquired hospital.
- *Additions to a Hospital's Formulary*—In considering whether to add a new drug to its formulary, a hospital looked at the accumulation of reports and actions taken by other institutions as documented in MedMARx. The information was used in two ways: (a) to determine if the errors were severe enough to deny the drug's addition to this hospital's formulary; and, (b) to determine what preventative measures could be incorporated in this hospital's processes to allow adding the drug.
- *Dispensing by Robotics*—A hospital interested in purchasing a robot to dispense medications reviewed its MedMARx data and identified which dispensing errors might be prevented by the robot. The reduction in health care costs realized by preventing such errors justified the investment in new technology.
- *Medication Omissions*—A notable trend of treatment omissions for respiratory therapy led respiratory therapy directors from hospitals across a health system to convene. The reasons for the omissions were two-fold: (1) patients were not in their rooms at treatment times because they were receiving therapy elsewhere in the hospital; and, (2) patients were refusing therapy. Two possible solutions are being tested. First, a new method of scheduling treatments will bring various caregivers to the patient's bedside in turnstile fashion so that respiratory, occupational, and other therapies are appropriately sequenced. Second, the hospitals are now actively explaining to patients the need for each treatment.

(b) Actions by USP

Data collected through its reporting programs enable USP to evaluate and implement drug product standards, and in some cases practice standards and requirements, aimed at preventing errors. The following examples describe some of the steps taken by USP in response to medication error reports. The standards that have been developed as a result of USP's error reporting programs have emerged from USP's Council of Experts, which has a number of Expert Committees that develop appropriate standards to reduce medication errors.

- *Product and Nomenclature Standards*—Deaths reportedly due to the accidental misadministration of concentrated Potassium Chloride Injection led to (1) changing the official USP name to Potassium Chloride for Injection Concentrate to give more prominence to the need to dilute the product prior to use; (2) a requirement that labels bear a boxed warning that reads: "Concentrate: Must be Diluted Before Use;" and (3) a unique requirement that the cap for this drug must be black in color and must be bear an imprint in a contrasting color with the words: "Must be Diluted."

- *Product Standards and Practice Recommendations*—Deaths reportedly due to the confusion and resultant injection of the anticancer drug, Vincristine Sulfate for Injection, directly into the spine instead of into the vein, resulted in changes in the requirements for packaging by pharmacies and manufacturers preparing ready-to-use doses. Each dose, whether prepared by the manufacturer or the pharmacist, now must be wrapped in a covering labeled "FOR INTRAVENOUS USE ONLY" and that covering may not be removed until the moment of injection.
- *Nomenclature Standard*—Deaths reportedly due to the name similarity of Amrinone (cardiotonic) and Amiodarone (cardiac depressant) have led USP and the United States Adopted Names (USAN) Council to change the official and nonproprietary name of Amrinone to Inamrinone to distinguish the two.
- *Product Standard*—Deaths reportedly due to the inadvertent mix-up of neuromuscular blocking agents (which paralyze the respiratory system) with other drugs, have led to recommended changes in standards of this therapeutic class of neuro-muscular blocking agents. The standards would add warnings and color differentiation to the labeling and packaging of the products.
- *Practice Recommendations*—A study of MER and MedMARx data in pediatric populations led to the development of recommendations for error avoidance in this population. The recommendations are aimed at all disciplines across all health care settings and include packaging and labeling recommendations as well as recommendations for compounding and dosing medications safely.

(c) USP leadership activities

Because MER and MedMARx are the only private-sector, national medication error reporting systems, USP is uniquely situated to play a leadership role in national and international efforts to improve patient safety.

The USP commitment to medication error prevention is broader than merely collecting data. USP has enrolled a number of MedMARx-participating hospitals in a long-term project called "Strategic Research Partnerships" to propose indicators of quality and best practice standards for use of specific medications. The first project involves Heparin, a drug revealed by both MER and MedMARx data to be commonly involved in errors. These hospitals aim to create a standard protocol for Heparin therapy, implement the protocol, and develop best practices for prescribing, dispensing, administering and storing the drug which will address the reasons for recurring errors.

Because of its long history in medication error reporting and prevention, USP participates in many collaborative efforts at the national and state levels to reduce health care errors. Thus USP is involved in (ongoing activities are *italicized*):

- Veterans Administration Adverse Drug Event Working Group Project
- Veterans Administration Work Group on Nomenclature and Taxonomy for Creating a Medication Error Reporting System
- JCAHO Expert Panel on Medication Safety
- *Pittsburgh Regional Healthcare Initiative, AHRQ Grant Advisor on Improving Patient Safety: Health Systems Reporting, Analysis, and Safety Improvement Research Demonstrations*
- *National Quality Forum Safe Practices Steering Committee, Vice Chair of Technical Advisory Panel to the NQF Committee*
- *Health Research and Education Trust of the AHA, Commonwealth Grant Advisor on Reducing Medication Errors, Pathways for Medication Safety.*
- *University of North Carolina, AHRQ Grant for Centers for Education and Research on Therapeutics—Reporting Adverse Drug Events in Infants, Children, and Adolescents*
- *American Academy of Family Physicians, AHRQ Grant Advisor on Developing Center for Education and Research on Patient Safety in Primary Care*
- *University of Pennsylvania, AHRQ Grant Advisor on Developing Innovative Approaches to Improving Patient Safety*
- *Maryland Patient Safety Coalition*

IV. RECOMMENDED CONGRESSIONAL ACTION

USP believes that its reporting systems have already contributed to improvements in patient safety. But the full potential of USP's reporting programs remains to be realized, and Congress can help accelerate this progress. Specifically, USP urges Congress to create a more conducive legal environment for reporting medical errors through enactment of a federal medical error reporting privilege. Such a privilege would strengthen reporting systems and thereby foster the development of systems to prevent medical errors.

Many states have established peer review privilege statutes to encourage self-evaluation in the interest of improving the quality of healthcare. But the extent and application of state protections vary, and state laws do not necessarily protect information that is reported outside the hospital, for example to a national reporting system. In some states, the privilege is explicitly waived if information is provided to a third party. These policies discourage practitioners and facilities from sharing medication error reports with USP and other organizations.

In its landmark 1999 study "To Err is Human," the Institute of Medicine specifically endorsed establishment of a federal reporting privilege. Since then, USP has urged Congress to implement the IOM recommendation. For example, we have worked closely with Congresswoman Morella in the development of legislation she introduced in the 106th Congress (H.R. 3672) to establish a privilege for USP reporting systems. We understand that just yesterday, Congresswoman Morella reintroduced her bill with bipartisan cosponsorship. We urge serious consideration of the Morella bill, and any similar legislation that provides clear protection to practitioners and facilities that report medical errors for the purposes of improving patient safety.

We have also worked in coalition with the American Medical Association, the American Hospital Association, the American Nurses Association, the Joint Commission on the Accreditation of Health Care Organizations and other health care organizations to develop principles for the development of patient safety legislation. In brief, our principles call for the establishment of a federal privilege to encourage reporting in a non-punitive environment that encourages a culture of safety.

A federal privilege will encourage facilities and practitioners to report medication errors to USP in a consistent and uniform manner, thereby increasing the chances of identifying trends and implementing effective corrective measures that will help improve the quality of care for patients nationwide.

If strengthened in this manner, the USP reporting programs may lead to creation of a national database of medication errors. Such a database can be highly useful to Federal and State officials, practitioners, patients and others as they seek to understand patient risk and ways to reduce it. We contemplate a continually evolving database that can be used in many different circumstances and to different purposes. A great deal of work—and active participation from many constituencies—is needed to achieve USP's goals in this area and thereby improve health care in the United States and other countries as well.

CONCLUSION

USP looks forward to working with Congress and other stakeholders in the ongoing effort to improve patient safety. We especially look forward to working with Congress to strengthen legal protections that will result in greater use of reporting systems, and thereby fuel the development of system changes that will prevent errors before they occur.

Mr. BILIRAKIS. Please proceed.

Ms. COUSINS. Good morning, Mr. Chairman and members of the subcommittee. Thank you for this opportunity to demonstrate MedMARx.

MedMARx was developed based on USP's experiences and collaborations. Hospitals look to USP as a trusted intermediary with whom reports could be shared. Although this is a slide presentation, MedMARx is actually an Internet accessible data base.

When hospitals first access the system, the system randomly assigns a specific facility ID which becomes the hospital's PIN number of sorts in the system. Although USP knows what hospitals are enrolled and knows what IDs are registered in the system, USP has no way to match a hospital to a specific facility ID, thereby maintaining anonymity.

When accessing MedMARx for the first time, hospitals create a facility profile which captures characteristics such as bed size, type of facility, staffing levels, and services offered. MedMARx includes hospitals ranging in bed size from under 25 to more than 800. Currently, over 500 hospitals participate, including institutions of the Department of Veterans' Affairs and the Department of Defense.

MedMARx uses a standardized definition of medication error. Our experience shows that hospitals define error differently. Some hospitals define error as a deviation from the prescriber's order, thus presuming the order is correct. Other hospitals only capture errors at the point of administration and not in dispensing or prescribing.

The GAO report on adverse drug events noted that a broad definition of error means that the total number of errors reported will be inherently higher. Using the standardized category index, hospitals classify errors based on the severity of outcome to the patient. There are nine categories, including potential errors, intercepted errors, and harmless errors that reach the patient. The remaining categories reflect varying degrees of harm, including fatality.

Prior to using MedMARx, hospitals have focused only on harmful errors or only on errors that reach the patient, and have given little attention to potential or intercepted errors.

The next four slides capture the fields for basic report entry. MedMARx fields are an optimal mix of free text, together with structure and coding. The volume of data captured in each report is tiered so that more data is collected as the severity of the outcome increases. MedMARx data show that the most common types of errors are misdoses and wrong doses.

MedMARx captures causes of errors, contributing factors to the error, and location where the error occurred. The data show that the top cause of error is performance deficit, meaning that health professionals were trained to know better, yet erred nonetheless. Further analysis shows contributing factors here are distractions and workload increase.

Because MedMARx was designed to have a systems approach to medication error reduction, the program does not capture the names of individuals involved in the error, but rather the level of staff involved. These data help identify areas for focused policy development and training.

These final fields in basic report entry capture the learning that can be achieved by participating in a national data base. Hospitals are not only able to see the errors entered by other hospitals, but also able to learn what actions were taken and the details of those actions. At this point, the hospital can continue to enter information about the product and the patient.

For your information, the patient's age but not date of birth or other identifiers is captured as a risk factor and will be useful in studying errors in pediatric and elderly populations.

Various formats of output are available through the search function, including spreadsheets, graphs, and data export. A hospital can search its own data, other hospitals' data, or all data. The hospital selects certain search criteria, then generates the output.

This example shows the points in the medication use process where the errors occurred and the severity of those errors. To view the two records causing temporary harm, which are category E in red, that were committed in the prescribing phase, they would click to drill down on that area of the chart, and then click on the hyperlink to access the specific record.

Presently, a hospital can view its own data or all data submitted by other participants. This summer a complementary program called a multi-facility module will allow a health system to group the data for its hospitals as another subset. The health system's involvement will drive a higher level of participation by its hospitals, help identify error trends across the system, and help to design, implement, and monitor systemwide solutions to errors.

Thank you, Mr. Chairman, for this opportunity to demonstrate MedMARx.

Mr. BILIRAKIS. Thank you. Dr. Williams, does that complete your presentation?

Mr. WILLIAMS. Yes.

Mr. BILIRAKIS. Dr. Bonnie Westra is a PhD and an RN and here representing the American Nurses Association. Please proceed, Doctor.

STATEMENT OF BONNIE WESTRA

Ms. WESTRA. Good morning, Mr. Chairman and members of the subcommittee. I am Bonnie Westra, a registered nurse and former co-chair of the American Nurses Association's Committee on Nursing Practice Information Infrastructure, which is a committee of the Congress on Nursing Practice and Economics.

I thank you for the opportunity to address medical errors and technology, important issues for every nurse. The ANA is the only full service association representing the Nation's registered nurses through its 54 constituent member associations. Our members include RNs working and teaching in every health care sector across the entire United States.

Nurses are the largest health care workforce in the Nation, numbering more than 2.7 million nurses, 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 life span.

Nurses are always seeking to have better outcomes through their management with health care professionals in hospitals, clinics, community health centers, offices, nursing homes and also patient homes. We are the ones who provide the majority of direct patient care and who manage the technologies incorporated into health care experiences.

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 also are increasing the complexity of health care. Just think of premature infants in neonatal units or the burn victims from recent terrorist attacks. These patients are able to survive and to thrive when only a few years ago they could not.

Nurses in the units manage patients who are supported by complex technologies such as 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. Today's nurses are engaged in painstaking, complicated care. They have fewer support systems than ever before, and that significantly increases the potential for error.

Numerous opportunities for failure exist at many points, even in the simplest health care experiences. Nurses, in the role of patient advocate, often intercede to prevent system errors which may or may not result in patient harm. Appropriate technology applications can assist nurses in order to be able to prevent medical errors, but conversely, these same technologies can compromise the health care delivery process and even create more adverse outcomes.

Current health care information system resources can prevent errors by removing unreadable, handwritten orders and documentation. Errors can be significantly reduced if the information systems include decision support capabilities such as direct Internet access to journal articles and professional references, prompts and alerts, drug-to-drug and drug-to-food interaction alerts, and care pathways or protocols and clinical guidelines. But such robust capabilities remain useless if, in fact, nurses and other health care professionals don't have immediate access to the technologies, must engage in difficult or prolonged sign-on efforts, or have to make do with documentation or order entry systems that fails to meet the information needs.

Information systems and their software applications must be designed with user input, incorporating standardized data and processes, wherever possible. Nurses and other clinicians who actually use the system are the best source to identify data needed, how to match the way they think and work, and where to remove redundant data entry. Use of standard data enables abstraction of information from routine charting for quality assessment initiatives aimed at identifying and preventing medical errors.

Unless standardized data are built into routine charting, data cemeteries will result when information cannot be abstracted and systems can't talk to each other. The lack of interface between systems results in lack of accessible information to all of the patient's providers, potentially contributing to increased health care costs and delays in patient care.

New technologies need to be evaluated carefully. For example, voice recognition technologies have been recommended for the incorporation into health care practice settings to reduce medical errors. This has considerable potential, but also the potential for new medical errors emerge in the form of incorrect conversion of the audio file to digital content.

On the other hand, barcode technology is a mainstay within the business community and is now finally moving into the health care mainstream as a method to reduce medical errors. This technology can assist in ensuring the right patient receives the right medication in the right dose via the right route at the right time. However, delays in its use will continue to occur unless a single set of barcode standards are identified, acceptable hardware devices create reliable results, and health care professionals review their business processes to identify junctures and activities that can benefit from safe and effective barcode use within the practice settings.

Internet access and electronic mail, or e-mail, use continues to explode in consumers and health care professionals and the technologies in their daily lives. With these increases in communication between clinician and patient or between clinician and clinician,

however, we can actually create medical errors if we use informal communication processes, rather than using built-in algorithms, decision rules and documentation components of health care information systems that could be incorporated.

Proper use of any technology involves correct preparation of the user. This may involve formal education, but frequently it is informal or nonexistent learning experiences. With increasing budget constraints, such educational opportunities are cut, and users are expected to intuitively discover how to use technology. Trial and error may be fine when you are learning at home, but it is unacceptable in a dynamic hustle and bustle of a health care setting. Just in time learning is too late in a patient care emergency, and increases the risk of error.

Standards organizations, vendors, and health care professionals are partnering to integrate communications, documentation, and other standards into health care environments to be able to help and reduce the impact of medical errors. By establishing recognized language and data standards, everyone can use the same terms with the same definitions and meanings, and thereby prevent confusion and error. Standard product, procedure, and process naming conventions can then be programmed into information systems so that software is able to permit the user to select the correct items.

The recognized standards must accommodate all health care professionals in their practice. For example, the current HIPAA code sets at this time do not include complementary and alternative therapies nor the diagnoses, interventions and outcomes terms used by registered nurses in their diverse practice settings.

These few examples reflect the complexity of medical errors issues. Although medical technology is often most presented as the preventive or curative strategy for medical errors, unless nurses and other clinicians are involved in the design, implementation and evaluation of technology solutions, medical errors could actually increase. Quick fix technology fails to address the systems and cultural changes necessary to maximize patient safety and care.

Nurses strive to be partners within a nonpunitive system that meets the needs of patients and reduces the patient risk. Our nurses are providers who will ultimately implement the new technologies and, therefore, need to play a substantial role in the development, implementation, evaluation and redesign of these systems. Their contribution is integral to the prevention of medical errors.

Thank you very much.

[The prepared statement of Bonnie Westra follows:]

PREPARED STATEMENT OF BONNIE WESTRA, ON BEHALF OF THE AMERICAN NURSES ASSOCIATION

Good morning, Mr. Chairman and Members of the Subcommittee. I am Bonnie Westra, a registered nurse and former co-chair of the American Nurses Association's Committee on Nursing Practice Information Infrastructure, a committee of the Congress on Nursing Practice and Economics. Thank you for the opportunity to address medical errors and technology, important issues for every nurse. The American Nurses Association is the only full-service association representing the nation's registered nurses (RNs) through its 54 constituent member associations. Our members include RNs working and teaching in every health care sector across the entire United States.

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. Nurses touch patients and manage teams of healthcare professionals in hospitals, clinics, community health centers, offices, nursing homes and patient's homes, always seeking to have better outcomes. We are the ones who most often care for patients and manage the technologies incorporated into their healthcare experiences.

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, with fewer supports than ever before and significantly increased potential for error.

ERROR

Error is defined as the failure of a planned action to be completed as intended (an error of execution) or the use of a wrong plan to achieve an aim (an error in planning). (IOM, 2000) Numerous opportunities for failure exist at many points in even the simplest healthcare experience. Nurses, in the role of patient advocate, often intercede to prevent system errors which may or may not result in patient harm. Appropriate technology applications can assist the nurse in these efforts to prevent medical errors. Conversely, those same technologies can compromise the healthcare delivery process and create even more adverse outcomes.

The identification, resolution, and prevention of medical errors necessitates participation by every stakeholder, including registered nurses who are at the bedside, in examining and then improving the appropriate processes and systems. Such process improvement and re-engineering initiatives demand appropriate ongoing data collection and analysis strategies, implementation of standards and protocols to effect change, and measurement of outcomes that demonstrate success or failure in preventing the same or new types of error. Assessment of human factors associated with the proposed technology need appropriate attention. Computer-based information systems can assist in some of those activities.

HEALTHCARE INFORMATION SYSTEMS

Current healthcare information system resources can prevent errors by removing unreadable handwritten orders and documentation. Errors can be significantly reduced if the information systems include decision-support capabilities such as direct internet access to journal articles and professional references, prompts and alerts, drug-drug or drug-food interaction alerts, "order set" templates, and care pathways/protocols and clinical guidelines. But such robust capabilities remain useless if nurses or other healthcare professionals do not have immediate access to the technologies, must engage in difficult and prolonged sign-on efforts, or have to "make do" with a documentation or order entry system that fails to meet their information needs. Inadequate orientation and skills at making the system work optimally further contribute to failures of the systems.

For example, personal digital assistant devices (PDAs) or other larger handheld data entry units can aid in point of care data entry by nurses. However, if the available software applications do not support recording of standardized terms used to describe the assessments, diagnoses, interventions, and outcomes, nurses can not describe the patient, care activities and future plans. These elements are then lost to other nurses and healthcare professionals as they assume responsibility for patient care management. Similarly, lack of communications technology standards may also prevent effective information transmission to and from the PDA if network, software and hardware incompatibilities exist. And what about the practical aspects of the nurse having to carry yet another item in a pocket, in hand, or on a belt or waistband? Can the device accommodate right or left hand users? Are displays adequate for the viewer or must the nurse scroll through numerous screens to find the necessary information or data entry screen? Does the device remain charged long enough to allow completion of the necessary documentation or information seeking activities?

Information systems and their software applications provide significant volumes of clinical and administrative data and information. However, in order to assure that the data is most meaningful and that it relates to the appropriateness of the patient's care, nurses must be integral to the design and development of the system.

This ensures that information can be tapped for quality assessment initiatives aimed at identifying and preventing medical errors. The technology also provides the opportunity to reevaluate systems and processes already in place, as a means to reducing inefficiencies. Unfortunately, data cemeteries may be the more common result when information systems are unable to "talk" to each other or the reports can not be generated because documentation standards have not been implemented. Duplication results when the information gathered isn't accessible to all of the patient's providers, potentially contributing to increased healthcare costs and delays in patient care. These deficiencies are being targeted by HIPAA rules and various standards initiatives such as HL7, ASTM, ANSI, and DICOM.

VOICE RECOGNITION

Voice recognition technologies have been recommended for incorporation into healthcare practice settings to reduce medical errors when clinicians refuse or cannot complete manual data entry processes in an information system. Although errors caused by poorly written orders and documents have been removed with voice recognition systems, the potential for new medical errors emerges in the form of incorrect conversion of the audio file into digital content.

When considering implementation of this technology to reduce medical errors, nurses find such a strategy less useful because of the concern for maintaining the confidentiality of patient information. Nurses are highly mobile healthcare professionals who frequently document assessments and caregiving information. They usually work in noisy and populated work centers, patient's private homes, and busy community clinics. Such locations do not support confidentiality of patient information that may be dictated into an information system microphone.

Currently specific "machine" training for voice recognition systems must be completed for each individual user, not a small task for the regular and float nursing staff assigned to a busy hospital nursing unit or clinic. To further complicate any voice recognition system implementation plans, the current practice for registered nurses incorporates report activities that are completed at end of shift or at time of transfer of patient care to another provider. Therefore, this technological approach to medical error reduction and prevention could prove cumbersome and may be difficult to implement for this group of professionals.

BARCODE TECHNOLOGY

Barcode technology is a mainstay within the business community and is now finally moving into the healthcare mainstream as a method to reduce medical errors. Potential uses include barcodes for supplies and pharmacy products, as well as unique patient, staff, and location identification labels. This technology can assist in ensuring the right patient receives the right medication in the right dose via the right route at the right time. Implementation delays will continue to occur until a single set of barcode standards are identified, acceptable hardware devices create reliable results, and healthcare professionals review business processes to identify junctures and activities that can benefit from safe and efficient barcode use within practice settings. Provisions must be made for effective backup strategies that must accommodate times of network or electrical power failures. For example, packaging of unit dose medications needs standardization of barcode labeling, an initiative being addressed by device vendors, pharmaceutical and pharmacy representatives, and must include consumers, nurses and other healthcare professionals. Education and Training

Proper use of any technology involves correct preparation of the user. This may involve formal, or most frequently, informal or non-existent learning experiences. With increasing budget constraints, such educational opportunities are cut and users are expected to intuitively discover how to use the technology. Trial and error may be fine when learning how to use a computer, computer application, cell phone, PDA, or some other device or procedure in the privacy of the home, but is unacceptable in the dynamic hustle and bustle of a healthcare setting. Just in time learning is too late in a patient care emergency and increases the risk of error.

Instruction manuals may not have been purchased, may not be current for the newest software application, or disappear if attached to the device. The paper or online manuals may not be understandable to the user as many frustrated cell phone users can attest. Human factors considerations may not have been incorporated in the learning materials.

Healthcare professionals are obligated to maintain their skills, knowledge, and competence to provide quality care without errors. Academic preparation for entry into practice and continuing education professional experiences need to provide opportunities for acquisition and refinement of computer and information management

skills, understanding of new processes and technologies, and the appreciation of prevention of medical errors and development of quality assessment and implementation programs. Addition of such curriculum content involves faculty preparation and funding for supporting technologies.

ROLE OF STANDARDS

Standards organizations, vendors, and healthcare professionals are partnering to integrate communications, documentation, and other standards into the healthcare environment to help prevent errors or reduce the impact of medical errors. By establishing recognized language and data standards, everyone can use the same terms with the same definitions and meanings and thereby prevent confusion and error. Standard product, procedure, and process naming conventions can then be programmed into information system software programs to permit the user to select the correct item.

The recognized standards must accommodate all healthcare professionals in their practice. For example, recognized HIPAA code sets do not yet include complementary and alternative therapies, nor the diagnoses, interventions and outcomes terms used by registered nurses in their diverse practice settings. Incorporation of standardized language of practice will permit appropriate data collection and reporting, improved information management strategies, and knowledge generation activities. This supports incorporation of appropriate protocols and practice guidelines into practice to prevent errors and track outcomes and variances that may need to be identified as medical errors. The secondary review of clinical documentation about diagnosis, interventions and outcomes will finally permit more accurate accounting of actual or potential medical errors, whether an error in the planning or an error in the execution of the plan.

UNIQUE PATIENT IDENTIFIER

Although not yet available and not considered a technology by some, the unique patient identifier is significant for nurses patients to prevent errors in the practice environment. Nurses care for patients across every setting and need to share extensive amounts of information about these individuals, groups, and populations with colleagues and other health professionals. Continuity of care between home health, hospital, long term care or hospice settings is a mandate. Reliance on name or hospital number does not help the nurse in confirming the correct patient information is being accessed or displayed when the individual uses the name Mary Smith today but was identified as Kathleen Mary Jones a month ago before her final divorce decree.

ELECTRONIC MAIL AND INTERNET ACCESS

Internet access and electronic mail (e-mail) use associated with healthcare delivery continues to explode as consumers and healthcare professionals include these technologies in their daily lives. Consumers are using the billions of electronic worldwide web pages for information about health promotion, disease characteristics, and treatment options. Healthcare professionals respond to resultant consumer questions about care options and decisions and may use select available Web educational materials as quality patient education resources.

Increasing reliance on e-mail communications, between clinician and patient or between clinician and clinician, opens new avenues for medical error prevention or generation, depending on the viewpoint. For example, patients can raise their questions before taking a dietary supplement or vitamin that may interact with a prescribed medication or treatment. Similarly, patients may alert the clinician of an observation or response that could become a significant problem if allowed to continue.

However, on the negative side, use of electronic mail can create medical errors because this somewhat informal communication mechanism does not incorporate the checks and balances provided in the carefully tested, built in algorithms or rules-based order entry and documentation components of healthcare information systems. Similarly, medical errors may result when confidentiality and security measures, like public-key and encryption technologies, are not in place to prevent tampering or public disclosure. A unique patient identifier becomes even more important in this environment where e-mail addresses may be shared by multiple users and e-mail content should be linked to the appropriate patient's clinical record.

Potential medical error opportunities exist in the arena of web-based personal health records. Internet services may broker patient health information stored on the website which may include marketing of inappropriate products to the individual that may result in medical errors. Potentials for incorrect reporting of laboratory or other results exist that then become parts of the individual's personal health

record. Medical errors may occur if clinicians consider these results to be valid and reliable measurements and use them to make decisions about a patient's care.

CULTURE AND CONTEXT

Incorporation of technology solutions into practice requires active integration by the healthcare professional in each work setting. The past practice has been to purchase the technology and then expect nurses and other healthcare professionals to welcome the new tools, gadgets, or processes. However, imposition of these solutions may not yield the preferred outcomes and may even result in the creation of medical errors. Careful evaluation of the setting before and after the implementation to validate the appropriateness of the technology solution and resultant outcomes occurs infrequently. This evaluation process, rarely done, must include examination of the impact of change on the organization's culture and patient outcomes within the healthcare system.

CONCLUSION

These few examples reflect the complexity of the medical errors issue. Although technology is most often presented as the preventive or curative strategy for medical errors, nurses find that not to be the case in most instances and view it as "technology looking for an application." "Quick fix" technology fails to address the systems and cultural changes necessary to maximize patient safety and care. Nurses strive to be partners within a non-punitive system that meets the needs of patients and reduces patient risk. They are the providers who will ultimately implement these new technologies and therefore need to play a substantial role in the development, implementation, evaluation and redesign of these systems. Their contribution is integral to prevention of medical errors.

Reference

Committee on Quality of Health Care in America, Institute of Medicine. (2000). *To err is human: Building a safer health system.* Washington, DC: National Academy Press.

Mr. BILIRAKIS. Thank you, Doctor. As a follow-up to your comments, Dr. Westra, do any of the State licensing boards for nurses require skills training in technology as part of their licensing renewal process?

Ms. WESTRA. I would like to probably follow up with that on some written testimony. My experience in working with schools of nursing is I am not sure that it is required as part of licensure. However, curriculum development has moved heavily as of 10 years ago to start incorporating computerization as part of the basis for nursing practice. But I will ask ANA to follow up with some written testimony on licensure.

Mr. BILIRAKIS. Great. We would appreciate that.

Dr. O'Leary, have you found that accredited organizations are complying with your patient safety standards, and maybe you can share with us what might be the most challenging of your expectations in that regard.

Mr. O'LEARY. Well, I think our early experience—the newest of the patient safety standards were introduced last July. So we have a modest base of experience, but the early indications are good.

I think the really great challenge here lies in achieving a culture of safety inside organizations, and just a couple of comments about that. It is really necessary that this be led by the chief executive officer of the organization. It is not really a delegatable function, and people in the organization are not going to believe that it is safe to report medical errors and adverse events unless it really is safe, and unless the organization takes action when something happens.

That is going to be a slower process. One of the things that our new standards do require is the introduction of new engineering

principles called Failure Mode and Effects Analysis. That is a new concept inside health care organizations, but maybe progressively we will see some of these hospitals hiring engineers. it would be a great stride for us.

Mr. BILIRAKIS. What sort of attitude are you getting from them in response to all that?

Mr. O'LEARY. I'm sorry, I can't hear you.

Mr. BILIRAKIS. What attitude do you see among these hospitals and other health facilities?

Mr. O'LEARY. Well, I think that patient safety is high on their screen. I think the reality that everyone is facing that resources are very limited; there are hospitals that worry about making payroll on Monday. They need to be persuaded that investing in patient safety is good for their future, individually good for the CEO, a career enhancing decision, and I think some believe that and some don't.

Our hospitals are strapped. I would come back to an earlier remark here. You know, I know that Mr. Scully has commissioned a recent study that showed that hospitals have adequate operating margins, but that is a steady state circumstance in which our patients remain at very high risk.

We are understaffed, not just for nurses but across the board. One of the things that always gets cut when money is tight is adequate training and orientation of staff, and all of this is happening in the face of the introduction of new and more complex drugs, procedures, technologies.

This is a little frightening, and I think we do have a challenge in figuring out how we are going to infuse more funding into the infrastructure of our hospitals and assure that that money goes to the right places to buttress patient safety activities.

Mr. BILIRAKIS. Dr. O'Leary, we have had three technologies shared with us here today, and there are others out there. How does a hospital select the one that they feel would be best for them? Is it a matter of cost? Is it perhaps tied into the way the hospital currently functions? How do they make that decision?

Mr. O'LEARY. Well, I think we get down to very simple things like size, financial stability, and applicability of the technology to the organization. Quite frankly, I think that we almost need to use kind of a camel's nose approach by looking at technologies that are relatively less expensive and more likely to yield results in order to, one, produce savings for organizations and, two, show them that these investments are worthwhile so that we work our way to things like computerized physician order entry, which many of us believe very passionately will work as long as there is adequate training and appropriate safeguards built into that technology. But you see, many organizations don't have those resources, and they are making difficult choices about what they select.

One way to make these things happen, of course, is to require it by law or regulation, but we do that with some hazard, because a lot of these rules and regulations do not follow the one-size-fits-all rule. We have to be careful.

Mr. BILIRAKIS. Well, thank you. My time is about to expire. So I am going to yield to Ms. Capps. Are you replacing Mr. Brown? All right, Mr. Green.

Mr. GREEN. In fact, I'll ask a question that Ms. Capps would probably want to ask. Ms. Westra, you mentioned in your testimony that sometimes nurses are presented with new technologies, and some we have seen today, expected to figure out how to do it without formal training.

Now it is one thing if I buy a home computer and try to put it in myself, but as you mentioned, nurses are working in an environment where they can't afford to learn to operate a new device by trial and error. Could you elaborate on the importance of a facility's commitment to provide accurate training when implementing these new technologies?

Ms. WESTRA. It is my experience that basic training is provided with new technology. If you look at the development of nursing curriculum or any other curriculum, there are stepping stones to learning, and it is one thing to name something and to define it. It is another to actually be able to trouble shoot with it.

Oftentimes, for instance, the industry I work in is community based practice or home care. Nurses are left floundering out in the home care with new technology, and when things fail, you know, understanding how the complexities of it works, that is the level of education oftentimes that does not occur.

I think basics are there, and I think that we need to really take a look at, with the tight financial environments in health care, how do we actually support agencies, not because they don't care but that they really need to figure out how to financially provide more education at a higher level of education and not just entry level education with technology.

Mr. GREEN. Mr. Chairman, with that I would like to yield the remainder of my time to Ms. Capps before we end up having to leave to go vote.

Mr. BILIRAKIS. Ms. Capps is recognized.

Ms. CAPPS. I appreciate my colleague yielding, and I also would follow up with Dr. Westra.

From my perspective, I guess maybe a bias as a nurse, we heard wonderful progress in technology along this panel, and I support and applaud all of it. This is what our ingenuity in this country does best, and responding to the studies of errors is sobering and people have responded to it. But the rubber hits the road at the place where the patient and the health practitioner interact with each other, whether it is in a home setting, whether it is in the emergency room, whether it is in critical care units.

I am going to zero in on nurse shortage, 125,000 positions open today for RNs, the bulk of the people who do actually put into practice the industry and our own desires to rectify errors. So I am going to ask Dr. Westra about education and training of nurses and how we can do this better, and also if you would comment—it is kind of a two-pronged one—tell us how we could improve the level of training, and give nurses the feeling of competence and the skills so that they can be competent and also the downside of when this is not in place. What is it like to be floundering in the setting that you described?

Ms. WESTRA. Well, it is my experience that coming out of school today nurses have a fairly broad background in terms of being able to practice. The specialty within health care is overwhelming.

I used to work at Mayo Clinic. I worked in the emergency room. For a year I did what we call float nursing. I was not prepared to be specialized in orthopedic nursing, to be specialized in all of the technology and the critical care area where I would float to frequently.

People would do their best to help you understand, you know, what was going on, but the number of new technologies continuously coming through—you know, one IV pump is different than the next IV pump when you are working with it. So I think basic education really helps prepare for basic nursing to be able to graduate, but it really doesn't provide the experience level that you need on an ongoing basis.

I am concerned in the nurse shortage not only about recruitment of people into the profession and being able to support people to get through nursing education. I am also concerned about retention. In Minnesota we had a strike last year which was devastating in the Twin Cities area, and one of the biggest issues that occurred as part of that strike was the mandatory overtime.

Try to work, you know, 10, 12, 16 hours in an ICU with complex technology, patients crashing around you, and the very, very, very difficult medication management that you are doing when you are tired. It doesn't work well, and then have it be mandatory. This does not bode well for retention of nurses. So we need to be able to retain nurses as well as recruit new nurses into the practice.

Ms. CAPPS. And mandatory overtime is not something that hospitals like to impose. They tell me that they are doing it because there is a shortage.

Ms. WESTRA. They are desperate.

Ms. CAPPS. They are desperate, and if I could just follow up with the average age of a nurse today is somewhere in the mid-40's. It is a workforce that is aging. You talk about nurses coming out of school today, those who come out and are equipped. We also have the challenges of continuing and the opportunity for a career ladder so that specialty training can be made available with these more complex techniques that would provide the kind of beside care and kind of care that we want.

I know I have used—I'm taking my time now, Mr. Chairman. I won't ask for anymore.

Mr. BILIRAKIS. We can't even go into your time as yet, because we have a vote.

Ms. CAPPS. We have a vote. I understand.

Mr. BILIRAKIS. Why don't we just go ahead and cut it at this point, Mr. Green's time having expired, and then when we return, if somebody is back on this side, we will go here. If not, we will go right over here.

Ms. CAPPS. Thank you very much.

Mr. BILIRAKIS. Thank you. Will you please excuse us for—I'm not really sure how long. I think we may have two votes. We will be back as soon as we can.

[Brief recess.]

Mr. BILIRAKIS. The chairman will now yield to the gentleman, Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman, and I apologize on behalf of the committee also and the way you sometimes unfortunately get

treated here. As the chairman said, those of you that have never been here wonder about this place, and those of you that have been here before also wonder about this place, but are used to wondering about this place.

I have a couple of questions for Mr. Hethcox. The products you have shown today are impressive in their potential to reduce errors. I would think, and be almost certain, that many hospitals, other facilities, would be eager to take advantage of the products that you and others have offered.

I have heard, though, that some hospitals are reluctant to implement new technology, because there is a lack of uniform standards in the health care information technology field. Tell us about that, if you would.

Mr. HETHCOX. My assumption from your comment would be that what they are referring to is when you go into most health systems, you find that there have been varying philosophies around the information infrastructure, whether it is a completely integrated one, vendor system supporting all the clinical departments as well as the patient information systems or a philosophy that says basically we are going to select the best of breed, so we are going to buy a laboratory system. We will buy a general ledger system. We will buy a materials management system, a pharmacy system, etcetera, and get best of breed.

What you typically have, at least in that latter situation, is a lot of great functionality that is oriented toward the specific functionality of what that department does, like the pharmacy department or a bedside charting system for nursing or the materials management system, but health care really is a team sport. When you look at it, everybody needs to be able to play together, and too frequently we've got information systems that are, in fact, fragmented to where they might work very nicely for some subset of the institution but not well across the board for all the disciplines that need to access data that's critical.

In patient safety, for example, being a pharmacist one of the things that we are real concerned about is what about lab values? Well, if our pharmacy system doesn't have the capability of communicating with the laboratory system so that we get real time reports on abnormal lab values, we could easily be dispensing medications that, frankly, are contraindicated for that patient without being aware of it.

So I think you are starting to see, as you have heard a little this morning already, institutions trying to find ways to link the communications. In some cases it is better; in some cases, it is worse.

Through Pyxis, because we do have to take information feeds from a number of those systems that are sometimes disparate, we have developed a great interfacing capability and, frankly, are working today with most all the information infrastructure systems that are out there, but it is through an interface process and, frankly, a lot of the technologies that are in the marketplace today do not have that expertise for interface resident within their company structure. That presents a unique set of challenges.

Mr. BROWN. You mentioned health care is a team sport nowadays. Talk, if you would, of the connection between a hospital's decision to use your technology and its commitment to devoting to

human resources needed to manage it in terms of when Cardinal might come in and selling a product and training. Run through that briefly, if you would.

Mr. HETHCOX. Well, let me use Pyxis maybe as an example to put a real life case before us, since that is the technology we talked about this morning. Let me back up to a point of saying that, with our Pyxis products, we employ a group of folks that are referred to as professional associates. These are nurses and pharmacists that have come out of the practice world after a number of years having used the Pyxis equipment.

They really become the counselors and the resource to help the customer, the institution, really, if you would, size and develop their implementation plans for the equipment that is being brought in. So part of what we do is provide user type expertise to help in identifying what should be structured, how it should be implemented, and to work with the hospital staff in doing the training.

The additional thing that we have recognized within the Pyxis offerings is the number of folks, especially in the nursing side of things, that we touch with the equipment and the imperative that each nurse understands how to use that equipment effectively. We have changed our training mode from one where we used to have people literally leave the work site to go to San Diego for a "train-the-trainer" process. They in turn had to come back to the hospital, train other trainers, and it just kind of filtered down, very complex, time consuming process that is just really incompatible with today's marketplace with the nursing shortage, etcetera.

So we have literally gone to Web based training, and the nurses are left, in many cases, doing a lot of the training on the patient care area without ever having to leave their patient station. It becomes more of a flexible process incorporated into the work environment, but one that is built around competency standards, checkoffs as they do their self-study to validate that they, in fact, did comprehend how to use the equipment, etcetera.

So we feel that we have tried to bring a very effective tool to the marketplace with that training.

Mr. BROWN. Thank you, Doctor. One more question, if I could. Dr. Williams, you talked about medical errors and reporting systems and strengthening reporting systems. That, obviously—you are collecting the data, doing a better job of a systematic reporting system, so it's just sort of a systematic reporting, doesn't automatically translate into useful information.

Run through, if you would, the process that USP uses to turn reports on errors into information a hospital can use, beginning from the time the error is committed and reported until the hospital implements it.

Mr. WILLIAMS. Okay. Well, it is an excellent question. First of all, Ms. Cousin has talked about how MedMARx itself has a whole bunch of capability to issue reports that a hospital can use internally. Hospitals can also work with other hospitals and with USP in the main data base analysis.

Now USP, in addition, creates annual reports of the data base for each year. We have prepared one already for 1999, which we can certainly make available to the committee. We are finishing the one for 2000, which again we can make available to the com-

mittee, and we will try to create one for each year annually that not only talks about the year itself but prior years as well.

Then finally, I think USP wants to work very vigorously with partners and stakeholders in the hospitals to issue action items, alerts, specific reports, and also support for the research efforts.

Mr. BROWN. Dr. O'Leary, the root cause analysis that the Joint Commission has encouraged hospitals and other facilities to use is, I think, a pretty valuable tool. The Commission, however, I think, has a valuable role, a role beyond education, beyond sort of promoting—both encouraging and promoting education.

Tell us more about your role in accrediting hospitals, managed care organizations, other facilities, in light of ensuring that these facilities do better in terms of implementing, after gathering the data and analyzing mistakes, to better prevent those mistakes. Run through that, if you would.

Mr. O'LEARY. Well, actually, the framework that we adopted in the early 1990's was just really a continuous quality improvement framework. It really requires an organization to select key areas to measure, analyze data, and make systems changes based upon the data, and then remeasure to show that they achieved improvements.

We have new standards going into place in July, for instance, which will require the use of measures that are sensitive to nurse staffing and to staffing of other health care professionals, with the expectation that when those measures show that there is a problem, that we will require an effective analysis and identification of the underlying problem and appropriate action, whether that is the need for more nurses, more commonly more training of nurses, or what have you.

Our Sentinel Event data base, for instance, found that in 24 percent of the instances across all of these events, there is a staffing numbers related problem. In more than twice those instances, there are problems related to the training and orientation of nurses for the kind of tasks that they are supposed to be doing.

This coming July we will also establish a series of national patient safety goals and specific recommendations associated with those goals. This is a new venture, because for the first time, above and beyond the broader standards framework that is accreditation, we will be requiring our organizations to comply with what, in essence, are clinical practice guidelines. So we are getting down to the nitty gritty level in terms of expectations.

So what, in essence, started as an educational vehicle, the Sentinel Event Alerts, has come to the point of urging and now requiring that certain things happen. I think that you can look for that effort to expand over time.

Mr. BROWN. Dr. Westra, would you want to either comment on that or on sort of—My question to Mr. Hethcox, the first question I asked, in terms of training when the systems are brought into a hospital and the training is done jointly with the hospital and Cardinal or the hospital and other providers, other vendors, if you will, sort of the nurses' role in that. Are you satisfied with the way hospitals are bringing nurses into the training and dealing with these systems after the data is gathered?

Ms. WESTRA. The majority of health care facilities do have education departments or designated staff who are responsible for education with nurses. As I mentioned earlier, I think we are seeing initial education about equipment when it comes into play. I think a lot of the trouble shooting is where the challenges are. So we need to take a look at having incremental learning modules, I believe, where it is initially how do you use it, but then how do we develop expertise across staff in terms of the trouble shooting that happens.

One of the things that I think is real important is that, as we take a look at health care and where health care is delivered, we have been tightening the belt on the inpatient side so that more and more health care is being delivered in community based settings and long term care facilities.

You have a lot less support out in those facilities for dollars for education and staff available for doing trouble shooting and education. I think with the aging population, it is critical that we take a look at the preparation for people to practice in those settings and to be able to do much more advanced types of trouble shooting, because technology is really—I mean, it has gone down to a level of practice that I can't believe.

When I worked in a hospital, you know, using IV pumps was something that took specialized training. Now we just send people home with them and tell family to take care of them, as well as a much more complex level of training. So we need to take a look at how we not only train our staff but how our staff are prepared to train our patients, because they are the ones that are managing a lot of the technology when we are not in the inpatient setting.

Mr. BROWN. Thank you. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I would like to finish up unless others come in. I referred to the Institute of Medicine's 1999 report where they estimated that between 44,000 and 98,000 Americans die each year as a direct result of potentially preventable mistakes.

Now that is quite a gap. So when we use the word estimate, that is quite an estimation. So I don't know what the proper figure is. But Dr. Ganske earlier in his opening statement referred to the lack of proper definition, and each hospital is on its own in defining that sort of thing.

A general question in that connection: In your estimation are we finding more preventable type of hospital errors these days than used to be the case? Maybe when I say used to be the case, maybe we go back to prior to technology. We've got all this technology we have heard about here today, and yet we are talking about almost as many as 98,000, 100,000 deaths attributable to medical errors. Any comments on that, brief comments, if you would, please. Dr. O'Leary.

Mr. O'LEARY. I don't think anyone knows what the real baseline is. Even the figures you site were based upon medical record reviews that were probably close to 10 years old by the time they were published. Some people would say those are probably underestimated, because they were based on things that were written in medical records, and what about the things that were not, and they only talked about hospitals, after all, and there are a lot of other settings.

I would think, though, that if you looked at how we are doing on the things that were reflected in that study, that we have probably done a lot in terms of reducing those errors. But health care changes radically every day. We've got the new drugs, the new procedures, the new technologies. We are introducing new benefits and new risks every day, and there are major challenges in training people in even identifying what those risks are and building safety into the systems that support the care. That is really the challenge for the future.

What we do have is the attention of care providers now, and we need to capitalize on that opportunity.

Mr. BILIRAKIS. More so than we have had that attention in the past?

Mr. O'LEARY. That is true.

Mr. BILIRAKIS. Dr. Westra, do you agree?

Ms. WESTRA. I do, and just one last plug, if I may. That is, as we take a look at technologies, one of the most critical technologies that we have is the information that we try to use to communicate effectively. As one of the speakers mentioned earlier, the more we can get to standardization of data so that we can interface data across systems, I think the better off we are.

There is a tremendous effort underway right now, including HL7, SNOMED, the HIPAA legislation, a tremendous volume of standardized data organizations working to take a look at how we can build information technology. I think, if there is anything that comes out of this hearing, the more we can support standardization of processes and information so that, in fact, we can communicate effectively, I think the better off that we will be, and the contribution of this committee could make would be tremendous.

Mr. BILIRAKIS. Okay. That really leads me into the last question. I was asked by a member of the press as I was hustling to make the vote did I anticipate that we would have legislation as a result of this hearing, as a result of the problem in general.

I said, that is the reason you hold a hearing. Legislation is not always the answer in and by itself. But none of you, I don't think, and I have asked Cheryl to remind me, have mentioned that additional legislation is required. Should there be maybe some legislation on our part to maybe standardize the definition? Should there be legislation? How can Congress help? I know, additional dollars for additional manpower, nurses, etcetera, but I mean aside from that, which we are familiar with those problems. There's no doubt about it. Yes, sir? Go ahead, Mr. Freeman.

Mr. FREEMAN. Mr. Chairperson, our belief, certainly from our perspective, would be that it is always important for us to be partners and working with each other between the government and industry. Our belief also in this perspective is that, as I think you heard this morning, many of us in the health care industry are working on our own to address the significant challenges that exist in health care.

Our belief in general would be that we can, and will, address these issues moving forward. It does take significant leadership among those of us in the health care industry and, quite frankly, our industry is behind what has been done in other industries historically, particularly high tech manufacturing.

The biggest challenge we face, I believe, includes in part technology innovation, but even more importantly, behavioral change in health care. So much of health care today still thinks that, if we get it right 95 percent of the time, that's okay. But since every occurrence of a defect is a human life, think about a 95 percent correct rate. That's 95 percent. It was great in high school. It's not great today in health care.

That means you have got 50,000 parts per million or individuals out of every 1 million that are inadequately being served. So striving for perfection is an attitude adjustment that we in health care are starting to make.

You heard it from various members of our panel here this morning, and we believe the best way to make that happen is for us to take the lead as opposed to encountering perhaps multitudes of additional regulations, in fact, that will drive us in perhaps unproductive ways to change health are.

Mr. BILIRAKIS. Good point. Dr. O'Leary, very briefly, if you could, please, sir.

Mr. O'LEARY. First of all, I don't think we need legislation for a new language or taxonomy. We have an initiative to do that. It is being broadly shared.

Mr. BILIRAKIS. Can that become standard or uniform?

Mr. O'LEARY. We can standardize the language, and we need to do that, I think, for a variety of important reasons. The legislation, I think, that we do need is protection against the discovery or release of these adverse events and the underlying causes.

We have a data base. It is the best and the richest of the data bases on the stuff. We've got less than half a percent of the real cases out there. If we are going to learn from these events, we have to have access to the information, and there is a huge show over that, and I think that is a role that Congress could play.

Mr. BILIRAKIS. Okay. Dr. Williams.

Mr. WILLIAMS. Well, I think we would echo that, too. We certainly support the privileged aspects of the bills that are under consideration, and speaking as a standard setting body, I am delighted to hear the chorus of calls for good standards, which I could only agree will help reporting and help prevent these errors.

Mr. BILIRAKIS. Thank you, Doctor. The Chair now yields to Ms. Capps, and I would like to announce that one of the reasons she has returned, in addition to asking you some questions, is because we are going to hold that meeting on the nursing bill right after this hearing is over. Go ahead, Lois.

Ms. CAPPS. Thank you very much, Mr. Chairman, and I will be brief. I will sound, I suppose, like a one-note Charlie, but it was acknowledged by more than one person on the panel that the backbone of health care is the nursing profession. The delivery system is done in large part by nurses across this country. So errors are very much of concern to all of us who have the initials R.N. after our names.

I focused my initial questions to Dr. Westra, and maybe, Dr. Williams, you could help clarify for me, because you have collected so much data. From your data on medication errors, could you talk even just briefly about any way that staff shortages or numbers of nurses or that kind of issue plays a role in this?

Mr. WILLIAMS. Yes, Congresswoman. It's a very good point. One of the things MedMARx does is it captures contributing factors, and where contributing factors were noted, about 40 percent of the time people talked about staff issues, shortages, temporary help, other problems with staffing as contributing to the error.

Ms. CAPPS. So that it would be possible maybe, as we are beginning to wrap up this hearing, to say that one of the areas in which we can focus our attention to addressing medication errors could be with some staffing issues, dealing with the shortages, dealing with the workplace situations that impede with all of the technology that you have developed. Anyone else want to comment on that, I would be happy.

Mr. O'LEARY. Well, I will just comment. We have actually had an expert roundtable on the nurse staffing issue in place since last November, and one of the basic messages, I think, coming out of that is that America's nurses need to want to go to work in the morning, and the environment in which they are working now is not that environment.

There are a lot of issues there, but the thing that I am encouraged by is the success of the magnet hospital program——

Ms. CAPPS. Yes.

Mr. O'LEARY. [continuing] which tells me that it is possible. There are magnat hospitals with waiting lists for nurses in the face of this shortage, and these are environments in which others delegated authority to the floor nurse. There is attention to flexible scheduling. There is not mandatory overtime, because they don't need mandatory overtime, and all of the irritants have been addressed.

This kind of modeling, I think, holds out a lot of hope for the rest of America.

Ms. CAPPS. In other words, the irritants, stress, shortages, do contribute to medical errors?

Mr. O'LEARY. And we know that from our data base. While you were out, 24 percent of the adverse events in our data base relate directly to insufficient staff, and another almost twice that relate to inadequate training and orientation for the kinds of things that are being done today. This is very real.

Ms. CAPPS. I appreciate that you gave us the bright note, because there are many instances. We are focusing today on problems, on errors, on shortages, but when it comes together with the right kind of symmetry, it can be a marvelous thing to behold.

Mr. O'LEARY. Yes, it can.

Ms. CAPPS. Thank you. I yield back.

Mr. BILIRAKIS. And referring again to the RNs and the piece of legislation we are considering is, we feel, very, very important and very much needed.

Having said that, I also see some efforts being made on the local basis toward this. I know what used to be a junior college in our area is now a 4-year community college with emphasis on training nurses, teachers, nurses, particularly those two areas where there is such a shortage.

I was commencement speaker at the graduation the other night, Monday night, and there was maybe a page and a half full of RNs graduating, which is, I thought, terrific. I am not saying that that

is the sole answer, but that is certainly a part of it. So there are other nongovernment groups out there also who see this shortage and who are trying to address it.

Well, all right. That terminates this hearing. Again, I apologize for that great big gap of time that you had to wait. The least we could have done is told you to take time to go get something to eat, but we—or buy them lunch. I misjudged. But in any case, thank you so much.

Again, as per usual, we will be submitting written questions to you, and hopefully, you will respond to those written questions in a timely fashion to help us out here.

Again going back to that question I asked about legislation, any ideas toward that end, if we don't know what your thoughts are toward that end, we can't, obviously, consider it. Thank you very much.

The hearing is adjourned.

[Whereupon, at 1 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

PREPARED STATEMENT OF AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

The American Academy of Orthopaedic Surgeons (AAOS), representing 18,000 board-certified orthopaedic surgeons, appreciates Chairman Bilirakis' 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 for all health care recipients.

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 fel-

lowship 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 also 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, 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 Bilirakis, Ranking Member Brown, 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 report-

ing 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.

PREPARED STATEMENT OF AMERICAN FEDERATION OF LABOR AND CONGRESS OF INDUSTRIAL ORGANIZATIONS

On behalf of the working men and women of the AFL-CIO, we congratulate Chairman Tauzin and Members of the Committee for conducting this hearing on such a vitally important aspect of our health care system: reducing medical errors. The

AFL-CIO represents 13 million members and their families. We are purchasers and consumers of health care; many are also working on the front lines of patient care. Reducing medical errors and ensuring patient safety is an issue that affects us all.

A recently released report from The Commonwealth Fund estimated that nearly 23 million people have experienced a medical error of some kind, either personally or through a family member. Those numbers echo the findings of a highly regarded 1999 Institute of Medicine (IOM) report that found up to 98,000 deaths occur each year as a result of medical errors at a cost of $29 billion. IOM further found that the use of information technology is key to reducing medical errors and improving quality health care delivery.

With today's hearing, the committee will examine ways technology can be used to help reduce medical errors, saving both lives and health care resources. One such technology—computerized physician order entry (CPOE) systems—ensures that patients are not prescribed dangerous combinations of medication and are given the appropriate medication in the proper dosage. Some studies have found the use of CPOE systems have reduced medication errors by as much as 88 percent. The AFL-CIO supports legislation that would provide grants to hospitals and skilled nursing facilities to purchase information technology specifically designed to reduce medication errors, including CPOE systems. The Medication Errors Reduction Act, H.R. 3292, is currently in the Energy and Commerce Committee.

However, as important and effective as this technology is, it is just one part of what must be a comprehensive effort to reduce medical errors and prevent avoidable injury and death. Another IOM report found medical errors to be the result of poorly designed systems, rather than careless mistakes of individual health care providers. Following the lead of those industries that have significantly improved their safety records, the IOM report noted that restructuring health care workplace systems so that they are geared towards safety would play a vital role in reducing medical errors. One way to do this is by developing a system for reporting errors in a blame-free environment, which would allow for the root cause analysis necessary to identify system-wide solutions to compromised patient safety.

A comprehensive approach to reducing medical errors will also address the link between patient safety and poor working conditions, including personnel shortages and requiring nurses to work overtime in order to solve gaps in staffing. The Joint Commission on Accreditation of Healthcare Organizations has found that when examining serious medical errors, almost one quarter of them have inadequate nurse staffing as a major underlying factor. Faced with insufficient staffing, many employers have opted to require nurses to work overtime. Not only is this practice of mandatory overtime making the nurse shortage more acute, it is compromising patient care. The capacity to deliver high quality care is seriously compromised when nurses are exhausted from long hours of work and insufficient time off. The likelihood of making an error in judgment, misreading a patient chart, or missing an important indicator while observing or examining a patient increases significantly when nurses are exhausted.

We urge the committee to consider these additional steps to reducing medical errors and ensuring patient safety. We support your efforts here today and would like to work with the Members of the Committee to develop and enact a comprehensive solution that will benefit health care institutions and workers, as well as the patients they serve.

PREPARED STATEMENT OF DAVID G. SCHULKE, EXECUTIVE VICE PRESIDENT, 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 utilization management and quality assurance. 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 projects reduce 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, QIOs accelerate 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	29%
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.

QIO CONFIDENTIALITY REQUIREMENTS

The confidentiality of information collected or developed by a Medicare 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 significantly 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 practitioners 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.

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.

PREPARED STATEMENT OF THE AMERICAN MEDICAL ASSOCIATION

On behalf of our physician and medical student members, the American Medical Association (AMA) appreciates Chairman Bilirakis' initiative in calling this hearing today to discuss the important issue of patient safety and quality of care.

The issue of safety and quality of care for patients in our nation's health care system has long been a concern of the AMA. The elimination of health system errors is not only a high priority for the AMA, it is also an important ethic of the medical profession. As an association founded on the commitment of physicians to improving the quality of medical care, **we believe that any error that harms a patient is one error too many.**

AMA'S COMMITMENTS TO PATIENT SAFETY AND QUALITY IMPROVEMENT

The AMA has been a pioneer in the effort to reduce health care system errors and ensure that our patients receive safe, quality health care. For example, in 1996, the American Association for the Advancement of Science, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and the AMA joined with the Annenberg Center for Health Sciences to convene the first multidisciplinary conference on errors in health care. Since that time, several initiatives in patient safety have been undertaken at the state and national level, such as preventing patient injuries due to medication errors. Given the importance of this issue, in 1997 the AMA also established the National Patient Safety Foundation (NPSF), a broad-based partnership of health care clinicians, consumer advocates, health product manufacturers, public and private employers and payers, researchers, regulators, and policymakers, which is now an independent not-for-profit organization. Through leadership, research support, and education, the NPSF is committed to making patient safety a national priority.

In 1999, the public's attention became further focused on the issue of patient safety and quality of care when the Institute of Medicine (IOM) released its report entitled, *To Err is Human: Building a Safer Health System.* While much of the information in the 1999 IOM report is not new, there is much that is new and exciting in the public and private sector's response to the issues raised in that report. For instance, the AMA has been working in a concerted manner with the federal government on several of its initiatives to improve patient safety. In 2001, Health and Human Services (HHS) Secretary Tommy Thompson created the HHS Patient Safety Task Force, comprised of the Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC). Under the dedicated leadership of John Eisenberg, MD, Director of AHRQ, the Task Force has pursued an ambitious effort to create a federal confidential, non-identifiable database of information collected on patient safety events so that important research can be conducted and shared and interventions can be designed to prevent future health care errors. The AMA serves in an official advisory role to the Task Force and its important work. The AMA also is a founding member of, and a liaison board member to, the National Quality Forum (NQF), a public-private partnership created in 1999 that seeks to develop consensus among key stakeholders in the private sector as well as state and federal governments on performance measures and patient safety practices to improve health care quality.

The AMA believes health professionals and organizations should be encouraged to report and evaluate health care errors and to share their experiences with others in order to prevent similar occurrences. We also believe that true reform must include all components of the health care system and not focus only on individual components. Hospitals, physicians, nurses, pharmacists, drug and device manufacturers, nursing homes, and others must all work together to identify, study, and solve system-wide problems that could cause errors or adverse outcomes. Towards this end, in 2000 the AMA joined with over 20 other national health care organizations to form a coalition to develop a set of General Principles for Patient Safety Reporting Systems (see attachment A) that constitute the five essential elements of effective reporting systems. The General Principles underscore the point that, for error reporting systems to be successful, they must be constructed in a non-punitive manner that provide appropriate confidentiality protections. Currently, over 90 national and state-based health care organizations have endorsed these principles (see attachment B).

In 2001, the IOM released a report entitled, *Crossing the Quality Chasm: A New Health System for the 21st Century.* This report calls for action to "improve the American health care delivery system as a whole, in all its dimensions of quality, for all Americans." The AMA supports the 2001 IOM report's central conclusion that innovative changes are needed within the current health care system to ensure all Americans receive high quality care. As the report states, many of the current problems cannot be solved simply by asking physicians and other health care professionals to try harder. Real, meaningful systemic change is needed.

The AMA shares the IOM's view that health care should be safe, effective, patient-centered, timely, efficient, and equitable. In fact, many AMA programs and initiatives are already addressing these areas of concern. As discussed above, the AMA is a leader in addressing patient safety issues. In addition, the AMA is involved in several efforts aimed at helping physicians adopt evidence-based clinical guidelines in caring for their patients. Key efforts include: the **National Guideline Clearinghouse**™ (NGC™)—sponsored by the AMA, AHRQ, and the American Association of Health Plans (AAHP)—offering an internet-based repository of clinical practice guidelines designed to assist physicians in their clinical decision-making; the **Practice Guidelines Partnership (PGP)**—composed of 13 of the largest national medical specialty societies, AMA, AHRQ, American Hospital Association, JCAHO, and CMS—is working together to identify issues relevant to appropriate development, evaluation, and implementation of clinical practice guidelines; the **Clinical Quality Improvement Forum (CQIF)**—hosted annually by the AMA—brings together national experts in clinical quality to share information that health care professionals can use in their own work to improve patient care; the **Quality Care Alert (QCA)**—a collaborative effort by the AMA and specialty societies that results in concise mailings and Web site postings to alert physicians to important gaps between medical knowledge and practice; and the **Physician Consortium for Performance Improvement**—convened by the AMA—brings together clinical content and methodology experts from over 50 medical specialty societies, AHRQ, and CMS to identify and develop clinical measures that result in improved patient care. Further, the **Collaborative** is a cooperative effort of JCAHO, the National Committee for Quality Assurance, and the AMA to identify and promote clinical performance measures.

These efforts are important pieces of a larger puzzle. As the 2001 IOM report makes clear, transforming the current system cannot rest solely on the shoulders of health care professionals. There needs to be a broad commitment from all sectors if the goals and the vision put forth in the 2001 IOM report are to be achieved. In our quest to improve the current system, however, we must not disrupt all the good things happening in medicine today. Despite its systemic problems, our health care system is still the best in the world. The 2001 IOM report is a call to all of us to develop a system that can deliver the promise of high quality health care to all our patients. The AMA stands ready and willing to do its share and we look forward to working with others to build a better health care system for all Americans.

RECENT FEDERAL ACTIVITY TO ADVANCE PATIENT SAFETY AND IMPROVE QUALITY

There have been several notable efforts at the federal level to address patient safety and quality of care issues over the past few years. In fact, Congress has already taken several steps to move toward creating a "culture of safety." A few years back, Congress passed specific legislative language to reduce errors in the health system. In December 1999, the Healthcare Research and Quality Act of 1999 (P.L. 106-129) was enacted into law to reauthorize the AHRQ (formerly AHCPR). **In Section 912(c) of this law, Congress clearly showed its commitment to reduce errors in the health care system by, inter alia, directing AHRQ to conduct and support research and build private-public partnerships to: "(1) identify the causes of preventable health care errors and patient injury in health care delivery; (2) develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and (3) disseminate such effective strategies throughout the health care industry"** (emphasis added).

When Congress created the Medicare Payment Advisory Commission (MedPAC) as part of the Balanced Budget Act of 1997, it directed MedPAC to look at issues related to quality of care for Medicare beneficiaries. Accordingly, MedPAC's June 1999 Report to Congress contains seven recommendations to Congress addressing the issue of "health care errors under Medicare." In its report, MedPAC recommends that the Secretary of HHS establish patient safety as a quality improvement priority for Medicare and take steps to minimize preventable errors in health care delivery.

More recently, Congress has provided additional funding for patient safety research. In its fiscal year 2001 budget, the AHRQ was appropriated $50 million to: further understand when, how, and under what circumstances errors occur; identify the causes of errors; develop tools, data, and research needed to foster a national strategy to improve patient safety; and work with public and private partners to apply evidence-based approaches to the improvement of patient safety. In fiscal year 2002, AHRQ received additional funding to work with CDC, FDA, and CMS in developing a common vocabulary to link existing patient safety reporting systems and to assist those who develop such systems.

Also, in February 2001, the AHRQ announced it would fund up to 13 cooperative agreements to sponsor demonstration projects to assess the effectiveness of various methods of collecting and using information to reduce errors. AHRQ is awarding $25 million annually in fiscal years 2001-2003 to support these agreements. Further, in January 2001, the AHRQ changed the name of its Center for Quality Measurement and Improvement to the Center for Quality Improvement and Patient Safety (CQuIPS) to reflect the AHRQ's new responsibilities for patient safety—consistent with the 1999 IOM report.

CURRENT PATIENT SAFETY REPORTING SYSTEMS

Currently about 20 states have enacted some reporting mechanism for health care errors. State programs vary considerably with regard to the types of reports required, with some involving anonymous submission of aggregate data and others involving individual, named incident reports. In some states, participation is mandatory, while in others it is voluntary. A number of medical specialty societies also have sophisticated programs that collect information about patient outcomes, adverse events, and other quality indicators. Perhaps most well known is the Closed Claims Project of the American Society of Anesthesiologists.

On a national level, the United States Pharmacopoeia has implemented a voluntary medication error reporting program, known as MedMarx. This program is guided by the National Coordinating Council for Medication Error Reporting and Prevention. The FDA has implemented the MedWatch reporting system for serious adverse events associated with medical products. The Department of Veterans Affairs has a number of health system error reporting projects, and the aviation industry is often cited as an example from which important lessons can be learned. The National Transportation Safety Board has an Accident/Incident Database, which applies only to data on actual aviation accidents. Aviation safety incidents (near misses) are voluntarily reported under the Aviation Safety Reporting System (ASRS), which is funded by the Federal Aviation Administration and administered by the National Aeronautics and Space Administration. The ASRS collects, analyzes, and responds to voluntarily submitted aviation incident reports, maintaining confidentiality, in order to lessen the likelihood of future accidents. The success of this system is based on its approach of looking for solutions to prevent future accidents, not on establishing blame.

Congress should consider the effectiveness of these existing programs in searching for workable and sound policies and procedures that promote the collection of data that are valid and reliable and which, ultimately, resulted in improved patient safety.

CREATING A CULTURE OF SAFETY THOUGH FEDERAL LEGISLATION

The AMA strongly supports the principal underlying the 1999 IOM Report that the health care system needs to transform the existing culture of blame and punishment that suppresses information about errors into a "culture of safety" that focuses on openness and information sharing to improve health care and prevent adverse outcomes. The AMA also supports the 1999 IOM's focus on the need for a system-wide approach to eliminating adverse outcomes and improving safety and quality, instead of focusing on individual components of the health system in an isolated or punitive way.

This transformation to a "culture of safety" requires the initiative of Congress to pass legislation that will encourage reporting of health care errors without the fear of punishment. We believe that the primary goal of patient safety legislation should be to facilitate the development of a confidential, non-punitive, and evidence-based system for reporting health care errors so that such errors can be identified and analyzed to improve patient safety by preventing future errors.

The general approach should allow the AHRQ to certify entities to collect error reports from health care providers (e.g., hospitals) and providers of services (e.g., physicians), analyze such reports, provide direct feedback to the providers, and

make recommendations on ways to reduce errors. The certified entities could also report non-identified information on improving patient safety directly to the AHRQ. The AHRQ would act as the lead agency for the dissemination of information learned about reducing errors and improving patient safety and the quality of care.

For an error reporting system to be truly effective, it is essential that reports on health care errors remain confidential (except for consensual sharing of information with other certified entities) and privileged (i.e., not subject to discovery or subpoena). Currently, information about errors is not adequately shared because of fear among health care professionals and organizations of legal reprisal. The absence of federal protections for information reported to a certified entity would discourage participation in such a system and impede patient safety improvement efforts. The integrity of a certified entity could be ensured by allowing the AHRQ to rescind certification if regulatory standards are not maintained.

In such a system, only health care error reports developed for reporting to a certified entity would be protected—the underlying facts of any error event, medical records, and documents maintained separately from the error reporting system would not be protected. All information that is required to be reported under state or any other law would not be affected, and any information that is subject to legal discovery under current and future laws would remain discoverable. There is a very broad and strong consensus of agreement on this legislative approach among the organizations that endorsed the General Principles for Patient Safety Reporting Systems. Also, there are efforts in the Senate to develop a federal patient safety reporting system consistent with this approach. We support these efforts and encourage the House to adopt a similar approach.

MedPAC and JCAHO have made recommendations to Congress that are consistent with the approach outlined above. The June 1999 MedPAC Report recommends that Congress enact legislation "to protect the confidentiality of individually identifiable information relating to errors in health care delivery when that information is reported for quality improvement purposes." The IOM Report states that MedPAC's recommendation is a "promising alternative." Likewise, JCAHO has testified that it has been seeking federal legislative protection to protect from disclosure information developed in response to a sentinel event and shared with an accreditor.

The matter of accountability for negligent or incompetent actions is already well established in our health care and judicial systems for physicians and other health care providers. State and Federal courts, state licensing boards, and accrediting bodies such as JCAHO all function to maintain accountability and standards. However, the very fear of existing legal liability or its misapplication are the greatest hurdles to pioneering patient safety efforts.

For example, when the Anesthesia Patient Safety Foundation was founded, legal liability was a major concern. The creative approach employed by the anesthesiologists was to start by looking at claims that have already been settled or closed. Unfortunately, waiting for a case to settle or close before a problem can be discussed without the fear of litigation needlessly delays important feedback that otherwise could result in an immediate solution. **Congress can help create a culture of safety by allowing medical professionals to convene to discuss patient safety problems and potential solutions without having their discussions, findings, or recommendations become the basis for class action or other lawsuits. If the fear of litigation continues to pervade efforts to improve patient safety and quality, our transformation into a culture of safety on behalf of our patients may never be fully realized.**

Non-punitive approaches have yielded useful results in related contexts. For example, Congress should consider the experience of the past several decades in preventing hospital-acquired infections. With the scientific support of the CDC and AHRQ, hospital epidemiologists and physicians specializing in hospital-based infectious diseases have systematically undertaken thousands of investigations of endemic and epidemic infections. These studies have been done in a blame-free environment in which learning was the major goal. The infection controllers observed that spontaneous reporting of infections and broad, voluntary surveillance provided misleading information. They recognized the need for targeted, systematic surveillance and focused objectives for the infection control program, as well as for simple, clear definitions of infections. Hospital-acquired infection rates have declined precipitously as a result of these efforts.

CONCLUSION

The AMA believes that true reform must include all components of the health care system and not focus only on individual components. Hospitals, physicians,

nurses, pharmacists, drug and device manufacturers, nursing homes, and others must all work together and be encouraged to work together to identify, study, and solve system-wide problems that could cause errors or adverse outcomes. Our common goal must be to detect errors and system barriers to make corrections before a patient is harmed.

Adding more regulation and more mandates is not the answer to improving patient safety and quality. It is important for Congress to recognize the efforts already being implemented in both the public and private health care delivery systems before passing legislation. When and if legislation is enacted, we must all be certain that it will support and enhance the initiatives already underway, and not set back these efforts. As stated in the 1999 IOM Report, a system must be designed to detect, prevent, and minimize health care system hazards to reduce errors. This can be achieved best by first acknowledging that the vast majority of health care system errors are not intentional and must be distinguished from truly negligent behavior. The focus must remain on reforming the system, not punishing the individual. We must collectively focus our efforts on identifying solutions that benefit patients.

Nationwide dissemination of the identified solutions would do a great deal to improve the safety of the nation's health care system. As it has done with dissemination of practice guidelines, Congress should support the AHRQ's charge to disseminate current information on patient safety and prevention of adverse events, and provide sufficient grants to research currently available data.

The AMA is committed to continuing and redoubling our efforts to work with Congress and our partners in the health care system to achieve a system in which patients are assured of safe, quality health care. We appreciate having the opportunity to submit this statement for the Record and commend Chairman Bilirakis and this committee for focusing on needed improvements in patient safety and quality of care.

ATTACHMENT A

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.

The following organizations support these principles (as of May 2001): Academy of Managed Care Pharmacy; American Academy of Child and Adolescent Psychiatry; American Academy of Dermatology; American Academy of Facial Plastic and Reconstructive Surgery; American Academy of Family Physicians; American Academy of Neurology; American Academy of Ophthalmology; American Academy of Otolaryngology—Head and Neck Surgery; American Academy of Physician Assistants; American Association for Thoracic Surgery; American Association of Health Plans; American Association of Neurological Surgeons; American Association of Orthopaedic Surgeons; American Association of Pharmacy Technicians; American College of Cardiology; American College of Chest Physicians; American College of Emergency Physicians; American College of Medical Quality; American College of Nuclear Physicians; American College of Nurse-Midwives; American College of Obstetricians and Gynecologists; American College of Osteopathic Family Physicians; American College of Osteopathic Surgeons; American College of Physicians-American Society of Internal Medicine; American College of Preventive Medicine; American College of Radiology; American College of Surgeons; American Geriatrics Society; American Health Care Association; American Health Quality Association; American Hospital Association; American Medical Association; American Medical Group Association; American Nurses Association; American Osteopathic Association; American Pharmaceutical Association; American Psychiatric Association; American Society for Therapeutic Radiology and Oncology; American Society of Anesthesiologists; American Society of Cataract and Refractive Surgery; American Society of Clinical Oncology; American Society of Clinical Pathologists; American Society of General Surgeons; American Society of Health-System Pharmacists; American Society of Plastic Surgeons; American Urological Association; College of American Pathologists; Congress of Neurological Surgeons; Connecticut State Medical Society; Federation of American Hospitals; Hawaii Pharmacists Association; Healthcare Leadership Council; Idaho Medical Association; Institute for Safe Medication Practices; Iowa Medical Society; Joint Commission on Accreditation of Healthcare Organizations; Kentucky Medical Association; MedChi, The Maryland State Medical Society; Medical Association of Georgia; Medical Group Management Association; Medical Society of Delaware; Medical Society of the District of Columbia; Medical Society of New Jersey; Medical Society of the State of New York; Michigan State Medical Society; Minnesota Medical Association; Mississippi State Medical Society; Missouri State Medical Association; National Association of Psychiatric Health Systems; National Committee for Quality Assurance; National Patient Safety Foundation; New Hampshire Medical Society;

New Mexico Medical Society; North American Society of Pacing and Electrophysiology; Ohio State Medical Association; Oncology Nursing Society; Oregon Medical Association; Oklahoma State Medical Society; Premier; Renal Physicians Association; Rhode Island Medical Society; Society of Critical Care Medicine; Society of Nuclear Medicine; Society of Thoracic Surgeons; South Carolina Medical Association; South Dakota State Medical Association; State Medical Society of Wisconsin; Texas Medical Association; U.S. Pharmacopeia; Utah Medical Association; VHA, Inc.; Washington State Medical Association; and Wyoming Medical Society.

PREPARED 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 private 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.

PREPARED STATEMENT OF AMERICAN SOCIETY OF RADIOLOGIC TECHNOLOGISTS

Mr. Chairman and members of the Committee: On behalf of the 96,000 members of the American Society of Radiologic Technologists (ASRT) and the millions of patients we serve, I want to thank you for this opportunity to contribute to this dia-

logue on the role technology plays in reducing medical errors and improving patient safety.

Radiologic technologists are the health professionals responsible for performing diagnostic imaging examinations and for planning and delivering radiation therapy treatments. Radiologic technologists use some of the most complex equipment in the medical field, including magnetic resonance scanners, computed tomography units and positron emission tomography machines. The images that radiologic technologists obtain with this equipment are used to diagnose many diseases and injuries.

Remarkable advances have been made in medical imaging technology during the past few years. However, the technology is ineffective unless the health care professional operating it is capable of maximizing its potential. Every medical imaging examination is operator-dependent. In other words, the diagnostic quality of any medical image is directly linked to the skill and competence of the person who obtained the image. Individuals must have extensive education and training to perform the exam correctly.

Because our members have a key role in diagnosis, the ASRT is committed to finding ways to reduce medical errors in the radiology arena. Accurate diagnosis leads to recovery and cure, while inaccurate diagnosis leads to additional testing, delays in treatment and extended suffering by the patient. In addition, diagnostic errors cost the U.S. health care system millions of dollars annually in unnecessary medical bills.

The ASRT strongly believes that the best way to improve the quality of radiologic care is to improve the qualifications of the caregivers. That is why the ASRT, along with 17 other radiologic science organizations, supports the *Consumer Assurance of Radiologic Excellence bill* (H.R. 1011). The CARE bill would establish minimum educational and credentialing standards for personnel who plan and deliver radiation therapy and who perform all types of medical imaging examinations except sonography. The ASRT believes the establishment of these standards will have a significant beneficial impact on the safety of patients undergoing radiologic procedures, as well as reduce the number of medical errors caused by improper diagnosis. The CARE bill will ensure that personnel are qualified to operate the high-tech equipment that has been entrusted to them.

More than 220,000 registered radiologic technologists work in the United States. Registered radiologic technologists graduate from an accredited educational program, pass a national certification examination and obtain continuing education in their field. Unfortunately, thousands of unqualified individuals also work in the medical imaging field. That's because 12 states and the District of Columbia do not license people who provide medical imaging or radiation therapy services. In states where no regulations exist, anyone is permitted to perform these procedures, sometimes after just a few weeks of on-the-job training. And even in states that do regulate radiologic technologists, some of the licensing laws are so weak that they offer patients little protection from unqualified personnel.

The Consumer Assurance of Radiologic Excellence bill would protect patients by requiring personnel to prove that they are qualified, through education and credentialing, to perform radiologic examinations and deliver radiation therapy treatments. The CARE bill has 49 cosponsors in the U.S. House of Representatives.

Currently, mammography is the only medical imaging procedure regulated by the federal government. In 1992, the Mammography Quality Standards Act (MQSA) set educational, credentialing and experience guidelines for the personnel who obtain and interpret mammograms. Many question why the personnel who obtain mammographic images are regulated, while those who obtain x-ray, MRI and CT images are not. Mammography makes up only 8 to 10 percent of the total number of medical imaging procedures performed in the United States annually. "While this emphasis on quality in breast imaging is laudable, [evidence] suggests that more attention needs to be devoted to improving the quality of the other types of x-ray exams as well," stated a 1992 article.[1]

More than 300 million radiologic examinations are performed annually in the United States, at an annual cost of nearly $22 billion.[2] If only 0.5 percent of those medical images is performed improperly, more than 4,000 defective medical images would be produced every day of the year.

To Err is Human, the Institute of Medicine's 1999 report on patient safety, states that 17 percent of preventable medical errors are errors in diagnosis.[3] The ASRT believes that a significant number of these diagnostic errors may be attributed to poorly performed medical imaging examinations. After all, an underexposed chest x-ray cannot reveal pneumonia, just as a poor quality MRI scan cannot reveal a malignant lesion. Poor imaging examinations are a threat to patient health and safety.

Dr. Lucian Leape, a professor at the Harvard School of Public Health and a chair of the IOM commission that produced the *To Err is Human* report, estimates that physicians misread 20 percent of angiograms and 15 percent of chest x-rays for pneumonia.[4] In many of these cases, it is likely that the films presented to the physician are misread because their technical quality is poor. In a 1990 article concerning the misdiagnosis of lung cancer,[5] researchers at Michigan State University wrote, "If the quality of the image is so poor that a reasonably responsible and prudent radiologist would not have interpreted it, then poor image quality alone may be a source of negligence." A poor technique produces films with little or no diagnostic value.

Because the technology used in the radiology department is so complex, most patients would not recognize incompetence or poor quality work. "If an illness is not detected as early as it could have been because of a shoddy x-ray . . . the patient probably never knows it," according to an article in the Dec. 24, 1999, *Birmingham News.*[6] "The reason public outcry is not louder and malpractice suits more common is that most patients have no idea they may be getting substandard care."

Errors made by unqualified personnel can result in unreadable images, which may have disastrous ramifications for the patient. The patient may be required to undergo additional unnecessary tests, he may receive treatment for a condition he does not have, or he may receive no treatment at all. In each scenario, the patient's health and safety are threatened.

The simplest and best way to improve the quality of radiologic care is to establish educational and credentialing standards for the personnel who perform the exams. Licensing and credentialing radiologic personnel would build reliability and consistency into the way medical images are obtained and help standardize their level of quality. Only qualified, competent personnel should be allowed to perform these procedures.

The Consumer Assurance of Radiologic Excellence bill (H.R. 1011) will ensure a minimum level of education, knowledge and skill for those who perform radiologic procedures. Ultimately, it will improve the quality and safety of patient care.

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PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR QUALITY

During the last decade, steadily mounting evidence has focused on the problems of prescription drug errors. We now have a great deal of knowledge of what the problems are and their causes, and yet these problems persist. Adverse events resulting from medical mismanagement are estimated to affect anywhere from 1% to 30% of hospitalized patients [1,2]; of these, drug-related complications are the most common type of adverse event.[3] An estimated one-fourth to one-half of all adverse drug events among hospital patients are the result of medication errors.[4,5] The annual cost of these drug errors is estimated at $3-4 billion.[6] And one in three Americans say they have been affected by serious medical mistakes, of which 28% involve a medication error.[7] What seem to be lacking are widely accepted methods for dealing with the problems and solid commitment for following through.

This paper proposes methods for dealing with these shortcomings—methods arising out of multidisciplinary perspectives for dealing with complex systems. It also makes a case for making smart use of technology-based solutions to prescription drug problems and for addressing cultural factors that hinder advances in reducing medication errors.

A set of broad principles underlying quality improvement in health care can be found in a position paper [8] written by the Health Care Quality Special Interest Group of the American Society for Quality's Health Care Division and the Society for Healthcare Epidemiology of America. Those principles relate to prescription drug errors as well as the entire range of health care quality issues and form a basis for many of the points raised here. That position paper is attached and should be considered an integral part of this report.

Complex Systems

The seemingly simple act of prescribing and dispensing medication is actually part of a highly complex system in which errors can appear at many points. The entire process encompasses everything from manufacture and distribution through dispensing and use, and errors affecting the safety of the patient who takes the drug can occur at any of several points. Many of these errors arise as a result of poorly designed complex systems. This was a principle conclusion of the now widely known Institute of Medicine report titled *To Err Is Human: Building a Safer Health System.*

Headway in reducing prescription drug errors will come only when a critical mass of people on the front lines and in administrative decision-making positions gain understanding of these complex systems and working knowledge of an array of tools meant to be applied to the design, analysis, and operation of complex systems. Clearly, in our health care delivery systems we have not yet reached that critical mass.

Tools

These tools can be broadly classified into two main types: the tools of process management and the tools of quality management. Among the former are tools and techniques for breaking down any system, simple or complex, into its essential processes, revealing inputs and outputs at various points in the process, "customers" and their requirements, key relationships, and measurements at appropriate points that will indicate if actual improvements have been made.

Basic quality tools such as control charts and simple problem-solving tools are known to have widespread applicability in health care settings. Two especially promising methodologies for health care applications are Failure Mode and Effects Analysis (FMEA) and Root Cause Analysis.

FMEA, primarily a system design tool, is used to identify and prevent known and potential problems from reaching the customer—in this case, the patient receiving the medication. It begins with a process map of the system and proceeds to catalog ways in which things could go wrong in the system. The causes and effects of each failure mode are identified. These potential failures are assigned a risk priority by evaluating their likely severity, detectability, and frequency of occurrence. Prioritizing potential failures points the way to making the most effective changes in a system design or in an existing system.

Root Cause Analysis identifies the most basic reasons for an undesirable condition—and the most obvious opportunities for improvement in present operations and for preventing problems or faults from being introduced into the system in the first place.

Any quality tools must, of course, be applied within a logical framework for improvement. Such a framework is provided by several complementary approaches: the Baldrige criteria, the ISO 9000 quality management system standards, and the Six Sigma methodology, which taken together are three key drivers of quality in an organization and which are finding increased use in health care.

ISO 9000 is the approach that assures that a minimum standard of quality is controlled in routine operations. This system of management of quality does not by itself provide competitive advantage or assure the long-term strength of an organization. It merely declares that the quality system that is documented is being followed regularly.

Guidelines have been developed for the use of ISO 9000 quality systems standards by health services organizations. *IWA-1 Quality Management Systems—Guidelines for Performance Improvements*[9] is based on the ISO 9004:2000 standard. It contains much of the text of ISO 9004:2000, supplemented by specific guidance for its implementation in the health care sector. The guidelines provide a framework for the design and improvement of process-based quality management systems by health care organizations. The guidelines are voluntary and they are not intended for certification or accreditation.

The value of ISO 9000 in health care is in the area of writing down procedures and documenting. Clearly defined policies and procedures that would pass muster in an ISO 9000 audit are not widely found in most pharmacies. And it is not uncommon for different patient care units and different shifts in the same organization to follow different procedures for accomplishing the same medication goal. There are currently more than 600 ISO 9000 registrations in health care worldwide,[10] and the number is rising.

The Baldrige performance excellence model focuses on enhancing competitiveness by providing criteria for performance that represents an aspiration level for most organizations, i.e., targets and practices that stretch the thinking and approach of the organization's leaders.

Together, ISO 9000 and Baldrige assessment provide a lower control limit and an upper target for performance.

When Six Sigma is added to this consolidated approach to quality, the formula becomes much more complete. Unlike Baldrige and ISO 9000, Six Sigma is a highly prescriptive approach for delivering quality in the design of products and services and in the work processes that deliver them. Six Sigma is a rigorous process for learning about the sources of variation that cause defects in production processes, service delivery mechanisms, and administrative procedures. Each step in the Six Sigma problem-solving process requires the use of a specified sequence of analytical tools in order to obtain profound knowledge about process operations. Six Sigma is a methodology to eliminate variation from work processes, which is precisely the aim of efforts to reduce prescription drug errors.

There are a handful of hospitals in the United States that are using the Six Sigma methodology. One of these, Froedtert Memorial Lutheran Hospital in Milwaukee, showed significant improvement in medication delivery by continuous IV infusion.[11] Thirty days after implementation of the Six Sigma strategy, Level 1 discrepancies fell from 47.4% to 14%; Level 2 discrepancies fell from 21.1% to 11.8%; and Level 3 discrepancies fell from 15.8% to 2.9%. The discrepancies were classified into these three categories based on the deviation of the actual infusion rate from the prescribed dose rate (Level 1 being less than 1 ml/hr discrepancy and Level 3 being more than 5 ml/hr discrepancy). Substantial efforts are ongoing to move toward the goal of a six-sigma level of control.

It is instructive to note that Froedtert's was a multidisciplinary effort among physicians, nurses, pharmacists, and administrators. The group developed a process map that revealed nine key steps in the administration of 22 medications delivered by continuous IV infusion. Each of these steps was subjected to FMEA to identify the two most error-prone steps in the IV infusion process, which became the target steps for reducing errors. Root cause analysis was performed to determine true causes of discrepancies in infusion rates.

The National Patient Safety Foundation and the American Society for Quality recently formed an alliance to develop a Patient Safety Toolbox. The major component of this project is the provision of Six Sigma training for health care professionals.

Use of these tools is in its infancy in health care settings. While there have been several published studies of the use of FMEA, there are no published studies of continuing follow-up in these cases. There appears to be inadequate commitment to the necessary steps of re-measurement and continuing application beyond an initial demonstration project and to making these steps standard procedure. Necessary system changes have proven difficult to implement.

Rapid advances are being made in two areas that hold great promise for reducing medication errors: technology-based solutions and development of clinical guidelines and evidence-based best practices models. Both of these are useful at the patient/provider interface, where the art of medicine comes into play.

There is an array of new technological tools bringing helpful changes at the patient/provider interface. Hand-held computers running software such as ePocrates can provide on-the-spot, current information about a medication. Physicians report that patients feel confident when they see their physicians consulting this source of immediate information. Other software such as i-Scribe is starting to make an impact in reducing handwriting errors. And barcoded patient wristbands also introduce a measure of error proofing into the system. Understanding the science of human error and using that understanding to error-proof system designs is an important step. Adoption of these and other technological advances into physicians' practice patterns needs to be systematically encouraged.

Clinical practice guidelines condense the knowledge of many individuals and institutions. These evidence-based best-practices models help the physician in his or her practice and are growing in use and importance.

In the pharmaceutical manufacturing and distribution processes there is a long history of the use of both simple and sophisticated quality methods. Quality is sufficiently high that we almost take it for granted, but there is a continuing need for vigilance in these areas. Furthermore, manufacturers and distributors have a role to play in efforts to reduce current levels of medication errors, particularly in the areas of packaging and storage. Making look-alike and sound-alike drugs different in their outward appearance, packaging, and handling requirements can reduce the occurrence of human error in the administration of drugs to patients.

Cultural Factors

For any of these approaches to take hold and have any lasting effect, attention must first be paid to numerous cultural factors that enable system-wide organizational change. First and foremost is the need to establish a non-punitive environ-

ment in which causes for errors can be examined and corrected, an environment where the emphasis is on fixing and preventing problems rather than assigning blame. Instituting policies and procedures that encourage self-reporting and discourage disciplinary action for human error is a logical first step.

There must also be a willingness to routinely bring interdisciplinary perspectives to bear on the challenges of reducing prescription drug errors. When the problems call for smart design and redesign of systems of work, much can be gained when physicians and nurses, pharmacists, epidemiologists, administrators, academics, and quality engineers join their skills and knowledge to the effort.

A growing body of knowledge relating to specific institutional practices and procedures for reducing medication errors is arising out of the work of groups such as the Institute for Healthcare Improvement, National Patient Safety Foundation, American Society of Health-System Pharmacists, and the Joint Commission on Accreditation of Healthcare Organizations. It is not our purpose to repeat these well-documented efforts. Rather, the important contribution we can make is to point the way toward methodological approaches that these groups and others interested in health care quality can implement in order to achieve breakthroughs in reducing prescription drug errors.

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QUALITY AND QUALITY IMPROVEMENT IN HEALTH CARE SERVICES

David Birnbaum, PhD, MPH, Ron Berglund, MPH, CHE, CQmgr, Ulises Ruiz, MD, PhD, FACS and the Health Care Quality Special Interest Group* of the American Society for Quality's Health Care Division and of the Society for Healthcare Epidemiology of America

ABSTRACT

Recent national debates over methods to reduce errors in health care have tended to ignore the pertinent heritage of early clinical and administrative pioneers of quality in hospitals who had the courage to "break the rules" and innovate, hospital epidemiology, and the industrial quality sciences. Critical appraisal of evidence in reports fueling those debates, as well as in other documents; consideration of all stakeholders' opinions; and development of effective solutions requires interdisciplinary effort. We acknowledge that historic improvements in public health quality have contributed significantly to improving longevity and reducing the burden of many diseases; however, the focus of this position paper is on acute care services. As a profession, healthcare has been paralyzed. The system which we are observing was 'designed' to produce the outcome we are measuring, and no amount of policy tinkering or additional resources thrown at measurement will have significant im-

pact: well-considered structural changes are required to prevent system failures. This position paper, developed by an international, interdisciplinary group, examines central issues and associated evidence to assist facilities and healthcare professionals in responding to emergent challenges.

I. AN INTERDISCIPLINARY APPROACH TO IMPROVING HEALTH CARE QUALITY

Specific conclusions and recommendations in the Institute of Medicine's report *To Err Is Human* 1[1] challenge us to build a system of new processes that will create a "Safer Health System". As an international, interdisciplinary group of academics, hospital epidemiologists, infection control practitioners, management engineers, medical administrators, nurses, pharmacists, physicians, and other health professionals dedicated to improving health care services, we are addressing issues raised by that body of work which apply to all countries and include:

- National governments should set national goals for patient safety, develop knowledge and understanding of errors in health care, while funding the dissemination and communication of activities to improve patient safety.
- There should be countrywide mandatory reporting systems that would provide for the collection of standardized information by regional governments about adverse events that result in death or serious harm. Reporting should begin with hospitals and expand to other health service organizations.
- There should be encouragement for the development of voluntary reporting efforts including the review and coordination of sponsors and users of external reporting systems.
- Peer review protection for data related to patient safety and quality improvement should be expanded.
- Performance standards and expectations for health professionals should focus greater attention on patient safety.
- Agencies that regulate drugs (e.g. US Food and Drug Administration) should increase attention to the safe use of drugs in both pre-and post-marketing processes.
- Health care organizations and professionals should, make continually improving patient safety programs a declared and serious aim that includes defined executive responsibility.
- Health care organizations should implement proven medication safety practices.

While no one can disagree with the need to continuously improve health services and organizations that provide them, the report's dependence on government intervention, its implication that health care professionals have not been paying attention to patient safety, and even the estimated number of patient deaths attributed to errors, may be misleading.[2] When the problems of nonconformance, adverse outcomes, and errors are examined from system, process, epidemiologic and quality engineering perspectives, these problems frequently are rooted in technical deficiencies of health care delivery systems rather than isolated action of individuals alone. This is not a new conclusion,[3] having been addressed by WHO-Europe in 1982,[4] and through different perspectives of the traditional role and responsibilities of caregivers.[5,6,7,8] Our position is that permanent outcome improvement and error reduction are possible only when deficient processes that make errors likely are systematically improved through evidence-based approaches.

There are many lessons from decades of experience in hospital epidemiology and infection control that apply to other types of adverse outcomes in the broader context of health care service system failure. SENIC (the Center for Disease Control's 10-year $12-million Study on the Efficacy of Nosocomial Infection Control) assessed the cost-effectiveness of hospital infection control programs and identified those program elements associated with reducing patients' risk of infection.[9] Surveillance is a cornerstone of what has been called the premier quality assessment program in United States hospitals,[10] and these proven surveillance methods have been applied beyond nosocomial infection. Nettleman and Nelson, for example, employed standard prospective surveillance methods to document frequency and distribution of events that caused or had potential to cause patient injury, as well as sensitivity, efficiency and cost of using different clinical information sources.[11] Epidemiology, which provides the scientific basis for public health, has been successful in discerning complex relationships in health care institutions but has been less successful in promoting permanent system-wide changes there.

Traditional tools of quality control and quality management, proven in monitoring and improving defined processes of other industries, similarly had mixed success in national demonstration projects on quality improvement in health care.[12] Epidemiology is not incompatible with these tools of monitoring and change,[13] and in fact provides a complementary aiming mechanism to better position their use in the

complexities of health care services.[14] Novel interdisciplinary approaches to improving quality have not been a mainstream feature in health care, but are not unprecedented,[15,16,17] and have more potential to succeed than the more common single-discipline, prescriptive, rule-based approaches. However, to succeed in the future, we need to understand why seemingly successful novel programs of the past have not persisted to be today's paradigms.

The difficulties most likely to be faced when introducing and implementing such concepts in the health care sector have been described as *"early cynicism, issues of cultural fit to the complex nature of the health care sector itself, and resistance from the traditional professional identities of key role-holders"* [18] and as "quality being the flavor of the month, . . . a poor appreciation of TQM concepts, principles and practices, . . . a lack of structure for TQM activities and ineffective leadership." [19] On the other hand, many reports show successful introduction and use of various quality tools and techniques in health care organizations. In a review of the introduction of Total Quality Management (TQM) at a number of sites within the UK National Health Service, it was found vital that the medical staff, clinical directors, nurses and all health professionals at all levels of the organization, and cross functionally, be involved from the very beginning and that there needs to be ongoing education and training. It also was found essential for senior managers to be fully committed to the introduction of the chosen model and a carefully planned implementation.[20] Design and implementation of a Quality Management Plan in the Spanish Health System also revealed some of the advantages and obstacles described above,[21,22] as also found by a European study in 113 hospitals of 10 countries.[23] Novel interdisciplinary approaches have to be understood and applied as a global culture change when introducing system and process thinking in the daily operations of health services. Trying to apply traditional tools and methods of quality without having set the appropriate organizational cultural ground will be regarded by health professionals as foreign and non-applicable, which may explain the mixed success of these initiatives.[24] Consequently new approaches are being implemented in Spain,[25] as elsewhere.

II. DEFINITION OF TERMS

Being a special interest group formed from societies with heritages of industrial quality sciences and of epidemiology, we turn to those directions for definitions. W. Edwards Deming, a luminary of modern quality precepts, placed great emphasis on the need for clear operational definitions. Epidemiology, similarly, achieves clarity when technical terms are used precisely. We therefore choose to adopt terms defined by established, internationally-recognized bodies including the World Health Organization (WHO, which published pertinent definitions on its web pages (http://www.who.int/aboutwho/en/definition.html & http://www.who-umc.org/defs.html); the International Standards Organization (ISO) and American National Standards Institute (ANSI);[26] International Epidemiology Association (IEA, which published definitions in its dictionaries.[27]); and the US Institute of Medicine (IOM).

Quality is more than just the absence of error. The definition of quality in health care, as well as related terms (including nonconformance, adverse outcome and error) can be viewed from five perspectives:

1. scientific research
2. consumer of service (patients and the public at large)
3. dictionaries such as Webster's Medical Dictionary
4. accreditation, regulatory and other agencies or professional associations
5. Type one and two errors and the potential impact of both

THE PERSPECTIVE OF SCIENTIFIC RESEARCH

Health and health care quality are multidimensional constructs. Researchers create operational measures to define domains of these constructs, as illustrated in Figure 2;[28] working conditions and worker satisfaction should be considered an additional domain of health system performance measurement. We must be concerned as to whether measures selected within each domain are sufficiently precise, accurate, reliable, and meaningful to guide necessary decisions.

When we look at quality defined by scientific conclusion we look at various disease rates including the ever-present nosocomial infection. The assessment of health care quality is a complex problem. National Committee for Quality Assurance (NCQA) reports and press releases note improvement in quality ratings of organizations it surveyed last year, and NCQA requirements have created an imperative for all health plans to build the information systems needed to track and improve performance. However, as we've learned from our experience monitoring nosocomial infection rates, an overall or "crude" rate masks patterns in its composite "specific"

rates.[29] Similarly, some aspects monitored by NCQA show improvement while others show room for improvement. Assurance of improvement in service quality requires methods that can be applied in a wide range of settings.[30] Meaningful assurance also requires the type of "Patient-Oriented Evidence that Matters" (POEMS) recommended by advocates of evidence-based health care, and there is evidence suggesting that accreditation standing or other typical measures are not highly correlated with consumers' rating of care.[31] Just as fundamental changes in health care delivery systems are needed to reduce the risk of system failures, fundamental changes in research funding and contracting models may be needed to reduce the risk of misinformation.[32,33] Scientific research can answer questions, but we need to be sure the right questions are being asked and answered.

THE PERSPECTIVE OF CUSTOMERS, CLIENTS, PATIENTS, AND THE GENERAL PUBLIC

A quality systems perspective typically considers quality as satisfying both internal and external customers. All internal and external customers don't necessarily see quality as an absence of infections, a reduction in mortality rates, or an increase in trained personnel. Each wants the health care services provider to meet their own valid customer needs. As such, internal customers (health care providers, departments and suppliers within the system) and external customers (patients, their families and communities) have unique needs. An organization has to assure that all its processes are controlled. A care giver has to assure that their patients are adequately informed about the products or service offered, the risks involved, and the outcomes expected so that individuals looking to them for care can make the most appropriate decision. Agreement between those who provide a good or service and those who desire a good or service is the major focus of any quality improvement approach, and is recognized as a client-focus approach However, there is more to health care quality than patient satisfaction alone, and satisfaction is a complex construct that is not simple to survey meaningfully.[34] Although it recently became more common in health services to refer to patients as clients or customers, we believe that this is still not well understood terminology in the whole of the services sector. "Customers" brings to mind the informed consumer of competitive economics. Referring to patients as clients or customers may be misleading for health care providers and consumers not familiar with contemporary quality improvement terminology and approaches in health services for two reasons. First, historically, patients know less about their condition and the health care that might help them than their physician. The physician is the patient's agent, and provides expert advice. Despite efforts by groups like the international Cochrane Collaboration to monitor and objectively assess the ever-growing body of research literature,[35] as well as quantitative and critical appraisal methods applied by individual practitioners,[36] much of that advice often must be based on expert opinion in the face of incomplete evidence. Many patients may be becoming better informed today, in no small part due to development of internet-based resource sites and support groups, and an informed customer is consistent with tenets of quality improvement philosophies. However, quality of information from those resources is quite variable, and the majority of individuals who seek health care seek a special relationship with the professional who provides that care. Second, patients do not value health care per se, they value health; "health care" is an intermediate good that people consume (based on expert advice) in hopes of deriving a health benefit. Many patients, and especially those under duress of serious illness, do not have the time, interest, or ability to gain sufficient knowledge to be equally informed as their health care provider. So, no matter how much information patients receive, choosing your surgery is never going to be like buying a car. People can judge very well how well their car works. The quality of their surgery (or other treatments) is much harder to judge. The outcome of each surgery or treatment is clear and self-evident as a success, partial success, or failure in meeting expectations, but in most cases the technical issues pertaining to quality are not as easy to judge on a case-by-case basis (viz. assuming expectations were realistic, it is difficult if not impossible for individuals to judge whether their condition would have improved anyway without or despite the intervention; whether it failed to improve or suffered adverse outcome due to subtle or transient differences in skill or performance levels given the probabilistic rather than deterministic nature of health care; or whether the best that a given provider offers is commensurate with risk-adjusted performance of providers elsewhere). All but the most flagrant technical problems require population-based evaluation, the realm of epidemiology, and state-of-the-art in meaningful risk-adjusted-metrics has raised concerns about several so-called "report card" metrics. From the perspective of some health economists, it is less subject to misinterpretation to use the word patient when talking about someone receiving care from a physician or other health care professional.

Only when we are explicitly talking about people choosing between, for example, HMOs in the USA, or between health care professionals, or deciding whether to buy supplemental insurance, then the health economics perspective of "customers" could make sense. The special nature of patient relationships requires holistic yet practical approaches which engage "the entire membership of individual health care providers."[37]

Some health systems and organizations are at present using these terms with increasing ease, once they have fully understood their meaning. Indeed, in this spirit, the recent ISO Industry Workshop Agreement 1 (IWA-1) document acknowledges the term "patient-client". A related problem is changing the culture of the health sector. A system or organization trying to change culture faces well-known resistance of caregivers to loss of traditional role and responsibilities. That is one reason why physicians have been entrenched, up to not so long ago, in the classical technical quality assurance approach where no challenge is accepted. This traditional approach assures their role as patient's agent which overcomes the role of the provider of expert advice. As provider, one has to discuss advice with customers and reach an agreement with them about it. Continuous Quality Improvement (CQI) might be able to reconcile the trade-offs from both perspectives.[38,39] However, at present, referring to patients as clients or customers in an organization with no CQI culture might be misleading.

The Henry Ford Healthcare System when approached by some of its major automotive-industry customers decided to use the customers' definition of a quality organization and they have seen better "health care measures" and "a noticeable increase in the number of clients from the automobile industry wishing to use their facility".[40]

THE PERSPECTIVE OF DICTIONARY DEFINITIONS

The definition of error based upon the medical dictionary states that it is a "deviation from right or truth; a mistake; a blunder; sin."[41] This is pretty strong language especially the "sin" part when we look at our customers. "Medical error" is not defined in such sources, and we do not consider pejorative dictionary definitions of "error" pertinent. We suggest that only dictionaries and definitions published by well-recognized expert bodies (such as WHO, ISO, ANSI, IEA) be considered.

THE PERSPECTIVE OF ACCREDITATION, REGULATORY AND OTHER AGENCIES OR PROFESSIONAL ASSOCIATIONS

Adverse event (also known as adverse reaction or adverse outcome) is defined by IEA. We accept the IEA definition to describe "an undesirable or unwanted consequence of a preventive, diagnostic, or therapeutic procedure"; we recognize that further classification of such events that do cause harm is consistent with the IOM definitions. This definition of adverse event is also consistent with the more recent ISO Industry Workshop Agreement (IWA-1) definition ("any event which is not consistent with the desired, normal or usual operation of the organization. Typically these are documented and require the completion of an incident report"). If non-conformance is serious and distinctive, the event can also be known as a "sentinel event" which requires immediate corrective action.

Nonconformance is defined by ISO. We accept ISO and ANSI descriptions of nonconformance, and recognize that further classification of such events that could cause harm is consistent with the IOM definitions. Depending upon the regulatory body, the definition of error can go from a "sentinel event" to a missed signature on a piece of paper even though all the required services were rendered. Health care actions traditionally have been governed by policies, procedures and clinical practice guidelines. Professional society and institutional policies stipulate clear boundaries for acceptable practice; violation of those boundaries is subject to disciplinary action by professional colleges, societies, or institutional administrations. Failure of such bodies to communicate with each other has permitted continuing incompetent practice of individuals who relocated, again a system failure. Institutional procedures define the steps expected to complete an activity; while there may be choices between procedures, deviation from steps within a procedure requires justification (or, if frequent, a change in the written procedure). Although some feel that deviation from clinical practice guidelines constitutes error, there is longstanding evidence that such guidelines do not guide practice,[42,43] numerous examples of expert consensus (as opposed to graded evidence) guidelines being inconsistent with the underlying evidence; further, while such guidelines can form a basis for audit, expert opinion holds that guideline-derived evaluation represents "a tool, not a rule" to understand and inform rather than coerce practice.[44] We conclude that deviation from procedure or practice guideline can be justified but requires documentation of reason (a brief

description of professional judgment); deviation per se is not medical error, but failure to document or inadequate justification may be.

We accept the IOM report definition of error ("failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim"),[1] as well as its perspective that much can be learned from the analysis of errors, not all errors result in adverse events, and not all adverse events are preventable or the result of error. Thus, error is one category of system failure in which nonconformance through action, inaction, or incomplete documentation is evident.

A more complete focus on quality and error reduction has been found by several organizations that have moved from compliance to ongoing systematic process control and improvement. Memorial Medical Center of West Michigan in Ludington Michigan now uses the State of Michigan to perform the required Medicare/ Medicaid certification and has developed a clear set of customer expectations which not only meet customer requirements but all Federal and State requirements while saving thousands of dollars a year in external regulatory audits.[45] This is one example of the emerging use of ISO 9001:2000, ISO 9004:2000 and IWA-1 as a basis for health care quality management systems, documents, and standards.

THE PERSPECTIVE OF TYPE I AND TYPE II ERROR

Surveillance and screening programs are subject to two types of misclassification error, which correspond to the two types of statistical error: Type I (also known as alpha-error or producers' risk) and Type II (also known as beta-error or consumer's risk). The consequences of false-positive Type I error (unfairly damaged reputations; excess cost of unnecessary inspection, investigation, and possible rejection of good product; misguided changes to policy or procedure) and false-negative Type II error (missed cases, with lost potential to prevent injury or loss) must be considered to achieve optimal balance. Although high sensitivity, specificity, and predictive accuracy all are desired, when compromises are necessary surveillance systems and screening programs typically place different emphasis on these. Screening programs are designed to intervene in each case as early as possible to avoid further harm, and tend to follow very sensitive initial screens with a more specific confirmatory step (thus, for example, programs to prevent medication error may be more concerned with false-negative than false-positive initial assessments). Surveillance programs are designed to monitor whether systems are operating within expectation as well as detect incipient trends, but trigger intervention on trends rather than on a case-by-case basis (thus, for example, infection surveillance programs may be more concerned with damage to credibility caused by false-positives so emphasize specificity over sensitivity). Sensitivity and specificity refer to the proportion of true cases and true non-cases correctly identified, respectively. The CDC (Center for Disease Control & Prevention) SENIC and NNIS (National Nosocomial Infection Surveillance) programs have demonstrated the importance of clear, explicit target event definitions as a requirement for effective surveillance or screening programs. When we look at Type I or Type II errors the question always gets back to the process in question. Finding the right balance for each process in question is the key to producing cost-effective programs. The Wayne Regional Orthopedics PLLC instituted a new systematic approach to error reduction and improved quality which during the installation year improved its customer satisfaction by 8%, reduced its data entry errors from 30% to 10% and was able reduce unnecessary staff costs.[46]

III. CAUSES AND SOLUTIONS FOR HEALTHCARE SYSTEM FAILURE

Healthcare is just recently returning to outcome-based assessment of quality, first introduced by Ernest Codman in the early 1900s, following decades of focus on standards to govern structure, process and output alone.[47] The complementary nature of epidemiology and systems engineering techniques in this return has been noted.[48] This introduces concepts of processes, systems and system fundamentals. The ISO Quality management system-fundamentals and vocabulary definition states: "Process—a set of interacting activities, which transforms inputs into outputs.

Note 1. Inputs to a process are generally outputs of other processes.

Note 2. Processes in an organization are generally planned and a carried out under controlled conditions to add value.

Note 3. A process which the conformity of the resulting product can not be readily or economically verified is frequently referred to as a special process."[49]

This leads to a realization that the outcome we are measuring reflects a misdesign or at least a lack of design of the system which we are observing, and no amount of policy tinkering or additional resources thrown at measurement will have significant impact: well-considered structural changes are required to prevent system failures. All stakeholders must be engaged in evidence-based review of im-

provement priorities, system changes, and evaluation of the impact of system changes: essentially, the familiar CQI *Plan-Do-Check-Act cycle* (Figure 3) guided by approaches like ABNA,[15] the IOM Model Process for Technology Assessment,[50] etc. Applied research, in-service education, and ongoing training are essential components to create so-called learning organizations that embody this (organizations that learn and progress through continuous improvement of their processes).

Applied research in both the epidemiologic and CQI approaches considers the framework of *Structure-Process-Output-Outcome,* while other approaches that have been used in health care focus on *Structure-Process-Output* regulation and simply assume causal relationships between given regulated activity and desired outcome. Research has shown that such assumptions have not always been valid, leading on occasions to regulated activity that was not effective, cost-effective, nor in some cases even safe. Assessing outcomes of a specific health system, service, or institution requires an estimate of the best that can be achieved (attainment) and of the least that can be demanded (performance), given that the *raison d'être* of a health system is to protect and improve population health and not to thrive on disease. Applied research and assessment of performance, in turn, must be linked with assessment and delivery of effective education and training.

According to the ISO 9004:2000 IWA-1:

"Ongoing training—The organization should review qualifications periodically to identify and provide necessary in-service training to all instructors and staff to enable instruction personnel to carry out their tasks with minimal supervision. If in-service is not available and this impairs the quality of instruction, then a staff communication procedure within the quality system should be considered to address this. Records should show a periodic review of training needs.

NOTE: The prerequisites, objectives, standards of assessment, instructional strategies, necessary controls, and the materials used for instruction shall be available.

"Identification of patient family education/training programs—The organization should use the results of an initial patient evaluation/assessment and review of the patient health record, if any, to identify training needs of the patient and/or family or others as appropriate. The organization should maintain records of patient and/or family or others training as appropriate. Where applicable, these records should be included in the patient health record. The organization should ensure that the patient and/or family or others can demonstrate the ability to perform prescribed activities, if any. Any instruction plan should require that conditions for learning include safe classrooms, free of health hazards and physical distractions. Supporting services should reinforce learning and not interfere with the learning process."[51]

Human System response (special cause variation) may be defined as how a human being responds to an assemblage of objects arranged after some distinct method, usually logical or scientific (a system of processes) based upon their *training* and experiences.

Quality Management Systems and their advantages require us to focus on what a Quality Management System is and what advantages the various existing systems present to ensure quality and reduce medical errors. The most commonly defined systems include among others: ACHCS in Australia, CCHSA in Canada, ANAES in France, ALPHA from ISQua, PACE and NIAZ in Netherlands, HAPNZ in New Zealand, UKAS in UK, COHSASA in South Africa, PAHO for South America, JCAHO, NCQA and URAC in USA; ISO 9001:94 and 9002:94 are being used as basic systems in Australia, Finland, Ireland, Israel, New Zealand, Spain, Sweden, Switzerland, USA.

Our question is to decide if these sets of requirements and guidelines constitute a management system or are they external regulations designed to meet selected requirements of selected customers. If we accept that they are selective in what they regulate and not a complete system, then our focus will be easy. To build a quality management system we would want to include the perspective shown in Figure 1. This figure is taken from the IWA-1 which gained world wide approval during "An interactive ISO-sanctioned workshop (which) took place in Detroit, MI, January 18-19.2001, involving 135 healthcare professionals representing 17 countries. IWA-1 will provide guidelines to health service providers for implementing or improving quality management systems (QMSs) based ISO on ISO 9004:2000 Quality management systems-Guidelines for performance improvements."[51]

We will follow the lead of these 135 individuals if we request that all health care services in the USA be subject to the HCFA Program Safeguard, Statement of Work, Attachment J-1, Paragraph 10.A.3 and become ISO compliant. Currently only American contractors annually performing work totaling more than $1million under all Task Orders has to become ISO compliant. Currently this involves over 30 organizations including some Blue Cross/Blue Shield organizations. ISO 9001:94 and 9002:94

are being currently used in other countries around the world, as indicated above. Our recommendation is that all health systems, services and organizations within a five year period from the publication of this document, will set in motion quality management systems based upon the IWA-1 QUALITY MANAGEMENT SYSTEMS—Guidelines for process improvement in health service organizations; Based on ISO 9004:2000 Second edition 2000-12-15 Quality management systems "Guidelines for performance improvements (Systèmes de management de la qualité—Lignes directrices pour l'amélioration des performances. 1/19/2001.)

IV. OTHER LOGISTICAL CONSIDERATIONS

FINANCIAL IMPLICATIONS

Resource allocation for improvement activity is an important consideration with two dimensions: Infrastructure to support infection control and epidemiology departments as well as other service units,[52,53,54] and financial incentives as well as non-financial incentives to change care provider practice patterns. In the USA, despite the HMO movement, the majority of care is still provided in the fee for service mode. Some feel that this does not present individual providers' much incentive for efficiency and appropriate levels of care. Others feel that the fee for service system as implemented in the US engenders a lot of motivation for efficiency. Reimbursements are relatively fixed, so providers must be efficient in order to make money. Competition does stimulate efficiency; however, we should be talking about effectiveness, too. There are no "well baby visit" fee items in many health jurisdictions, nor other incentives to spend more time doing a thorough job on health promotion and humane support aspects of primary care. Fee for service doesn't encourage primary care practitioners to provide non-fee-reimbursable services, to refer out of system when in the patient's best interest but not the Health Maintenance Organization's financial interest, nor to consider more system-efficient approaches that aren't cost-effective for individual physicians (e.g. renewing prescriptions over the phone rather than billing for an office visit since only office visits are on the fee schedule). On the other hand, salary without consideration of efficiency and meaningful accountability or profit can breed complacency, doesn't encourage facilities to innovate or reinvent themselves to better meet stakeholders' needs. Perhaps we need to look to other industries for models of employee ownership and profit-sharing! One interesting suggestion in the last IOM report is to base reimbursement on quality of service. At present, hospitals (and doctors) get paid the same for doing things poorly. Payers fixated on least cost (notoriously HMOs) only want it cheap. The shift to HMOs in the United States is a good example of a great shift of power from providers to insurers, who now largely control access to health professionals. Other models to finance healthcare through public and private providers are in place in other countries. One covers all or most citizens through mandated employer and employee payments to insurance or sickness fund, another relies mainly on tax revenues and public provision. The cost of poor quality needs to be factored into monetary incentives.

In developing a position on improving health care quality, the utility of quality improvements and cost of quality deficiencies must be on the agenda. If we accept that the Taguchi quality loss function is valid, then cost must be an element in quality improvement decisions. While many clinicians acting as agent of their patients still argue for technical quality at any cost, other stakeholders today have more realistic and balanced views. In evaluating quality improvements as a reduction of poor quality performance, resources often are redistributed with no increase in total cost for improvements achieved. Quality is free to that point,[55] somewhere beyond which the Taguchi loss function recognizes an optimal point where the next unit of improvement will no longer cost less but start to increase the cost of the unit of care being provided, a point where costs, benefits, and cost-effectiveness must be considered by all stakeholders. To economists, "costs" means opportunity costs, the value of the lost opportunities to do something else. Insurance payments and victim compensation payments, while important to those who pay or receive them, are actually transfer payments, not costs; they do not affect society's overall resource use, just its distribution. The major opportunity costs of adverse events in health services relate to lost enjoyment of life of victims and their families, as well as waste in healthcare resources and time by duplication of effort, and *ad hoc* attempts to correct poor quality processes. In health services as in any other organization, organizational waste may represents at least 20% and up to 40-50% of the total costs.[12] Recent breakthrough strategic methods like Six-Sigma, which tries to enhance the predictability of positive outcomes, seem to prove that reducing rate of defects (adverse events and errors) to roughly 3.4 per million opportunities (nearly error-free, 99.99966% perfect, performance) is possible in industrial applications and deserves

further consideration in health service applications. After a Six-Sigma program was implemented, one organization's radiology cost per procedure decreased from $68.13 to $49.[56] As a guiding framework for producing new evidence, we might consider another health economics tool: the Technology Assessment Iterative Loop, an iterative process with literature review informing research design, and evaluation results informing future literature review, in a continuing cycle of improving information and methods.[57]

INFORMATICS IMPLICATIONS

Organizations of businesses that contract for health care services, notably the LeapFrog Group (http://www.leapfroggroup.org), have admonished health care to speed up introduction of information technology. The VA system, among others, has been perfecting paperless medical records for several years and some hospitals are completely paperless. Some have even developed rule-based artificial intelligence to identify potential problems when early prevention or intervention still is possible. Bar code medication administration systems have been introduced in recent years. These systems can be extremely helpful,[58,59] but if there is poor planning new problems do arise and staff may circumvent cumbersome processes. Even if all stakeholders are involved from the beginning, new challenges arise. Complex computer systems can introduce as many problems as they solve if effective quality safeguards are missed.[60] Automation cannot be ignored as part of the solution, but is not a panacea.

V. RECOMMENDATIONS

1. Proven quality management methods should be implemented in all healthcare delivery settings.
2. We encourage applied research in order to understand what needs to be measured to define health care quality, then develop appropriate measurement parameters. Patient-Oriented Evidence that Matters, to borrow a phrase from the evidence-based health movement, should be collected and evaluated in individual facilities and network initiatives among them.
3. These initiatives should promote the integration of epidemiologic methods and industrial tools of quality in healthcare institutions. Epidemiologic principles should guide collection of data on adverse events and system failures that could cause adverse outcomes, as well as root cause analysis to determine whether error or other factors explains these events. Continuous quality improvement as well as technology assessment principles should guide development of appropriate interventions.
4. Healthcare institutions should go beyond typical health care methodology and "steal shamelessly and implement profusely" the things that work in other industries where accidents and errors have been reduced.
5. Expert working groups should determine applicability of proposed or best practice ("benchmark standard") methods to the international healthcare community, considering both developed and developing countries.
6. Interdisciplinary working groups should consider how we can expect health services providers to honestly report errors and near misses without fear of having to defend themselves against legal or administrative retribution.
7. Special interest groups, such as this one, should be used as an efficient means of communicating requests for proposals, grant opportunities, and of forming liaisons.
8. We should preserve traditional relationships, such as CDC with the healthcare epidemiology and infection control community, and develop new collaborative initiatives from current, successful activities.
9. Within a five year period from the publication of this document, health services organizations should set in motion quality management systems based upon the IWA-1 QUALITY MANAGEMENT SYSTEMS—Guidelines for process improvement in health service organizations, based on ISO 9004:2000 Second edition 2000-12-15 Quality management systems "Guidelines for performance improvements.

With the development of the ISO 9004:2000 quality management systems for all health services and systems, the various funding agencies, insurers and or service users will have a consistent quality standard to depend upon. For Federal funding agencies in the United States or Canada, they could follow the ISO Audit principals to guarantee performance and the customers (i.e. Company sponsored health plans will be sure that this major supplier meets the minimum world quality ISO guidelines).

Adverse event and error reporting system would become the province of the organization using its internal Audit process for Non-conformities and customer required "corrective action" which will lead to preventive actions. External compliance will be possible using the ISO registration system for those health systems which choose

to become ISO registered, or for those using the different current approaches for accreditation or the JCAHO, NCQA or URAC delegated reviews. The reviews are a method for state governments and the federal governments in the United States and Canada to use non-government organizations to review the service providers to whom they make payments. We propose that the ISO Registrars serve the same purpose as is currently provided by JCAHO, NCQA or URAC should a health service organization decide to become ISO registered.

ACKNOWLEDGEMENTS:

Members of the special interest group at the time this position paper was ratified are: Brazil: Mariangela Cavalcante, MD, MPH; Cresio Pereira, MD, MSc. **Canada:** Brian Addison, RN, CQA; David Birnbaum, PhD, MPH; Joanne Langley, MD, MSc, FRCPC; Shirley Paton, MN, RN; Virginia Roth, MD, FRCPC; Sam Sheps, MD, MSc; Geoffrey Taylor, MD, FRCPC; Rebecca Warburton, PhD. **Germany:** Michael Kramer, MD, MPH. **Greece:** Dr Harry Angelopulos. **Italy:** David Paterson, MD. **Japan:** Nahoko Shindo, MD, PhD. **Spain:** Angel Asensio, MD, PhD; Maxima Lizan, MD, PhD, Ulises Ruiz, MD, PhD, FACS; Toni Trilla, MD, MSc. **United Kingdom:** Barry Cookson, MRCP, FRCPath. **United States:** Mel Alexander; Elias Anaissie, MD; Jean Barry-Walker, PhD, RN; Murray Batt, MD; Ron Berglund, MPH; Robert Burney, MD; Mickey Christensen, P.E; Bill Credé, MD; Richard Dixon, MD, FACP; Mark Eckman, MD; Jeffrey Engel, MD; Marvin Fojtasek, MD; Nelson Gantz, MD; Don Graham, MD; Peter Gross, MD; Tracy Gustafson, MD; Jim Hinderlang; Amy Beth Kressel, MD; Steve Kritchevsky, PhD; Tammy Lundstrom, MD; R. Michael Massanari, MD; MS; Glen Mayhall, MD; Howard Nadworny, MD; Dan Nafziger, MD, MS; Mary Nettleman, MD, MS; Gary Noskin, MD; Gary Preston, PhD; Salah Qutaishat, PhD, CIC; Tom Reiley, MD; Jon Rosenberg, MD; Thomas Rushton, MD; Charles Salemi, MD, MPH; Ken Sands MD MPH; Marisel Segarra-Newnham, PharmD, BCPS; David Simmons, ScD, PE, CCE, CQE; Kathleen Stillwell, RN, MPA, HSA; Bernadette Sullivan, MBA, CIC; Alan Tice, MD; Allison Weinmann, MBBS; Todd Wiblin, MD, MS; Lynda Winterberg RN, MBA, CPHQ.

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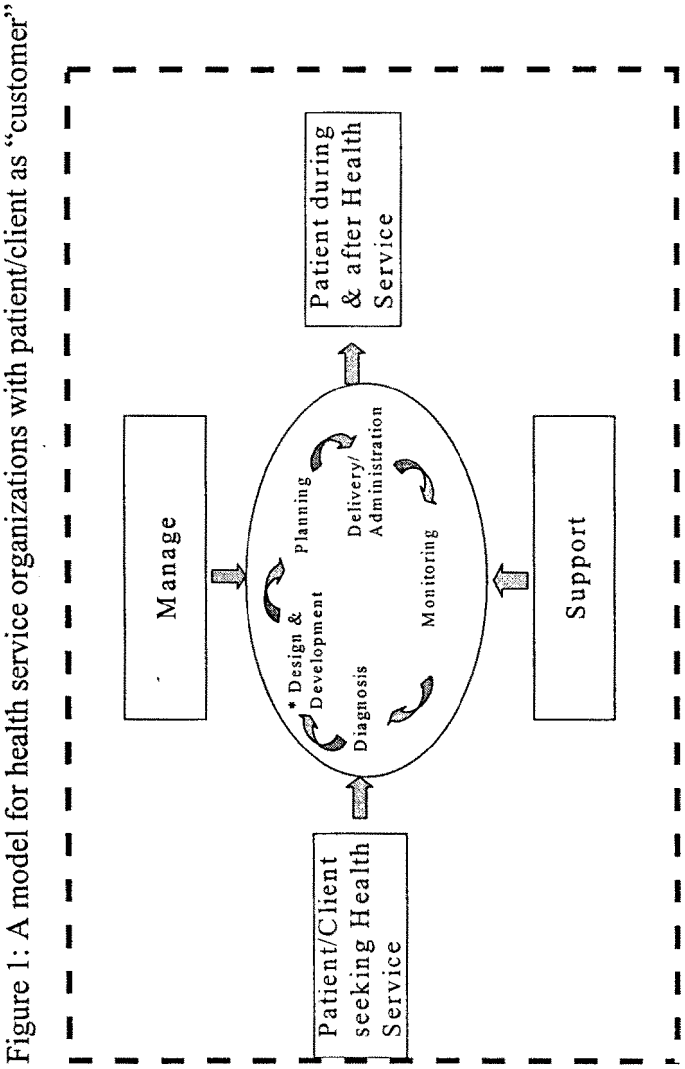
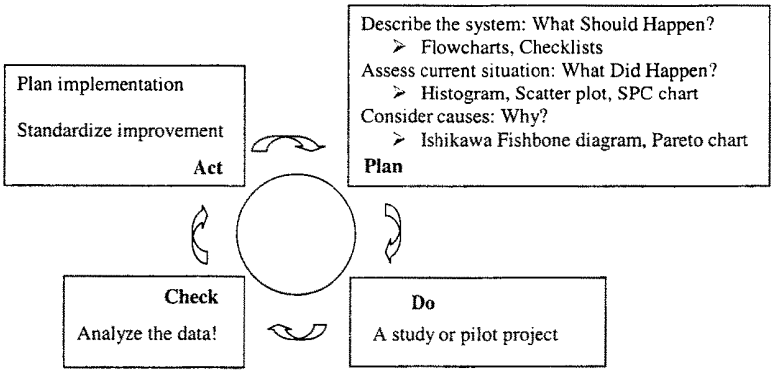


Figure 1: A model for health service organizations with patient/client as "customer"

Figure 2: Domains and operational measures of health quality[28]

I. Health Status			
Health Conditions	**Human Function**	**Well-Being**	**Deaths**
Asthma, arthritis, depression, diabetes, chronic pain	Disability days, activity limitations	Self-rated health, mastery, self-esteem	Life expectancy, leading causes of death
II. Non-medical Determinants of Health			
Health Behaviours	**Living & Working Conditions**	**Personal Resources**	**Environmental Factors**
Tobacco, drugs, alcohol, physical activity, diet	Poverty, education, employment, housing, crime, decision latitude	Early childhood development, social supports, life stresses	Air, water quality, toxic exposures, ecologic integrity
III. Health System Performance			
Acceptability	**Accessibility**	**Appropriateness**	**Competence**
Patient satisfaction	Influenza immunization, mammography, PAP smears, wait time (cardiac)	C-section & vaginal birth after C-section rates	
Continuity	**Effectiveness**	**Efficiency**	**Safety**
	Transplant & cancer survival, TB, HIV, measles, joint replacement, injury	May not require hospitalization, alternate levels of care, average length of stay, surgical day care rates	Hip fractures while in facility
IV. Community & Health System Characteristics			
Demographics, per capita expenditures, health personnel, hospital beds & volumes of service provided.			

Figure 3: The Continuous Quality Improvement (CQI) PDCA Cycle (as developed from Shewhart and Deming[61]).



PREPARED STATEMENT OF JONATHAN HARDING, MEDICAL DIRECTOR, FALLON CLINIC

My name is Jonathan Harding and I am the Medical Director of the Fallon Clinic, based in Worcester, Massachusetts. Fallon Clinic, a multi-specialty medical group practice, is part of the Fallon Healthcare System, which also includes Fallon Community Health Plan and the Fallon Foundation. The health plan is closely integrated with the medical group, as was the case with many of the first managed care plans in the country, and we believe that adherence to this model is one reason why Fallon has been recognized over the years as a leader in health care quality and patient satisfaction. We would like to commend the House Energy and Commerce Committee for holding this hearing, "Reducing Medical Errors: A Review of Innovative Strategies to Improve Patient Safety."

We are committed to providing quality health care to our patients, and we demonstrate this commitment daily. Below are some examples of the initiatives Fallon Clinic has implemented over the past couple of years to enhance patient safety. Unless otherwise noted, all existing projects were funded out of Fallon Clinic operations. There is much more we can do. We know what to do. We know how to do it. We only require resources—in programming, measurement, information technology systems, and/or personnel at many levels—to implement additional programs.

1. *Adverse drug events recurrence prevention:* Once an adverse reaction to a drug, in hospital, nursing home, or from an ambulatory prescription, is identified and reported, the patient should not be inadvertently re-challenged with the same agent. At Fallon Clinic, we trained our physicians, nurses, and others to report any adverse drug event, through a paper reporting process, e-mail, a reporting form on our intranet, an adverse event hotline, and other means. We identified over 500 adverse events in a year, which a clinical pharmacist reviewed. Notations were made in the paper chart, the electronic chart, and in the pharmacy dispensing profile for each patient, so that physicians of any specialty would not prescribe that drug again, and pharmacists would not dispense the drug again to that patient even if prescribed.

This project continues, and we seek to expand it to increase identification of adverse events. While our physicians, case management nurses, and nurse practitioners who detect these events in hospitals and nursing homes are encouraged to report these events, we currently do not get reporting of the events directly from facilities, nor does our prior adverse event information get transmitted to the hospitals where our patients are subsequently hospitalized, and we would like to work to develop those links.

We also have experimented with computerized algorithms which detect potential adverse drug events from pharmacy, laboratory, outpatient medical visit, and inpatient claims data, and flag them for pharmacist review. The key is to only flag prescriptions with a high yield of true adverse events. We would like to expand this study, and further refine and implement these algorithms, to detect and prevent more adverse drug events. We would also like to create linkages to laboratory data to capture even more information, create even more sophisticated algorithms, and detect yet more ADEs. We are allocating $12,000 from two prior awards for our

ADE program to create a laboratory result database, but then must find funding to create, test, and implement the algorithms.

2. *Adverse drug events prevention:* Our adverse drug event prevention system also allowed us to create a database of adverse events, by drug and by type of event. That database identified specific problematic drugs, and we have chartered teams of clinicians to develop programs to prevent such events. Warfarin was the drug with the most adverse events, mostly bleeding. We developed Warfarin prescribing and monitoring guidelines, and trained special Warfarin nurses on implementing these guidelines in the monitoring of patients on this drug. We developed an intranet-based patient dose/test result tracking system so that these nurses can enter their data on each patient on the drug, and so that information is available to the primary care physicians and specialists who treat each patient, at whatever site the patient is seen.

The second most common cause of adverse drug events was diuretic induced electrolyte abnormalities. We would like to implement programs to reduce these errors simultaneously with our efforts to reduce Warfarin errors.

3. *Concurrent drug administration errors prevention:* Our pharmacy network (owned by the medical group) implemented a program of computer screening and flagging of potential duplicate, interacting, contraindicated, or poly-pharmacy prescribing before dispensing. Physicians and pharmacists worked together to develop rules and our Information Services department developed the programs to implement the rules. As a result, before a drug is dispensed to a patient, a pharmacist may get a warning of a potential adverse effect from the drug. The pharmacist can then contact the prescriber to ensure that the prescriber was aware of that potential problem, and to jointly develop an alternative treatment plan if such is warranted.

For several drugs that are often malprescribed, we require prior authorization. This ensures we can enforce drug prescribing guidelines concurrently.

4. We have *retrospective prescribing error prevention programs.* For example, we notify physicians who have prescribed drugs that are relatively contraindicated in certain age groups, especially pediatric and geriatric, of that potential drug-age interaction and ask them to reassess them. We perform drug use review, comparing prescribing practices to drug prescribing guidelines and identifying variations. We could do more. We would like to increase the number of drug use reviews. And, we could detect patients on drugs that require laboratory or visit monitoring but for which we have no claim for such monitoring, and notifying physicians of this lapse, before complications ensue.

5. We have *prospective prescribing error prevention programs.* These include development and dissemination of drug prescribing guidelines, notification to physicians of drug recalls, new literature about specific drugs, warnings about common drug interactions or toxicities, and other education about appropriate prescribing. We maintain a telephonic drug information service to provide prescribers a real-time consultation about the best drug therapy given a patient's specific situation.

We would like to institute clinical pharmacist review of the drug profile of new patients to the practice; a brown bag program to identify patients who do not understand their drug regimen; review of the prescriptions of patients who do not fill called-in prescriptions (pharmacist return-to-stock lists) to detect dangerous patient non-compliance; and other programs to ensure patients take the drugs that they need for optimum health.

6. *Maldispensing Error Prevention:* In a small percentage of dispensed drug prescriptions, a patient, a pharmacist, a nurse, or a physician detects an error in the prescription. Perhaps the wrong drug was dispensed to a patient, or a wrong dose or form of the correct drug was given to the patient. In some cases, the wrong instructions were written on the prescription. This occurs for a variety of reasons, including translation errors (if the pharmacist misreads a doctor's handwriting), human error, switched bottles between two patients arriving at the pharmacy at the same time, and for a variety of other causes.

Our pharmacy system monitors and reports dispensing errors by category and site, and feeds this information back to prescribers and dispensers. This allows changes in processes to reduce such errors. Examples of such changes include: giving feedback to physicians about handwriting; encouraging pharmacists to confirm prescriptions verbally in the event of any doubt, confirming the patient's diagnosis to ensure the prescription is appropriate for the patient, reinforcing the need to confirm the patient's identity, changing the location of look-alike and sound-alike drugs to avoid mal-dispensing, and a variety of other interventions.

Tracking such errors also allows us to benchmark our dispensing performance of sites against each other, and against similar information from other organizations, when available.

7. *Chemotherapy administration safety:* Chemotherapy drugs have a narrow therapeutic index. Accurate dosing is critical. Dosing is often based on new and experimental treatment protocols, so that physician and nursing staff are not familiar with the doses. And dosing is often complex, based on weight, body mass index, or other patient specific variables. We established processes to ensure patients get the correct dose dispensed by pharmacy and administered by nursing. This project involves use of specific forms, procedures to double check orders before and after drug mixing, education of pharmacists and nursing staff and medical staff.

8. *Reducing "lost to follow-up"* Current clinical guidelines recommend that patients at high risk of cancer recurrence get specified screening at specified, multiyear intervals. We developed cancer risk registries to track required monitoring of patients who need secondary screening studies, including colonoscopy, PSA, follow-up PAP smears, mammography, chest x ray or CT scan have the recommended test done in the required time interval. If not, reminders are sent to the patients' primary care physicians reminding them of the needed screening test.

The Clinic has expended several hundred thousand dollars to this effort over the past two years. With additional funding, we could expand this program to more diagnoses. We could add additional cancer types in which screening for recurrence with specified tests at specified intervals is recommended. Also, we would like to enter patients with identified small abdominal aortic aneurysms into our registry to ensure they have regular follow-up as indicated by guidelines for care.

The Fallon Clinic maintains a *retrospective Quality Assurance* program to identify, track to resolution, and trend for prioritization and systemic action, episodes of low quality. We maintain an atmosphere of openness to admitting errors, in order to learn of as many such episodes as possible. When the issues are identified, interdepartmental or intradepartmental teams of staff develop systems to prevent the episodes from recurring. This program is expensive to maintain, but is necessary to detect and fix errors that could potentially affect patient safety.

9. The Fallon Clinic maintains a *Peer Review program,* which, on the basis of peer judgments, determines if standards of care have been met in specific cases. When appropriate, corrective actions are taken—focused on the individual or on the systems of care—to prevent recurrence of any breaches in the standard of care. Our systems to assess prior care are overwhelmed by the volume of cases reviewed. We could widen our net of potential referral sources and expand the degree of scrutiny with more resources. We already expend clerical, nursing, and physician resources to review hundreds of cases each year.

10. The Fallon Clinic also maintains a *prospective quality assurance program.* We select important aspects of clinical care for many departments, design or adopt measurements of these aspects of care, and measure our performance against goals, benchmarks, or expectations. If we do not meet our own goals, we take actions—system redesign, education, reminders, or others—to improve our performance. JCAHO mandates such programs for Hospitals, and NCQA-accredited HMOs must have such programs, but these requirements do not apply to physician practices. Our state Department of Public Health does mandate a Patient Care Assessment program, but our quality improvement activities go beyond the requirements of the regulations.

11. *Specialty Clinics:* patients with diseases that are complex and require the involvement of physicians in multiple specialties often must make multiple appointments, receive conflicting advice, or may get referred back and forth between specialists. Even when these obstacles are avoided, a sequence of multiple consultations takes time and may delay appropriate treatment to the detriment of the patient.

The Fallon Clinic has developed multi-specialty clinics for treatment of breast cancer (oncology, surgery, radiation therapy, social services), diabetes (endocrinology, podiatry, diabetic educators), and incontinence (gynecology, urology, and physical therapy). We have plans for several other such clinics—for peripheral vascular disease, infertility, breast cancer diagnosis, chronic pain, and other conditions. We believe that after an initial investment of management and physician time, and marketing, these multidisciplinary clinics will be self-sustaining. The only limitation to the development of such clinics is the start-up investment of management and staff time.

We would also like to develop an intranet based *obstetrical registry* to ensure that physicians and midwives have access to clinical assessment and laboratory data on patients at any site they are seen, including outpatient offices and the Labor and Delivery suite. This will ensure that clinical information is available when patients present with pre-term labor, even when offices are closed. It will also allow us to correlate obstetrical outcomes with pre-natal care processes. While Fallon Clinic has historically had low prematurity and low birth weight rates compared to national averages, this registry may allow us to improve further upon this record.

There are many, many ideas in the marketplace of patient safety initiatives; ideas are not the rate-limiting step in implementing medical error reduction. What we need is a commitment to reducing the incidence rate of medical errors and the resources to make patient safety a reality. At Fallon, I believe we have a high level of such commitment. We also devote a steadily increasing amount of resources to safety programs, and are fortunate to be able to count on some project aid in addition to our own outlays in order to fund them. However, we are limited—as are the rest of the provider community and the health plans—by the economics of health care delivery these days: too few reimbursement dollars for an ever-increasing level of demand. We look forward to a solution to this resource constraint in the form of a policy commitment at the national level to help the medical community reduce medical errors. With that support we can put in place the measures that we know will save lives. I want to thank the members of the committee for putting this matter on the national agenda.

PREPARED STATEMENT OF PREMIER, INC.

Premier, Inc., a strategic alliance of leading not-for-profit hospitals and health systems nationwide, appreciates the opportunity to share our perspectives on healthcare quality, patient safety, and adverse medical events. There are, perhaps, no issues of greater significance in the healthcare arena today than the sustained improvement of care quality and the reduction of systemic error. We thank Health Subcommittee Chairman Mike Bilirakis (R-FL) and Ranking Member Sherrod Brown (D-OH) for holding today's hearing.

The 1999 Institute of Medicine report, *To Err is Human,* and its 2001 sequel, *Crossing the Quality Chasm,* engendered a maelstrom of public attention on medical errors and patient safety. Initially, public policy debate coalesced around the controversial notion of mandatory versus voluntary reporting of medical errors and adverse drug events (ADEs). Subsequent discussion was diverted from rhetorical, litigious finger-pointing and individual blame in favor of more pointed analysis of systemic shortcomings and cultural reform.

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. In the drive for sustained medical error reduction, the importance of education and lessons learned cannot be overstated.

Premier hospitals have long prioritized patient safety and the pursuit of sustained quality improvement in the delivery of care. The IOM reports, and subsequent accounts by other independent organizations, validate our core belief that quality improvement in the health delivery system can be achieved and sustained when multitiered, systemic approaches are employed in support of an open environment that replaces a culture of blame with that of safety, education, information-sharing and the pursuit of technological and clinical innovation.

Support for a non-punitive reporting environment that prioritizes prevention and the correction of systemic shortcomings ought to serve as the launch pad for any congressional action. Premier believes that a comprehensive confidential reporting system—one that does not focus on individual culpability or organizational blame—would effectively facilitate the sharing of safety and error-related information among health organizations, and foster collaboration with other providers.

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 peer institutions, and to determine areas ripe for measurable improvement. In collaboration with the Institute for Healthcare Improvement (IHI), we have launched clinical performance initiatives (CPIs) in such key areas as medication management and adverse drug event (ADE) prevention, and stroke, community-acquired pneumonia, cardiac (coronary artery bypass) care. Armed with comparative data supporting evidence-based evaluation of processes and practices, health systems working together can delve deeper, further and faster into the realm of safer, higher quality healthcare than they ever could alone. As the 1999 IOM report concluded, the core problem in healthcare service delivery is most certainly *not* a lack of effort or conviction on the part of the individuals within those settings. Rather, investigators argued, the systems necessary to foster and facilitate improvement must be developed. Premier's healthcare informatics databases were built with this notion in mind. (As addenda to this statement, please find the commentary of Premier President and CEO Richard Norling, published in the Feb. 18, 2002 *Modern*

Healthcare, and a fact sheet outlining Premier's activities in the sharps safety arena. Both documents offer additional insight into our philosophy of healthcare quality and safety improvement, and detail the initiatives and programs through which we put our philosophy into living, breathing practice.)

The Premier Safety Institute, 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 CPI, for example, integrates new and existing projects to improve patient outcomes by measurably reducing ADEs and supporting drug utilization improvements. The aim of this patient safety collaborative is to reduce the average number of preventable ADEs at participating hospitals by 50 percent by June 2004.

This week, the Safety Institute reported on the results of two six-month field evaluations of safety-equipped syringes and phlebotomy (blood-drawing) devices to better assess clinical efficacy and practitioner preference. The studies were designed to identify safety device performance considerations that would contribute to innovative product design, as well as gain member clinician input for Premier's contracting process. Premier currently leads the industry in offering its hospitals access to sharps safety devices from 15 contracted business partners. The landmark 2000 needlestick safety and prevention legislation, upon whose crafting Premier offered guidance and support, stands as a critical tool in the effort to protect caregivers from injurious needlesticks and blood-borne infections, like HIV and Hepatitis C.

Premier is also a passionate champion of 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. We believe Congress ought to facilitate such implementation as yet another innovative strategy for improving patient safety.

HHS Secretary Tommy Thompson echoed this sentiment last November at a hearing before the full Energy and Commerce Committee on bioterrorism preparedness:

> I have said on several occasions that bar-coding technology has mass potential for safeguarding against medical mistakes. Since September 11, we are all the more aware of how critical it is to shore-up and expedite the healthcare supply chain and delivery function—so we can save more lives, especially in times of crises.

Numerous public and private organizations have engaged in campaigns, programs, and initiatives to foster the desired changes outlined here. 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. One 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 wealth of knowledge and clinical information to be mined from Premier's informatics databases can prove instrumental in this and similar efforts.

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 was gratified to learn that this year, AHRQ plans to zero-in on patient safety; quality and disparity reporting, the translation of research into clinical practice, and consumer education. We support full agency funding for these priorities.

Again, we appreciate this opportunity to provide a statement for the record on issues of such paramount importance as patient safety and care quality.

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