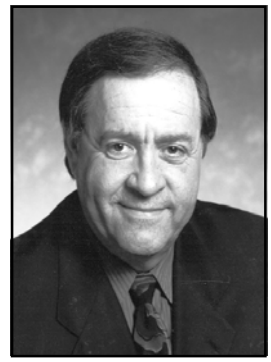

"We are making progress against medical errors but much more effort is needed. . . . No one should ever expect perfection, zero errors, or "six sigma." What we should expect, and what I believe is attainable, are zero patient injuries."

Michael R. Cohen

(2002)

At the time he received this award, Michael R. Cohen was President, Institute for Safe Medication Practices, coeditor of ISMP Medication Safety Alert!, *and adjunct associate professor of pharmacy at Temple University in Philadelphia.*

Prescription for Safety in Health Care

Ladies and gentlemen, officers of ASHP and the Southeastern Michigan Society of Health-System Pharmacists, members of the Whitney Award Selection Committee, and members of the dais: Thank you so much for the honor you are giving me tonight. When I received the telephone call from Dr. Manasse telling me that I had won the Whitney Award, I was completely taken by surprise. I had no idea that I had even been nominated. Although I did secretly harbor at least some hope that one day my colleagues might feel I was worthy of such an honor, the truth is I never really considered myself in the same league as the outstanding pharmacists who are the previous winners. I feel so honored by this award, and I want to

thank everyone in the room tonight and countless others who were unable to attend but who wrote or e-mailed their congratulations for helping me celebrate this accomplishment.

I want to begin by letting you know what a wonderful and supportive family I have. We are extremely close, and they share in the award tonight because almost all of them also happen to work at the Institute for Safe Medication Practices (ISMP)! My wife, Hedy, a registered nurse, is a vice president of ISMP. She is often the person that you speak with if you call to ask for help. As far as I know, she has never turned anyone away—ever—whether a patient or a health professional. Thank you, Hedy. My daughter, Rachel, is project coordinator at ISMP. She is a registered dietitian and therefore also handles drug and nutrition issues. And just to make sure you have a full understanding of the degree to which we support nepotism, my "aunt" Mimi Spiegel handles fulfillment, my mom, Elinore, is a volunteer, and my son-in-law, Neil Brown, helps to prepare certain reports for our board of trustees meetings. They are all here tonight, as is my other daughter, Jennifer, her husband Mitch, my sister Rosanne and brother-in-law, Paul Burnstein, and my uncle, Jerry Orman. Not here are the grandchildren: grandsons Brett and Ethan and granddaughter Sydney. To all of them, I say thanks. I share this honor with you tonight.

Let me also say thanks to my staff. First, for putting up with my family! I also want to give them special thanks for all of the support they have given to me. Most of all, I want to thank them for their creative abilities and hard work. I honestly do not understand how anyone can be so lucky to work with such talented, team-oriented, dedicated people. I want to especially thank the other members of our executive staff besides my wife. These are Allen Vaida, Judy Smetzer, and Susan Proulx, president of our Med-ERRS Division. Without the contributions these people have made and their incredible dedication, we clearly would not be successful in our work. I also want to thank our trustees, especially all of the original members—in particular, George Di Domizio who has played a major role in our success.

I would also like to cite the efforts of ASHP, USP, and FDA, all of which have supported our work in patient safety. Too often, you do not see the behind-the-scenes work that these organizations accomplish in the name of patient safety. I would especially like to thank my friends Jerry Phillips of FDA and Diane Cousins of USP. Jerry has worked hard within the agency to address specific medical product errors through changes in policies that he has personally guided. We are indebted to Jerry for progress that has been made and for other advances that are now underway. Diane has provided steadfast leadership on patient safety issues and reporting programs at USP for many years, and she also established the National Coordinating Council on Medication Error Reporting and Prevention, which has had many accomplishments. Thank you, Diane. Let me also say thanks to those who volunteer their services on our editorial review board. Besides our own staff, every issue of our *ISMP Medication Safety Alert!* is reviewed by at least 5–10 outside reviewers as well as members of our board. Let me thank Dan Sheridan, Tom Burnakis, James Reinhart, John Gosbee, David U, John Senders, Chris Marucci, and Steve Meisel for their ongoing help.

The first person I called after Henri telephoned me was Neil Davis. I can remem-

ber "the" conversation with him in his office at Temple University Hospital in late 1974 about starting a medication error column in the journal *Hospital Pharmacy*. The sole focus of the column was to be what happened, never who did it. He realized that errors were not really about carelessness or being lazy, but instead they were caused by poor systems and processes that set people up to make errors. Neil had already written a first installment (4 U of insulin seen as 40 units was error number 1), and he showed it to me and asked if I would like to use it to initiate an ongoing feature in the journal. The first column was printed in March 1975, and the column is still published today by Facts and Comparisons. Along the way I have met many terrific people in medicine, nursing, and pharmacy. I especially thank Neil for the opportunity he afforded me and for the mentoring that he provided. Without his assistance and support, I would not be standing before you tonight. His foresight has, I believe, as much as anyone's, paved the way for improvements in all aspects of patient safety.

When we first started writing this column, we were faced with many difficulties. From what source would I be able to gather enough material to sustain a monthly column about actual medication errors that had, in many cases, injured a patient or even caused a fatality? Although we promised that all reports would be handled in confidence and published anonymously, why would anyone ever want to risk sharing such information with me, when it might wind up being published? With no track record, why would anyone trust that reporting an error to us would be a safe thing to do? Well, it did not take very long to realize that I had seriously underestimated the level of altruism provided by our colleagues who are pharmacists and pharmacy technicians. They knew right from the very start that by sharing their stories with us so that we could investigate, analyze, and publish their and our prevention recommendations, they provided an opportunity for others to learn from their experience and perhaps prevent another patient from being harmed. From day 1, there has never been a time when we were short on material. And this was 30 years ago, long before it was popular to report errors—long before even the Aviation Safety Reporting Program had gotten under way! Of all the people that we, especially I, have to thank tonight, special recognition goes to those who have placed their trust in us, enough to share their stories and sometimes their grief. Their only motivation is the hope that the information they share will make a difference.

A great deal of progress has been made since those early days. When we began, the culture then was certainly not as it is today. Although Barker, Kimbrough, and Heller[1] had already begun to inspire us with their research and scholarly work on detecting medication errors in hospitals, the subject was still largely a nonissue with the public. There was no *ER,* no *Dateline NBC,* no Institute of Medicine (IOM) report,[2] and no state-mandated reporting programs that made "medication error" a household phrase and struck fear into the hearts of patients everywhere. It was, in many ways, still a perfect world in medicine. Doctors and pharmacists simply did not make mistakes, or so the public thought. In my nursing column, which began in *Nursing 77,* I was not permitted to let patients die. They could experience an error, but they were always brought back. Nurses did not kill anyone. If there was a serious error, they saved them. I also remember receiving discouragement from some in the

hospital community. In one case, a hospital administrator wrote to my hospital CEO to make sure that he knew what I was doing would embarrass hospital staff, scare patients, and prevent patients from seeking care.

I also can well remember, as recently as 1992, when Neil and I agreed to appear on the very first segment of the premiere edition of *Dateline NBC* (March 31, 1992) to discuss several fatal error-related issues. No one spoke openly about medical errors at that time, especially to consumer audiences. That first program aired on a Monday. On *Saturday Night Live*, two days before the premiere, I remember well a 30-second promo that aired nationally. As I watched, I saw my image flash quickly across the TV screen. I was pointing to a large pile of USP and FDA MedWatch reports documenting 70 lidocaine deaths because of a poorly designed syringe that allowed massive overdoses. The announcer blurted, "Join us as we investigate misplaced faith in the medical system. Nearly 100,000 people die every year from a hidden danger—medication errors!" I honestly did not think anyone in medicine would ever talk to me again. In reality, only good came out of it. It was clear that the deaths were due to a syringe system that was flawed, not to careless practitioners. The syringe was soon pulled off the market.

As time went on, more and more people began to understand the system-based cause of medication errors. Publicity about medication errors began to grow. During the mid-1990s, Leape[3] published his famous essay, "Error in Medicine," that described how understanding and applying lessons from human factors could contribute greatly to patient safety. Leape et al.[4] drew additional attention to the problem with their work that tied medication errors to system-based causes. Then, almost simultaneously, a number of high-profile events involving fatal medical errors began to appear in media reports. Incidents in Florida, Massachusetts, and Illinois captured the public's attention as never before. There was now a serious concern in health care about medical error. The IOM then began to develop a series of reports on the quality of health care in America. We learned for the first time that errors made in the course of medical care are one of the leading causes of death, accounting for more lost lives than automobile accidents, breast cancer, or AIDS. Medical error was now out of the closet.

The response to the November 1999 IOM report has been astounding, and we are seeing early progress. Government responded with funding support for research on medical errors. President Clinton signed an executive order calling for government agencies to respond to the IOM report and develop plans for improving the quality of care offered to patients served by federal medical agencies, the Department of Veterans Affairs, and military hospitals. The Quality Interagency Coordination Taskforce was formed to coordinate these government efforts, including new patient safety efforts at FDA. Professional health care organizations, especially pharmacy organizations such as ASHP, have responded in very positive ways to offer support for member efforts to improve patient safety. The pharmaceutical industry has undertaken improvement efforts as well. For example, trademark attorneys now almost always test their product names before submitting their applications to FDA. Technology companies have responded, developing point-of-care drug administration sys-

tems and prescribing systems. Finally, practitioners and the organizations they work within have also responded to the IOM report. Committees have been formed, local and regional efforts have been undertaken between groups of organizations, and much more time and resources are being spent on quality improvement efforts. In short, we have seen unprecedented support for system improvements in health care. In all my years in health care, I cannot recall any other time when the health care community has worked together in such a unified effort. However, we should not be ready to celebrate just yet.

Errors and other adverse events still occur with frequency and cause unbearable human suffering at a tremendous financial cost. Direct-to-consumer prescription drug advertising, the large number of new drugs and technologies, and the proliferation of over-the-counter products introduced every year further complicate medication use, as has an increasingly elderly population with acute and chronic conditions requiring complex treatment strategies. In light of these facts, much can and should still be done to enhance medication safety.

Having been involved in patient safety efforts as a pharmacist and safety advocate for nearly 30 years, I hope that you will not mind if I take the liberty of discussing several focal points where I believe action is specifically needed. Consider this my prescription for safety in health care. Without it, we are unlikely to reach our goal of never harming a patient because of a medical error.

Accountability for error prevention

Accountability is first. Sometimes I marvel at how far we have *not* come on this issue. Even when we seem to understand the system-based causes of errors, it is still hard for many of us to let individuals "off the hook" when they are involved in errors. Some have even suggested that a nonpunitive approach to error reduction could lead to increased carelessness as people learn that they will not be punished for their mistakes. Typically, when an error happens, all accountability falls on individuals at the sharp end of an error where the caregiver–patient interaction occurs. But accountability—not for zero errors but for making patient safety job number 1—should be equally shared among all health care stakeholders. A punitive focus on individuals involved in medical error is dangerous. It inhibits open discussion about errors, creates a defensive and reactive environment, and hinders careful and unbiased consideration of the system-based root causes of errors. Health care systems are further weakened, especially if the sole responsibility for safe medical practices rests upon individuals, compared with strong systems that make it difficult for practitioners to make errors.

Individuals. In part, *Webster's Dictionary* defines accountability as an obligation to provide a satisfactory explanation or to be the cause, driving force, or source. These definitions help us to understand the need for a more appropriate patient safety accountability model. In this model, accountability lies not in performing perfectly but in identifying system weaknesses, implementing system-based solutions, and inspiring and embracing a culture of safety. Individuals in the work force (staff) should be held accountable for speaking out about patient safety issues, voluntarily reporting

errors and hazardous situations, and sharing personal knowledge of what went wrong when an error occurs. They must maintain competency and be willing to change practices to enhance safety and quality. The work force should also be held accountable for working together as a team, not as autonomous individuals.

Health care leaders. Often overlooked is the need for health care leaders to be held equally accountable for making it safe and rewarding for the work force to openly discuss errors and patient safety issues. A nonpunitive approach is not possible unless there is support from top leaders. From pharmacy middle managers to directors and all the way up the leadership chain, people must truly understand that errors are just symptoms of a diseased system, and error prevention efforts must be directed at the weaknesses in the system, not at individuals.

In my way of thinking, leaders must be held accountable for understanding and addressing barriers to safe practice, such as distractions, unsafe workloads, the presence of unsafe equipment, and the availability of unsafe medical products. The work force must be empowered to ask for help when needed. Leaders should position patient safety as a priority in the organization's mission and engage the community and staff in proactive continuous quality improvement (CQI) efforts, including an annual self-assessment of patient safety. Finally, leaders and staff alike need to follow the safety literature continuously and offer visible support to their colleagues who have been involved in errors.

Health care purchasers. This model of shared accountability spreads far beyond the walls of individual health care settings. Others are also accountable for reducing errors. Purchasers of health care should provide incentives and rewards for patient safety initiatives. For example, government and health care insurers must adopt efforts similar to those undertaken by the Leapfrog Group. Leapfrog is a coalition of the nation's largest companies, all of whom purchase health care benefits for their employees. Leapfrog is publicly recognizing hospitals for the adoption of safety improvements that they have identified, such as computerized prescriber order-entry systems.

Industry and regulatory authorities. We have learned much from practitioner reports, including evidence that a large percentage of medication errors are attributable, at least in part, to commercial labeling, packaging, and nomenclature issues. As a result, the U.S. pharmaceutical industry has sufficient information on which to base improvements in the labeling, packaging, and naming of pharmaceuticals aimed at reducing the risk of errors. Therefore, FDA and the companies that produce medical devices, pharmaceutical products, health care computers and software, and other health-related products should be held accountable for premarket evaluation and continuous improvement in the design of devices, products, labels, and packages.

In recent years, FDA has made a commitment to this area, but it is underfunded for this needed effort and must have more resources to accomplish all that is necessary. Products are still being approved with confusing labels and with packages that are poorly designed. Postmarketing, practitioners are frustrated with the length of time it takes to resolve product-related problems. The level of accountability must be raised. When reporters identify a serious label problem that has contributed to re-

peated drug overdoses, the problem must be addressed in a timely fashion. Yet in too many cases, instead of an adequate investigation with a resulting change, we receive a communication from the company to let us know its effort was simply to inform appropriate individuals and enter the information into its database for continued monitoring. Too often companies fail to realize the possibility that a product defect may be contributing to user error.

Even when label or package improvements are made for safety reasons, it often takes many months to reach active inventories as companies wait until old inventory is exhausted. Worst of all, packaging and labeling changes made in the United States are not introduced into worldwide distribution. For example, working with ISMP Canada, we have identified a number of safety issues that have been addressed in the United States but not in Canada, despite fatal errors.[5] If manufacturers and regulators of products used worldwide fail to translate the lessons we have learned in the United States into the wider global market, is there any reason to believe that the United States is benefiting from lessons learned in other countries? Are lessons learned in other countries being translated into industry actions here, or are we just waiting for accidents to happen here in large enough numbers before taking action? Both ISMP Canada and ISMP Spain are committed to working with ISMP in the United States to facilitate efforts with the pharmaceutical industry and regulatory agencies in their respective countries, and we are hoping that we will soon be successful in establishing additional affiliates in other countries.

Both ISMP and ASHP are also frustrated with industry's response to practitioner requests for bar coding of pharmaceutical packages, particularly unit dose packages. For example, of great concern is a recent ISMP survey revealing not only that bar coding of packages is not widely available, but often the unit dose package itself is no longer being provided with products formerly packaged in unit dose form or is not being provided when new products are launched.[6] While FDA is expected to issue a federal mandate shortly to require bar coding of pharmaceutical products, will this lead to an even greater elimination of the unit dose package as companies refuse to commit necessary resources to meet the requirement? Let us hope not.

Academia, professional organizations, and the public. Academia, professional organizations, and the public must also become accountable. Educators should seek patient safety information and incorporate it in new curriculum design. We performed an informal assessment at the end of 2001 and found that only a handful of pharmacy schools required medical error prevention coursework as part of their core curriculum, and only a handful provided an elective course. All professional schools, not just pharmacy schools, should begin to offer courses on medical safety (e.g., human factors, issues surrounding the culture of safety, technology, process design). Otherwise, how will we ever really begin to change our culture and understanding regarding errors? Professional organizations should support local and national voluntary reporting systems and disseminate important patient safety information to their members. The public should be encouraged to ask questions and stay informed about their medical care. But encouragement is not enough. The patient must become a partner in his or her care and not just blindly accept medications and treatments

without a thorough understanding. This may mean that patients will have to wait longer for their prescriptions in order to speak with a pharmacist to review their medications. This is what shared accountability is all about.

Licensing and accrediting bodies. Regulatory, accrediting, and licensing bodies should be held accountable for adopting standards related to error-reduction recommendations that arise from expert analyses of adverse events and scientific research. Rather than have the same mistakes happening again and again throughout the country, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), state pharmacy boards, and others must work to identify the most common serious types of errors, work with licensees and experts to develop prevention recommendations, and provide oversight to assure wide adoption at practice locations. I am happy to say that JCAHO has recently done exactly this with its approach to sentinel events and formation of a Sentinel Event Advisory Group, on which Dr. Manasse and I sit. In addition to their normal patient safety activities, beginning in 2003, hospitals will be held accountable for addressing six JCAHO-specified important safety issues annually. However, many state boards of pharmacy, nursing, and medicine, in their misguided efforts to hold practitioners individually accountable, fail to take an active role themselves in error prevention. Rarely do the boards or state health departments inform practitioners about specific errors or provide oversight to assure that practitioners and organizations are held accountable for addressing system changes that the board has recommended. Anyone who has ever reviewed a state board newsletter can attest to the space devoted to disciplinary actions versus the space devoted to communicating patient safety information.

Organizational leaders and other stakeholders who simply hold the work force accountable when an error happens are inappropriately delegating their own responsibility for patient safety. We must stop blaming and punishing those closest to an error and instead accept a model of shared accountability to collectively translate our sincere concern for patient safety into effective system-based error solutions.

Required CQI activities

Data from the USP–ISMP Medication Error Reporting Program reveal that medication-related problems are repetitive in nature. An incident of misuse in one setting is likely to repeat itself in another. Most importantly, the system changes necessary to prevent errors are similar, and a growing body of literature is available to guide these efforts. Tragically, too many organizations and individual providers do not believe similar incidents could happen to them. They fail to use information about errors occurring elsewhere as a roadmap for improvement in their own organization or practice. It is not until a serious error hits home that aggressive prevention efforts are implemented. With so much evidence-based information about error prevention at hand, there is little excuse for reacting to errors after they happen instead of preventing them. We need to shorten the interval between the lessons learned by errors and the widespread corrective action to prevent future errors.

The development and implementation of CQI efforts should be the highest priority in all pharmacies. Such efforts must be aimed specifically at preventing well-known

and repetitive categories of prescribing and dispensing errors, which erode patient confidence in our health care system. For example, pharmacies should be required to seek medication safety information and use it proactively to prevent medication errors. At the same time, safety issues recognized internally and reported by patients must be documented and analyzed, and a process must be established to determine the best strategies to prevent future problems and ensure implementation. An annual survey to assess consumer perceptions of the quality of pharmaceutical products and professional services might also be required to supply additional information on which to base improvement strategies.

Informational tools like our *ISMP Medication Safety Alert!* publication or ISMP's *Quarterly Action Agenda*, which is a readily available list of medication problems compiled quarterly from our nation's reporting programs, can be a backbone of any CQI effort. The very purpose of the USP–ISMP Medication Error Reporting Program—indeed the purpose of any type of safety reporting program and the expert recommendations that stem from it—is to guide the implementation of quality improvement initiatives by practitioners and organizations. If this is not accomplished, the value of any medical safety reporting program is diminished. Thus, we must ensure that information flowing from error reporting programs is efficiently transformed into learning programs to prevent future errors. Research-based information, anecdotal reports of adverse events, reports from JCAHO's *Sentinel Event Newsletter*, and information from other sources are also instrumental in this effort. ISMP is prepared to assist professional licensing boards, health departments, accreditation agencies, regulatory authorities, and individual organizations in using such informational tools to develop effective CQI strategies that can successfully stop repetitive medical errors.

Practice sites should also be required to conduct self-assessments at least annually to help prioritize improvement projects. In a cooperative project with the American Hospital Association, ISMP developed and distributed the ISMP Medication Safety Self-Assessment to virtually all U.S. hospitals. This weighted self-assessment instrument provides a list of nearly 200 effective medication error-reduction strategies in the general hospital setting. Nearly 1500 hospitals participated fully in the project, which resulted in a large national database of hospital efforts to improve patient safety with medications. This database will allow health care providers to identify areas of weakness and focus improvement activities on system elements and characteristics that are known to be effective for preventing patient harm. We will also be able to track improvement efforts in the nation's hospitals over time by repeating the process at a later date. Recently, the American Pharmaceutical Association Foundation and the National Association of Chain Drug Stores funded our research to develop and implement a similar self-assessment tool for the nation's community pharmacies (chain, independent, and hospital and clinic ambulatory care pharmacies). This effort is now under way. Both efforts were endorsed by ASHP.

While 1500 hospitals completed the hospital assessment and sent data to ISMP, there are over 5000 acute care hospitals in the United States. Through 1000 follow-up telephone calls to a randomized list of hospitals, we learned that many more hospitals would have participated had it not been for advice given to them by some state and

national hospital organizations to seek legal counsel before returning data to us. This letter instilled a renewed fear of discoverability in a future lawsuit, which had a chilling effect on the ability of hospitals to participate in this extremely valuable project. Unless the basic problem, discoverability of information used in quality improvement projects, is addressed by Congress, we will continue to lose valuable opportunities to address costly (both human and financial) patient safety issues. Along with error reports sent to national and state reporting programs, records of quality improvement activities must be afforded protection under available state peer review or other protective statutes and thus protected from discovery during civil litigation. It should be noted that legislation has already been passed in some states to require quality improvement activities in addition to written policies and procedures in the state's pharmacies. A process must be in place to detect and analyze medication errors and disseminate prevention recommendations. Importantly, information that is part of the proceedings and records of review must be protected from discovery. California, Texas, and Florida have quality improvement requirements that include the protective provisions, and several other states are now considering them. This should be a nationwide standard.

Quality improvement requirements should involve all participants in pharmaceutical care, including claims processors and pharmacy benefit managers. Unfortunately, payment policies actually contribute to error. Inadequate payment to pharmacies, lack of standards for claims processing, numerous interruptions, and phone calls for prescription reimbursement adjudication and preapproval have resulted in less available time for drug monitoring and patient education activities. An example of this is requiring pharmacists to dispense drugs at a dose higher than prescribed and making patients split the tablets—an error-prone process—to decrease the cost of a prescription medication.

Surely, CQI activities benefit the health care provider and public since they offer the potential for reducing the number of prescription errors. A study by Ernst and Grizzle[7] provided a recent analysis of prescription drug-use problems in the United States and estimated that drug misuse costs the economy more than $177 billion each year. Also, a recent survey conducted by the Commonwealth Fund reported that more than one in five families had experienced a medical error resulting in a serious problem.[8] Clearly, we must have required quality improvement activities to reduce this unnecessary societal burden.

Conclusion

We are making progress against medical errors but much more effort is needed. An important area of focus is the need for shared accountability among all stakeholders. No one should ever expect perfection, zero errors, or "six sigma." What we should expect, and what I believe is attainable, are zero patient injuries.

(For the complete list of references cited, please see page 1517 of the *American Journal of Health-System Pharmacy,* Aug. 15, 2002.)

Harvey A. K. Whitney Award Lectures (1950–2005)

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