

# Withdrawal/Redaction Sheet

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001. note	re: phone number (1 page)	n.d.	P6/b(6)
002. form	re: Sentinel Event Questionnaire Executive Summary (partial) (1 page)	02/17/2000	P6/b(6)

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**COLLECTION:**

Clinton Presidential Records  
 Domestic Policy Council  
 Devorah Adler  
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**FOLDER TITLE:**

Errors [Folder 4]

2012-0463-S

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### RESTRICTION CODES

**Presidential Records Act - [44 U.S.C. 2204(a)]**

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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- b(1) National security classified information [(b)(1) of the FOIA]
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- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

# Medical Errors Blamed for Many Deaths

*As Many as 98,000 a Year  
In U.S. Linked to Mistakes*

By RICK WEISS  
Washington Post Staff Writer **A1**

As many as 98,000 Americans die unnecessarily every year from medical mistakes made by physicians, pharmacists and other health care professionals, according to an independent report released yesterday that calls for a major overhaul of how the nation addresses medical errors.

More Americans die from medical mistakes than from breast cancer, highway accidents or AIDS, according to the report from the Institute of Medicine, an arm of the National Academy of Sciences. That costs the nation almost \$9 billion a year, the congressionally chartered research group concluded.

Yet while other areas of the U.S. economy have coordinated safety programs that collect and analyze accident trends, including those that track nuclear reactor accidents, highway crashes and airline disasters, there is no centralized system for keeping tabs on medical errors and using that information to prevent future mistakes.

If such a system were put in place, the report predicts, the number of deaths from medical mistakes could be cut in half within five years.

"These stunningly high rates of medical errors, resulting in deaths, permanent disability and unnecessary suffering, are simply unacceptable in a medical system that promises first to 'do no harm,'" said William C. Richardson, president of the W.K. Kellogg Foundation and chairman of the expert committee that compiled the blunt, 223-page report.

Several medical and public policy organizations have addressed the issue of medical errors since the widely reported death of Boston Globe health columnist Betsy Lehman, who died from a chemotherapy overdose in 1995. But experts said the prestige of the National Academy of Sciences, and in particular its specific proposal to create a federal office to oversee medical accident trends and devise strategies for prevention, could spur real change.

"There's not a controversy here," said David Eddy, a senior adviser to the Pasadena-based health mainte-

nance organization Kaiser Permanente Southern California and an expert in evidence-based medicine. "It's an ideal opportunity to increase quality and decrease costs."

Medical errors can range from a simple miscommunication about a drug's name during a telephone call between a doctor and a nurse to the erroneous programming of a complex medical device at the end of a busy hospital night shift. They include wrong diagnoses from mislabeled blood tubes, mistaken treatments because of poorly labeled drugs, improper dosing because of faulty calculations and a simple lack of communication as a patient gets passed from one provider to the next.

To address the wide range of problems, the report calls for mandatory federal reporting requirements for serious medical accidents. And it calls upon Congress to create and fund a national patient safety center within the Department of Health and Human Services, which would be charged with developing better systems for tracking and preventing patient injuries.

The report also suggests that minor medical errors that have not resulted in serious injuries or death be collected in a confidential database, not available for public review. The hope is that by reducing health care providers' legal exposure and the risk of lawsuits, doctors, hospitals and others may be more open about their errors, and thus give the nation a chance to learn from their mistakes.

"Safety is a cultural matter, and unless you create a cultural environment in which it becomes safe to talk about errors and near misses, you can't get to work on the root causes of error," said Donald M. Berwick, a Harvard professor of health care policy and president of the Institute for Healthcare Improvement, a not-for-profit educational and research organization, who was one of 19 experts who worked on the report.

"You can't use fear or blaming of individuals as a foundation for safety improvement," Berwick said. "We want to set up an environment where more errors will be revealed."

The report concludes that most errors are not the result of flagrant recklessness but occur because of the cumulative opportunities for human error that arise in today's

complex medical system. Most are medication errors, Berwick said. "People get the wrong drug or the wrong dose or they get it at the wrong time or it's given to the wrong patient."

Part of the problem is that many new drugs have similar names, which are easily confused when orders are given by voice or are handwritten.

"Physician handwriting has traditionally not been something that has been looked upon highly by calligraphers," said Peter Honig, deputy director of the Food and Drug Administration's office of postmarketing drug risk assessment, the federal unit responsible for tracking medication errors.

Within the past year, Honig said, the FDA has created a "medical errors group" with the explicit job of

preventing medication errors. The team reviews new package designs and proposed names for new drugs to make sure they are not too similar to existing ones. In some cases, companies are also addressing the problem, Honig said. Recent ads in medical journals from the makers of the arthritis drug Celebrex, for example, warn doctors not to confuse their product with the anti-seizure drug Cerebyx or the antidepressant Celexa.

Most serious mistakes occur in busy settings such as emergency rooms and intensive care units, according to the report. In some cases they occur because medicines are kept in stock at concentrations known to be toxic, when they probably should be stored in the diluted forms in which they are intended to be given.

# Bradley: U.S. Spread Too Thin

*Candidate Calls for Fewer Interventions and More Alliances*

By MIKE ALLEN  
Washington Post Staff Writer

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MEDFORD, Mass., Nov. 29— Bill Bradley called today for the United States to reduce its unilateral overseas interventions and instead work with the United Nations and other international organizations to build security in a world that lacks the Cold War's predictability.

"We cannot give an open-ended humanitarian commitment to the world," Bradley said, charting his foreign policy in a discussion with Tufts University students. "The United States has been spread very thin over a wide territory in the world and has not had the impact that we seek to have in places that we do get involved."

Bradley contended that America has neither the resources nor the wisdom to soothe every hot spot. "The key is to get multilateral efforts to intervene earlier, before things reach the point where only there is a military option," he said. "That requires partners in the world to do this, alliances with international organizations."

In a rebuke to Vice President Gore, his rival for the Democratic presidential nomination, Bradley also said that the United States had "missed a real opportunity" in responding to overtures from Rus-

sian leaders in the years since the fall of communism. He said the Clinton administration focused too much on encouraging Russia to adopt domestic economic reforms, instead of pushing for deep reductions in nuclear arms and other weapons.

Though carefully measured, Bradley's comments placed him firmly to the left of Gore and other presidential candidates on foreign policy issues. While Republican frontrunner George W. Bush and other GOP candidates have also criticized the Clinton administration's foreign interventions, Brad-

ley differs from them in calling for greater reliance on the United Nations and other international organizations.

Bradley's call for more extensive and far-reaching negotiations with Russia on arms control and other issues is also distinctive. He said today he would work to negotiate a new missile-reduction treaty with Moscow, even though

the START II treaty reducing nuclear warheads has never been ratified by the Russian parliament. "I am in favor of moving beyond START II, even in the absence of ratification by Russia, to negotiations on START III," he said, giving a goal of reducing arms stocks to 1,000 to 2,000 warheads for each side.

Bradley opposes the immediate deployment of a national missile defense, a step that would require renegotiating or breaking the antiballistic missile treaty with Russia. He favors ongoing research but is concerned about the diplomatic consequences of deployment. Gore has said he wants to negotiate with Russia about the deployment of the system while Bush has said he would build it even over Russian objections.

Bradley endorsed an open world trading system, but said the World Trade Organization should give labor organizations and environmentalists a role in shaping the rules of international commerce, allow such groups to file "friend-of-the-court" briefs in trade disputes and let such organizations participate in subcommittees within the WTO.

But the former senator's most striking comments concerned U.S. interventions abroad, an area where the Clinton administration has built a long and controversial record with missions in Haiti, Bosnia, Kosovo and elsewhere. Robert Kagan, a specialist in foreign policy at the Carnegie Endowment for International Peace, said Bradley "wants to wrap overseas intervention around Al Gore's neck in the same way that Republicans in Congress have wanted to wrap it around President Clinton's neck."

Speaking at the Fletcher School of Law and Diplomacy, which was founded in the midst of the Great Depression in an effort to boost internationalism at a time of isolationism, Bradley described "a disturbing paradox, where we're more powerful than ever before, but we're also more vulnerable to a variety of threats."

"The great risk of nuclear holocaust with the Soviet Union has receded," he said. "But there are a multitude of smaller threats—from troubling dictators like Iraq, to poorly safeguarded nuclear warheads in Russia, to the increasingly dangerous situation on the Korean peninsula to transnational terrorists."

Bradley declared that "in this new world, the next president has an even heavier burden, which is to try to create a comprehensive framework for peace and security and prosperity." He said the United States must work through international institutions to "help mold this international system."

He said that too many United States policies, and even its military strategy, are remnants from those days when enemies were

clear and friends were obvious. "The choices are no longer so stark," he said.

Bradley said he would work to restore one mindset of the Cold War, when "men and women of goodwill in both parties joined together to do what was in America's best interest."

"There was an old saying that political division stopped at the water's edge," he said. "Sadly, that consensus has vanished. Foreign policy has become more of a political football, or is made to score domestic political points. I deplore that. One of the things that I will try to restore if I become president of the United States is a bipartisan foreign policy consensus."

Drawing an implicit contrast with Bush, Bradley said he was comfortable with international affairs and had needed no crash course. "I've been thinking and speaking and writing about foreign policy for more than 20 years," he said.

Bradley had planned to give a formal foreign policy address today, but postponed that to an un-

determined time for reasons his staff would not disclose. Instead he simply outlined the framework of his policy and then answered questions from the students, joking that he would move to the next questioner if he didn't know the answer or thought the inquiry was stupid. At one point, he said that when he was 9 or 10 years old, he had designed his own bomb shelter, marking spaces for a cot, his favorite books and his basketball.

Walter Mead, senior fellow at the Council on Foreign Relations,

said Bradley's approach distinguished him at a time when the other candidates were promoting "an aggressive style of national leadership."

"Bradley is saying that United States influence in the world is greatest, and costs the least, when the United States cooperates with other leading powers," he said.

However, Ted Galen Carpenter, the Cato Institute's vice president for defense and foreign policy studies, said he saw "a fundamental contradiction" in the idea of a more robust United Nations and a more passive United States, given the country's dominance in that organization.

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# NEWS RELEASE

FOR IMMEDIATE RELEASE

# DRAFT

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## AMERICAN HOSPITAL ASSOCIATION LAUNCHES MEDICATION SAFETY CAMPAIGN

Partnering with the Institute for Safe Medication Practices

Washington (December 9, 1999) – In an effort to reduce medication errors in hospitals and health systems the American Hospital Association (AHA) is initiating a medication safety campaign that will help hospitals examine and improve their efforts toward medication error reduction and prevention.

As part of the campaign, the AHA will partner with the Institute for Safe Medication Practices (ISMP), Huntingdon Valley, Pa. – a premier organization in the area of medication error safeguards and reporting. The ISMP will help AHA provide hospital leaders with a checklist of successful practices for reducing errors that can be adopted in every hospital. The checklist is formulated from the work of experts and organizations that have been studying medication error, including ISMP, the Institute for Healthcare Improvement, the Massachusetts Coalition for the Prevention of Medical Errors, the National Coordinating Council on Medication Reporting and Prevention, the National Patient Safety Partnership and many others.

“Our nation’s hospitals deliver the best health care in the world, but we also need to be the best at providing that care with as little risk as possible,” said AHA President Dick Davidson. “It is tragic when any patient’s safety is compromised, and it’s our job to address this. We’re pleased to partner with the Institute for Safe Medication Practices to provide leadership and technical expertise to hospitals.”

The initiative will focus on medication errors, which make up the largest percentage of all medical errors. The commitments of the campaign include:

- Sharing the successful practices list with every hospital and health system.
- Developing a "medication safety awareness test" for use by hospitals developed by ISMP that surveys hospitals' medication error prevention systems.
- Tracking implementation by the hospital and health system field of the practices for reducing and preventing errors on an ongoing basis.
- Working with national experts to develop a model medication error reporting process.
- Serving as a clearinghouse of information and resources for the hospital field on medication error.

"We are delighted to join the AHA on this medication safety effort because it will take commitment from the leaders of hospitals and health systems to bring this issue the attention it deserves," said Michael Cohen, ISMP president. "ISMP already has a system in place that quickly reports medication errors as they occur nationally. Many hospital pharmacists, health care workers and analysts access it regularly. And we will be encouraging hospitals who haven't tapped into this to do so."

The Institute for Safe Medication Practices (ISMP) is a nonprofit organization that works closely with healthcare practitioners and institutions, regulatory agencies, professional organizations and the pharmaceutical industry to provide education about adverse drug events and their prevention. The Institute provides an independent review of medication errors that have been voluntarily submitted by practitioners to a national Medication Errors Reporting Program (MERP) operated by the United States Pharmacopeia (USP). Information from the reports may be used by USP to impact on drug standards. All information derived from the MERP is shared with the U.S. Food and Drug Administration (FDA) and pharmaceutical companies whose products are mentioned in the reports.

The American Hospital Association is a not-for-profit association of health care provider organizations and individuals that are committed to health improvement of their communities.

The AHA is the national advocate for its members, which includes 5,000 hospitals, health care systems, networks, and other providers of care, and 37,000 individuals. Founded in 1898, the AHA provides education for health care leaders and is a source of information on health care issues and trends. For more information, visit the AHA web site at [www.aha.org](http://www.aha.org).

# AHA Quality Advisory

# DRAFT



AHA's Quality Advisory, a service to AHA members, will be produced whenever there is a significant development that affects the job you do in your community.

## Improving Patient Safety by Reducing and Preventing Medication Errors

December 6, 1999

To All AHA Members:

*Primum non nocere.* Above all, do no harm. Healers have lived by this motto for thousands of years. The minimum our patients expect from us is safe and compassionate care when they enter a hospital. And they deserve to get it.

But today, in the complex, high-tech world of medicine, our best intentions can have unwanted consequences. And those consequences are contributing to the public's eroding confidence and trust in the health care system.

Following up on discussions with the AHA Board of Trustees and Regional Policy Boards on improving hospitals' accountability to their communities, the AHA is developing an initiative to help you improve patient safety by reducing and preventing medication errors. To provide leadership and technical expertise in this effort, we have formed a relationship with the Institute for Safe Medication Practices (ISMP), a not-for-profit research and education organization dedicated to reducing the incidence of medication error throughout the health system.

This is what you can expect from us in the coming months.

First, we will provide you with strategic and practical advice to reduce the potential for and incidence of medication error. To jump start this initiative, we are attaching several successful practice recommendations compiled from respected sources.

Next, together with ISMP, we are developing a "Medication Safety Awareness Test" that will help you assess your progress on implementing recommendations in your hospital, and that will enable us to track and demonstrate your success at improving medication safety.

(More)

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The recommendations that follow can greatly improve patient safety. The first set can be implemented immediately; they focus on standardization and simplification of processes that will likely reduce the potential for human error. The second set require changes to existing organizational systems; they will likely require a longer-term implementation plan and may rely on computerization of the physician order-entry and pharmacy dispensing processes.

Here are some ways to get started:

- ◆ Organize a senior management team to review and discuss the attached recommendations. This team could include the CEO, chief medical officer, chief operating officer, chief nurse executive, director of pharmacy, risk manager, director of information systems, and others. Some organizations also include patients on this team. Assess your organization's processes as they compare to the recommendations and track your progress on implementing changes.
- ◆ Review your policies and procedures for reporting and investigating errors. Create an open, non-punitive culture that evaluates and corrects errors.
- ◆ Review information about incidents that occur within your institution and use it to find opportunities for improvement.
- ◆ Make sure your staff takes advantage of the tremendous amount of information available from organizations like the ISMP, the Institute for Healthcare Improvement, the Food and Drug Administration, the U.S. Pharmacopeia, the National Coordinating Council on Medication Error Reporting and Prevention, the National Patient Safety Foundation, and the American Society for Health-System Pharmacists.
- ◆ Please be certain to keep your Board of Trustees and organized medical staff up to date on all the actions you're taking.

Look for more from us in the near future. We'll provide strategic and practical advice on reducing error, and we'll be your clearinghouse for information and resources. We're committed to helping you create a safer, more effective, and more efficient health care system.



Dick Davidson  
President

December 6, 1999

# AHA Quality Advisory

December 6, 1999



## Improving Patient Safety by Reducing and Preventing Medication Errors

### Background

Most of what has been learned in recent years about how to reduce medication error and increase patient safety is based on two principles. First, although errors are committed by individuals, they happen because of the systems in which those individuals work. As a result, reducing error will require us to design and implement more error-resistant systems. Second, we have to create an environment in which we can learn from our mistakes – a safe, non-punitive environment that supports open discussion of errors, their causes, and ways to prevent them.

These principles have a common denominator – they require the leadership and commitment of senior executives and medical staff to create change within our organizations.

### Common Sources of Error

Medication systems in hospitals are complex and multi-layered, involving many steps and many individuals. This complexity ripens the opportunity for error. Error can occur at any stage – prescribing, ordering, dispensing, administering, or monitoring the effects of a medication. According to the Institute for Safe Medication Practices, some common sources of medication error in health systems include:

**Unavailable Patient Information:** Critical patient information (diagnoses, lab values, allergies, drug contradictions, etc.) is often unavailable to pharmacy, nursing, and medical staff prior to dispensing or administering drugs.

**Unavailable Drug Information:** Pharmacists often are not readily available on patient care units and written resources may not be up-to-date, which can lead to dose miscalculations or ignorance of drug interactions. Because errors occur most often during the prescribing and administration stages, accessible drug information must be readily available and close at hand for all staff who prescribe and administer drugs.

**Miscommunication of Drug Orders:** Failed communication is at the heart of many errors. This includes poor handwriting, confusion of drugs with similar names, careless use of zeroes and decimal points, confusion of metric and apothecary systems, use of inappropriate abbreviations, ambiguous or incomplete orders, and, sometimes, conflicts between practitioners.

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**Problems with Labeling, Packaging and Drug Nomenclature:** Most drugs are dispensed through unit dose systems that parse medications into smaller-sized doses. These systems, however, do not always provide for thorough preparation, packaging, and labeling of medications, with screening and checking by both nursing and pharmacy personnel, and they may not be available throughout every unit in the hospital (e.g., ERs and ICUs). Drug administration procedures often do not ensure that medications remain labeled until they reach the patient's bedside, a frequent source of error.

**Drug Standardization, Storage, and Stocking:** Stocking multiple concentrations of the same drug, or storing drugs in look-alike containers or in ways that obscure drug labels, may contribute to error. Lack of safety procedures for use of automated dispensing technology or inadequate check systems may also contribute to errors.

**Drug Device Acquisition, Use and Monitoring:** Lack of standardization in drug delivery devices, improper default settings, unsafe equipment (e.g., free-flow infusion pumps), and the lack of independent check systems for verifying dose and rate settings can all contribute to device-related errors.

**Environmental Stress:** Environmental factors like lighting, heat, noise, and excessive interruptions, can affect individual performance. The process of transcribing orders is particularly vulnerable to distractions in the environment, as staff transcribing orders are exposed to noise, interruptions, non-stop unit activity, and too-long or double shifts.

**Limited Staff Education:** Many practitioners are not as aware as they should be of situations within their own organizations that have been reported as error-prone, or of similar information published in professional literature.

**Limited Patient Education:** Medication use is a multi-step, multidisciplinary process that begins and ends with the patient. Patient education about medications – what they are taking, why they are taking it, and how they should take it – is essential to successful medication administration. Patients can be partners in the prevention of error while hospitalized and need to be educated to safely self-administer medications when they go home.

**Quality Improvement Processes and Risk Management:** Health facilities need systems for identifying, reporting, analyzing, and correcting errors and identifying trends, and measurement systems for tracking the effect of system changes. Also, too few organizations take into consideration information from outside sources about errors that have occurred elsewhere. But above all, health organizations need to cultivate a non-punitive approach to error that will encourage frank identification and analysis of errors when they occur.

### **Steps for Reducing and Preventing Medication**

These potential sources of error can be controlled if we design safer systems. With this in mind, AHA has attached to this advisory a list of successful practices for reducing and preventing medication error and for improving overall patient safety within our hospitals and health systems. We encourage your team to review this list of recommendations, plan for implementation, and begin to track your progress.

### Our Sources

The recommendations were culled from these reliable sources that are leaders in the effort to reduce and prevent medication errors, and we are grateful for their pioneering efforts. They are excellent resources for your organization's reduction and prevention efforts. They include:

- ◆ American Society of Health-System Pharmacists (ASHP) ([www.ashp.org](http://www.ashp.org))
- ◆ Institute for Healthcare Improvement (IHI) ([www.ihl.org](http://www.ihl.org))
- ◆ Institute of Medicine (IOM) ([www.national-academies.org](http://www.national-academies.org))
- ◆ Institute for Safe Medication Practices (ISMP) ([www.ismp.org](http://www.ismp.org))
- ◆ Joint Commission on Accreditation of Healthcare Organizations (JCAHO) ([www.jcaho.org](http://www.jcaho.org))
- ◆ Massachusetts Coalition for the Prevention of Medical Errors ([www.mha-link.org](http://www.mha-link.org))
- ◆ National Coordinating Council on Medication Error Reporting and Prevention (NCCMERP) ([www.nccmerp.org](http://www.nccmerp.org))
- ◆ National Patient Safety Partnership (NPSP)
- ◆ U.S. Pharmacopeia ([www.usp.org](http://www.usp.org))

Further information is available from the resources listed below.

### Books

1. Cohen, Michael R., Ed. *Medication Errors*. Washington, D.C. American Pharmaceutical Association. 1999. *(Contains a special chapter on high-risk medications and dangerous abbreviations; rich with insight and practical advice on reducing the risk of error.)*
2. Corrigan, Janet, et al. *To Err is Human.: Building a Safer Health System*. Washington, D.C.: National Academies Press. 1999. *(Comprehensive overview of the subject of medical error, containing many practical suggestions and recommendations from several trusted sources.)*
3. Leape, Lucian, et al., *Reducing Adverse Drug Events*. Boston, MA: Institute for Healthcare Improvement. 1998. *(Concepts to reduce adverse events and a model for improvement.)*

### Patient Information Brochures

1. *Your Role in Safe Medication Use: A Guide for Patients and Families* is available from the Massachusetts Hospital Association at [www.mhalink.org](http://www.mhalink.org)
2. *Partners in Quality: Taking an Active Role in Your Health Care* is available from the Hospital Association of Pennsylvania at [www.hap2000.org](http://www.hap2000.org)
3. *How to Take Your Medications Safely* is available from the ISMP at [www.ismp.org](http://www.ismp.org)
4. *Just Ask!* is available from the US Pharmacopeia at [www.usp.org](http://www.usp.org)

### Information on Safe Medication Practices

From the Institute for Safe Medication Practices

- ◆ *ISMP Medication Safety Alert!*
- ◆ *Urgent Error Advisories*

From the United States Pharmacopeia

- ◆ *Dangerous Abbreviations*
- ◆ *Practitioner Reporting Alerts*
- ◆ *Drug Quality Alerts*
- ◆ *Look-alike Sound-alike Name Lists*

From the Joint Commission on Accreditation of Healthcare Organizations

- ◆ *Sentinel Event Alerts*

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# ***Successful Practices***

## ***for Medication Error Reduction and Prevention***

### **Immediate changes (process redesign)**

*The following steps can be implemented immediately by hospitals and health systems. They focus on standardization and simplification of medication system processes.*

#### ***Fully implement unit dose systems***

- Maintain and systematically use unit-dose distribution systems (either manufacturer-prepared or repackaged by the pharmacy) for all non-emergency medications throughout the hospital. Unit dose systems should include, in addition to packaging, systems for labeling and order screening.
- Stress the need for dose adjustment in children, older persons, and patients with renal or hepatic impairment.

#### ***Limit the variety of devices and equipment***

- For example, limit the types of general purpose infusion pumps to one or two.

#### ***Develop special procedures and written protocols for high-alert drugs***

- Use a multi-disciplinary approach. These include written guidelines, checklists, dose limits, pre-printed orders, double-checks, special packaging, special labeling, and education.
- Limit the number of possible concentrations for a drug, particularly high-alert drugs like morphine and heparin. Such standardization will allow the use of premixed solutions from manufacturers or centralized preparation of IV medications in the pharmacy.

#### ***Ensure the availability of up-to-date drug information***

- Make updated information on new drugs, infrequently used drugs, and non-formulary drugs easily accessible to clinicians prior to ordering, dispensing, and administering medications (e.g., have pharmacists do rounds with doctors and nurses; distribute newsletters and drug summary sheets; use computer aids; and provide access to formulary systems and other internal resources).
- Review error potential for all new products, including a literature review, before any drug or procedure is approved for use; reassess six months to one year later.

### ***Educate staff***

- Provide physicians, nurses, pharmacists, and all other clinicians involved in the medication administration process with orientation and periodic education on ordering, dispensing, administering, and monitoring medications.
- Distribute information about known drug errors from outside organizations like ISMP and USP.

### ***Educate patients***

- Patients should be educated in the hospital, at discharge, and in ambulatory settings about their medications, what they are taking, why they are taking it, and how to use it safely.
- Encourage patients to ask questions about their medications.
- Encourage health care providers to work with pharmacists on patient education when patients receive certain classes of medications or are discharged on more than five medications.

### ***Ensure the availability of pharmacy expertise***

- Have a pharmacist available on-call when pharmacy does not operate 24-hours a day.
- Make the pharmacist more visible in patient care areas – consider having pharmacy personnel make daily rounds on units, or enter orders directly into computer terminals on patient care units.

### ***Standardize prescribing and communication practices***

- Avoid certain dangerous abbreviations (see ISMP and USP for examples); identify a list of unacceptable abbreviations that will not be used in your institution.
- Include all elements of the order -- dose, strength, units (metric), route, frequency, and rate.
- Use full names (preferable generic).
- Use computerized reminders for look-alike and sound-alike drug names
- Use metric system only.
- Use preprinted order sheets whenever possible in non-computerized order systems.

### ***Standardize multiple processes, such as:***

- Doses
- Times of administration (for example, antibiotics)
- Packaging and labeling
- Storage (for example, placing medications in the same place in each unit)
- Dosing scales (for example, insulin, potassium)
- Protocols for the use and storage of high-alert drugs

## **Longer-term changes (systems redesign)**

*The following steps will require substantial changes to existing organizational systems; they will likely require a longer-term implementation plan and a continual focus on improvement; many of the recommendations rely on computerization in the physician order-entry and pharmacy dispensing processes.*

### ***Develop an effective system to monitor and report adverse drug events***

- Review policies for how your organization encourages reporting and analyzing errors throughout the institution.
- Encourage open communication and feedback.
- Ensure no reprisals for reporting of errors.

### ***Increase the use of computers in the medication administration system***

- Encourage the use of computer-generated or electronic medication administration records.
- Begin planning for implementation of computerized prescriber order entry systems when technically and financially feasible in light of a hospital's existing resources and technological development.
- Consider the use of machine-readable code (i.e., bar coding) in the medication administration process.
- Use computerized drug profiling in the pharmacy.
- Be a demanding customer of pharmacy system software; encourage vendors to incorporate and assist in implementing an adequate standardized set of checks into computerized hospital pharmacy systems (e.g., screening for duplicate drug therapies, patient allergies, potential drug interactions, drug/lab interactions, dose ranges, etc.).

### ***Institute 24-hour pharmacy service if possible ...***

*... alternatively, utilize night formularies and careful drug selection and storage procedures. Resist allowing non-pharmacists to enter the pharmacy.*

# Computerized Realistic Simulation: A Teaching Module for Crisis Management in Radiology

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**OBJECTIVE.** Computerized realistic simulation technology has been used as a training tool in fields such as aviation and military training and in the nuclear power industry. More recently, it has been adapted for use in anesthesia crisis resource management. We describe the effectiveness of a simulation program like that used by anesthesiology departments that we developed to teach radiologists the principles of crisis management.

**MATERIALS AND METHODS.** A mock CT scanner and patient simulator were used to simulate the environment in which radiologists encounter crises. Twenty-four residents attended the training program, four at each half-day session. Two responded to and two observed an initial crisis, after which they attended a lecture and watched a videotape review. The second pair then participated in a different crisis scenario. The scenario order was randomized. All scenarios were videotaped and randomly reviewed by two physicians not involved with the course. The following behavioral qualities of the participating residents were evaluated using a five-point scale, ranging from poor (1) to excellent (5): global assessment, communication skills, use of support personnel, use of resources, and role clarity. Residents then rated the course on a five-point scale using the following criteria: overall course usefulness, attainment of course goals, realism of scenarios, quality of lecture, and quality of videotape review.

**RESULTS.** The trainees who had attended the lecture and watched the videotape review before participating in a scenario consistently scored higher than those who had not in the following areas (score after training/score before training): global assessment, 4.08/2.50; communication skills, 4.09/2.67; use of support personnel, 4.17/3.00; use of resources, 4.00/2.92; and role clarity, 4.17/2.67. Moreover, the participants gave the course the following average ratings: overall usefulness, 4.93; attainment of course goals, 4.78; realism of scenarios, 4.63; quality of lecture, 4.63; and quality of videotape review, 4.85.

**CONCLUSION.** Although the critical assessment of a teaching method is difficult and subjective by nature, the improvement in behavioral performance scores suggests that simulation technology effectively conveyed the principles of crisis management. The course ratings show that the program was well accepted by participants.

Crisis management is not a new concept, although formal training in this field is not typically incorporated into the curriculum of a radiology residency [1]. As radiologists, we may encounter crisis situations in both inpatient and outpatient settings that are often related to the administration of IV contrast agents. As the first physician who is present to examine the patient, we are responsible for the proper initial treatment of the patient. Decisions and actions during the first few minutes of a crisis may critically affect patient outcome.

Effective management of a crisis situation requires both technical and behavioral skills [2]. Technical skills, for the most part, are straightforward and involve understanding and

implementing treatment algorithms. One resource for radiologists is a manual published by the American College of Radiology that is entitled *The Manual on Iodinated Contrast Media* (1998, 3rd ed.), although the techniques described in the manual may have been modified by particular practices at individual institutions. Some institutions also require house and attending staff to be certified in basic life support, advanced cardiac life support, or both.

Despite possessing technical expertise, clinicians will still make errors that may be related to behavioral skills. In fact, an estimated 65-70% of the adverse incidents associated with the administration of anesthesia, like those associated with piloting an airplane, are attributed at some

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level to human error despite the technical expertise of those involved [3]. These skills are an essential component to crisis management but are less amenable to formal teaching. In addition, quantifying the incremental benefit or effectiveness of such a teaching program is difficult.

Realistic simulation is used to teach crisis management skills to a variety of professionals such as pilots, military personnel, firefighters, and nuclear power plant workers [1, 4]. Within the field of medicine, realistic simulation is successfully used to train residents how to administer anesthesia [5-7]. Computerized mannequin simulators enable the simulation of re-creation of the environment in which a real crisis occurs, and the effectiveness of this training tool has been proven [8, 9].

At our institution, computerized realistic simulation has been successfully incorporated into the anesthesiology department's training program. Because we recognize that radiologists are also called on to manage crisis events and that our department does not teach these skills, we developed an analogous program for radiology residents. We sought to evaluate whether improved performance in a simulated crisis could result from attending one training session. Furthermore, we wished to determine if our intensive, hands-on program would be accepted by radiology residents.

**Materials and Methods**

**Simulation Center**

A patient simulator (Eagle Simulation, Binghamton, NY) was fixed to resemble a patient in a CT scanner radiology suite (Fig. 1). Equipment available for use in the room included a power injector, manual and electronic patient monitoring devices, medications, and IV and patient resuscitation supplies. The mannequin was capable of exhibiting real-life physiologic responses such as radial and carotid pulses, pupillary and lid reflexes, and temperature probe readings; in addition, the mannequin generated breathing sounds and those of a person's heart and voice. These attributes were under semiautomated remote control and responded dynamically. IV placement and medication administration is through brachial, antecubital, or forearm veins.

Participants were instructed to approach the mannequin as they would a live patient and to expect the responses described. The control console was located in a separate room. The operator had both direct and televised visualization of the room but could not be seen by the participants.

**Scenarios**

Two scenarios (A and B) were developed. Each scenario was designed to be sufficiently complex to include a variety of potential crises a radiologist may encounter (Appendix 1). The algorithms had branch points that were activated by a specific therapeutic measure administered by the participants. The end-



Fig. 1.—Photograph shows interaction between two residents and CT nurse.

points of a scenario was resolution of the patient's symptoms, stabilization of the patient, transfer of the patient to another unit, or patient death. Both a radiology nurse and technologist were present or available to simulate a typical hospital environment.

**Subjects**

Both radiology residents and fellows involved in administering IV contrast media participated in the training program. The 24 participants were divided into six groups, each of which attended one half-day session at the center. The course was conducted for three consecutive days, and both scenarios A and B were run during each session. The order of the scenarios was reversed after each session so that each scenario occurred with equal frequency (i.e., six times) in the first and second position and to eliminate or average out performance variability that may have been related to the degree of difficulty of a scenario. Two trainees were assigned to manage each scenario, and all scenarios were videotaped for review. The remaining two trainees were allowed to watch the scenarios through a one-way glass window.

Regardless of the order of the scenarios, an intervening review session was held for all trainees. During this session, a videotape of an airplane crash was shown and discussed to highlight the importance of crew behavior in case of a mishap. A lecture and discussion of the principles of crisis management (Appendix 2) followed the videotape. The videotape of the initial scenario was then reviewed and critiqued by all trainees. After this critique, the two trainees who had watched the first scenario managed the second one. All trainees reviewed the videotape of the second scenario. At the completion of a half-day session, the trainees responded anonymously to a written questionnaire on which they rated various subjective parameters related to their perception of the value of the course. A five-point standard ordinal rating scale was used, with scores of 1 to 5 ranging from poor to excellent. The following parameters were rated: overall course usefulness, attainment of course goals, realism of case scenarios, quality of lecture, and quality of videotape review.

**Analysis**

Two reviewers, an anesthesiologist with experience at the simulation center and a radiologist with no affiliation with the center, evaluated the videotapes of the scenarios. The two reviewers were not involved at any level in the radiology simulation

course and were unaware of whether scenarios had occurred before or after the training session. All tapes were independently reviewed twice. The first review was to establish the range of behavioral responses in the entire group of trainees. The second review took place within 1 month of the first review. For the second review, a standard ordinal rating scale of one to five (i.e., poor to excellent) was used to grade the behavioral parameters listed in Appendix 2. The scores of the two reviewers were averaged for each scenario, and the results were then separated by parameter and by when the scenario occurred (i.e., either the scenario that occurred before or the one that occurred after the training session). The Wilcoxon's signed rank test was performed to determine significance of differences. Interobserver variability was expressed as a percentage agreement within one percentage point on the scoring scale.

**Results**

Reviewer agreement was considered good to excellent in the scoring of the behavioral parameters. The ratings were within one point for 73% of the parameters and within two points for 98%.

The behavioral parameters of those participants who were evaluated for scenarios occurring after the review session had higher average scores than those who managed a scenario before attending the review session. The results were the following (behavioral parameter, score after training/score before training): global assessment, 4.08/2.50; communication skills, 4.09/2.67; use of support personnel, 4.17/3.00; use of resources, 4.00/2.92; and clarity of roles, 4.17/2.67. The differences were significant for the following behavioral parameters: global assessment,  $p < .03$ ; use of support personnel,  $p < .03$ ; and use of resources,  $p < .03$ . A trend toward improvement in performance after attending a review session was seen for the following behavioral parameters: clarity of roles ( $p < .06$ ) and communication skills ( $p < .06$ ).

The subjective parameters of the overall usefulness of the course as rated by the 24 participants were uniformly ranked close to excellent. The average score for each parameter was the

## Crisis Management Training Using Computerized Simulation

following: overall course usefulness, 4.93; attainment of course goals, 4.78; realism of case scenarios, 4.63; quality of lecture, 4.63; and quality of videotape review, 4.85.

## Discussion

Simulation technology is successfully used in many fields. Its value as a tool to teach and refine technical and behavioral skills has been proven and is well accepted [2, 3, 8]. With realistic simulation, an attempt is made to re-create all aspects that are associated with a specific event. Other forms of simulation may be more limited, with the goal of the exercise being to teach a single task. Within the medical field, several anesthesiology departments have effectively incorporated this teaching tool into their residency training program. The simulation center at our institution is managed and primarily used by members of the department of anesthesiology.

The department of radiology at our institution manages a didactic program that consists of two classroom lectures in which contrast media use and the detection and treatment of contrast material reactions are reviewed. Because we recognize that behavioral components are important in the management of a crisis and are not easily incorporated into formal training, we adapted the simulation program on the basis of the anesthesiology model for our department. Although a case scenario approach has been used [10], this report, the first in the radiology literature to our knowledge, describes the use of realistic simulation in the training of radiologists to manage crisis. Our findings suggest that improved performance in the management of a crisis results during one training session.

Subjectively, as shown by results of the questionnaires about the training that trainees completed, all trainees enjoyed the course and found it to be a highly worthwhile educational experience. The novel approach was so well received by the participants that we were encouraged to expand its scope. Fully evaluating a new teaching technique such as this one, particularly its impact on performance, is difficult. Although the subjective ratings are an important measure of participant acceptance, these ratings do not necessarily correlate with the effectiveness of the program.

Designing measures of objective performance are challenging because of the subjective nature of the behavioral parameters being assessed. Our approach was to have two independent observers randomly review and score each videotaped session for several defined cri-

teria. The course directors agreed that these criteria represented important behavioral goals of the program. The observers were not involved with the course and did not have knowledge as to whether a particular session was one that had occurred before or after trainees had attended the lecture and videotape review. The results of their evaluations indicate that a program that combines the hands-on experience of realistic simulation with teaching in the principles of crisis management can be effective.

Several limitations are inherent to a study such as this one. Two questions of concern are the following: Will the improvement in performance during the course translate into better real-life decisions? And if so, how long will this effect last? These assessments will require at least the establishment of a performance rating program within the department itself and long-term monitoring of course participants. In addition, to more accurately measure the effects of training, a control group of nonparticipants would need to be similarly followed. This task is daunting and its impracticality may limit such an in-depth investigation.

We have just conducted the second annual course, for which we developed new case scenarios. Resident and fellow trainee participants included an approximately equal number of first-time and second-time attendees. A study of the previous year's attendees who attend training a second time is planned to discern if any residual effects of program participation can be discerned.

Simulation training, by its nature, is expensive and can be labor intensive. The cost increases with the degree of fidelity. We attempted to re-create crisis events encountered by radiologists with close attention to the physical appearance of the environment, functionality of equipment and drugs, and support personnel typically available or involved including one anesthesiologist (who ran the control center of the simulator), one radiologist, one radiology nurse, and one technologist. The cost per trainee for a half-day session in the initial course was approximately \$500. By increasing the number of participants from four to six per half-day, the cost was reduced to \$300 per trainee. This price is close to that of similar courses that do not offer the hands-on experience of a simulation. The simulation training course is continuing-medical-education-approved for which credits are available.

Simulation centers are not widely available, but this factor may not limit their use. Trainees could travel to attend a course at such a center,

just as they would for other courses at scientific or review meetings. The program could be offered as an additional workshop to a radiology department's ongoing course schedule. We are also considering options such as live teleconferencing of crisis events or using videotapes to illustrate the principles being taught. These approaches would make the content of the course available on a more widespread basis and thus also significantly reduce the cost to participants. The trade-off is the loss of the experience of actually being involved in the crisis—an experience that is difficult to quantify.

In summary, this study has shown that realistic simulation technology can be an effective teaching tool for radiology trainees in the principles of crisis management. The course was well regarded by the participants and can successfully be incorporated into a training program.

## Acknowledgment

We wish to thank Steven E. Seltzer for his support and guidance in developing the simulation center course and in editing this manuscript.

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**Scenario A****Patient**

70-year-old man

**Medical History**

Penicillin and bee sting allergies, hypertension, depression

**Medications**

Propranolol hydrochloride, fluoxetine hydrochloride, IV antibiotic

**Indication**

Dyspnea, fever, back pain; differential diagnosis of pneumonia versus ruptured aneurysm

**Study To Be Performed**

CT chest with IV contrast material

**Clinical Progression****Step I**

- Patient presents with progressive dyspnea that leads to laryngeal edema.
- Patient's condition is thought to be related to administration of IV contrast material. Treatment of presumed reaction to contrast material is unsuccessful as long as antibiotic drip is on. Trainees must realize reaction is actually caused by the IV antibiotic administered in the emergency department.

**Step II**

- Patient develops hypotension but has a normal-to-slow heart rate.
- Trainees must recognize that patient is taking beta blocker and be able to distinguish an anaphylactic reaction from a vasovagal reaction.

**Step III**

- Patient develops abdominal pain.
- Trainees must differentiate between a ruptured aneurysm and intestinal angina caused by epinephrine.

**Step IV**

- Technologist informs trainee that IV contrast material was not administered (only if resident fails to detect that power injector is still loaded).
- Trainee must realize that power injector is still loaded.

**Scenario B****Patient**

35-year-old woman

**Medical History**

Diabetes, history of cardiomyopathy, recent cardiac transplantation

**Medications**

Prednisone, glucophage

**Indication**

Follow-up heart transplantation examination

**Study To Be Performed**

CT chest with IV contrast material

**Step I**

- Patient presents for follow-up heart transplantation examination.
- Trainee must tell patient to stop glucophage, order follow-up laboratory tests, and inform referring clinician.

**Step II**

- IV contrast material extravasates during treatment, and patient develops vasovagal reaction.
- Trainees must realize that because the heart transplant lacks the vagus nerve, bradycardia will not respond to atropine.
- Trainee must order administration of IV fluids.

**Step III**

- Patient shows signs of progressive dyspnea.
- Trainee must realize that progressive dyspnea is caused by fluid overload and is not associated with laryngeal edema or bronchospasms from the administration of contrast material.
- Trainee must treat patient with furosemide and morphine, instead of with epinephrine for anaphylaxis.

**Step IV**

- Patient develops respiratory arrest.
- Trainees must call for anesthesia to perform intubation.

**APPENDIX 2: Principles of Crisis Management****Global Assessment**

- Avoids fixations
- Verbally reviews case to ensure clarity
- Generates new ideas

**Communication**

- Addresses patient and coworkers directly
- Uses nonjudgmental language

**Use of Support Personnel**

- Calls for help when appropriate
- Asks for support from personnel who are able to provide such support

**Use of Resources**

- Shows readiness for action
- Proves an understanding of systems
- Exhibits technical knowledge
- Shows ability to get needed supplies and equipment

**Role Clarity**

- Participates as a leader rather than as a follower
- Articulates goals
- Manages event

February 3, 1998

Dean Joseph Martin  
25 Shattuck St., Suite A111  
Boston, MA 02115

Dear Dean Martin:

We are writing to express our enthusiasm for the simulator program at the Center for Medical Simulation and to encourage you and the medical school to further expand support for this program.

We represent the first group of medical students who have had the good fortune to be involved with The Center for Medical Simulation (CMS). As background, the Center was started in the mid-1990s by the anesthesia chiefs at the Harvard teaching hospitals as an innovative way to prepare their residents for the challenges they would be facing in their day-to-day work. Over the following years, the directors began to realize that the Simulator would be valuable to a much wider range of physicians in training. Several departments, including Radiology and Emergency Medicine, have realized the potential of this learning experience and have integrated the Simulator sessions into their residency training programs.

In 1998, the directors at CMS expanded the curriculum to include third year medical students. To demonstrate the value of Simulator-oriented skills to students at an earlier stage of professional development, the CMS staff recruited forty-eight third year medical students in their surgical clerkship at the Beth Israel-Deaconess Medical Center to take part in one simulator session. Subsequently, fifteen students agreed to take part in three additional simulations.

During our first Simulator experience, small teams of us were presented with a patient, Mr. Martin, who had multiple problems relating to volume status. Our pulses raced, even as Mr. Martin's became impalpable, and we were frankly overwhelmed. We could not efficiently collect information. We did not effectively communicate with each other. We failed to recognize and utilize our resources. We could not prioritize or delegate the tasks necessary to care for Mr. Martin adequately. Ultimately, patient care suffered.

We were fortunate that our Simulator education did not end with Mr. Martin's impending demise. Over the subsequent three sessions, we gained competence and confidence. The CMS staff presented us with a framework for successful event management. They taught us multiple techniques for communicating effectively during high stress situations. They emphasized the importance of actively defining task assignments for the efficient use of time and resources. They helped us develop techniques for managing a chaotic and volatile environment.

Using this framework, the life-threatening issues that had bombarded and paralyzed us in the initial session became a series of manageable events. We discovered we could enter daunting situations calmly, devise a coherent strategy as a team, and move forward with a flexible plan of action. Though we worked with different team members during each session, our individual and team effectiveness tangibly improved. By the last sessions, we were working together as effective clinical care teams. We also began to confidently integrate our medical knowledge into these stressful clinical settings. In fact, our experience served as a perfect bridge between classroom learning and clinical education. The Simulator's real-life scenarios demanded rapid, coherent demonstration of our ability to: (1) apply pathophysiology to a clinical situation; (2) generate differential diagnoses; and (3) choose optimum treatment. The debriefing sessions that followed each scenario solidified the connections between theory and practice. It is unfortunately too rare in the first year of clinical education for students to appreciate their own increasing competence. In contrast, these simulator sessions generated immediate feedback that both demonstrated progress and inspired further growth.

The Simulator stands out as our most important educational adventure at Harvard Medical School. We feel empowered by the experience. We now have a framework for clinical event management that will benefit us, our colleagues, and most important, our patients. Already we are beginning to approach acute clinical situations with an organized idea of how to manage them. As we move into our careers, our medical knowledge will increasingly complement the management strategies that we have learned. We cannot imagine entering the profession without this structure.

We urge the medical school to increase support for the Center for Medical Simulation and to help integrate their work into the medical school curriculum. The Simulator approach represents a logical extension of the case-based, cooperative learning method at HMS. The event management skills are teachable, learnable, and applicable to many

situations. The opportunity to apply our knowledge and then to reflect upon the results was invaluable. Ultimately, we hope that every medical student will have this opportunity to learn in such an exciting, enduring, and rewarding way.

Thank you for your time and consideration. Please feel free to contact us with any questions.

Sincerely,



Arash Anoshiravani, HMS IV  
(617) 424-1509



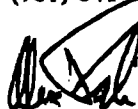
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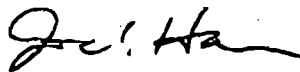


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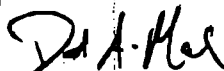
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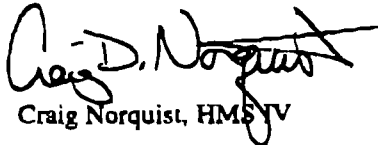
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WHEN DOCTORS MAKE MISTAKES

*The real problem isn't how to stop bad doctors from harming, even killing, their patients. It's how to prevent good doctors from doing so.*

BY ATUL GAWANDE

I—CRASH VICTIM

AT 2 A.M. on a crisp Friday in winter, I was in sterile gloves and gown, pulling a teen-age knifing victim's abdomen open, when my pager sounded. "Code Trauma, three minutes," the operating-room nurse said, reading aloud from my pager display. This meant that an ambulance would be bringing another trauma patient to the hospital momentarily, and, as the surgical resident on duty for emergencies, I would have to be present for the patient's arrival. I stepped back from the table and took off my gown. Two other surgeons were working on the knifing victim: Michael Ball, the attending (the staff surgeon in charge of the case), and David Hernandez, the chief resident (a general surgeon in his last of five years of training). Ordinarily, these two would have come later to help with the trauma, but they were stuck here. Ball, a dry, imperturbable forty-two year-old Texan, looked over to me as I headed for the door. "If you run into any trouble, you call, and one of us will peel away," he said.

I did run into trouble. In telling this story, I have had to change significant details about what happened (including the names of the participants and aspects of my role), but I have tried to stay as close to the actual events as I could while protecting the patient, myself, and the rest of the staff. The way that things go wrong in medicine is normally unseen and, consequently, often misunderstood. Mistakes do happen. We think of them as aberrant; they are anything but. The emergency room was one floor up, and, taking the stairs two at a time, I arrived just as the emergency medical technicians wheeled in a woman who appeared to be in her thirties and to weigh more than two hundred pounds. She lay motionless on a hard orange plastic spinal board—eyes closed, skin pale, blood

running out of her nose. A nurse directed the crew into Trauma Bay 1, an examination room outfitted like an O.R., with green tiles on the wall, monitoring devices, and space for portable X-ray equipment. We lifted her onto the bed and then went to work. One nurse began cutting off the woman's clothes. Another took vital signs. A third inserted a large-bore intravenous line into her right arm. A surgical intern put a Foley catheter into her bladder. The emergency-medicine attending was Samuel Johns, a gaunt, Ichabod Crane-like man in his fifties. He was standing to one side with his arms crossed, observing, which was a sign that I could go ahead and take charge.

If you're in a hospital, most of the "moment to moment" doctoring you get is from residents—physicians receiving specialty training and a small income in exchange for their labor. Our responsibilities depend on our level of training, but we're never entirely on our own: there's always an attending, who oversees our decisions. That night, since Johns was the attending and was responsible for the patient's immediate management, I took my lead from him. But he wasn't a surgeon, and so he relied on me for surgical expertise. "What's the story?" I asked. An E.M.T. rattled off the details: "Unidentified white female unrestrained driver in high-speed rollover. Ejected from the car. Found unresponsive to pain. Pulse a hundred, B.P. a hundred over sixty, breathing at thirty on her own . . ." As he spoke, I began examining her. The first step in caring for a trauma patient is always the same. It doesn't matter if a person has been shot eleven times or crushed by a truck or burned in a kitchen fire. The first thing you do is make sure that the patient can breathe without difficulty. This woman's breaths were shallow and rapid. An oximeter, by means of a sensor placed on her finger, measured the oxygen saturation of her blood. The "%2 sat" is normally more than ninety-five per cent for a patient breathing room air. The woman was wearing a face mask with oxygen turned up full blast, and her sat was only ninety per cent. "She's not oxygenating well," I

*Physicians are meeting behind closed doors in hospitals all over the country to talk candidly about their sometimes deadly errors.*

announced in the flattened-out, wake-me-up-when-something-interesting-happens tone that all surgeons have acquired by about three months into residency. With fingers, I verified that there wasn't any object in her mouth that would obstruct airway; with a stethoscope, I confirmed that neither lung had collapsed. I hold of a bag mask, pressed its clear facepiece over her nose and mouth, and squeezed the bellows, a kind of balloon with a one-way valve, shooting a litre of into her with each compression. After a minute or so, her oxygen came up to a comfortable ninety-eight per cent. She obviously needed our help with breath. "Let's tube her," I said. That meant putting a tube down through her vocal cords and into her trachea, which would insure a clear airway and allow for mechanical ventilation.

Johns, the attending, wanted to do the intubation. He picked up a Mac 3 laryngoscope, a standard but fairly primitive looking L-shaped metal instrument for prying open the mouth and throat, and slipped the shoehornlike blade deep into mouth and down to her larynx. Then he yanked the handle up toward the ceiling to pull her tongue out of the way, her mouth and throat, and reveal the vocal cords, which sit like fleshy tent at the entrance to the trachea. The patient didn't wince or gag: she was still cold.

"Suction!" he called. "I can't see a thing."

He sucked out about a cup of blood and clot. Then he picked up the endotracheal tube—a clear rubber pipe about the diameter of an index finger and three times as long—and tried to guide it between her cords. After a minute, her sat started to fall.

"You're down to seventy per cent," nurse announced. Johns kept struggling with the tube, trying to push it in, but it banged vainly against the cords. The patient's lips began to turn blue.

"Sixty per cent," the nurse said.

Johns pulled everything out of the patient's mouth and fitted the bag mask back on. The oximeter's luminescent-green readout hovered at sixty for a moment and then rose steadily, to ninety-seven per cent. After a few minutes, he took the mask off and again tried to get the tube in. There was more blood, and there may have been some swelling, too: all the poking down the throat was probably not helping. The sat fell to sixty per cent. He pulled out and bagged

her until she returned to ninety-five per cent.

When you're having trouble getting the tube in, the next step is to get specialized expertise. "Let's call anesthesia," I said, and Johns agreed. In the meantime, I continued to follow the standard trauma protocol: completing the examination and ordering fluids, lab tests, and X-rays. Maybe five minutes passed as I worked.

The patient's Sats drifted down to ninety-two per cent—not a dramatic change but definitely not normal for a patient who is being manually ventilated. I checked to see if the sensor had slipped off her finger. It hadn't. "Is the oxygen up full blast?" I asked a nurse.

"It's up all the way," she said.

I listened again to the patient's lungs—no collapse. "We've got to get her tubed," Johns said. He took off the oxygen mask and tried again.

Somewhere in my mind, I must have been aware of the possibility that her airway was shutting down because of vocal cord swelling or blood. If it was, and we were unable to get a tube in, then the only chance she'd have to survive would be an emergency tracheostomy: cutting a hole in her neck and inserting a breathing tube into her trachea. Another attempt to intubate her might even trigger a spasm of the cords and a sudden closure of the airway—which is exactly what did happen.

If I had actually thought this far along, I would have recognized how ill-prepared I was to do an emergency "trache." Of the people in the room, it's true, I had the most experience doing tracheostomies, but that wasn't saying much. I had been the assistant surgeon in only about half a dozen, and all but one of them had been non-emergency cases, employing techniques that were not designed for speed. The exception was a practice emergency trache I had done on a goat. I should have immediately called Dr. Ball for backup. I should have got the trache equipment out—lighting, suction, sterile instruments—just in case. Instead of hurrying the effort to get the patient intubated because of a mild drop in saturation, I should have asked Johns to wait until I had help nearby. I might even have recognized that she was already losing her airway. Then I could have grabbed a knife and started cutting her a tracheostomy while things were still relatively stable and I had time to proceed slowly. But for whatever reasons—hubris, inattention, wishful thinking, hesitation, or the uncertainty of the moment—I let the opportunity pass.

Johns hunched over the patient, intently trying to insert the

tube through her vocal cords. When her sat once again dropped into the sixties, he stopped and put the mask back on. We stared at the monitor. The numbers weren't coming up. Her lips were still blue. Johns squeezed the bellows harder to blow more oxygen in.

"I'm getting resistance," he said.

The realization crept over me: this was a disaster. "Damn it, we've lost her airway," I said. "Trache kit! Light! Somebody call down to O.R. 25 and get Ball up here!"

People were suddenly scurrying everywhere. I tried t not let panic take hold. I told the surgical intern to get a sterile gown and gloves on. I took a bactericidal solution off a shelf and dumped a whole bottle of yellow-brown liquid on the patient's neck. A nurse unwrapped the tracheostomy kit - a sterilized set of drapes and instruments. I pulled on a gown and an new pair of gloves while trying to think through the steps. This is simple, really, I tried to tell myself. At the base of the thyroid cartilage, the Adam's apple, is a little gap in which you find a thin, fibrous covering called the cricothyroid membrane. Cut through that and—voila! You're in the trachea. You slip through the hole a four-inch plastic tube shaped like a plumber's elbow joint, hook it up to oxygen and a ventilator, and she's all set. Anyway, that was the theory.

I threw some drapes over her body, leaving the neck exposed. It looked as thick as a tree. I felt for the bony prominence of the thyroid cartilage. But I couldn't feel anything through the rolls of fat. I was beset by uncertainty—where should I cut? should I make a horizontal or a vertical incision?—and I hated myself for it. Surgeons never dithered, and I was dithering.

"I need better light," I said.

Someone was sent out to look for one.

"Did anyone get Ball?" I asked. It wasn't exactly an inspiring question .

"He's on his way," a nurse said.

There wasn't time to wait. Four minutes without oxygen would lead to permanent brain damage, if not death. Finally, I took the scalpel and cut. I just cut. I made a three-inch left-to-right swipe across the middle of the neck, following the procedure I'd learned for elective cases. I figured that if I worked through the fat I might be able to find the membrane in the wound. Dissecting down with scissors while the intern held the wound open with retractors, I hit a vein. It didn't let loose a lot of blood, but there was enough to fill the

wounds. I couldn't see anything. The intern put a finger on the bleeder. I called for suction. But the suction wasn't working; the tube was clogged with the clot from the intubation efforts. "Somebody get some new tubing," I said. "And where's the light?"

Finally, an orderly wheeled in a tall overhead light, plugged it in, and flipped on the switch. It was still too dim; I could have done better with a flashlight.

I wiped up the blood with gauze, then felt around in the wound with my fingertips. This time, I thought I could feel the hard ridges of the thyroid cartilage and, below it, the slight gap of the cricothyroid membrane, though I couldn't be sure. I held my place with my left hand.

James O'Connor, a silver-haired, seen-it-all anesthesiologist, came into the room. Johns gave him a quick rundown on the patient and let him take over bagging her.

Holding the scalpel in my right hand like a pen, I stuck the blade down into the wound at the spot where I thought the thyroid cartilage was. With small, sharp strokes—working blindly, because of the blood and the poor light—I cut down through the overlying fat and tissue until I felt the blade scrape against the almost bony cartilage. I searched with the tip of the knife, walking it along until I felt it reach a gap. I hoped it was the cricothyroid membrane, and pressed down firmly. Then I felt the tissue suddenly give, and I cut an inch-long opening. When I put my index finger into it, it felt as if I were prying open the jaws of a stiff clothespin. Inside, I thought I felt open space. But where were the sounds of moving air that I expected? Was this deep enough? Was I even in the right place?

"I think I'm in," I said, to reassure myself as much as anyone else.

"I hope so," O'Connor said. "She doesn't have much longer."

I took the tracheostomy tube and tried to fit it in, but something seemed to be blocking it. I twisted it and turned it, and finally jammed it in. Just then, Ball, the surgical attending, arrived. He rushed up to the bed and leaned over for a look. "Did you get it?" he asked. I said that I thought so. The bag mask was plugged onto the open end of the trache tube. But when the bellows were compressed the air just gurgled out of the wound. Ball quickly put on gloves and a gown.

"How long has she been without an airway?" he asked.

"I don't know. Three minutes."

Ball's face hardened as he registered that he had about a minute in which to turn things around. He took my place and summarily pulled out the trache tube. "God, what a mess," he said. "I can't see a thing in this wound. I don't even know if you're in the right place. Can we get better light and suction?" New suction tubing was found and handed to him. He quickly cleaned up the wound and went to work.

The patient's sat had dropped so low that the oximeter couldn't detect it anymore. Her heart rate began slowing down—first to the sixties and then to the forties. Then she lost her pulse entirely. I put my hands together on her chest, locked my elbows, leaned over her, and started doing chest compressions.

Ball looked up from the patient and turned to O'Connor. "I'm not going to get her an airway in time," he said. "You're going to have to try from above." Essentially, he was admitting my failure. Trying an oral intubation again was pointless—just something to do instead of watching her die. I was stricken, and concentrated on doing chest compressions, not looking at anyone. It was over, I thought.

And then, amazingly, O'Connor: "I'm in." He had managed to slip a pediatricsize endotracheal tube through the vocal cords. In thirty seconds, with oxygen being manually ventilated through the tube, her heart was back, racing at a hundred and twenty beats a minute. Her sat registered at sixty and then climbed. Another thirty seconds and it was at ninety-seven per cent. All the people in the room exhaled, as if they, too, had been denied their breath. Ball and I said little except to confer about the next steps for her. Then he went back downstairs to finish working on the stabwound patient still in the O.R.

We eventually identified the woman, whom I'll call Louise Williams; she was thirty-four years old and lived alone in a nearby suburb. Her alcohol level on arrival had been three times the legal limit, and had probably contributed to her unconsciousness. She had a concussion, several lacerations, and significant soft-tissue damage. But X-rays and scans revealed no other injuries from the crash. That night, Ball and Hernandez brought her to the O.R. to fit her with a proper tracheostomy. When Ball came out and talked to family members, he told them of the dire condition she was in when she arrived, the difficulties "we" had had getting access to her airway, the disturbingly long period of time that she had gone without oxygen, and thus his uncertainty about how much brain function she

still possessed. They listened without protest; there was nothing for them to do but wait.

## II—THE BANALITY OF ERROR

To much of the public—and certainly to lawyers and the media—medical error is a problem of bad physicians. Consider some other surgical mishaps. In one, a general surgeon left a large metal instrument in a patient's abdomen, where it tore through the bowel and the wall of the bladder. In another, a cancer surgeon biopsied the wrong part of a woman's breast and thereby delayed her diagnosis of cancer for months. A cardiac surgeon skipped a small but key step during a heart-valve operation, thereby killing the patient. A surgeon saw a man racked with abdominal pain in the emergency room and, without taking a C.T. scan, assumed that the man had a kidney stone; eighteen hours later, a scan showed a rupturing abdominal aortic aneurysm, and the patient died not long afterward.

How could anyone who makes a mistake of that magnitude be allowed to practice medicine? We call such doctors "incompetent," "unethical," and "negligent." We want to see them punished. And so we've wound up with the public system we have for dealing with error: malpractice lawsuits, media scandal, suspensions, firings.

There is, however, a central truth in medicine that complicates this tidy vision of misdeeds and misdoers: *all* doctors make terrible mistakes. Consider the cases I've just described. I gathered them simply by asking respected surgeons I know—surgeons at top medical schools—to tell me about mistakes they had made just in the past year. Every one of them had a story to tell.

In 1991, *The New England Journal of Medicine* published a series of landmark papers from a project known as the Harvard Medical Practice Study—a review of more than thirty thousand hospital admissions in New York State. The study found that nearly four per cent of hospital patients suffered complications from treatment which prolonged their hospital stay or resulted in disability or death, and that two-thirds of such complications were due to errors in care. One in four, or one per cent of admissions, involved actual negligence. It was estimated that, nationwide, a hundred and twenty thousand patients die each year at least partly

as a result of errors in care. And subsequent investigations around the country have confirmed the ubiquity of error. In one small study of how clinicians perform when patients have a sudden cardiac arrest, twenty-seven of thirty clinicians made an error in using the defibrillator; they may have charged it incorrectly or lost valuable time trying to figure out how to work a particular model. According to a 1995 study, mistakes in administering drugs—giving the wrong drug or the wrong dose, say—occur, on the average, about once for every hospital admission, mostly without ill effects, but one per cent of the time with serious consequences.

If error were due to a subset of dangerous doctors, you might expect malpractice cases to be concentrated among a small group, but in fact they follow a uniform, bell-shaped distribution. Most surgeons are sued at least once in the course of their careers. Studies of specific types of error, too, have found that repeat offenders are not the problem. The fact is that virtually everyone who cares for hospital patients will make serious mistakes, and even commit acts of negligence, every year. For this reason, doctors are seldom outraged when the press reports yet another medical horror story. They usually have a different reaction: *That could be me.* The important question isn't how to keep bad physicians from harming patients; it's how to keep good physicians from harming patients.

Medical-malpractice suits are a remarkably ineffective remedy. Troyen Brennan, a Harvard professor of law and public health, points out that research has consistently failed to find evidence that litigation reduces medical-error rates. In part, this may be because the weapon is so imprecise. Brennan led several studies following up on the patients in the Harvard Medical Practice Study. He found that fewer than two per cent of the patients who had received substandard care ever filed suit. Conversely, only a small minority among the patients who did sue had in fact been the victims of negligent care. And a patient's likelihood of winning a suit depended primarily on how poor his or her outcome was, regardless of whether that outcome was caused by disease or unavoidable risks of care.

The deeper problem with medical malpractice suits, however, is that by demonizing errors they prevent doctors from acknowledging and discussing them publicly. The tort system makes adversaries of patient and physician, and pushes each to offer a heavily slanted version of events. When things go wrong, it's almost impossible for a physician to talk to a patient honestly about

mistakes. Hospital lawyers warn doctors that, although they must, of course, tell patients about complications that occur, they are never to intimate that they were at fault, lest the "confession" wind up in court as damning evidence in a black-and-white morality tale. At most, a doctor might say, "I'm sorry that things didn't go as well as we had hoped."

There is one place, however, where doctors can talk candidly about their mistakes, if not with patients, then at least with one another. It is called the Morbidity and Mortality Conference—or, more simply, M. &M.—and it takes place, usually once a week, at nearly every academic hospital in the country. This institution survives because laws protecting its proceedings from legal discovery have stayed on the books in most states, despite frequent challenges. Surgeons, in particular, take the M. &M. seriously. Here they can gather behind closed doors to review the mistakes, complications, and deaths that occurred on their watch, determine responsibility, and figure out what to do differently next time.

### III—SHOW AND TELL

AT my hospital, we convene every Tuesday at five o'clock in a steep, plush amphitheater lined with oil portraits of the great doctors whose achievements we're meant to live up to. All surgeons are expected to attend, from the interns to the chairman of surgery; we're also joined by medical students doing their surgery "rotation." An M. & M. can include almost a hundred people. We file in, pick up a photocopied list of cases to be discussed, and take our seats. The front row is occupied by the most senior surgeons: terse, serious men, now out of their scrubs and in dark suits, lined up like a panel of senators at a hearing. The chairman is a leonine presence in the seat closest to the plain den podium from which each case is presented. In the next few rows are the remaining surgical attendings; these tend to be younger, and several of them are women. The chief residents have put on long white coats and usually sit in the side rows. I join the mass of other residents, all of us in short white coats and green scrub pants, occupying the back rows.

For each case, the chief resident from the relevant service—cardiac, vascular, trauma, and so on—gathers the information, takes the podium, and tells the story. Here's a partial list of cases from a typical week (with a few changes to protect

confidentiality): a sixty-eight-year old man who bled to death after heartvalve surgery; a forty-seven-year-old woman who had to have a reoperation because of infection following an arterial bypass done in her left leg; a forty-four-year-old woman who had to have bile drained from her abdomen after gallbladder surgery; three patients who had to have reoperations for bleeding following surgery; a sixty-three-year-old man who had a cardiac arrest following heart bypass surgery; a sixty-six-year-old woman whose sutures suddenly gave way in an abdominal wound and nearly allowed her intestines to spill out. Ms. William's case, my failed tracheostomy, was just one case on a list like this. David Hernandez, the chief trauma resident, had subsequently reviewed the records and spoken to me and others involved. When the time came, it was he who stood up front and described what had happened.

Hernandez is a tall, rollicking, good old boy who can tell a yarn, but M.& M. presentations are bloodless and compact. He said something like: "This was a thirty-four-year-old female unrestrained driver in a high-speed rollover. The patient apparently had stable vitals at the scene but was unresponsive, and brought in by ambulance unintubated. She was G.C.S. 7 on arrival." G.C.S. stands for the Glasgow Coma Scale, which rates the severity of head injuries, from three to fifteen. G.C.S. 7 is in the comatose range. "Attempts to intubate were made without success in the E.R. and may have contributed to airway closure. A cricothyroidotomy was attempted without success."

These presentations can be awkward. The chief residents, not the attendings, determine which cases to report. That keeps the attendings honest—no one can cover up mistakes—but it puts the chief residents, who are, after all, underlings,

## AN OLD-FASHIONED HIERARCHY

in a delicate position. The successful M. &M. presentation inevitably involves a certain elision of detail and a lot of passive verbs. No one screws up a cricothyroidotomy. Instead, "a cricothyroidotomy was attempted without success." The message, however, was not lost on anyone.

Hernandez continued, "The patient arrested and required cardiac compressions. Anesthesia was then able to place a pediatric E.T. tube and the patient recovered stable vitals. The tracheostomy was then completed in the O.R."

So Louise Williams had been deprived of oxygen long enough to go into cardiac arrest, and everyone knew that meant she could easily have suffered a disabling stroke or been left a vegetable.

Hernandez concluded with the fortunate aftermath: "Her workup was negative for permanent cerebral damage or other major injuries. The tracheostomy was removed on Day 2. She was discharged to home in good condition on Day 3." To the family's great relief, and mine, she had woken up in the morning a bit woozy but hungry, alert, and mentally intact. In a few weeks, the episode would heal to a scar.

But not before someone was called to account. A front-row voice immediately thundered, "What do you mean, 'A cricothyroidotomy was attempted without success?'" I sank into my seat, my face hot.

"This was my case," Dr. Ball volunteered from the front row. It is how every attending begins, and that little phrase contains a world of surgical culture. For all the talk in business schools and in corporate America about the virtues of "flat organizations," surgeons maintain an old-fashioned sense of hierarchy. When things go wrong, the attending is expected to take full responsibility. It makes no difference whether it was the resident's hand that slipped and lacerated an aorta; it doesn't matter whether the attending was at home in bed when a nurse gave a wrong dose of medication. At the M. &M., the burden of responsibility falls on the attending.

Ball went on to describe the emergency attending's failure to intubate Williams and his own failure to be at her bedside when things got out of control. He described the bad lighting and her extremely thick neck, and was careful to make those sound not like excuses but merely like complicating factors. Some attendings shook

their heads in sympathy. A couple of them asked questions to clarify certain details. Throughout, Ball's tone was objective, detached. He had the air of a CNN newscaster describing unrest in Kuala Lumpur.

As always, the chairman, responsible for the over-all quality of our surgery service, asked the final question. What, he wanted to know, would Ball have done differently? Well, Ball replied, it didn't take long to get the stab-wound patient under control in the O.R., so he probably should have sent Hernandez up to the E.R. at that point or let Hernandez close the abdomen while he himself came up. People nodded. Lesson learned. Next case.

At no point during the M. &M. did anyone question why I had not called for help sooner or why I had not had the skill and knowledge that Williams needed. This is not to say that my actions were seen as acceptable. Rather, in the hierarchy, addressing my errors was Ball's role. The day after the disaster, Ball had caught me in the hall and taken me aside. His voice was more wounded than angry as he went through my specific failures. First, he explained, in an emergency tracheostomy it might have been better to do a vertical neck incision; that would have kept me out of the blood vessels, which run up and down—something I should have known at least from my reading. I might have had a much easier time getting her an airway then, he said. Second, and worse to him than mere ignorance, he didn't understand why I hadn't called him when there were clear signs of airway trouble developing. I offered no excuses. I promised to be better prepared for such cases and to be quicker to ask for help. Even after Ball had gone down the fluorescent-lit hallway, I felt a sense of shame like a burning ulcer. This was not guilt: guilt is what you feel when you have done something wrong. What I felt was shame: was what was wrong. And yet I also knew that a surgeon can take such feelings too far. It is one thing to be aware of one's limitations. It is another to be plagued by self-doubt. One surgeon with a national reputation told me about an abdominal operation in which he had lost control of bleeding while he was removing what turned out to be a benign tumor and the patient had died. "It was a clean kill," he said. Afterward, he could barely bring himself to operate. When he did operate, he became tentative and indecisive. The case affected his performance for months.

Even worse than losing self-confidence, though, is reacting defensively. There are surgeons who will see faults everywhere except in themselves. They have no questions and no fears about

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their abilities. As a result, they learn nothing from their mistakes and know nothing of their limitations. As one surgeon told me, it is a rare but alarming thing to meet a surgeon without fear. "If you're not a little afraid when you operate," he said, "you're bound to do a patient a grave disservice."

The atmosphere at the M. & M. is meant to discourage both attitudes—self-doubt and denial—for the M. & M. is a cultural ritual that inculcates in surgeons a "correct" view of mistakes. "What would you do differently?" a chairman asks concerning cases of avoidable complications. "Nothing" is seldom an acceptable answer.

In its way, the M. & M. is an impressively sophisticated and human institution. Unlike the courts or the media, it recognizes that human error is generally not something that can be deterred by punishment. The M. & M. sees avoiding error as largely a matter of will—of staying sufficiently informed and alert to anticipate the myriad ways that things can go wrong and then trying to head off each potential problem before it happens. Why do things go wrong? Because, doctors say, making them go right is hard stuff. It isn't damnable that an error occurs, but there is some shame to it. In fact, the M. & M.'s ethos can seem paradoxical. On the one hand, it reinforces the very American idea that error is intolerable. On the other hand, the very existence of the M. & M., its place on the weekly schedule, amounts to an acknowledgment that mistakes are an inevitable part of medicine.

BUT why do they happen so often? Lucian Leape, medicine's leading expert on error, points out that many other industries—whether the task is manufacturing semiconductors or serving customers at the Ritz-Carlton—simply wouldn't countenance error rates like those in hospitals. The aviation industry has reduced the frequency of operational errors to one in a hundred thousand flights, and most of those errors have no harmful consequences. The buzzword at General Electric these days is "Six Sigma," meaning that its goal is to make product defects so rare that in statistical terms they are more than six standard deviations away from being a matter of chance—almost a one-in-a-million occurrence.

Of course, patients are far more complicated and idiosyncratic than airplanes, and medicine isn't a matter of delivering a fixed product or even a catalogue of products; it may well be more complex than just about any other field of human endeavor. Yet everything we've learned in the past two decades—from cognitive

psychology, from "human factors" engineering, from studies of disasters like Three Mile Island and Bhopal—has yielded the same insights: not only do all human beings err but they err frequently and in predictable, patterned ways. And systems that do not adjust for these realities can end up exacerbating rather than eliminating error.

The British psychologist James Reason argues, in his book "Human Error," that our propensity for certain types of error is the price we pay for the brain's remarkable ability to think and act intuitively—to sift quickly through the sensory information that constantly bombards us without wasting time trying to work through every situation anew. Thus systems that rely on human perfection present what Reason calls "latent errors"—errors waiting to happen. Medicine teems with examples. Take writing out a prescription, a rote procedure that relies on memory and attention, which we know are unreliable. Inevitably, a physician will sometimes specify the wrong dose or the wrong drug. Even when the prescription is written correctly, there's a risk that it will be misread. (Computerized ordering systems can almost eliminate errors of this kind, but only a small minority of hospitals have adopted them.) Medical equipment, which manufacturers often build without human operators in mind, is another area rife with latent errors: one reason physicians are bound to have problems when they use cardiac defibrillators is that the devices have no standard design. You can also make the case that onerous workloads, chaotic environments, and inadequate team communication all represent latent errors in the system.

James Reason makes another important observation: disasters do not simply occur; they evolve. In complex systems, a single failure rarely leads to harm. Human beings are impressively good at adjusting when an error becomes apparent, and systems often have built-in defenses. For example, pharmacists and nurses routinely check and counter-check physicians' orders. But errors do not always become apparent, and backup systems themselves often fail as a result of latent errors. A pharmacist forgets to check one of a thousand prescriptions. A machine's alarm bell malfunctions. The one attending trauma surgeon available gets stuck in the operating room. When things go wrong, it is usually because a series of failures conspire to produce disaster.

The M. &M. takes none of this into account. For that reason, many experts see it as a rather shabby approach to analyzing error

and improving performance in medicine. It isn't enough to ask what a clinician could or should have done differently so that he and others may learn for next time. The doctor is often only the final actor in a chain of events that set him or her up to fail. Error experts, therefore, believe that it's the process, not the individuals in it, which requires closer examination and correction. In a sense, they want to industrialize medicine. And they can already claim one success story: the specialty of anesthesiology, which has adopted their precepts and seen extraordinary results.

IV—NEARLY PERFECT

AT the center of the emblem of the American Society of Anesthesiologists is a single word: "Vigilance." When you put a patient to sleep under general anesthesia, you assume almost complete control of the patient's body. The body is paralyzed, the brain rendered unconscious, and machines are hooked up to control breathing, heart rate, blood pressure—all the vital functions. Given the complexity of the machinery and of the human body, there are a seemingly infinite number of ways in which things can go wrong, even in minor surgery. And yet anesthesiologists have found that if problems are detected they can usually be solved. In the nineteen-forties, there was only one death resulting from anesthesia in every twenty-five hundred operations, and between the nineteen sixties and the nineteen-eighties the rate had stabilized at one or two in every ten thousand operations.

But Ellison (Jeep) Pierce had always regarded even that rate as unconscionable. From the time he began practicing, in 1960, as a young anesthesiologist out of North Carolina and the University of Pennsylvania, he had maintained a case file of details from all the deadly anesthetic accidents he had come across or participated in. But it was one case in particular that galvanized him. Friends of his had taken their eighteen-year-old daughter to the hospital to have her wisdom teeth pulled, under general anesthesia. The anesthesiologist inserted the breathing tube into her esophagus instead of her trachea, which is a relatively common mishap, and then failed to spot the error, which is not. Deprived of oxygen, she died within minutes. Pierce knew that a one-in-ten-thousand death rate, given that anesthesia was administered in the United States an estimated thirty-five million times each year, meant thirty-five

hundred avoidable deaths like that one.

In 1982, Pierce was elected vice-president of the American Society of Anesthesiologists and got an opportunity to do something about the death rate. The same year, ABC's "20/20" aired an expose that caused a considerable stir in his profession. The segment began, "If you are going to go into anesthesia, you are going on a long trip, and you should not do it if you can avoid it in any way. General anesthesia [is] safe most of the time, but there are dangers from human error, carelessness, and a critical shortage of anesthesiologists. This year, six thousand patients will die or suffer brain damage." The program presented several terrifying cases from around the country. Between the small crisis that the show created and the sharp increases in physicians' malpractice-insurance premiums at that time, Pierce was able to mobilize the Society of Anesthesiologists around the problem of error.

He turned for ideas not to a physician but to an engineer named Jeffrey Cooper, the lead author of a groundbreaking 1978 paper entitled "Preventable Anesthesia Mishaps: A Study of Human Factors." An unassuming, fastidious man, Cooper had been hired in 1972, when he was twenty-six years old, by the Massachusetts General Hospital bioengineering unit, to work on developing machines for anesthesiology researchers. He gravitated toward the operating room, however, and spent hours there observing the anesthesiologists, and one of the first things he noticed was how poorly the anesthesia machines were designed. For example, a clockwise turn of a dial decreased the concentration of potent anesthetics in about half the machines but increased the concentration in the other half. He decided to borrow a technique called "critical incident analysis"—which had been used since the nineteen-fifties to analyze mishaps in aviation—in an effort to learn how equipment might be contributing to errors in anesthesia. The technique is built around carefully conducted interviews, designed to capture as much detail as possible about dangerous incidents: how specific accidents evolved and what factors contributed to them. This information is then used to look for patterns among different cases.

Getting open, honest reporting is crucial. The Federal Aviation Administration has a formalized system for analyzing and reporting dangerous aviation incidents, and its enormous success in improving airline safety rests on two cornerstones. Pilots who report an incident within ten days have automatic immunity from punishment, and the

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reports go to a neutral, outside agency, NASA, which has no interest in using the information against individual pilots. For Jeffrey Cooper, it was probably an advantage that he was an engineer, and not a physician, so that anesthesiologists regarded him as a discreet, unthreatening interviewer.

The result was the first in-depth, scientific look at errors in medicine. His

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detailed analysis of three hundred and fifty-nine errors provided a view of the profession unlike anything that had been seen before. Contrary to the prevailing assumption that the start of anesthesia ("takeoff") was the most dangerous part, anesthesiologists learned that incidents tended to occur in the middle of anesthesia, when vigilance waned. The most common kind of incident involved errors in maintaining the patient's breathing, and these were usually the result of an undetected disconnection or misconnection of the breathing tubing, mistakes in managing the airway, or mistakes in using the anesthesia machine. Just as important, Cooper enumerated a list of contributory factors, including inadequate experience, inadequate familiarity with equipment, poor communication among team members, haste, inattention, and fatigue.

The study provoked widespread debate among anesthesiologists, but there was no concerted effort to solve the problems until Jeep Pierce came along. Through the anesthesiology society at first, and then through a foundation that he started, Pierce directed funding into research on how to reduce the problems Cooper had identified, sponsored an international conference to gather ideas from around the world, and brought anesthesia-machine designers into safety discussions.

It all worked. Hours for anesthesiology residents were shortened. Manufacturers began redesigning their machines with fallible human beings in mind. Dials were standardized to turn in a uniform direction; locks were put in to prevent accidental administration of more than one anesthetic gas; controls were changed so that oxygen delivery could not be turned down to zero.

Where errors could not be eliminated directly, anesthesiologists began looking for reliable means of detecting them earlier. For example, because the trachea and the esophagus are so close together, it is almost inevitable that an anesthesiologist will sometimes put the breathing tube down the wrong pipe. Anesthesiologists had always checked for this by listening with a stethoscope for breath sounds over both lungs. But Cooper had turned up a surprising number of mishaps—like the one that befell the daughter of Pierce's friends—involving undetected esophageal intubations. Something more effective was needed. In fact, monitors that could detect this kind of error had been available for years, but, in part because of their expense, relatively few anesthesiologists used them. One type of monitor could verify that the tube was in the

trachea by detecting carbon dioxide being exhaled from the lungs. Another type, the pulse oximeter, tracked blood-oxygen levels, thereby providing an early warning that something was wrong with the patient's breathing system. Prodded by Pierce and others, the anesthesiology society made the use of both types of monitor for every patient receiving general anesthesia an official standard. Today, anesthesia deaths from misconnecting the breathing system or intubating the esophagus rather than the trachea are virtually unknown. In a decade, the over-all death rate dropped to just one in more than two hundred thousand cases—less than a twentieth of what it had been.

And the reformers have not stopped there. David Gaba, a professor of anesthesiology at Stanford, has focussed on improving human performance. In aviation, he points out, pilot experience is recognized to be invaluable but insufficient: pilots seldom have direct experience with serious plane malfunction anymore. They are therefore required to undergo yearly training in crisis simulators. Why not doctors, too? G

Gaba, a physician with training in engineering, led in the design of an anesthesia-simulation system known as the Eagle Patient Simulator. It is a lifesize, computer-driven mannequin that is capable of amazingly realistic behavior. It has a circulation, a heartbeat, and lungs that take in oxygen and expire carbon dioxide. If you inject drugs into it or administer inhaled anesthetics, it will detect the type and amount, and its heart rate, its blood pressure, and its oxygen levels will respond appropriately. The "patient" can be made to develop airway swelling, bleeding, and heart disturbances. The mannequin is laid on an operating table in a simulation room equipped exactly like the real thing. Here both residents and experienced attending physicians learn to perform effectively in all kinds of dangerous, and sometimes freak, scenarios: an anesthesia-machine malfunction, a power outage, a patient who goes into cardiac arrest during surgery, and even a cesarean-section patient whose airway shuts down and who requires an emergency tracheostomy.

Though anesthesiology has unquestionably taken the lead in analyzing and trying to remedy "systems" failures, there are signs of change in other quarters. The American Medical Association, for example, set up its National Patient Safety Foundation in 1997 and asked Cooper and Pierce to serve on the board of directors. The foundation is funding research, sponsoring conferences, and

Simulator

attempting to develop new standards for hospital drug-ordering systems that could substantially reduce medication mistakes—the single most common type of medical error.

Even in surgery there have been some encouraging developments. For instance, operating on the wrong knee or foot or other body part of a patient has been a recurrent, if rare, mistake. A typical response has been to fire the surgeon. Recently, however, hospitals and surgeons have begun to recognize that the body's bilateral symmetry makes these errors predictable. Last year, the American Academy of Orthopedic Surgeons endorsed a simple way of preventing them: make it standard practice for surgeons to initial, with a marker, the body part to be cut before the patient comes to surgery.

The Northern New England Cardiovascular Disease Study Group, based at Dartmouth, is another success story. Though the group doesn't conduct the sort of in-depth investigation of mishaps that Jeffrey Cooper pioneered, it has shown what can be done simply through statistical monitoring. Six hospitals belong to this consortium, which tracks deaths and complications (such as wound infections, uncontrolled bleeding, and stroke) arising from heart surgery and tries to identify various risk factors. Its researchers found, for example, that there were relatively high death rates among patients who developed anemia after bypass surgery, and that anemia developed most often in small patients. The fluid used to "prime" the heart-lung machine caused the anemia, because it diluted a patient's blood, so the smaller the patient (and his or her blood supply) the greater the effect. Members of the consortium now have several promising solutions to the problem. Another study found that a group at one hospital had made mistakes in "handoffs"—say, in passing preoperative lab results to the people in the operating room. The study group solved the problem by developing a pilot's checklist for all patients coming to the O.R. These efforts have introduced a greater degree of standardization, and so reduced the death rate in those six hospitals from four per cent to three per cent between 1991 and 1996. That meant two hundred and ninety-three fewer deaths. But the Northern New England cardiac group, even with its narrow focus and techniques, remains an exception; hard information about how things go wrong is still . There is a hodgepodge of evidence that latent errors and systemic factors may contribute to surgical errors: the lack of standardized protocols, the surgeon's

inexperience, the hospital's inexperience, inadequately designed technology and techniques, thin staffing, poor teamwork, time of day, the effects of managed care and corporate medicine, and so on and so on. But which are the major risk factors? We still don't know. Surgery, like most of medicine, awaits its Jeff Cooper.

## V—GETTING IT RIGHT

IT was a routine gallbladder operation, on a routine day: on the operating table was a mother in her forties, her body covered by blue paper drapes except for her round, antiseptic-coated belly. The gallbladder is a floppy, fingerlength sac of bile like a deflated olive-green balloon tucked under the liver, and when gallstones form, as this patient had learned, they can cause excruciating bouts of pain. Once we removed her gallbladder, the pain would stop.

There are risks to this surgery, but they used to be much greater. Just a decade ago, surgeons had to make a six-inch abdominal incision that left patients in the hospital for the better part of a week just recovering from the wound. Today, we've learned to take out gallbladders with a minute camera and instruments that we manipulate through tiny incisions. The operation, often done as day surgery, is known as laparoscopic cholecystectomy, or "lap chole." Half a million Americans a year now have their gallbladders removed this way; at my hospital alone, we do several hundred lap choles annually.

When the attending gave me the go-ahead, I cut a discreet inch-long semicircle in the wink of skin just above the belly button. I dissected through fat and fascia until I was inside the abdomen, and dropped into place a "port," a half-inch-wide sheath for slipping instruments in and out. We hooked gas tubing up to a side vent on the port, and carbon dioxide poured in, inflating the abdomen until it was distended like a tire. I inserted the miniature camera. On a video monitor a few feet away, the woman's intestines blinked into view. With the abdomen inflated, I had room to move the camera, and I swung it around to look at the liver. The gallbladder could be seen poking out from under the edge.

We put in three more ports through even tinier incisions, spaced apart to complete the four corners of a square. Through the ports on his side, the attending put in two long "graspers," like small-

scale versions of the device that a department-store clerk might use to get a hat off the top shelf. Watching the screen as he maneuvered them, he reached under the edge of the liver, clamped onto the gallbladder, and pulled it up into view. We were set to proceed.

Removing the gallbladder is fairly straightforward. You sever it from its stalk and from its blood supply, and pull the rubbery sac out of the abdomen through the incision near the belly button. You let the carbon dioxide out of the belly, pull out the ports, put a few stitches in the tiny incisions, slap some Band-Aids on top, and you're done. There's one looming danger, though: the stalk of the gallbladder is a branch off the liver's only conduit for sending bile to the intestines for the digestion of fats. And if you accidentally injure this main bile duct, the bile backs up and starts to destroy the liver. Between ten and twenty per cent of the patients to whom this happens will die. Those who survive often have permanent liver damage and can go on to require liver transplantation. According to a standard textbook, "injuries to the main bile duct are nearly always the result of misadventure during operation and are therefore a serious reproach to the surgical profession." It is a true surgical error, and, like any surgical team doing a lap chole, we were intent on avoiding this mistake.

Using a dissecting instrument, I carefully stripped off the fibrous white tissue and yellow fat overlying and concealing the base of the gallbladder. Now we could see its broad neck and the short stretch where it narrowed down to a duct—a tube no thicker than a strand of spaghetti peeking out from the surrounding tissue, but magnified on the screen to the size of major plumbing. Then, just to be absolutely sure we were looking at the gallbladder duct and not the main bile duct, I stripped away some more of the surrounding tissue. The attending and I stopped at this point, as we always do, and discussed the anatomy. The neck of the gallbladder led straight into the tube we were eying. So it had to be the right duct. We had exposed a good length of it without a sign of the main bile duct. Everything looked perfect, we agreed. "Go for it," the attending said.

I slipped in the clip applier, an instrument that squeezes V-shaped metal clips onto whatever you put in its jaws. I got the jaws around the duct and was about to fire when my eye caught, on the screen, a little globule of fat lying on top of the duct. That wasn't necessarily anything unusual, but somehow it didn't look right. With the tip of the clip applier, I tried to flick it aside, but, instead of a

little globule, a whole layer of thin unseen tissue came up, and, underneath, we saw that the duct had a fork in it. My stomach dropped. If not for that little extra fastidiousness, I would have clipped off the main bile duct.

Here was the paradox of error in medicine. With meticulous technique and assiduous effort to insure that they have correctly identified the anatomy, surgeons need never cut the duct. It is a paradigm of an avoidable error. At the same time, studies show that even highly experienced surgeons inflict this terrible injury about once in every two hundred lap choles. To put it another way, I may have averted disaster this time, but a statistician would say that, no matter how hard I tried, I was almost certain to make this error at least once in the course of my career.

But the story doesn't have to end here, as the cognitive psychologists and industrial error experts have demonstrated. Given the results they've achieved in anesthesiology, it's clear that we can make dramatic improvements by going after the process, not the people. But there are distinct limitations to the industrial cure, however necessary its emphasis on systems and structures. It would be deadly for us, the individual actors, to give up our belief in human perfectibility. The statistics may say that someday I will sever someone's main bile duct, but each time I go into a gallbladder operation I believe that with enough will and effort I can beat the odds. This isn't just professional vanity. It's a necessary part of good medicine, even in superbly "optimized" systems. Operations like that lap chole have taught me how easily error can occur, but they've also showed me something else: effort does matter; diligence and attention to the minutest details can save you.

This may explain why many doctors take exception to talk of "systems problems," "continuous quality improvement," and "process reengineering." It is the dry language of structures, not people. I'm no exception: something in me, too, demands an acknowledgment of my autonomy, which is also to say my ultimate culpability. Go back to that Friday night in the E.R., to the moment when I stood, knife in hand, over Louise Williams, her lips blue, her throat a swollen, bloody, and suddenly closed passage. A systems engineer might have proposed some useful changes. Perhaps a backup suction device should always be at hand, and better light more easily available. Perhaps the institution could have trained me better for such crises, could have required me to have operated on a few more goats.

a~

Perhaps emergency tracheostomies are so difficult under any circumstances that an automated device could have been designed to do a better job. But the could-haves are infinite, aren't they? Maybe Williams could have worn her seat belt, or had one less beer that night. We could call any or all of these factors latent errors, accidents waiting to happen.

But although they put the odds against me, it wasn't as if I had no chance of succeeding. Good doctoring is all about making the most of the hand you're dealt, and I failed to do so. The indisputable fact was that I hadn't called for help when I could have, and when I plunged the knife into her neck and made my horizontal slash my best was not good enough. It was just luck, hers and mine, that Dr. O'Connor somehow got a breathing tube into her in time.

There are all sorts of reasons that it would be wrong to take my license away or to take me to court. These reasons do not absolve me. Whatever the limits of the M. & M., its fierce ethic of personal responsibility for errors is a formidable virtue. No matter what measures are taken, medicine will sometimes falter, and it isn't reasonable to ask that it achieve perfection. What's reasonable is to ask that medicine never cease to aim for it.



UNITED STATES SENATE  
WASHINGTON, DC 20510

February 3, 2000

The Honorable Togo West  
Secretary  
U.S. Department of Veterans Affairs  
810 Vermont Avenue, N.W.  
Washington DC 20420

Dear Secretary:

Late last year, the Institute of Medicine found that that preventable medical errors in hospitals are a leading cause of death in our Nation. The Institute found that over half of the adverse medical events that occur each year are preventable, causing the deaths of as many as 98,000 Americans annually and adding as much as \$29 billion to our nation's health care spending.

The IOM stated that "health care is a decade or more behind other high-risk industries in its attention to ensuring basic safety." For example, our health care system has not matched commercial aviation's efforts to ensure basic safety that resulted in eliminating all airline deaths on domestic flights in 1998.

We are concerned that many of the deaths and serious injuries occur in federal programs including Medicare, Medicaid, the Federal Employees Benefits program, Veterans' Health, and the Department of Defense's health care program - Tricare.

In all, these programs account for almost half of the health care expenditures in the United States and cover approximately 90 million beneficiaries. Total deaths in these programs may number in the tens of thousands each year.

As a first step to reform, we are examining the recommendations identified by the Institute of Medicine as "a roadmap to ward a safer health system."

On January 23, the New York Times reported that federal officials have already rejected one of the recommendations in the IOM report -- requiring hospitals to report all deaths and serious injuries. The basis for rejecting this recommendation in isolation from the other recommendations and the status of deliberations on the other recommendations was not described.

Would you please tell us:

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# United States Senate

WASHINGTON, DC 20510

February 3, 2000

The Honorable William S. Cohen  
Secretary of Defense  
The Pentagon  
Washington DC 20301

Dear Mr. Secretary:

Late last year, the Institute of Medicine found that preventable medical errors in hospitals are a leading cause of death in our Nation. The Institute found that over half of the adverse medical events that occur each year are preventable, causing the deaths of as many as 98,000 Americans annually and adding as much as \$29 billion to our nation's health care spending.

The IOM stated that "health care is a decade or more behind other high-risk industries in its attention to ensuring basic safety." We are concerned that many of the deaths and serious injuries occur in federal programs including Medicare, Medicaid, the Federal Employees Benefits program, Veterans' Health, and the Department of Defense's health care program - Tricare.

In total, these programs account for almost half of the health care expenditures in the United States and cover approximately 90 million beneficiaries. Total deaths in these programs may number in the tens of thousands each year.

As a first step to reform, we are examining the recommendations identified by the Institute of Medicine as "a roadmap toward a safer health system."

On January 23, the New York Times reported that some federal officials have already rejected one of the recommendations in the IOM report -- requiring hospitals to report all deaths and serious injuries. The basis for rejecting this recommendation in isolation from the other recommendations and the status of deliberations on the other recommendations was not described. However, we read that the Department of Defense will soon be requiring military hospitals to report medical errors and that such reports will be kept confidential.

In light of these reports, would you please tell us:


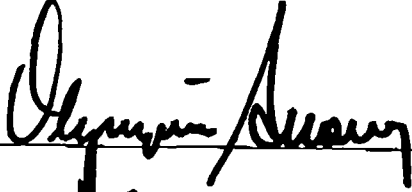
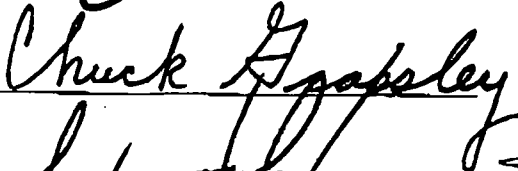
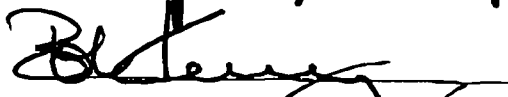
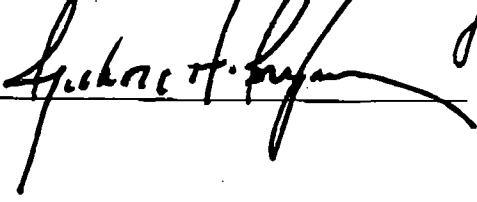

- 1) How many preventable deaths occur each year in the Department of Defense, including how many deaths you expect to occur this year.
- 2) Your plan for achieving the Institute of Medicine's goal of reducing preventable medical error

by fifty percent over the next five years.

3) Your basis for deciding to keep reported medical errors confidential.

Congress and the Administration must take seriously the IOM's goal of reducing medical errors by at least 50 percent over five years. We look forward to hearing from you as quickly as possible.

Sincerely,

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 _____	 _____

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# United States Senate

WASHINGTON, DC 20510

February 3, 2000

The Honorable Donna E. Shalala  
Secretary of Health and Human Services  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington DC 20201

Dear Madam Secretary:

Late last year, the Institute of Medicine found that that preventable medical errors in hospitals are a leading cause of death in our Nation. The Institute found that over half of the adverse medical events that occur each year are preventable, causing the deaths of as many as 98,000 Americans annually and adding as much as \$29 billion to our nation's health care spending.

The IOM stated that "health care is a decade or more behind other high-risk industries in its attention to ensuring basic safety." For example, our health care system has not matched commercial aviation's efforts to ensure basic safety that resulted in eliminating all airline deaths on domestic flights in 1998.

We are concerned that many of the deaths and serious injuries occur in federal programs including Medicare, Medicaid, the Federal Employees Benefits program, Veterans' Health, and the Department of Defense's health care program - Tricare.

In all, these programs account for almost half of the health care expenditures in the United States and cover approximately 90 million beneficiaries. Total deaths in these programs may number in the tens of thousands each year.

As a first step to reform, we are examining the recommendations identified by the Institute of Medicine as "a roadmap to ward a safer health system."

On January 23, the New York Times reported that federal officials have already rejected one of the recommendations in the IOM report -- requiring hospitals to report all deaths and serious injuries. The basis for rejecting this recommendation in isolation from the other recommendations and the status of deliberations on the other recommendations was not described.

Would you please tell us:

- 1) How many preventable deaths occur each year in the federal health programs under your supervision, including how many deaths you expect to occur this year.
- 2) Your basis for accepting or rejecting the Institute of Medicine's recommendations including mandatory reporting of deaths.
- 3) Your plan for achieving the Institute of Medicine's goal of reducing preventable medical error by fifty percent over the next five years.

Congress and the Administration must take seriously the IOM's goal of reducing medical errors by at least 50 percent over five years. We look forward to hearing from you as quickly as possible.

Sincerely,

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Department of Veterans Affairs  
 Veterans Health Administration  
 Office of the Under Secretary for Health  
 810 Vermont Avenue, N.W.  
 Washington, DC 20420  
 Fax: 202.273.7090



Date: 2/2/2000 # of Pages to Follow: 1  
 To: MICHAEL JENNINGS  
DEVORAH ADLER Phone: 202.456.5557 (fax)  
 From: TOM GARTHWRIGHT, VA

Comments: I'M STILL LEARNING ABOUT PATIENT SAFETY — AS  
 A RESULT OF ANOTHER HEARING AND A SESSION AT THE JFK  
 SCHOOL OF GOVT ON MEDICAL ERROR LAST WEEK, I PROVIDE  
 THE ATTACHED AS AN EVOLUTION OF MY THINKING. COPY TO  
 JOHN EISENBERG @ AHRQ/QUIC.

Please call 202.273. 5781 if you have any questions.

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All others are hereby notified that receipt of this message does not waive any applicable privilege or exemption from disclosure and that any dissemination, distribution, or copying of this communication is prohibited.

If you have received this communication in error, please notify us immediately at the telephone number shown above. Thank you.

## Thoughts on Patient Safety

February 2, 2000

The public has a need for:

- a safer system
- disclosure and compensation for injury
- ability to chose a safe system for care

The development of a safer system requires:

- ability of organizations to disclose error without threat of adverse publicity
- ability of individuals in organizations to disclose errors without threat of punishment
- analysis and discussion of mistakes (broad disclosure increases the likelihood of creative and effective solutions)
- implementation of new standards

Six part proposal:

1. Full disclosure of error to patient or family [full disclosure is simply the right thing to do; provides an incentive for just compensation and honest admission as the risk of publicity is dependent on the patient]
2. Mandatory reporting of error to a state and national safety database - either protected by statute from disclosure or reported in de-identified manner [cannot do rates of error as identification is ultimately voluntary and denominator is not measurable – thus, the most honest are likely to appear most error prone; cannot fix problems if they are not identified and shared; would need clear standards for what is to be reported]
3. Separate voluntary reporting system similar to Aviation Safety Reporting System [mandatory and voluntary systems are complementary and in aviation have yielded significantly different information]
4. Rigorous process of analysis of the safety database and formal adoption of new safety standards [requires an open process to identify new standards which every system must implement; might be best to start with a new standard setting body with representation from healthcare organizations *and* patients; recent examples of such standards might include the universal use of pulse oximetry in anesthesia, the removal of concentrated KCl from medical wards, etc.]
5. Required implementation of safety standards [at a minimum, public disclosure of safety standards so patients could ask and select providers based on adherence to those standards; stronger statement might be making adherence to new safety standards a condition of participation in Medicare]
6. Recurring audits [either by existing organizations such as Peer Review Organizations or Joint Commission on Accreditation of Health Care Organizations; or new organizations] with public disclosure of:
  - adherence to policy to disclose errors to the patient or family
  - adherence to mandatory database reporting
  - implementation of safety standards
  - implementation of an effective safety program

Thomas L. Garthwaite, MD





# 'Premium' plasma

## Isn't 'regular' blood safe enough?

**Y**ou've probably heard the horror stories about people who go into the hospital for minor surgery and leave with AIDS or hepatitis from a contaminated blood transfusion. One recent response to the frightening prospect of blood-borne illness: brand-name blood.

The American Red Cross and V.I. Technologies, a biotech firm better known as Vitex, recently placed full-page ads in major Sunday newspapers urging people to "ask your physician for it by name!" "It" is PLAS+SD, the first blood-plasma product bearing a brand name and backed by an ambitious marketing campaign. The Red Cross, which supplies roughly half the nation's blood, has an exclusive agreement to supply Vitex with plasma—the liquid part of the blood, rich in antibodies and clotting compounds—then to distribute the finished product nationwide. The new plasma gets washed in chemicals that de-

stroy any viruses that cause AIDS (by far the deadliest risk from blood) or hepatitis C (by far the most common transfusion risk). The price of the Red Cross' premium plasma: roughly 2½ times the price of regular.

Meanwhile America's Blood Centers, a group of nonprofit blood banks that supply the rest of the nation's blood, has developed a competing product: donor-retested plasma. This plasma is quarantined for several months until the donor is retested for any delayed signs of the worrisome viruses—indicators that might have eluded the first test. Donor-retested plasma costs about 60 percent more than regular. The chance of getting the AIDS or hepatitis C virus from either premium plasma: virtually zero.

But despite all the hubbub about the new plasmas, a third, quieter innovation called nucleic-acid testing (NAT) is actu-

ally more important. The new test can detect the virus itself, not just the telltale signs of the virus, which can take weeks or months to appear. So NAT should radically shrink the old testing loophole—the chance of missing a delayed sign of the virus—that created the need to retest the donors or destroy the viruses in the first place. By the time this issue of CONSUMER REPORTS is

### A new test should slash the chance of viral contamination.

published, virtually all blood in the U.S. will be screened with the new test.

Moreover, washing and retesting are technically feasible only for plasma. But plasma accounts for only about one of every seven units (pints) of blood transfused in the U.S. (Most of the other units contain either red cells, which transport oxygen, or platelets, which help stop bleeding.) In contrast, NAT can spot viruses in *any* component of the blood and can thus help protect everyone who gets a transfusion.

The new blood and the new test raise two crucial questions: How safe is the U.S. blood supply? And is either of the premium plasmas worth the price?

### Dramatic improvement

In the 1970s high rates of hepatitis from transfusions triggered a sweeping re-examination of blood banks' procedures. Most important, the banks stopped collecting blood from paid donors, who were more likely than unpaid donors to be sick.

The advent of AIDS in the early 1980s forced further reforms. The riskiest donors—intravenous-drug abusers and gay men—were asked not to donate or were screened out by questionnaires, interviews, or physical exams. And new tests were developed to detect the AIDS virus in donor blood. The payoffs were huge.

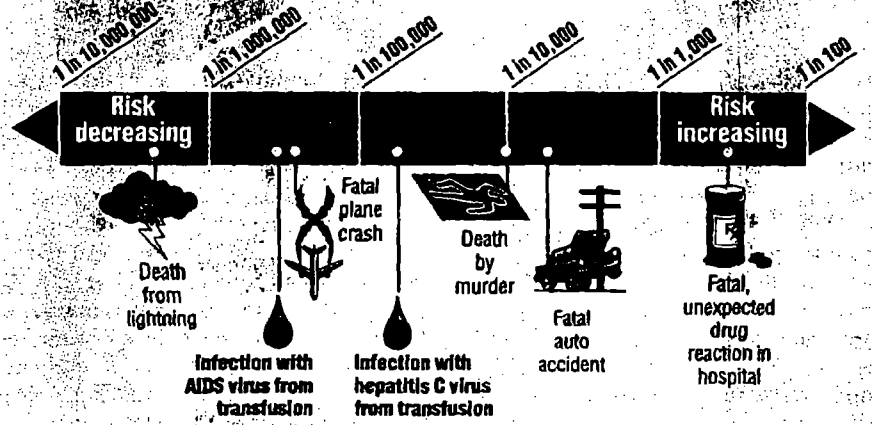
In 1984, the year before blood banks got an AIDS-virus test, 714 transfusion recipients were infected with the disease, according to a 1997 government report. Over the next 12 years, a total of just 38 cases of AIDS were linked to transfusions of blood that had tested negative for the virus—and the vast majority of those cases occurred in the early years,

### What's the risk?

This chart compares the average chances of a hospital patient's being infected from a transfusion against the annual risk of other life-and-death events. Transfusion data are for two units of blood, the amount often given during routine surgery such as knee replacement. (However, some complicated cases—such as heart surgery, care for car-crash victims, or organ transplantation—may require far more units than that.)

The transfusion risks shown here should become even slimmer as nucleic-acid testing is phased in (see story).

As the chart shows, the likelihood of infection from a two-unit blood transfusion is substantially less than the chance of being murdered or of being killed in an auto accident during the year. Indeed, for a hospital patient, the greatest risk shown here is dying from an unexpected adverse reaction to some medication.



Sources: Goodnough, L., et al., *New England Journal of Medicine*, vol. 30, no. 6 (transfusion risks); Lazarou, J., et al., *JAMA*, vol. 279, no. 15 (adverse drug reactions); Laudan, L., *The Book of Risks*, John Wiley, 1994.

Illustrations by Jack Tom

# National Patient Safety Partnership

For more information, contact:  
VA Public Affairs, 202-273-5700

May 12, 1999

## FOR IMMEDIATE RELEASE

### HEALTHCARE LEADERS URGE ADOPTION OF METHODS TO REDUCE ADVERSE DRUG EVENTS

Washington, D.C. – A coalition of healthcare organizations today released recommendations for reducing the occurrence of adverse drug events.

Stressing that this is a problem that neither government nor individual healthcare organizations can solve working alone, Kenneth W. Kizer, M.D., M.P.H., U.S. Department of Veterans Affairs' (VA) Under Secretary for Health, said the public-private National Patient Safety Partnership<sup>1</sup> is urging consumers, healthcare practitioners, healthcare provider organizations and healthcare purchasing cooperatives to adopt successful methods of preventing adverse drug events.

"Treatment-related adverse drug events are a major problem in this country that exact high costs in patient morbidity and mortality as well as dollars," said Dr. Kizer. "The Partnership can make significant patient safety improvements through advocacy of best practices to reduce errors associated with prescribing, purchasing, dispensing and administering of medications."

The patient safety group encouraged healthcare practitioners and healthcare provider organizations to commit to certain best, or model, practices and work together to implement them, in partnership with consumers, patient advocacy groups, and the pharmaceutical industry. Their recommendations follow.

- more -

<sup>1</sup>The NPSP is a voluntary public-private partnership dedicated to reducing preventable adverse medical events. Its members include American Hospital Association\*, American Medical Association\*, American Nurses Association\*, Association of American Medical Colleges\*, Agency for Health Care Policy and Research, Food and Drug Administration, Health Care Financing Administration, Joint Commission on Accreditation of Healthcare Organizations\*, Institute for Healthcare Improvement\*, National Institute for Occupational Safety and Health, National Patient Safety Foundation at the AMA\*, Department of Defense – Health Affairs, and Department of Veterans Affairs\*.

\*Charter Organizations

## Adverse Drug Events -- Page 2

**To reduce the occurrence of adverse drug events** (events that can cause, or lead to, inappropriate medication use and patient harm),

### **Patients can:**

- Tell physicians about all medications they are taking and responses/reactions to them
- Ask for information in terms they understand before accepting medications

### **Providing Organizations and Practitioners can:**

- Educate patients
- Put allergies and medications on patient records
- Stress dose adjustment in children and older persons
- Limit access to high hazard drugs
- Use protocols for high hazard drugs
- Computerize drug order entry
- Use pharmacy-based IV and drug mixing programs
- Avoid abbreviations
- Standardize drug packaging, labeling, storage
- Use "unit dose" drug systems (packaged and labeled in standard patient doses)

### **Purchasers can:**

- Require machine-readable labeling (barcoding)
- Buy drugs with prominent display of name, strength, warnings
- Buy "unit of use" packaging (aka "unit dose")
- Buy IV solutions with two sided labeling

-more-

### Adverse Drug Events -- Page 3

To reduce the potential for taking a medication that was not prescribed for them or cannot be safely taken by them, patients should ask the following five sets of questions before accepting prescription drugs.

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

###

# — National Patient Safety Partnership —

## Statement Regarding Its Initiative to Reduce Preventable Adverse Drug Events

May 12, 1999

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

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

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

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

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

<sup>2</sup> Adapted from the USP Quality Review – Definition of Medication Errors

## **Model Practices to Prevent Adverse Drug Events<sup>3</sup>**

### **Current Best Practices For Patients/Consumers**

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

1. Patients (or their personal advocates) should always inform their physician or other healthcare practitioner of all medications they are taking (NB: This includes prescription medication, over-the-counter medication and dietary supplements.) as well as about any and all allergies or previous adverse drug experiences they have experienced before accepting any new medication. Patients should not assume that information previously provided has been communicated or has been considered prior to a medication being prescribed or administered.
2. Patients (or their personal advocates) should request information about medications in terms that they can understand, both at the time the medication(s) is/are being prescribed and when they are received. This applies to prescription and over-the-counter medications. Patients should ask for information about the intended use or purpose of the drug, possible drug-drug interactions, potential hazards associated with taking several medicines (e.g., more than 3 drugs at the same time), and about changes in the appearance of any medications they have been taking (such as when a prescription refill is a different color from what had previously been taken). Before accepting or receiving a prescription, the patient should always ask the following questions:
  - Is this the drug my doctor (or other health care provider) ordered? What is the trade and generic name of the medication?
  - What is the drug for? What is it supposed to do?
  - How and when am I supposed to take it and for how long?
  - What are the likely side effects? What do I do if they occur?
  - Is this new medication safe to take with other over-the-counter or prescription medications, or dietary supplements, that I am already taking? What food, drink, activities, dietary supplements or other medication should be avoided while taking this medication?

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

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

**Current Best Practices For Providing Organizations and Practitioners**

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

3. Educate patients, family members and other caregivers about all medications (both prescription and over-the-counter, including dietary supplements) that are used. (Emphasis should be placed on the hazards of polypharmacy, drug-drug interactions and possible adverse effects.) Patients and caregivers should be encouraged to ask for information about all medications and dietary supplements, especially when new medications are prescribed or changes in medications are made.
4. Prominently display critical patient information, such as drug allergies and medication regimens, on every patient record.
5. Emphasize the need for dose adjustment in children and elderly patients. In some elderly patients, a reduction in dose may be required because of age-related changes in body mass and organ function.
6. Limit accessibility to and control the use of highly toxic or other high-hazard drugs such as potassium chloride or concentrated epinephrine.
7. Insist on the development and use of protocols for highly toxic or hazardous drugs or those with a narrow therapeutic range. (Computerized drug order entry systems can be especially important in facilitating this with alerts, restrictions or suggestions for safer substitutes.)
8. Computerize drug order entry whenever possible. If computerized drug order entry is not feasible, then use pre-printed order forms for drugs in inpatient settings and, where appropriate, in ambulatory care settings.
9. Utilize pharmacy-based intravenous (IV) admixture programs.
10. Avoid the use of abbreviations whenever possible; if abbreviations are used, they should be standardized throughout the organization and their use minimized.
11. Standardize approaches and processes for drug storage locations, internal packaging or labeling and delivery, and require use of the standardized approaches and processes.
12. Use unit dose drug distribution systems for inpatient care; also use such systems for outpatient care, where appropriate.

**Current Best Practices For Purchasers**

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

13. Require machine-readable labeling, such as a barcoding system, complete with pertinent information such as lot number and expiration date.
14. Preferentially purchase products that have labels with name of drug, concentration and warnings prominently displayed and that otherwise incorporate human factors evaluation into naming, labeling and packaging processes. (For example, the use of large type or contrasting colors to avoid look-alike packaging or unheeded warnings.)
15. Preferentially purchase and utilize "unit of use" packaging in inpatient settings; also use such packaging in outpatient (ambulatory care) settings, where appropriate.
16. Preferentially purchase intravenous (IV) solutions with contents and concentration prominently displayed on both sides of the container.

**Even Better Practices In the Future**

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

**DRAFT: PRESIDENT CLINTON TAKES STRONG NEW STEPS TO IMPROVE  
HEALTH CARE QUALITY AND ENSURE PATIENT SAFETY**

**December 7, 1999**

Today, President Clinton will sign an executive memorandum directing the Federal Quality Interagency Coordination (QuIC) Task Force report back to him in 60 days with an action plan to improve health care quality and ensure patient safety through the prevention of medical errors. The President also directed the Office of Management and Budget, the Domestic Policy Council, and the Department of Health and Human Services to develop health care quality and patient safety initiatives for the FY 2001 budget; directed the Health Care Financing Administration to integrate patient safety initiatives into the Medicare program; and announced a new, multi-million dollar investment in research programs to improve health care quality. In addition, the President praised the American Hospital Association for the strong new steps it is taking, including issuing guidance on preventing medical errors to all 5,000 member hospitals, to improve quality of care and protect patient safety. The new actions being taken by the President today build upon the Clinton-Gore Administration's longstanding commitment to improving health care quality.

**INCONSISTENCIES AND AVOIDABLE ERRORS IN MEDICAL PRACTICE COST LIVES AND UNDERMINE HEALTH.** Ensuring that patients are free from accidental injury and preventing inappropriate or unsuccessful courses of treatment is critically important to both patients and providers. However, inappropriate utilization of services, unnecessary variations in the delivery of health care services, and preventable medical errors at all stages are responsible for tens of thousands of deaths, unnecessary illnesses, and instances of prolonged disability annually.

- **Preventable medical errors.** Over half of the adverse medical events occurring each year are due to preventable medical errors, placing at least 40,000 and as many as 98,000 Americans at unnecessary risk. More people die each year as a result of medical errors than from motor vehicle accidents, breast cancer, or AIDS. A recent study by the Institute of Medicine estimates that the cost associated with these unnecessary errors in lost income, disability, and health care costs is as much as \$29 billion annually. The financial impact of these errors is compounded by the cost of patients' loss of trust in the health care system and the physical and psychological discomfort associated with longer hospital stays or permanent disability.
- **Under-utilization of services.** Early detection and treatment for illnesses prevents unnecessary complications, higher costs, and premature mortality. For instance, despite the fact that early detection of breast cancer can prevent up to 30 percent of breast cancer deaths annually, 30 percent of women aged 52 to 69 do not receive regular mammograms.
- **Overuse of services.** The excessive and unnecessary delivery of health care services can increase costs without improving health and place patients at greater risk for injuries and complications. For example, an analysis of hysterectomies provided by seven managed care plans indicated that 16 percent were unnecessary. In another example, the overuse of

antibiotics imposes unnecessary health care costs and contributes to the emergence of antibiotic-resistant pathogens, causing as much as \$7.5 billion in unnecessary costs annually.

- **Variation in services.** There is a continuing pattern of wide variation in health care practice that cannot be accounted for by differences in the health status of patients, available resources, patient preferences, or clinical uncertainty. For example, the percent of C-section births in Washington state hospitals ranged from 0 to 43 percent. In another example, hospital discharge rates and lengths of stay in the Northeast were over 40 percent higher than in Western states. Such variation is a clear indicator that clinical practice does not ensure evidence-based practice in the United States.

**NEW ACTION TO IMPROVE HEALTH CARE QUALITY AND ENSURE PATIENT SAFETY.** Today, President Clinton will:

- **Issue an Executive Memorandum directing the Quality Interagency Coordination Task Force to develop new strategies to improve health care quality and protect patient safety.** Today, President Clinton will sign an executive memorandum directing the Quality Interagency Coordination Task Force (QuIC) to report back to him in 60 days with an action plan that: identifies medical errors that can be prevented through the use of decision support systems; includes proposals to eliminate barriers preventing adoption of information technology systems in different health care settings; proposes a strategy for the reduction of medical errors in Federal health care programs; detail specific actions that the Federal government can take with the private sector to reduce medical errors; provides a plan for continued, coordinated, collaboration on health care quality issues with the QuIC and the Quality Forum; provides technical support to the Health Care Financing Administration in the development of pilot projects implementing patient safety initiatives; and evaluate the feasibility and advisability of implementing or supporting the recommendations of the Institute of Medicine on patient safety.
- **Praise the American Hospital Association for launching a new medication safety campaign.** The President will praise the American Hospital Association for launching a new initiative to prevent patient medication errors that includes: sharing a list of “best practices” with every hospital and health system; developing a medication safety awareness test that surveys hospitals’ medication error prevention systems; tracking implementation by the hospital and health system field of the practices for reducing and preventing errors; and working with national experts to develop a model medication error reporting process.
- **Announce a new, multi-million dollar investment in research programs to improve health care quality.** President Clinton will announce that he will sign legislation in the coming days that will ensure that the Agency for Healthcare Quality and Research (AHQR), will invest over \$\_ million in FY 2000 in new research to prevent medical errors and promote patient safety. The President also announced that AHQR will increase its current investment in research focusing on the over and under utilization of services and geographic variation in the delivery of services by \_\_ percent over the next year.

- **Direct the Health Care Financing Administration to initiate the development of patient safety demonstration projects into the Medicare program.** Today, President Clinton will direct the Health Care Financing Administration (HCFA) to develop pilot projects that promote patient safety and improve health care quality. These new programs will be designed to reduce medical errors, prevent over and under-utilization of services, and assure the use of the most recent treatment protocols in the Medicaid, Medicare, and CHIP programs.
- **Direct the Office of Management and Budget to invest in health care quality and patient safety initiatives when developing the FY 2001 budget.** Today, the President will direct the Office of Management and Budget to work with the Domestic Policy Council and the Department of Health and Human Services to develop initiatives within the context of the FY 2001 budget that build on our current error prevention, quality improvement, and patient safety initiatives.

**THE CLINTON-GORE ADMINISTRATION'S LONGSTANDING COMMITMENT TO IMPROVING HEALTH CARE QUALITY.** Assuring quality through providing patient protections is a longstanding priority for the Clinton-Gore Administration. Over the past two years President Clinton and Vice President Gore have provided critical consumer protections to the 85 million Americans enrolled in Federal health plans and set the stage for the Congress to pass a strong, enforceable, Patients' Bill of Rights. In March of 1998, the President established the Quality Interagency Coordination Task Force, which has been instrumental in developing disease management protocols that have been adopted nationwide. The Vice President launched a public-private body known as the Quality Forum to coordinate Federal quality improvement efforts with the private sector to provide consumers with a consistent set of standards in order to base their health care choices on quality – not cost. In addition, the Departments of Defense and Veterans Affairs have been leaders in employing information technology to enhance their ability to provide higher quality of care to patients, including the use of electronic medical records for many of their patients.

NOT sent to HHS yet. AHA joining?

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The President also directed the Office of Management and Budget to invest in health care quality and patient safety initiatives when developing the FY 2001 budget; directed the Health Care Financing Administration to integrate patient safety initiatives into the Medicare, Medicaid, and CHIP programs; and announced a new, multi-million dollar investment in research programs to improve health care quality. The new actions being taken by the President today build upon the Clinton-Gore Administration's longstanding commitment to improving health care quality.

**INCONSISTENCIES AND AVOIDABLE ERRORS IN MEDICAL PRACTICE COST LIVES AND UNDERMINE HEALTH.** Inappropriate utilization of services, unnecessary variations in the delivery of health care services, and preventable medical errors are responsible for thousands of deaths, unnecessary illnesses, and instances of prolonged disability annually.

**Preventable medical errors.** Over half of the adverse medical events occurring each year are due to preventable medical errors, placing tens of thousands of Americans at unnecessary risk. More people die each year as a result of medical errors than from motor vehicle accidents, breast cancer, or AIDS. A recent study by the Institute of Medicine estimates that the cost associated with these unnecessary errors in lost income, disability, and health care costs is as much as \$29 billion annually. The financial impact of these errors is compounded by the cost of patients' loss of trust in the health care system, the physical and psychological discomfort associated with longer hospital stays or permanent disability, reduced school attendance, and lower levels of population health status.

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- issues*

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*Decision of industry or supply*
- Announced a new, multi-million dollar investment in research programs to improve health care quality. President Clinton announced that the Agency for Healthcare Quality and Research (AHQR), ~~AHQR~~ will invest over \$2 million in FY 2000 in new research, to be completed during the coming year, to prevent medical errors and promote patient safety. The President also announced that AHQR will increase its current investment in research focusing on the over and under utilization of services and geographic variation in the delivery of services by \_\_\_ percent over the next year.
- include the decision of*

Directed the Health Care Financing Administration to integrate patient safety initiatives into the Medicare, Medicaid, and CHIP programs. Today, President Clinton directed the Health Care Financing Administration (HCFA) to develop pilot projects that promote patient safety and improve health care quality. These new programs will be designed to reduce medical errors, prevent over and under-utilization of services, and assure the use of the most recent treatment protocols in the Medicaid, Medicare, and CHIP programs.
- will authority*

Announced he would sign legislation expanding the ability of the Agency for Health Care Quality and Research to explore issues related to patient safety. Today, the President announced that in the coming days, he would sign legislation that provides new authority to AHQR to explore on issues related to patient safety, including a specific directive to conduct research on medical errors. The legislation also eliminates the funding limit for projects financed by the Center for Education and Research on Therapeutics, allowing AHQR to increase its investment on research on the prevention of adverse medical events related to the use of pharmaceuticals.

*Reduce errors*

- Directed the Office of Management and Budget to invest in health care quality and patient safety initiatives when developing the FY 2001 budget. Today, the President directed the Office of Management and Budget to work with the Domestic Policy Council and the Department of Health and Human Services to develop initiatives within the context of the FY 2001 budget that build on and enhance the ongoing ~~work of the QulC~~ and to develop models of applied research that can be implemented in the public and private sectors.

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**THE CLINTON-GORE ADMINISTRATION'S LONGSTANDING COMMITMENT TO IMPROVING HEALTH CARE QUALITY.**

Assuring quality through providing patient protections is a longstanding priority for the Clinton-Gore Administration. Over the past two years resident Clinton and Vice President Gore have provided critical consumer protections to the 85 million Americans enrolled in Federal health plans and set the stage for the Congress to pass a strong, enforceable, Patients' Bill of Rights. In March of 1998, the President established the Quality Interagency Coordination Task Force, which has been instrumental in developing disease management protocols that have been adopted nationwide. The Vice President launched a public-private body known as the Quality Forum to coordinate Federal quality improvement efforts with the private sector to provide consumers with a consistent set of standards in order to base their health care choices on quality - not cost. In addition, the Departments of Defense, Commerce, and Veterans Affairs have been leaders in employing information technology to enhance their ability to provide higher quality of care to patients.

*(QulC)*

*Edmond*

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- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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RR. Document will be reviewed upon request.

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- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

March 13, 1998

REMARKS BY THE PRESIDENT  
ON HEALTH CARE QUALITY

The East Room

2:45 P.M. EST

THE PRESIDENT: Thank you very much. Mr. Vice President, thank you for your work on this issue and your interest in it. I thank Secretary Shalala, Secretary Herman, Secretary West, the members of the White House staff who worked on this. But especially let me thank the members of the commission and the Executive Director of the commission, Janet Corrigan. They have done a remarkable citizen service for the people of the United States of America and we're all very grateful to them. (Applause.)

As we approach a new century with all its stunning advances in science and technology, we know that many of them will come in medicine and health. We must act now to spread these breakthroughs and improve the quality of health care for every American. I accept the commission's report. I endorse your recommendations.

For five years we have worked to expand access to quality health care for the American people, step by step: health insurance coverage for people who move between jobs; expanded health care coverage for millions of children; strengthened Medicare with more preventive benefits. Last year, as the Vice President said, this commission recommended a Patient's Bill of Rights. Last month I acted to ensure by executive order that one-third of all Americans -- those in Medicare, Medicaid, veterans health care systems and other federal plans -- enjoy the benefits of this Patient's Bill of Rights.

Now these protections must be extended to all Americans. And in the remaining 68 days of this congressional session, Congress must take the next step and make the Patient's Bill of Rights the law of the land. (Applause.)

Now, as you have told America in this report, we must also seize this moment of opportunity to improve the quality of health care for all our people. For all its strengths, our health care system still is plagued by avoidable errors -- overused and underused procedures and gaps in the quality of care. For example, when hundreds of thousands of Americans are needlessly injured while in the hospital, when 18,000 Americans die of heart attacks that did not have to be fatal, when 80,000 women undergo unnecessary hysterectomies every year, surely we can do better.

This commission has drawn a road map for higher quality across American health care. Above all, our nation must develop uniform national standards so that health plans can compete on quality, not just cost; and so that health care consumers can judge for themselves. This is the best way to assure quality health care for all Americans.

We can take three steps to advance these high health care

standards. First, health care quality standards should be set at a forum bringing together providers, business and labor, consumers, insurers and government. I've asked the Vice President to convene this health care quality forum this June.

Second, I'm ordering federal agencies to create a task force to find ways to improve quality in the health care systems that we operate. The federal government must lead the way in lifting health care quality for all our people.

Third, I support this commission's recommendation to create a permanent Health Care Quality Council to set new goals and track our progress in meeting those goals. A council should be established by any health care quality legislation enacted this year.

We can make this year a time of real achievement in our mission to improve health care for every American. The American health care system has been the best in the world in the 20th century. If we press forward with medical research, enact a Patient's Bill of Rights, insist on high quality everywhere in America, continue to expand quality affordable coverage, protect and preserve Medicare and Medicaid, we can make American health care the best in the world in the 21st century.

Now I intend to sign an executive order to all the relevant agencies to make sure they work together to develop the standards you recommend for quality health care, first for those whom we reach, and hopefully as a model for all Americans.

Again, I thank this commission. I ask the people and the members of the press here present to remember just the single instances I cited from the commission's report of examples where we still have serious quality changes. And I ask you all to rededicate yourself to this purpose on this day.

Thank you very much. (Applause.)

END

2:52 P.M. EST

asked for comments  
by 3pm Friday

Sent to HHS /  
DOW tonight.

DRAFT: December 7, 1999

EXECUTIVE MEMORANDUM FOR THE QUALITY INTERAGENCY COORDINATION  
TASK FORCE

SUBJECT: IMPROVING HEALTH CARE QUALITY AND ENSURING PATIENT  
SAFETY

Assuring quality through patient protections is a longstanding priority for this Administration. Over the past two years, with the invaluable assistance of the Vice President, Secretary Shalala and Secretary Herman, this Administration has provided critical consumer protections to the 85 million Americans enrolled in Federal health plans and set the stage for the Congress to pass a strong, enforceable, Patients' Bill of Rights. Equally as important as assuring high quality health care services, however, is improving the quality of the services.

Inappropriate utilization of services, unnecessary variations in the delivery of health care services, and preventable medical errors are responsible for thousands of deaths, unnecessary illnesses, and instances of prolonged disability annually. Early detection and appropriate treatment for illnesses such as diabetes, breast and cervical cancer, and heart attacks can reduce mortality by over 40 percent. Millions of Americans receive health care services, such as unnecessary or inappropriate prescriptions or surgeries, that endanger health and increase costs. In addition, there is a continuing pattern of wide variation in health care practice, including regional variations, clearly indicating that the practice of health care has not caught up with the science of health care.

Preventable medical errors present an extraordinary example of the importance of efforts to ensure the safety of patients and the delivery of high quality health care services. A recent study by the Institute of Medicine indicates that over half of the adverse medical events occurring each year are due to preventable medical errors, placing ~~over half of the~~ <sup>tens of</sup> Americans at unnecessary risk. More people die each year as a result of medical errors than from motor vehicle accidents, breast cancer, or AIDS. The cost associated with these unnecessary errors in lost income, disability, and health care costs is as much as \$29 billion annually. The financial impact of these errors is compounded by the cost of patients' loss of trust in the health care system, the physical and psychological discomfort associated with longer hospital stays or permanent disability, reduced school attendance, and lower levels of population health status.

Last year, in order to begin to address these issues, I established the Quality Interagency Coordination Task Force (QICF), which is responsible for the dissemination of information on evidence based medical research, and has been instrumental in developing disease management protocols that have been adopted nationwide. The Vice President launched a public-private body known as the Quality Forum to coordinate our quality improvement efforts with the private sector to provide consumers with a consistent set of standards in order to base their health care choices on quality outcomes - not just cost. Although they have only been in operation for a short period of time, these entities are well on their way to making contributions to improving the delivery of high quality health care. In addition, the Departments of Defense, ~~Commerce~~, and Veterans Affairs have been leaders in employing information technology to enhance their ability to provide higher quality of care to patients. However, it is clear that more must be done.

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U.S. Department of Labor

Pension and Welfare Benefits Administration  
Washington, D.C. 20210



DATE: 12

TO: DEVORA  
(Name)

(Company) \_\_\_\_\_ (Room/Suite #) \_\_\_\_\_

(Phone #) \_\_\_\_\_ (Fax #) 456-5557

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FROM: Kaye Pestaina

**DAN MAGUIRE**  
U.S. Department of Labor  
Pension and Welfare Benefits Administration  
200 Constitution Avenue, N.W. - Room N5677  
Washington, D.C. 20210

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TOTAL NUMBER OF PAGES, INCLUDING THIS PAGE: 3

MY FAX NUMBER: (202) 219-6531

FOR CONFIRMATION: (202) 219-9044

COMMENTS:

This is the change that I left on  
your voice mail earlier re: exec order on  
patient safety.

\_\_\_\_\_  
\_\_\_\_\_

DRAFT: December 7, 1999

**EXECUTIVE MEMORANDUM FOR THE QUALITY INTERAGENCY COORDINATION  
TASK FORCE**

**SUBJECT: IMPROVING HEALTH CARE QUALITY AND ENSURING PATIENT  
SAFETY**

Assuring quality through patient protections is a longstanding priority for this Administration. Over the past two years, with the invaluable assistance of the Vice President, Secretary Shalala and Secretary Herman, this Administration has provided critical consumer protections to the 85 million Americans enrolled in Federal health plans and set the stage for the Congress to pass a strong, enforceable, Patients' Bill of Rights. Equally as important as assuring high quality health care services, however, is improving the quality of the services.

Inappropriate utilization of services, unnecessary variations in the delivery of health care services, and preventable medical errors are responsible for thousands of deaths, unnecessary illnesses, and instances of prolonged disability annually. Early detection and appropriate treatment for illnesses such as diabetes, breast and cervical cancer, and heart attacks can reduce mortality by over 40 percent. Millions of Americans receive health care services, such as unnecessary or inappropriate prescriptions or surgeries that endanger health and increase costs. In addition, there is a continuing pattern of wide variation in health care practice, including regional variations, clearly indicating that the practice of health care has not caught up with the science of health care.

Preventable medical errors present an extraordinary example of the importance of efforts to ensure the safety of patients and the delivery of high quality health care services. A recent study by the Institute of Medicine indicates that over half of the adverse medical events occurring each year are due to preventable medical errors, placing tens of thousands of Americans at unnecessary risk. More people die each year as a result of medical errors than from motor vehicle accidents, breast cancer, or AIDS. The cost associated with these unnecessary errors in lost income, disability, and health care costs is as much as \$29 billion annually. The financial impact of these errors is compounded by the cost of patients' loss of trust in the health care system, the physical and psychological discomfort associated with longer hospital stays or permanent disability, reduced school attendance, and lower levels of population health status.

Last year, in order to begin to address these issues, I established the Quality Interagency Coordination Task Force (QuIC), which is responsible for the dissemination of information on evidence based medical research, and has been instrumental in developing disease management protocols that have been adopted nationwide. The Vice President launched a public-private body known as the Quality Forum to coordinate our quality improvement efforts with the private sector to provide consumers with a consistent set of standards in order to base their health care choices on quality outcomes – not just cost. Although they have only been in operation for a short period of time, these entities are well on their way to making contributions to improving the delivery of high quality health care. In addition, the Departments of Defense, Commerce, and Veterans Affairs have been leaders in employing information technology to enhance their ability to provide higher quality of care to patients. However, it is clear that more must be done.

Computerizing and streamlining health care processes can improve health care quality, eliminate dangerous medical errors, lower costs by improving communications between doctors, eliminating redundant tests and procedures, and building automatic safeguards against harmful drug interactions and other adverse side effects into the treatment process. Despite this fact, very few public and private health plans, hospitals, and employers use these new techniques.

Therefore, I hereby direct the Quality Interagency Coordination Task Force, to report to me a set of recommendations on specific actions to improve health care outcomes and prevent medical errors in both the public and private sectors in a manner that does not unnecessarily and inappropriately infringe upon patient privacy in any way. This report shall:

- Identify prevalent medical errors that can be prevented through the use of decision support systems, such as patient monitoring and reminder systems;
- Propose steps to eliminate barriers preventing adoption of effective information technology systems in different health care settings in both the public and private sectors;
- Propose a strategy to reduce medical errors in Federal health care programs that will reduce medical errors and ensure patient safety;
- Detail specific actions that the Federal government can take with the private sector to reduce medical errors and improve patient safety nationwide, including continued collaboration on health care quality issues with the QUIC, the Quality Forum, and the National Center for Vital Statistics; and
- Provide technical support to the Health Care Financing Administration in the development of pilot projects implementing patient safety initiatives in Medicare, Medicaid, and CHIP.
- Evaluate the feasibility and advisability of the recommendations of the Institute of Medicine's Quality of Health Care in America Committee on patient safety, including the:
  - Creation of a Center for Patient Safety in the Agency for Healthcare Research and Quality;
  - Establishment of a nationwide mandatory reporting system on adverse events that result in death or serious harm to patients;
  - Encouragement of the development of voluntary reporting systems on medical errors;
  - Extension of peer review protections to data related to patient safety;
  - Inclusion of patient safety components in performance standards for health care organizations and health care professionals;
  - Requirement for the Food and Drug Administration to consider patient safety in pre and post-marketing processes for pharmaceuticals; and
  - Encouragement of private health care organizations to establish patient safety programs with defined executive responsibility and to implement proven medication safety practices.

*and the Department of Labor*

I direct the Department of Health and Human Services to serve as the coordinating agency to assist in the development and integration of recommendations and to report back to me within 60 days. The recommended actions should lay the foundation for a national system that prevents adverse medical events before they occur.

AHCPR  
# X



• to review develop  
measures to report  
errors & near misses

• explore preventable  
~~errors~~ <sup>errors</sup> →  
more safety standard

checklist; standard  
vocabulary & checker

• ~~preventable errors~~

qualitative → 3 mo.  
report → ~~3 mo.~~  
data → ~~3 mo.~~

CORTS  
# X

• specifically pharmaceutical  
errors next to one  
another places

misses station plugging  
in right concentrations.

current authority

\$ X dollars  $\rightarrow$  increased  
of effective utilization investment  
~~by Y~~ by Y

Time | use of tools that  
encourage  
evidence based med.

Organization factors X increase  
stopping levels  
design  
magnet

Jennifer  
Piper

Vet  
Seating chart

# for  
briefing  
memo.

~~8542~~

Nancy Ann

10/10/10

10/10/10

10/10/10

10/10/10

Therefore, I hereby direct the Quality Interagency Coordination Task Force to report to me with a set of recommendations relating to medical errors and patient safety. These recommendations should include specific actions to improve health care outcomes and prevent medical errors in both the public and private sectors in a manner consistent with the strong privacy protections that we have proposed. This report should

- ④ Identify additional strategies to reduce medical errors in federal health care programs. *make recommendations*
- ① Identify prevalent medical errors *in safety threats* that can be prevented through the use of decision support systems, such as patient monitoring, computerized information systems, and reminder systems.
- ⑤ Identify opportunities the Federal government can take to reduce medical errors and improve patient safety nationwide through collaborations with the private sector, including the Quality Forum.
- ② Evaluate the feasibility and advisability of the recommendations on patient safety issued by the Institute of Medicine's Quality of Health Care in America Committee.

I direct the Secretary of Health and Human Services to coordinate the development and integration of the recommendations and to report back to me within 60 days.

*Identify barriers*

*reference*

*3* *Identify a rule paper to address barriers that prevent* *while ensuring patient privacy*

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Oakbrook Terrace, IL 60181  
Phone: (630) 792-5269  
Fax: (630) 792-4269

**Joint Commission on  
Accreditation of  
Healthcare  
Organizations**

# Fax

**To:** Devora Adler

**From:** Karen Eberspacher

**Fax:** 202-456-5557

**Date:** February 17, 2000

**Pages:** 28

**Re:** Sentinel Event Questionnaire

**Urgent**     **For Review**     **Please Comment**     **Please Reply**     **Please Recycle**

**•Comments:** Please call me if you have not received all the pages.

## Sentinel Event Questionnaire Executive Summary

During March of 1999, state relations conducted a survey of state agencies to identify state requirements related to sentinel event reporting. The following represents significant findings from this survey.

### Methodology:

A written survey was distributed to 50 states, Puerto Rico, and the District of Columbia. Nonrespondants were contacted by phone.

- Requirements for reporting of health care sentinel events to the state:
  - 32 states, Puerto Rico, and the District of Columbia (67%) have responded either to the written survey or follow up phone survey.
  - 16 states and D.C. (33%) responded that there is a law that requires reporting of sentinel events: Alabama, Alaska, District of Columbia, Florida, Idaho, Iowa, Louisiana, Massachusetts, Minnesota, Nevada, New Jersey, New York, Pennsylvania, Tennessee, Texas, Washington, and Wisconsin.
  - 15 states and Puerto Rico (31%) responded there was no law currently in place that requires reporting of sentinel events to the state - California, Hawaii, Kentucky, Mississippi, Missouri, Montana, New Hampshire, New Mexico, North Dakota, Oklahoma, Oregon, Utah, Vermont, West Virginia, and Wyoming.
- Categories of sentinel events required to be reported to states:
  - **report unexpected patient deaths** (including suicide and restraint deaths) - 13 states and D.C. (27%) - Alabama, District of Columbia, Florida, Hawaii, Idaho, Iowa, Louisiana, Massachusetts, Minnesota, New Jersey, New York, Pennsylvania, Washington, and Wisconsin.
  - **report wrong site surgery** - 5 states (10%) - Florida, Massachusetts, New Jersey, New York, and Washington.
  - **report infant abduction and wrong infant discharge** - 6 states and D.C. (13%) - California, District of Columbia, Massachusetts, New Jersey, New York, Pennsylvania, and Washington.
  - **report rape of a patient** - 9 states and D.C. (19%) - Alabama, District of Columbia, Idaho, Louisiana, Massachusetts, Minnesota, New Jersey, New York, Pennsylvania, and Washington.
  - **report hemolytic transfusion reaction** - 6 states and D.C. (13%) - District of Columbia, Florida, Massachusetts, New Jersey, New York, Pennsylvania, and Washington.

## Sentinel Event Questionnaire Executive Summary

- **report major loss function due to treatment or surgery** - 5 states and D.C. (12%)
  - District of Columbia, Florida, Massachusetts, New Jersey, New York, and Washington.
- Other sentinel events reported to states include abuse, neglect and exploitation.
- Categories of health care organizations that submit data to the state:
  - **general and acute care hospitals** - 16 states and D.C. (33%) - Alaska, California, District of Columbia, Hawaii, Idaho, Louisiana, Massachusetts, Minnesota, Nevada, New Jersey, New Mexico, New York, Pennsylvania, Tennessee, Texas, Utah, and Washington.
  - **psychiatric hospitals or residential psychiatric centers** - 13 states and D.C. (27%) - California, District of Columbia, Hawaii, Idaho, Louisiana, Minnesota, Nevada, New Jersey, New Mexico, Oklahoma, Pennsylvania, Tennessee, Texas, and Utah.
  - **ambulatory surgery clinics** - 10 states (19%) - California, Minnesota, Nevada, New Jersey, New Mexico, New York, Pennsylvania, Tennessee, Texas and Utah.
  - **outpatient mental health clinics** - 3 states (6%) - New Mexico, Oklahoma, and Texas.
  - **nursing homes** - 16 states and D.C. (33%) - Alabama, Alaska, California, District of Columbia, Hawaii, Idaho, Indiana, Louisiana, Massachusetts, Minnesota, Nevada, New Jersey, New Mexico, Oklahoma, Pennsylvania, Tennessee, and Utah.
  - **home health agencies** - 12 states and D.C. (25%) - Alaska, California, District of Columbia, Idaho, Louisiana, Minnesota, Nevada, New Jersey, New Mexico, Oklahoma, Pennsylvania, Tennessee, and Utah.
  - **laboratories** - 2 states (4%) - Massachusetts and Nevada.
  - Other health care organizations include intermediate care facilities, developmentally disabled, group homes, CD, birthing centers, ESRD and group homes for child care.

### Other significant findings:

- Information is maintained in databases by 12 states (23%) - Alabama, Alaska, Florida, Massachusetts, Minnesota, Nevada, New Hampshire, New York, Tennessee, Texas, Utah and Wisconsin.
- 18 states and D.C. (37%) indicated that a follow up is done to assure corrective action - Alabama, Alaska, District of Columbia, Florida, Hawaii, Idaho, Iowa, Louisiana,

## Sentinel Event Questionnaire Executive Summary

Massachusetts, Nevada, New Hampshire, New Jersey, New York, Pennsylvania, Tennessee, Texas, Utah, Washington, and Wisconsin.

- Frequency of a state survey based on a reported event include:
  - 5 states and D.C. (12%) responded that a state survey is done in all cases - Alabama, Alaska, District of Columbia, Idaho, Nevada, and Texas.
  - 13 states (25%) responded that a state survey is done in some cases - Florida, Hawaii, Louisiana, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Pennsylvania, Tennessee, Utah, Washington, and Wisconsin.
  - 1 state (2%) requires a plan of correction - Florida.
  - 4 states (8%) refer the facility to other agencies - California, Hawaii, Massachusetts, and Minnesota.
  - States actions after review of events:
    - ▶ 2 states (4%) give fines - New Jersey and New York.
    - ▶ 1 state (2%) revokes licenses - Tennessee.
    - ▶ 12 states (23%) have sanctioned a facility - These sanctions range from an average of 1-3 times a year for the following states: Florida, Idaho, Iowa and Wisconsin.
- 15 states ( 29%) disclose information to the public, typically upon request.
  - Types of information disclosed are complaint investigation findings, incident reports, survey reports, statement of deficiencies and plans of correction.
- States indicated that a failure to submit data or report occurrences could trigger:
  - Actual facility citation
  - Deficiency citation
  - Warning letters
  - Fines
  - Corrective action plans
- States that require healthcare organizations to report other event data (not necessarily similar to Joint Commission's Sentinel Event definition) are Alabama, Alaska, Florida, Hawaii, Iowa, Louisiana, Massachusetts, Minnesota, Nevada, New Mexico, New York, Tennessee, Texas and Wisconsin (14 states, 27%).
- Percentage of facilities in 6 states (12%) that report data:

## Sentinel Event Questionnaire Executive Summary

State	Percentage
Hawaii	91%
Massachusetts	100%
New Mexico	5%
New York	100%
Tennessee	>5%
Wisconsin	>5%

- Number of adverse events reported in 10 states (19%) included:

State	1997	1998
Alaska	52	19
Florida	~5,000	~5,000
Iowa	6-12	6-12
Massachusetts	~350	~425
Minnesota	3,873	3,394
New Mexico	50	50
New York	~15,000	~15,000
Tennessee	~1,500	~1,500
Texas	343	369
Wisconsin	65	79

- 12 states (23%) responded that the reporting of adverse events has been useful.
  - Benefits of reporting cited included:
    - ▶ corrective measures are implemented as a result of reporting,
    - ▶ legally required patient care quality standards are being met,
    - ▶ provider awareness has increased that, in return, prevents occurrences,
    - ▶ preventive action has been taken.

# Sentinel Event Questionnaire Executive Summary

## Sentinel Event Questionnaire

Please reply via facsimile (630) 792-4269 by 3/11/99, or call us and we will take your answers over the phone.

The Joint Commission on Accreditation of Healthcare Organizations is asking that you please take a moment to fill out a brief survey to determine the effectiveness of laws and regulations that address unexpected occurrences involving death or serious physical or psychological injury (i.e., sentinel events, adverse incidents). We would like information about actual reporting, compliance levels, how information gets used, and access to the data.

- 1) Do you have a law that requires reporting of health care sentinel events to the state?  
Yes  No  (By sentinel event we mean: unexpected patient deaths (including suicide and restraint death), wrong site surgery, infant abduction or wrong infant discharge, rape of a patient, hemolytic transfusion reaction, major loss of function due to treatment or surgery.)
- 2) What kinds of events are reported? (Check all that apply)
  - unexpected patient deaths (including suicide and restraint death)
  - wrong site surgery
  - infant abduction or wrong infant discharge
  - rape of a patient
  - hemolytic transfusion reaction
  - major loss of function due to treatment or surgery
  - others \_\_\_\_\_
- 3) What categories of health care organizations must report? (Check all that apply)
  - general and acute care hospitals
  - psychiatric hospitals or residential psychiatric centers
  - ambulatory surgery centers
  - outpatient mental health centers
  - nursing homes
  - home health agencies
  - laboratories
  - pharmacies
  - others \_\_\_\_\_
- 4) What is done with the information reported?  
Is information entered into a database? Yes  No   
Number of cases currently in the database. \_\_\_\_\_  
Do you follow up to assure corrective action? Yes  No   
Is a state survey done? In all cases  In some cases  No   
Other action by the state? \_\_\_\_\_
- 5) Is information disclosed to the public? Yes  No   
Type of information \_\_\_\_\_
- 6) What do you do if organizations do not submit data or report occurrences?  
\_\_\_\_\_
- 7) How many times have you sanctioned a facility for failure to report each year?  
(approximate) \_\_\_\_\_
- 8) How many organizations have reported data? \_\_\_\_\_  
What percent of facilities does this represent? \_\_\_\_\_
- 9) How many adverse events were reported in 1997 \_\_\_\_\_ and 1998 \_\_\_\_\_?
- 10) Has the program been useful in improving care and reducing risks for errors? Yes  No   
Why or why not? \_\_\_\_\_

# Withdrawal/Redaction Marker

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
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002. form	re: Sentinel Event Questionnaire Executive Summary (partial) (1 page)	02/17/2000	P6/b(6)
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### COLLECTION:

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### FOLDER TITLE:

Errors [Folder 4]

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### RESTRICTION CODES

#### Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

#### Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

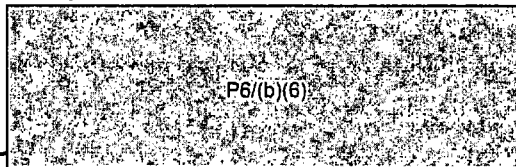
## Sentinel Event Questionnaire Executive Summary

State: \_\_\_\_\_ Name: \_\_\_\_\_

Title: \_\_\_\_\_ Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

Thank you so much for participating. If you have any questions, please call (630) 792-5269 the Division of Government Relations & External Affairs and ask to speak with Donna Nowakowski, Director; Kristin Hellquist, Associate Director; Karen Eberspacher, Coordinator; or Rita Fernandez-Sturm, Intern.

*Karen*



[002]

# Sentinel Event Questionnaire Executive Summary

## Sentinel Event Questionnaire Responses

### 1. Do you have a law that requires reporting of health care sentinel events to the state?

STATE	Yes	No	Comments
Alabama	✓		
Alaska	✓		
Arizona		✓	
Arkansas			Wouldn't share information.
California		✓	
Colorado			
Connecticut			
Delaware			
District of Columbia	✓		
Florida	✓		
Georgia			
Hawaii		✓	
Idaho	✓		
Illinois			
Indiana			
Iowa	✓		
Kansas			
Kentucky		✓	
Louisiana	✓		
Maine			
Maryland			
Massachusetts	✓		
Michigan			
Minnesota	✓		
Mississippi		✓	
Missouri		✓	
Montana		✓	
Nebraska			
Nevada	✓		
New Hampshire		✓	
New Jersey	✓		
New Mexico		✓	
New York	✓		
North Carolina			
North Dakota		✓	

## Sentinel Event Questionnaire Executive Summary

STATE	Yes	No	Comments
Ohio			
Oklahoma		✓	
Oregon		✓	
Pennsylvania	✓		
Rhode Island			
South Carolina			
South Dakota	✓		
Tennessee	✓		
Texas	✓		
Utah		✓	
Vermont		✓	
Virginia			
Washington	✓		
West Virginia		✓	
Wisconsin	✓		
Wyoming		✓	
Puerto Rico		✓	
<b>Totals</b>	<b>18</b>	<b>17</b>	

**2. What kinds of events are reported?  
(Check all that apply)**

STATE	Unexpected patient deaths (including suicide and restraint deaths)	Wrong site surgery	Infant abduction or wrong infant discharge	Rape of a patient	Hemolytic transfusion reaction	Major loss function due to treatment or surgery	Others
Alabama	✓			✓			serious injuries, burns
Alaska							abuse/neglect for vulnerable adults
Arizona							
Arkansas							
California			✓				
Colorado							
Connecticut							
Delaware							
District of Columbia	✓		✓	✓	✓	✓	
Florida	✓	✓			✓	✓	wrong pt surg/surg repair
Georgia							
Hawaii	✓						allegations of abuse, neglect, misappropriation of funds
Idaho	✓			✓			patient abuse/ neglect/ exploitation
Illinois							
Indiana							
Iowa	✓						elopement
Kansas							
Kentucky							
Louisiana	✓			✓			abuse, injuries of unknown origin
Maine							
Maryland							
Massachusetts	✓	✓	✓	✓	✓	✓	" We have circular letters for hospitals and nursing home reporting-call if you want copies."
Michigan							
Minnesota	✓			✓			abuse, neglect exploitation (financial)
Mississippi							

STATE	Unexpected patient deaths (including suicide and restraint deaths)	Wrong site surgery	Infant abduction or wrong infant discharge	Rape of a patient	Hemolytic transfusion reaction	Major loss function due to treatment or surgery	Others
Missouri							
Montana							
Nebraska							
Nevada							abuse, exploitation, neglect
New Hampshire							
New Jersey	✓	✓	✓	✓	✓	✓	anesthesia related events; disasters related to interruption of service
New Mexico							Abuse, neglect, exploitation
New York	✓	✓	✓	✓	✓	✓	(serious occurrence warranting DOH/DMH notification)
North Carolina							
North Dakota							
Ohio							
Oklahoma							
Oregon							
Pennsylvania	✓	✓	✓	✓	✓		serious compromise patient care
Rhode Island							
South Carolina							
South Dakota	✓			✓	✓		Patient elopement
Tennessee							unusual occurrences or events (left to org. discretion)
Texas							abuse and neglect
Utah							
Vermont							
Virginia							
Washington	✓	✓	✓	✓	✓	✓	
West Virginia							
Wisconsin	✓						suicides, restraint, isolation and psychotropic medication deaths
Wyoming							
<b>Totals</b>	<b>15</b>	<b>6</b>	<b>7</b>	<b>11</b>	<b>8</b>	<b>6</b>	

**3. What categories of health care organizations must report?  
(Check all that apply)**

STATE	General and acute care hospitals	Psychiatric hospitals or residential psychiatric centers	ASC	CM HCS	Nursing homes	Home health agencies	Laboratories	Pharmacies	Others
Alabama					✓				
Alaska	✓				✓	✓			
Arizona									
Arkansas									
California	✓	✓	✓		✓	✓			ICF, DD, daycare CD
Colorado									
Connecticut									
Delaware									
District of Columbia	✓	✓			✓	✓			ICF
Florida									
Georgia									
Hawaii	✓	✓			✓				ICF
Idaho	✓	✓			✓	✓			ICF
Illinois									
Indiana									
Iowa					✓				
Kansas									
Kentucky									
Louisiana	✓	✓			✓	✓			
Maine									
Maryland									
Massachusetts	✓				✓		✓		
Michigan									
Minnesota	✓	✓	✓		✓	✓			Group homes, MR/DD, CD
Mississippi									
Missouri									
Montana									
Nebraska									

STATE	General and acute care hospitals	Psychiatric hospitals or residential psychiatric centers	ASC	CM HCS	Nursing homes	Home health agencies	Laboratories	Pharmacies	Others
Nevada	✓	✓	✓		✓	✓	✓		All licensed facilities
New Hampshire									
New Jersey	✓	✓	✓		✓	✓			
New Mexico	✓	✓	✓	✓	✓	✓			
New York	✓		✓						
North Carolina									
North Dakota									
Ohio									
Oklahoma		✓		✓	✓	✓			centers DD, SA, group homes child care
Oregon									
Pennsylvania	✓	✓	✓		✓	✓			birth center
Rhode Island									
South Carolina									
South Dakota	✓	✓	✓		✓				Assisted Living, Chemical Dependency Inpatient Centers
Tennessee	✓	✓	✓		✓	✓			
Texas	✓	✓	✓	✓					ESRD
Utah	✓	✓	✓		✓	✓			
Vermont									
Virginia									
Washington	✓								
West Virginia									
Wisconsin									
Wyoming									

Utah?

#### 4. What is done with the information reported?

STATE	Is information entered into a database?	Number of cases currently in database.	Do you follow up to assure corrective action?	Is a state survey done?	Other action by the state
Alabama	Yes	19	Yes	In all cases	
Alaska	Keep log	?	Yes	In all cases primarily, nursing homes	
Arizona					
Arkansas					
California					Unusual occurrences are reported by facilities to L&C District Offices.
Colorado					
Connecticut					
Delaware					
District of Columbia			Yes	Yes	
Florida	Yes	5000 approx/yr	Yes	In some cases	Plan of correction
Georgia					
Hawaii	No		Yes	In some cases	Referred to other agencies
Idaho	No		Yes	In all cases	
Illinois					
Indiana					
Iowa	No		Yes		
Kansas					
Kentucky					
Louisiana	No	?	Yes	In some cases	Require facility investigation and report
Maine					
Maryland					
Massachusetts	Yes	Hospitals-2-3000 incidents (including complaints) Nursing homes-About 10,000/year	Some	In some cases	Referral to other agencies
Michigan					
Minnesota	Yes	20,000 past 5 yrs		In some cases	Refer reports to other agencies
Mississippi					
Missouri					
Montana					

STATE	Is information entered into a database?	Number of cases currently in database.	Do you follow up to assure corrective action?	Is a state survey done?	Other action by the state
Nebraska					
Nevada	Yes		Yes	In all cases	
New Hampshire	Yes	100	Yes	In some cases	
New Jersey	No	N/A	Yes	In some cases	Warning letters, fines
New Mexico					
New York	Yes	8,000 approx. 355 in categories noted above	Yes	In some cases	fines
North Carolina					
North Dakota	No		Yes	In some cases	
Ohio					
Oklahoma					
Oregon					
Pennsylvania	No		Yes	In some cases	
Rhode Island					
South Carolina					
South Dakota					
Tennessee	File kept		Yes	In some cases	Revoke licenses, summary suspension
Texas	Yes	Standard report not available	Yes	In all cases	N/A
Utah	Yes, substantiated findings		Yes, review only if statement of finding is issued	In some cases	
Vermont					
Virginia					
Washington	No	0	Yes	In some cases	
West Virginia					
Wisconsin	Yes	65-75 per year	Yes	In some cases	Actions range by severity. The Care Specialists and Committee review deaths quarterly. Inpatient has on site survey/ outpatient varies
Wyoming					

### 5. Is information disclosed to the public?

STATE	Yes, type of information	No
Alabama	Yes, HCFA 2567	
Alaska		
Arizona		
Arkansas		
California	Aggregate data: complaint investigation findings, number of complaints, and categories are disclosed to the public upon request.	
Colorado		
Connecticut		
Delaware		
District of Columbia	Yes	
Florida	On site survey; cited deficiencies.	
Georgia		
Hawaii		No
Idaho	survey reports / complaint letters	
Illinois		
Indiana		
Iowa		No
Kansas		
Kentucky		
Louisiana		
Maine		
Maryland		
Massachusetts	Yes, upon request (FOIA) - incidents reports, complaints, reports of investigations, statements of deficiency, plans of correction.	
Michigan		
Minnesota	Yes	
Mississippi		
Missouri		
Montana		
Nebraska	Yes	
Nevada	Yes, statement of deficiencies and plan of correction.	
New Hampshire		
New Jersey	Yes, report of incident and/or survey report, hospital fine are listed on internet	
New Mexico	Yes, if substantiated	
New York	Yes, findings, hospital specific aggregate data	
North Carolina		
North Dakota		
Ohio		
Oklahoma		
Oregon		
Pennsylvania		No
Rhode Island		

STATE	Yes, type of information	No
South Carolina		
South Dakota	Yes, only on HCFA 2567	
Tennessee		
Texas	Yes, as mandated by the open records act	
Utah	Yes, substantiated complaints	
Vermont		
Virginia		
Washington		No
West Virginia		
Wisconsin	Yes, incident specific (awareness) & yearly statistical report	
Wyoming		

(20) 270 0062

## 6. What do you do if organizations do not submit data or report occurrences?

STATE	
Alabama	Write deficiencies related to not reporting
Alaska	Facility can be cited monetary or suspension depending on severity
Arizona	
Arkansas	
California	If facilities fail to report unusual occurrences to the Department the Department can cite the facility
Colorado	
Connecticut	
Delaware	
District of Columbia	Write a deficiency
Florida	Cited, given opportunity to correct, subject to fines
Georgia	
Hawaii	Providers survey for citations for state/federal program requirements
Idaho	Adverse action/ civil monetary penalties
Illinois	
Indiana	
Iowa	Cite a deficiency
Kansas	
Kentucky	
Louisiana	Investigation as a complaint, cite deficiencies
Maine	
Maryland	
Massachusetts	citation of a deficiency
Michigan	
Minnesota	State deficiencies may resort to fine
Mississippi	
Missouri	
Montana	
Nebraska	
Nevada	Facilities would be cited for deficiencies
New Hampshire	
New Jersey	Possible fine and/or warning letter
New Mexico	Cite them
New York	Follow-up surveys
North Carolina	
North Dakota	
Ohio	
Oklahoma	
Oregon	
Pennsylvania	Has not happened; contact on citation
Rhode Island	
South Carolina	
South Dakota	Technical assistance on reporting requirements, written warnings, deficiencies
Tennessee	Deficiency given
Texas	A deficiency is given when failure to report is discovered.
Utah	
Vermont	
Virginia	

STATE	
Washington	Cite-require corrective action plan
West Virginia	
Wisconsin	cited for violating statutory reporting laws
Wyoming	

**7. How many times have you sanctioned a facility for failure to report each year? (approximate)**

STATE	
Alabama	23 in 1997 and 13 in 1998
Alaska	0
Arizona	
Arkansas	
California	
Colorado	
Connecticut	
Delaware	
District of Columbia	
Florida	3x/yr.
Georgia	
Hawaii	0
Idaho	1
Illinois	
Indiana	
Iowa	1-2
Kansas	
Kentucky	
Louisiana	0
Maine	
Maryland	
Massachusetts	
Michigan	
Minnesota	Approx. 5
Mississippi	
Missouri	
Montana	
Nebraska	
Nevada	Unknown
New Hampshire	
New Jersey	Less than 5
New Mexico	
New York	
North Carolina	
North Dakota	
Ohio	
Oklahoma	
Oregon	
Pennsylvania	0
Rhode Island	
South Carolina	
South Dakota	0
Tennessee	Less than 5%
Texas	N/A
Utah	
Vermont	
Virginia	
Washington	N/A

STATE	
West Virginia	
Wisconsin	1-2 per year
Wyoming	

## 8. ( This is a two part question)

STATE	How many organizations have reported data?	What percent of facilities does this represent?
Alabama	Numerous	
Alaska		
Arizona		
Arkansas		
California		
Colorado		
Connecticut		
Delaware		
District of Columbia		
Florida	Collects data but gave no numbers	gave no numbers
Georgia		
Hawaii	More than 40	91%
Idaho	Does not have database	Does not have database
Illinois		
Indiana		
Iowa	6-12	
Kansas		
Kentucky		
Louisiana	Most nursing homes and intermediate care facilities	
Maine		
Maryland		
Massachusetts	Approx. 75 hospitals, 500 nursing homes	All
Michigan		
Minnesota	Don't have number	Don't have number
Mississippi		
Missouri		
Montana		
Nebraska		
Nevada	Numerous	Numerous
New Hampshire		
New Jersey	Unknown, no database	Unknown
New Mexico	50	5%
New York	Approx. 260 hospitals	100% of hospitals
North Carolina		
North Dakota		
Ohio		
Oklahoma		
Oregon		
Pennsylvania	Don't know, no database	
Rhode Island		
South Carolina		
South Dakota	Stats not kept	
Tennessee		Less than 5%
Texas	Information not available	Information not available
Utah		
Vermont		
Virginia		

STATE	How many organizations have reported data?	What percent of facilities does this represent?
Washington	N/A	N/A
West Virginia		
Wisconsin	same- mostly adult mental health	under 5%
Wyoming		

### 9. How many adverse events were reported in

STATE	97'	98'	Comments
Alabama			
Alaska	52	19	
Arizona			
Arkansas			
California			
Colorado			
Connecticut			
Delaware			
District of Columbia			118 for two years
Florida	5,000	5,000	
Georgia			
Hawaii			
Idaho			
Illinois			
Indiana			
Iowa	6-12	6-12	
Kansas			
Kentucky			
Louisiana			
Maine			
Maryland			
Massachusetts	approx. 350	approx. 425	Hospitals only
Michigan			
Minnesota	3,873	3,394	
Mississippi			
Missouri			
Montana			
Nebraska			
Nevada			Unknown
New Hampshire			
New Jersey	Unknown	Unknown	
New Mexico	50	50	
New York	Approx. 15,000	Approx. 15,000	
North Carolina			
North Dakota			
Ohio			
Oklahoma			
Oregon			
Pennsylvania			
Rhode Island			

STATE	97'	98'	Comments
South Carolina			
South Dakota	Statistics not kept		
Tennessee	Approx. 1,500	Approx. 1,500	
Texas	343	369	
Utah			
Vermont			
Virginia			
Washington	N/A	N/A	
West Virginia			
Wisconsin	65	79	
Wyoming			

### 10. Has the program been useful in improving care and reducing risks for errors?

STATE	Yes	No	Why or why not?
Alabama	✓		Facilities are reporting and corrective measures are being implemented
Alaska	✓		Organizations are accountable (staff, administration) raises awareness of issue
Arizona			
Arkansas			
California	✓		Requiring facilities to report unusual occurrences to the Department is important and has been useful. The investigation of complaints/facility reported unusual occurrences is a key component of licensing and Certification's regulatory and enforcement functions to ensure that legally required patient care quality standards are being met.
Colorado			
Connecticut			
Delaware			
District of Columbia	✓		Yes, when elopements from a group home increased we insisted on the home installing an alarm system then they decreased
Florida			Don't know; many obstacles especially with politics
Georgia			
Hawaii	✓		Providers are more aware of incidents/prevent situations and take preventive action
Idaho	✓		
Illinois			
Indiana			
Iowa			Unknown
Kansas			
Kentucky			
Louisiana			
Maine			
Maryland			
Massachusetts	✓		Identifying root causes/solutions much of information has been useful for our coalition for prevention of medication errors.
Michigan			
Minnesota	✓		Absolutely makes facilities accountable
Mississippi			
Missouri			
Montana			
Nebraska			
Nevada	✓		Because citation has a possibility of sanction with monetary and civil penalties

STATE	Yes	No	Why or why not?
New Hampshire			
New Jersey			
New Mexico		✓	Not extensive enough
New York	✓		Program was redesigned and implemented statewide April 1, 1998 New York Patient Occurrence Reporting and Tracking System (NYPORTS)
North Carolina			
North Dakota			
Ohio			
Oklahoma			
Oregon			
Pennsylvania			Too early to tell; came in effect since 6/98
Rhode Island			
South Carolina			
South Dakota			Statistics not kept.
Tennessee	✓		
Texas			Statistical data not available
Utah			
Vermont			
Virginia			
Washington			New rule-effective today for first time
West Virginia			
Wisconsin	✓		Used for alerts, specific incidents
Wyoming			

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Michael Cohen ATA

Suggested Invitees

AHCPR(AHRQ) Requests

~~Donald Berwick~~, Institute for Healthcare Improvement (also Forum)  
Peter Thomas (also Forum)  
Bruce Bradley, GM (also Forum)  
Mark Smith, California Healthcare Foundation  
Ray Woosley, Georgetown University

IOM People

William Richardson, chair of IOM Committee, Kellogg Foundation  
Charles Buck, GE  
Christine Cassel, Mt. Sinai in NYC  
David Lawrence, Kaiser Foundation Health Plan  
Brent James, Intermountain Health Care  
Lucien Leape, Harvard  
Mary Wakefield, George Mason University

QuIC People

Secretaries Shalala and Herman, co-chairs  
~~John Eisenberg~~ (also AHRQ), operating chair  
Thomas Garthwaite (Acting undersecretary at the VA)  
Sue Bailey (DoD)  
Janice Lachance (also Forum)  
ADM Joyce Johnson (Coast Guard)  
Paul London (Commerce)

Forum

~~Gail Warden~~, (also IOM)  
~~Helen Smits~~

Association People

Jordan Cohen, Association of American Medical Colleges  
Mary Wooley, Research! America  
David Helms, AHSR  
Charles Kahn, HIAA  
Mary Jane England, Washington Business Group on Health (also Forum)  
Robert Graham, AAFP  
Beverly Malone, ANA  
Karen Ignani, AAHP  
Tom Reardon, AMA (also Forum)

Nancy Foster

301  
594  
1609

Tony Watson

Pharm's  
Pharmacy's  
Medicare  
Plan  
John  
Foster

IOM  
AMA

ATA

ANA

Business

Labor

Consumer

Quality

Forum

Insurance

(NCOA)  
(ICATO) 3 Kaiser  
person on  
board

Invest  
Conings

VA  
DoD

HCFA

OPM CMB

Eisenberg

Commerce

London

DOJ

8 + Admin  
officials



United  
Hospital Fund

Shaping New York's Health Care  
Information, Philanthropy, Policy.

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TO: Chris Jennings  
FROM: Jim Tallon  
DATE: December 2, 1999  
SUBJECT: Names

T: 202 456-5560  
F: 202 456-5557  
Three pages

Attached is a list of the Board of Directors of the Quality Forum, and a list of the members of the Quality Forum Framework Board.

As you will recall, the Framework Board is the "expert group" which will take the lead in developing a national strategy for quality information.

I have checked the Framework Board members who served on the IOM committee.

Note that Gail Warden, Chairman of the Board of Directors of the Quality Forum, also served on the IOM committee. I'd suggest that you use him as the lead representative of the Quality Forum in developing your plans. I've given him a heads-up on our conversation.

QF  
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