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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. email	John Eisenberg to Devorah Adler re: Comments on DPC Exec Summary (partial) (1 page)	02/12/2000	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20470

FOLDER TITLE:
Errors [Folder 1]

2012-0463-S
rc744

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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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]
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b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

"Eisenberg, John" <JEisenbe@AHRQ.GOV>
02/12/2000 05:57:11 PM

Record Type: Record

To: Devorah R. Adler/OPD/EOP

cc:
Subject: FW: Comments on DPC Exec Summary: IOM Errors Report

Chris and Devorah-

This is much better stylistically and, as you suggest, will be much easier for lay people to read. It deals effectively with the biggest challenge we had -- making it read like a single report and not an collection of responses from a variety of Federal agencies. That same advantage does present some challenges that we need to deal with in the next couple of days.

Here are some thoughts. Note that I have numbered the lines.

One issue is that DHHS's ASPA felt quite strongly that we should not do a side by side analysis of the IOM report and our response. I hope the new organization of the Executive Summary doesn't provoke a non-concurrence from them.

In general, we will need to reorganize Chapter 2 to be consistent with this. That should not be a problem. Taking Chapter 3 (which describes actions that go beyond the IOM) is more of a problem. Some of those initiatives may need to be added back to the summary. Ditto for Chapter 4. Also, are there items in Chapters 3 and 4 that should be added to the summary? How about the decision support and informatics plans?

I wonder if we adequately respond to Secretary Shalala's request that we make it clear very early in the report that we support the IOM recommendations and support both voluntary and mandatory reporting.

Of course, we need to get the numbers filled in by the relevant agencies (lines 60, 68, 71, etc.). Did you already tell them we need the numbers?

Shall we keep the summary list of all the detailed action items as an attachment to the summary or as part of it?

lines 23-29: Let's use the exact language of the IOM: Establish a national

focus; Identify and learn; Create safe practices

line 44: minor matter: needs space between lines

page 2: leaves out OPM and HCFA while mentioning other key QuIC agencies. There is language from earlier drafts to put back in.

line 127: A formatting matter: The subtitles need to be in bold if the "IOM Recommendation..." is, and perhaps a larger font

lines 114-121: Here is the place that I think we should articulate that difference, but also the complementarity, of reporting for learning and reporting for accountability. We can explain the strongly held belief of experts that disclosed reporting will tend to suppress reporting and make learning difficult (note testimony before Commerce Committee on February 9).

114-121: I think Nancy Ann Min Deparle was right that we need to state our enthusiasm for working with Congress on this.

line 120-121: The information is useful for more than learning, but also for accountability to a public that wants both assurances of safety and information to help them choose providers.

line 140: private sector entities and public sector partners

line 142: say consumers and patients or just patients

145-149: Also, solicitations for grants, support centers of excellence in patient safety in private sector, develop and evaluate tools for measurement and improvement

line 149: Be careful about promising that CQuIPS will make actual data available. It will make information available, but not necessarily raw data, even if re-identified. We want not to get embroiled in the debate over privacy regs.

line 180: also to policy makers, to clinicians and to patients (or the public, or whatever you want to call them other than consumers)

line 190: drop "to" in to ensure

line 195-202: Is this new? I don't see it in the text we did. I agree with it, but we may need to add language in the text and may need concurrence

line 206: add "or" in or negligence

line 217: Are you sure you want to start with DoD? Seems like a weak way to start

Somewhere in here we lost the HCFA PRO project and the emphasis on reporting for learning

line 230-234: These are actually patient safety practices. The word measures was used initially, but people confused the word as the noun for

measuring with the noun as in "taking a measure." Making it "practices" throughout will be less confusing.

line 234: We should state here that we encourage that this information be disclosed to the public voluntarily by hospitals.

line 243: We discussed how this merges two ideas that should be distinct: the idea that HCFA submitted re working with PROs, and the CQuIPS/AHRQ responsibility for working with states and others who have reporting systems to evaluate how they can work best (HHS and WH people felt strongly about the word "how" as opposed to "whether" they work)

Also, we seem to have lost the flavor of the HCFA plan to work with a state on public reporting of events that should never occur (What Jeff Kang calls "never events," and others call "egregious" events).

line 250: This should be a responsibility of CQuIPS, or of QuIC, led by CQuIPS

line 277-2981: Is this new? I don't recall it. Does it need to be added to text of report?

lines 283-287: As with mandatory reporting, this should be a responsibility of CQuIPS in AHRQ, or of QuIC led by CQuIPS

line 287: Shouldn't there be mention here of the peer review protections for voluntary reporting?

line 347-352: The FDA has urged inclusion of more language re: their contributions. They will be disappointed.

line 328-332: This should reflect the fact that professional accreditation and certification are not a state matter (while licensing is), but are generally the responsibility of the private sector, especially professional societies or other means of professional self-regulation.
It should be "state-based agencies and professional organizations," I think.

line 329-332: We should be cautious about offering technical assistance to "any state or professional agencies." This could be very costly and difficult to deliver effectively. Let's say the QuIC plans to offer technical assistance to organizations planning...."

line 377: minor matter: it should read "order entry"

line 378: minor matter: "phased into all DoD"

I will be around this weekend, but out tonight. I'd prefer to talk Sunday before 4 or after 10PM.

Nancy Foster and Gregg Meyer may send in additional edits tonight or tomorrow morning.

Thank you very much for what was clearly a lot of work that has made the summary much more readable and more easily understood.

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--John

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pager P6/(b)(6) [001]

-----Original Message-----
From: Devorah_R._Adler@opd.eop.gov [<mailto:Devorah_R._Adler@opd.eop.gov>
mailto:Devorah_R._Adler@opd.eop.gov]
Sent: Friday, February 11, 2000 11:14 PM
To: JEisenbe@AHCPR.GOV
Subject: from Chris J

---------- Forwarded by Devorah R. Adler/OPD/EOP on 02/11/2000
11:14 PM ----------

Devorah R. Adler
02/11/2000 11:11:20 PM

Record Type: Record

To: "Eisenberg, John" <JEisenbe@AHRQ.GOV>

cc:
Subject: from Chris J (Document link not converted)

Attached is our edited version of the executive summary. It does not in any way significantly alter our policy discussions or recommendations but rather focuses on preventing them in a manner that may be somewhat more structures and understandable to the lay reader.

I believe that this draft will better assure a more positive reception to your report and will enable us to better highlight the strong analysis and recommendations from the QuIC. Please review carefully -- we look forward to any comments you may have. I'm also concurrently forwarding copies to Dan, Gary, and Nancy Ann.

Let's talk soon --

cj

(See attached file: exec errors 2-11.doc)

 - *exec errors 2-11.doc*

Doing What Counts for Patient Safety: National Action to Reduce Medical Errors and Their Impact

To Err is Human: Building a Safer Health System, a report released late last year by the Institute of Medicine (IOM), shocked the nation by reporting that up to 98,000 Americans die each year as a result of preventable medical errors. The report concludes that the majority of these errors are the result of systemic problems rather than poor performance by individual providers, and outlined a four-pronged approach to prevent medical mistakes and improve patient safety.

On December 7, President Clinton directed the Quality Interagency Coordination Task Force (QuIC) to evaluate the recommendations in *To Err is Human* and to report back to him with a strategy to reduce medical errors and improve patient safety. This report responds to the President's request and recommends an action plan to implement Administration initiatives designed to help prevent mistakes in the nation's health care delivery system.

Institute of Medicine Recommendations

The IOM report recommends the establishment of a national goal of reducing the number of medical errors by 50 percent over 5 years. To that end, it outlined a four-tiered approach to reduce medical mistakes nationwide, including actions to:

- Create a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety; **too many creates in this**.
- Implement new efforts to identify and learn from medical errors through both mandatory and voluntary reporting systems;
- Raise standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups; and
- Implement safe practices at the delivery level.

Clinton-Gore Commitment to Improving Patient Safety

The Federal government has become a leader in promoting health care quality and improving patient safety. In early 1997, the President established the Advisory Commission on Consumer Protection and Quality in the Health Care Industry (Quality Commission) and appointed Health and Human Services Secretary Shalala and Labor Secretary Herman as co-chairs. The Quality Commission released two seminal reports focusing on patient protections and quality improvement. Subsequent to the Commission's second report on patient safety and quality improvement and consistent with its recommendations, the President established the Quality Interagency Coordination Task Force (QuIC), a umbrella organization also co-chaired by Secretary Shalala and Secretary Herman, to coordinate Administration efforts to improve quality. As he established the QuIC, the President stated that "For all of its strengths, our health care system still is plagued by avoidable errors."

Also consistent with the Quality Commission's recommendations, Vice President Gore launched the National Forum for Health Care Quality Measurement and Reporting. The "Quality Forum", a broad-based, widely representative private advisory body that develops standard quality measurement tools to help all purchasers, providers, and consumers of health care better evaluate and ensure the delivery of quality services. In addition to the work and significant potential of the QuIC and Quality Forum, other Federal agencies have made significant efforts to reduce medical errors and increase attention on patient safety.

The Agency for Healthcare Research and Quality (AHRQ) is the lead coordinating agency for the QuIC. It sponsors research examining the frequency and cause of medical errors and tests techniques designed to reduce these mistakes. It also examines issues more generally related to health care quality, including over and under-use of services.

The Departments of Defense (DOD) and the Veterans Affairs (VA), serving 3.5 million patients nationwide, have begun to implement computerized physician order entry systems, which have proven effective in reducing medical errors such as drug interactions. In addition, the Veterans Administration has implemented a computerized medical record in X percent of their 172 hospitals nationwide, making it possible to significantly reduce errors and correctly measure risks **Correctly measure risks? How will a computerized medical record do this?** by providing complete information about patients at the point of care. Over the past 3 years, the VA created an error reporting system, established four Centers of Inquiry for Patient Safety, and begun to use barcode technology to reduce errors in the use of medications.

The Centers for Disease Control and the Food and Drug Administration collect data on adverse events that are the result of treatment, such as hospital acquired infections and the unintended effects of drugs and medical devices. *[insert sentence on CDC reporting results]* FDA receives approximately 100,000 reports per year of adverse events associated with medical devices and over 250,000 reports of adverse events associated with pharmaceuticals. FDA estimates that over one-third of the adverse events associated with medical devices and ___ of the adverse events associated with pharmaceuticals are preventable. The Department of Labor's Pension and Welfare Benefit Administration (PWBA) has advised employers and plan decision makers to include quality among factors they consider in selecting health plans for employees.

While these agencies have made notable contributions to reducing preventable medical errors, additional and aggressive efforts are needed in and outside of the Federal government to reduce these mistakes. **The "these" is an indefinite reference**.

A National Epidemic **(This is not the right word and conveys a sense that errors were at some acceptable level before, but have we have had an outbreak of errors that is spreading rapidly through the country. I don't think we want to give anyone that impression.)**

It is clear that the rate **(not the rate, because we don't know the rate, and those who have studied the field would find this amusing. Can' we just say the number of errors?)** of error in the health care field is at unacceptably high levels. The Institute of Medicine's report estimates that more than half of the adverse medical events occurring each year are due to

preventable medical errors, causing the death of as many as 98,000 Americans. The cost associated with these errors in lost income, disability, and health care costs is as much as $29 billion annually. The consequences of medical mistakes are often more severe than the consequences of mistakes in other industries – leading to death or disability rather than inconvenience on the part of consumers – underscoring the need for aggressive action in this area. **Poorly designed cars, infant equipment, and toys, and airplanes that fall from the sky also have pretty horrific consequences. Not sure we need to assert that our work is more important than that of other industries in assuring safe use of products.**

A wide body of research, much of it funded by the AHRQ, **(I think we can claim to have funded key part of the research, but "much" is a bit of a stretch.)** supports the IOM conclusions. In a study of intensive care units, the correct medical intervention was taken 99 percent of the time, translating to 1.7 errors per day. One out of five of these errors were serious or potentially fatal (Leape, 1994). If the performance levels found in the ICU were was applied to the airline or banking industries, it would be the equivalent of 840 unsafe airplane landings per day and 320,000 checks being deducted from the wrong account per hour (Dean, 1996). A 1999 study of hospital admissions in Colorado and Utah demonstrated that in some health care systems, the number of errors is even higher. In these hospitals, the correct action was taken in only 96.3 percent of the time – an alarmingly high prevalence of adverse events (Gawande, 1999).

Many of these adverse events are associated with the use of pharmaceuticals, and are potentially preventable. The IOM estimates that the number of lives lost to preventable medication errors are estimated to account for over 7,000 deaths annually – more than the number of Americans injured at the workplace. In addition, medication related errors are estimated to increase hospital costs by $4,700 per admission – about $2 billion nationwide. **(These numbers look funny. We need to check them. The average cost per admission is somewhere around $11,000. This says that almost half of it is attributable to med errors. Also, the math here would indicate that there are about 425,500 admissions per year. From HCUP 1996 data, we know there are almost 35 million.)** A 1995 study estimated that problems related to the use of pharmaceutical drugs account for nearly 10 percent of all hospital admissions, and significantly contribute to increased morbidity and mortality in the United States (Bates, 1995). A 1991 study of hospitals in New York State indicated that drug complications represent 19 percent of all adverse events, and that 45 percent of these adverse events were caused by medical errors. In this study, 30 percent of the individuals with drug-related injuries died (Leape, 1991).

A Road Map for Action: The Federal Response

The QuIC agencies join the IOM's call for action to reduce errors, implement a system of public accountability, develop of a robust knowledge base about medical errors, and change the culture in health care organizations to promote the recognition of errors and improvement in patient safety. This report describes the actions that the QuIC agencies will take to build on current programs and develop new initiatives to reduce errors. In particular, it describes efforts to develop mandatory and voluntary reporting systems for the public to use in judging health care safety and making choices about their care. **This seems misleading. We have some efforts directed at providing public with information, but not all will do this.** Information from both

will enrich the base of knowledge that health care professionals can use to learn how to prevent errors.

The QuIC fully supports the IOM's goal of reducing the number of medical mistakes by 50 percent over 5 years and has developed a strategy that builds on the IOM recommendations and, in some cases, goes beyond them. This strategy is detailed below.

Create a National Focus to Enhance the Knowledge Base on Patient Safety

IOM Recommendation: Creating a Center for Patient Safety. The IOM recommends that Congress create a Center for Patient Safety within the Agency for Healthcare Research and Quality that will set the national goals for patient safety, track progress in meeting these goals, and issue an annual report to the President and Congress on patient safety. The Center should also enhance the current knowledge base on patient safety by developing a research agenda, funding Centers of Excellence, evaluating methods for identifying and preventing errors, and funding dissemination and communication activities to improve patient safety.

QuIC Response. The Administration endorses the IOM recommendation and is pleased that the President has included $20 million in the FY 2001 budget to create a new Center for Quality Improvement and Patient Safety at the Agency for Healthcare Research and Quality. **(This wording plays into the concern that folks expressed that this would just be an opportunity to create another federal bureaucracy. Folks on the IOM committee have told us that they have caught a lot of flack for proposing that another government organization be established. The truth is we aren't going to spend $20 million to create an organization. We are going to create it at little cost (new stationery and maybe a new hire or two) and spend $20 million on important research to get the error reduction effort moving. I think the Administration should take credit by not making it seem like the answer is a $20 million new bureaucratic organization. This is obviously a political call, and I defer to your judgment on how to portray it.)** The Center will work with private sector entities, including the Quality Forum, to develop national goals for patient safety; issue an annual report on the state of patient safety nationally; promote the translation of research findings into improved practices and policies; and educate consumers about patient safety. **Educating consumers requires big $$$ or big partnerships. This seems a bit ambitious as a promise.**

Within the next year, AHRQ will hold a national conference on patient safety to set coordinated research agendas across the field and lay the groundwork for future action to develop and encourage the expansion of error reporting systems. The Center will also develop a national clearinghouse for the data collected by voluntary and mandatory reporting systems that currently exist and make this data available to the public in a manner that protects privacy. **(As John indicated earlier, we aren't planning to make the data public, just the learnings about what factors are likely to cause errors –like having concentrated doses of drugs next to the diluted ones on the shelf in the nursing station ---- and how to reduce errors.)**

Identifying and Learning From Errors

IOM Recommendation: Establishing reporting systems nationwide. The IOM recommends that the Administration and the Congress move to establish a nationwide system of error reporting that includes both mandatory and voluntary components.

Mandatory Reporting Systems. The IOM recommends the development of a nationwide mandatory reporting system to provide for the collection of standardized information by state governments about adverse events that result in death or serious harm. The report states that adverse event reporting should initially be required of hospitals and eventually be required of other institutional and ambulatory care delivery systems. It recommends that this system should be implemented nationwide, linked to systems of accountability, and made available to the public. IOM concludes that **if** states choose not to implement the mandatory reporting system, HHS should serve as the responsible entity.

Voluntary Reporting Systems. The IOM report rejects the establishment of a national voluntary reporting system and offers a variety of options for more limited voluntary reporting systems that function in all 50 states and build on currently existing options, including the development of systems focused on selected areas, such as medications, surgery, and pediatrics or using a sampling technique to collect the full range of information from a limited subset of health care providers. The IOM recommends that more research be conducted to determine the best way to develop voluntary reporting systems that can identify potential precursors to error and prevent patient harm. It also recommends that the Congress extend peer review protections to data related to patient safety and quality improvement collected through voluntary reporting systems.

QuIC response. The Administration **(Here, and in a couple of other places, the QuIC is called "the Administration." Are you sure you want to imply that we are speaking on behalf of the Administration? I know the QuIC contitutes a substantial piece of it, but...)** agrees with the IOM that error reporting systems should be established in all 50 states, and that these systems should have both mandatory and voluntary components. **While this statement is true, it ignores the other systems that we think will provide valuable info --- like the Federal systems.** Well designed reporting systems serve two important functions – to hold health systems accountable for delivering high quality health care and to provide important information to researchers and health systems decision-makers that will improve patient safety. **(As discussed on the phone, well designed reporting systems are unlikely to be able to serve both masters of accountability and learning. The QuIC folks think that there is a natural bridge between the two --- that once you have learned that something works to reduce errors, you need to hold people accountable for implementing it and report on whether they do or not, but as this sentence stands, you couldn't get agreement on it from the QuIC)**

Mandatory Reporting Systems. The Administration supports the development of state-based systems to require the collection of standardized information on preventable adverse events that result in death or serious harm. We agree with the IOM that the scope of events targeted by mandatory reporting systems should be limited to serious and preventable adverse events associated with death or significant patient harm. **This sentence is actually problematic. We currently run mandatory systems that require a lot more reporting than this, such as the CDC's NNIS, the FDA required reporting of by-device manufacturers, the VA's system for**

all its hospitals. I can't imagine that you are suggesting that we abandon these mandatory reporting systems, but one could read that into this sentence. By limiting this required reporting system to the most profound challenges in the health care delivery system, this approach will most effectively target these problems. It will also minimize the cost to health care organizations of operating the oversight system and to ensure the availability of resources to appropriately follow up on and analyze reported events. **Again, problematic for the reasons noted above. Also, implies you are willing to wait until someone is killed or hurt before doing a root cause analysis and trying to avoid an error.** The QuIC believes that information collected through a mandatory reporting system should be aggregated by health system and made public. However, there should be no identification of patients or individual health care professionals. **Again, we explicitly don't do this with data currently gathered in our mandatory reporting systems --- they are mandatory, but designed to promote learning.**

We agree with the IOM that patients should have access to any and all information leading up to and including the occurrence of a preventable error that caused death or serious injury. **This is a statement with serious implications. Not only will ASPE need to think about this, but the lawyers at the Federal agencies with delivery sites will need to be consulted.** However, we believe that subsequent "root-cause" analyses undertaken to determine the internal shortcomings of the hospital's delivery system should not be subject to discovery in litigation and that appropriate legislation should be enacted to extend these peer review protections to this information. **To the extent we discussed this in the QuIC, we explicitly did not limit the information that was to be protected to the root cause analyses. We did think the entire report should not be discoverable, just like in the FAA and the current CDC systems. The sentence as written is not an accurate portrayal of what the QuIC believes.** Moreover, the QuIC believes that these mandatory reporting systems should not be used as a tool for punitive action by state and local authorities but rather as should be used as a mechanism for highlighting errors that can and should be prevented in the future. **This seems disingenuous at best. We want to hold organizations publicly accountable by releasing information to the public that will affect individuals choices of hospitals and other providers, and we are encouraging purchasers to use the information in their choices, but we don't want to use it to "punish" organizations. Exactly what do we think giving the market information to affect their choices will do if not punish the bad performers?**

It is important to note the QuIC believes that any legislation or administrative intervention in this area should not undermine individuals' rights to redress for criminal activity, malpractice, negligence. The QuIC does not support legislation that would allow safety reporting systems to serve as a shield for providers engaging in illegal or negligent behavior.

The IOM has a set of specific recommendations for the structure of a nationwide mandatory reporting system. The QuIC believes that, at this time, there is not sufficient evidence to determine whether establishing Federal requirements for reporting or encouraging the development and implementation of state-based mandatory reporting systems would be most effective. Therefore, in order to demonstrate the importance of implementing mandatory reporting systems and to create an environment in which there is more widespread support for their use, the Administration will take the following actions:

- *Implementing a mandatory reporting system in the over 300 hospitals operated by the Department of Defense.* Beginning this spring, the Department of Defense will invest $X million begin to implement a mandatory reporting system in its 300 hospitals serving approximately 8 million patients. This mandatory reporting system, which will be modeled on the system in operation at the Department of Veterans Affairs, will be fully implemented in ____ and will collect information on adverse events, medication errors, and other patient safety issues. This data will used to design corrective action to ensure patient safety. **What is said here is true, but the implication from the discussion above it is wrong. There is no intention to make this data available to the public. It is a mandatory confidential, reporting system for learning. As of last week, the DoD had no intention of allocating additional dollars for implementing it. Don't ask me how they planned to do it without an investment of $$$ in data collection and analysis, but I asked the question and was specifically told there were no funds being devoted to it.**

- *Expand mandatory reporting requirements for blood banks nationwide.* By the end of the year, the Food and Drug Administration (FDA) will improve the safety of transfusions by requiring all X blood banks and establishments dealing with blood products to report errors and accidents, such as mistyping blood and distributing contaminated blood products. Failure to report these incidents will result in _____. **~~Per conversation with FDA's CDER on Friday, they do not intend to expand this into hospital blood banks. It will only apply to those that are independent. Need to check with FDA for precise wording here.~~**

- *Identify a set of patient safety measurements critical to the identification of medical errors.* The QuIC will ask the Quality Forum to identify patient safety measures that should be adopted by all hospitals within six months and encourage their widespread use. Developing standardized measures lays the foundation for a uniform system of data collection and facilitates the development of these systems. **See John's note re: measures versus practices. It is vital that we be clear.**

- *Identifying issues related to the implementation of mandatory reporting systems.* Using the Quality Forum's recommendations for patient safety standards, the Health Care Financing Administration (HCFA) will develop a pilot project to implement mandatory reporting systems in up to X hospitals participating in the Medicare program. This pilot project will help identify issues related to the implementation of mandatory reporting systems and better inform states and health systems developing these systems. **This is to be done in partnership with one state that already has an existing mandatory reporting scheme. It will really be a modification of what the state requires to be reported.**

- *Determine the most effective way to present information on the incidence of medical errors to the public.* HCFA will work with the Quality Forum and states with mandatory reporting systems to establish a pilot project to determine how data on medical errors can be presented – and the impact of providing such information – to the general public and local policy officials. Since informing the public about the safety of their health care systems is a critical component of mandatory reporting systems, this pilot project will inform action on this issue.

This is really part of the demo above. The QuIC work group on Patient and Consumer info, which HCFA and OPM co-chair will be looking at the presentation issues in

collaboration with the Quality Forum. The only HCFA will do particularly will be to look at whether the info on "never events" is of particular use to consumers. The lack of success of the Medicare mortality statistics and the CABG data reported by NY and PA makes us at least somewhat skeptical that we can effectively communicate information that people want.

- *Examine existing mandatory reporting systems.* The QuIC will evaluate the effectiveness of currently existing mandatory reporting systems at the Federal and state levels and develop recommendations to improve them. This information will be presented to states and other organizations considering developing systems or who currently have existing systems in order to help them design effective reporting systems likely to improve patient safety.

We hope that these actions will encourage states to begin implementing their own mandatory reporting systems for preventable adverse events. The QuIC will monitor the number of states with mandatory reporting systems over the next three years. If all states have not implemented mandatory reporting systems within that time, the QuIC will develop recommendations to the President that would assure that all health care institutions are reporting serious preventable adverse events within the next 12 months. **("all health care institutions" is a bigger group than hospitals. Did you really mean all health care institutions?)**

Although currently the QuIC believes that moving towards a mandatory reporting system is the appropriate course of action, it is important to note that if research conducted by AHRQ and other agencies indicates that the implementation of these systems does not significantly enhance patient safety, these results will be included in the QuIC's final recommendations on this issue at the end of the three year period.

Voluntary Reporting Systems. The QuIC agrees with the IOM that voluntary reporting systems are a critical component of a national strategy to reduce errors. **Actually, what we agreed was that systems for learning were a critical component, and lots of the QuIC folks want to contribute information from their mandatory , but not disclosed, reporting systems to the learning data base This would include VA, DOD, CDC.** The information from voluntary reporting systems is usually gathered by an independent entity in order to identify patterns of error that apply to all health care systems. This information, which would include data on so-called "near-misses" that do not have immediate impact on patients, would be used to educate providers and alter systems of care to prevent harming patients. In order to encourage the development of voluntary reporting systems, the Administration will:

- *Implement a voluntary reporting system nationwide for Veterans Administration hospitals.* By the end of the year, the VA will implement a voluntary reporting system for both adverse events and "near misses" nationwide. Information will be collected by an independent external entity, analyzed, and disseminated to all VA health care networks to help prevent medical errors before they occur. **Actually, the VA system is mandatory. Jim Bagian doesn't like to talk about it in those terms, but the front office did tell everyone in the VA that they needed to report. They promised it would be non-punitive.**

- *Examine existing voluntary systems.* The QuIC will evaluate the effectiveness of currently existing voluntary reporting systems at the Federal and state levels and develop

recommendations to improve them. This study will make recommendations about which entity or entities would be best to collect, analyze, and disseminate information on frequently occurring errors and the best interventions to prevent them. **Loses the point that we are trying to bring these data sets together into one national data base.**

This comes across as pretty weak. What the QuIC believes, and what it said in the initial draft is that improvement will come from analysis and feedback that is developed through systems for learning, not through systems designed for accountability. If we think this is where the real progress is going to be made, which is also what the experts from other industries will tell you, then this is where the emphasis has to be.

Setting Performance Standards and Expectations for Safety

IOM Recommendation: Include patient safety in performance standards and expectation for health care organizations. The IOM recommends that regulators and accreditors should require health care organizations to implement meaningful patient safety programs with defined executive responsibility. Public and private purchasers should provide incentives to health care organizations to demonstrate continuous improvement in patient safety.

QuIC response. The QuIC reviewed current Federal activities and proposed several ways to improve safety through current oversight activities. These include:

- *Requiring the X hospitals in the Medicare program to implement patient safety programs.* By the end of the year, HCFA will publish regulations requiring all X hospitals participating in the Medicare program to have ongoing error reduction programs that emphasize reducing medication errors. In order to comply with this requirement, hospitals are likely to implement automated pharmacy order entry systems and include automatic safeguards built into the treatment process against harmful drug interactions and other adverse side effects.

- *Requiring the over 300 health plans in the Federal Employees Health Benefits Program to implement patient safety programs.* In their annual call letter to be issued in the spring of 2000, the Office of Personnel Management will announce that beginning in FY 2001, all health plans participating in the program will be required to include error reduction and patient safety techniques in provider contracts in order to improve the quality of care.

- *Educating private sector employers and employees about the importance of patient safety.* This year, the Department of Labor will include information on medical errors in the Health Benefits Education Campaign. This national effort educates employees about issues of quality and safety under their employer provided health benefits so that they can make informed health benefits decisions and educates employers in order to facilitate the provision of high quality, affordable health benefits to their employees. **This is true, but we might want to make the link to performance standards for health care organizations more transparent. Otherwise, it doesn't seem to fit.**

IOM Recommendation: Performance standards and expectations for health professionals should focus greater attention on patient safety. Periodic re-examination and re-licensing of

doctors, nurses, and other key providers should be conducted based on both competence and knowledge of safety practices. Professional societies should make a visible commitment to patient safety by establishing a permanent committee dedicated to safety improvement.

QuIC response. The QuIC is supportive of these goals, but recognizes and agrees with the IOM that these are state-based programs. However, the QuIC will provide technical assistance to any state or professional agencies seeking to ensure a basic level of knowledge for health care providers on patient safety issues or promote model patient safety programs that include evidence based best patient safety practices to provider organizations. **John commented about this.**

IOM Recommendation: FDA should increase attention to the safe use of drugs. Both pre and post-marketing processes should be improved to maximize safety in use. FDA should develop and enforce standards for the design of drug packaging and labeling that will maximize safety in use and require pharmaceutical companies to test proposed drug names to identify potential sources of confusion with existing drug names. In addition, the agency should work with physicians, pharmacists, consumers, and others to establish appropriate responses to problems identified through post-marketing surveillance activities.

QuIC response. The QuIC endorses the IOM recommendation. FDA currently has a strong program of pre and post-market surveillance, is pleased that the President has committed $33 million, **Is this the total amount? I know that the increase in FDA's budget was about 15 million for these activities, but that does not jibe with this figure or this percentage.** an increase of 39 percent over last year's funding level, in his FY 2001 budget to prevent medical errors associated with drugs and medical devices. It would:

- *Initiate new efforts to ensure that pharmaceuticals are packaged and marketed in a manner that promotes patient safety.* Within one year, FDA will develop new standards to help prevent medical errors caused by proprietary drug names that sound similar or packaging that looks similar, making it easy for health care providers to confuse medications. The agency will also develop new label standards by the end of the year that highlight common drug-drug interaction problems and other dosage errors related to medications.

- *Providing patient safety information to the public.* Within a year, FDA will provide access to databases linked to health care systems and other sources of adverse event and marketing data, and link these to existing registries of product users. **I am not sure what you meant to say here.**

Implementing Safety Systems in Health Care Organizations

IOM Recommendation: Health care organizations should make continually improved patient safety a declared and serious aim. Patient safety programs should provide strong, clear, and visible attention to safety; implement non-punitive systems for reporting and analyzing errors within their organizations; and incorporate well understood safety principles.

QuIC response. The QuIC supports this recommendation, and Federal agencies will take the following action.

The Department of Veterans Affairs. The VA is considered one of the national leaders in patient safety, having instituted patient safety programs in all of its 172 hospitals serving 3.5 million patients nationwide. This year, the VA will invest $X million to increase the requirement for patient safety training for staff from 20 to 25 hours a year and place "patient safety checklists" in operating rooms in every hospital nationwide.

The Department of Defense. Beginning this fall, the Department of Defense will begin the implementation of a computerized medical record, including an automated entry order system for pharmaceuticals, that will be phased to all DOD facilities over three years. **The DoD already has this in place in many of its facilities. It is upgrading it this fall, but it won't be new.** DOD will also pilot a new patient safety program in 10 hospitals that includes a special focus on improving the quality of care in "high hazard areas", including labor and delivery rooms, emergency rooms, operating rooms, and intensive care units. **This actually is not a DoD effort. It is a QuIC effort and there will be more than 10 teams from the DoD and lots of teams from other QuIC participating organizations in this Breakthrough collaborative. If we are going to mention this, we ought to at least talk about all of the participants.**

IOM Recommendation: Improve medication safety. Health care organizations should implement proven medication safety practices.

QuIC Response. The QuIC endorses this recommendation. This year, the Veterans Administration will invest $X million to complete the implementation of an automated order entry system in all of its hospitals and a barcoding system for the distribution of medications. A 1999 evaluation of this system indicates that it has reduced medication errors by 70 percent since its implementation. By the end of October 2000, the Department of Defense will invest $X million to implement an integrated pharmacy system that enables clinical screening for drug interactions at military and private pharmacies serving DOD beneficiaries nationwide. In addition, in order to comply with the new proposed requirement that hospitals participating in the Medicare program must have error reduction programs, hospitals are likely to implement automated pharmacy order entry systems. **While these data systems are important, they hardly constitute the whole of safe medication practices. There are lots of cases to highlight the dangers of keeping doses of drugs at the nurses stations, that indicate the need for clearer labelling, and so forth. We shouldn't make it sound like this is all we are doing.**

Conclusion

The bold actions called for by the IOM report require a collaborative response among Federal agencies and between government and the private sector. In this report, the QuIC proposes to take strong action on each and every one of the IOM recommendations to promote safer health care. While some of the recommendations of the IOM can be addressed individually by specific agencies, such as those proposed for AHRQ, FDA, DOD, and VA, the majority of the proposed actions require joint effort. Collaboration – federal agencies working together through the

QuIC, and with states and the private sector organizations – can more rapidly and more effectively improve patient safety. The QuIC and its participating agencies are eager to partner with a broad array of public, state, and private organizations in a national effort to reduce medical errors and improve patient safety.

add peer review protections language

The kind of information that is produced from these systems needs to be useful to those who can act on it. Learning systems must be designed to produce information for providers, drug and device manufacturers and others. Accountability systems must meet the information needs of the public, public policy makers, and purchasers. The data needs for accountability and those for learning are complementary but not identical.

The QuIC believes that the IOM is correct in identifying these information needs, and will take steps—in collaboration with a variety of other organizations—to begin to meet them.

add DoD & FDA blood products

no make consistent

Accountability

The Federal agencies are committed to providing the public with information about the safety of the health care delivery system, in general, and about the providers from which they can choose. To that end, the QuIC proposes the development of a mandatory system of reporting that reflects whether health care organizations have adopted key methods proven through research to be effective in reducing errors. This information will be made publicly available. As a start, OPM will require that the provider organizations with which it does business have patient safety programs in place and provide public information on what those programs do. This information will be disseminated broadly on OPM's Web site and through other mechanisms available to it. Methods for insuring this reporting are further described in "Raising the Standards for Health Care Organizations" and "Raising the Standards for Health Care Professionals," below.

point out public aspects of VA & DOD

Patients can reveal information about their care experiences, including errors that occurred during their care, that are not otherwise available. Systems will also be created that will enable patients to report errors and adverse events, using a standard reporting format that will complement the error reporting and collection activities of health care professionals and facilities. To collect such data, the QuIC will design a Web-based error reporting mechanism.

Within six months, HCFA, with a Peer Review Organization (PRO) program will develop a pilot of a confidential, penalty-free learning system with several hospitals on a voluntary basis.

is this consistent?

First, the PRO will assemble routine hospital error reports to create a highly confidential database of documented errors occurring in the participating hospitals. This database would include both near misses and actual patient harm. The PRO will use the standard taxonomy of medical errors adopted by the Quality Forum, and use the collected data for education and technical assistance, not for punitive actions. This is consistent with the educational strategy that PROs have adopted over the past decade.

Second, the PRO will provide support for provider and practitioner error reduction programs through participating in local root cause analysis of near misses as well as the episodic serious adverse events, to identify patterns of medical errors. The PRO will feed back and interpret information from the database, convene workgroups of interested and

expert parties, and facilitate the exchange of best practices that could be shared between participating hospitals. The PRO will also provide the data, with all identifiers removed, to AHRQ, HCFA, and other partners and investigators. With this information, the PRO will work with hospitals and practitioners on systems interventions to reduce medical errors.

While the aggregate database is being created, Federal agencies, such as the VA, CDC, and FDA will continue to examine their own data for critical information on why errors occur and how to avoid them. This information will continue to be communicated to appropriate health care organizations, manufacturers, and others who need to act on it. Once the database has been created, AHRQ will lead Federal efforts to expand both the knowledge of errors and communication with providers and others who can act on this information. Both information about methods shown to be effective in reducing errors and particular hazards will be communicated to providers.

The information about what methods have been shown to be effective in reducing errors will also be shared with organizations that have health care oversight or purchasing responsibilities, so that they can choose to incorporate them into their efforts to ensure accountability as appropriate. This forms a natural link between the learning systems and the accountability systems for error reduction. Health care provider organizations can be held responsible for adopting methods shown to be effective in reducing errors, and the public should be given information that demonstrates such initiatives are in place and are effective.

On January 14, 2000, President Clinton acknowledged these characteristics of successful safety reporting systems when he announced a program that will provide immunity from punishment to airlines' personnel when they report to the FAA operational and procedural errors that threaten passenger safety. The program's goal, much like that of patient safety systems, is to identify trends early and address them before they cause harm or injury.

add for mandatory systems

The program is committed to providing appropriate protections for data in the system, but the protections will depend on the nature of the data and reporting systems. Such statutory protections already exist in the Medicare program for mandatory reporting to the program's Peer Review Organizations (except when used in criminal investigations). These protections should be extended to protect voluntary reporting to achieve the greatest level of learning. The specific details of the appropriate legal protections must be negotiated with Congress, the industry, and States.

Previous discussion has focused on developing reporting systems for learning that deal with system-wide rather than individual performance issues. It is important to understand that individual performance issues are best addressed through credentialing, licensing, and other administrative mechanisms. The QuIC expects that will continue to be the case. However, it is important to note that safety reporting systems should never become a shield from necessary actions to address criminal activity or deliberately unsafe acts. The obligation to report these activities still exists, and mechanisms to address those issues should be maintained. For example, the Health Resources and Services Administration

(HRSA)-sponsored National Practitioner Data Bank records disciplinary actions taken against providers. It is maintained, in part, to help institutions carry out their responsibility for patient safety by searching for and reviewing records of applicants who are seeking staff appointments.

ACTIONS::

- The QuIC supports the extension of peer review protections to facilitate reporting of errors in a blame-free environment, and will propose considerations of confidentiality that will not undermine current mechanisms to address criminal activity or negligence.
- As part the development of the national reporting system, appropriate electronic protections (i.e., firewalls and encryption) will be constructed to ensure that the confidentiality of the patients involved and the clinician or institution providing the information is maintained, and that the information gathered will not be used for punitive purposes. Experience with reporting systems in other industries demonstrates that this approach encourages reporting of errors.

Patient Safety Programs

IOM Recommendation

therapy goals and incidents of adverse drug effects; safety issues; and staff, administrator, and practitioner performance.

add HCFA COP announcement

The current CoP require that hospitals meet State laws, which includes error reduction systems. Thus, Medicare rules support existing State requirements for confidential reporting, whether voluntary or mandatory.

Accreditation surveys monitor whether QAPI activities to reduce medical errors are occurring in Medicare participating hospitals. Enforcement actions will be taken only if such activities are not taking place. HCFA expects hospital accreditation organizations (i.e., JCAHO) to develop mechanisms for reporting and modify their standards to reflect the revised Medicare hospital CoP.

Purchasers, both public and private, have leverage to stress the importance of a safe environment in which to deliver patient care. This leverage must put a premium on medical error reduction through identification, systems approaches to resolution, and assessment of overall effectiveness. Both through its own purchasing power and by working closely with private purchasers, HCFA will institute financial and burden-reduction incentives to move providers to create a safer health care environment. In addition, HCFA, as a purchaser, will work with and support accreditation organizations' efforts to set standards for patient safety, to measure and report results, and to use these standards in their purchasing decisions. The Office of Personnel Management (OPM) will require that all plans with which it contracts be accredited by organizations that include

sponsor health services will collaborate in a four-part program to foster a reduction of medical errors and to promote health care quality This program will include:

1. **Programs that directly impact health care quality in the community:** HRSA, HCFA, OPM, and VA, with other appropriate agencies will foster community and professional programs that increase quality of health care (such as DQIP, the recently developed Diabetes Quality Improvement Project) and decrease errors (for example, pharmacy prescription surveillance programs). HRSA will use the Area Health Education Center (AHEC) Program and other programs that affect continuing professional education in the community to increase such error reduction and quality promotion programs.

2. **Quality Infrastructure Development:** Agencies such as DoD and VA, together with other agencies as appropriate, will develop studies and tools for error detection and reduction. These tools will reflect both internal experience as well as other scientific and evidence-based information.

3. **Health Professionals Education and Training:** HRSA, HCFA, and other Government agencies will foster development of courses and training materials that promote error reduction and patient safety by providing incentives through grants and contracts for the development of new curricula in health care quality and error reduction methodologies. These will explore clinical training programs that could incorporate the simulation models tested by VA, DoD, and others to reduce error in

CHAPTER 3

Beyond the IOM Report: Identifying and Implementing Additional Strategies

While the IOM report offered many useful recommendations for improving the safety of the health care system, additional actions can and should be taken to reduce errors. Federal agencies have been working on a variety of projects designed to reduce medical errors and, in many instances, are the national leaders in experimenting with programs intended to promote safety. With proper resources and authority, the agencies could undertake many more projects. A brief description is provided below of some of the current activities, as well as recommendations for additional activities to reduce errors through increased awareness of medical errors; commitment of substantial resources to further research; the use of information systems; and the redesign of systems, procedures, and medical products.

Building Public Awareness of Medical Errors

Information technology has tremendous potential to reduce errors in health care by providing information when it is needed, providing clinical feedback, and alerting providers to potential problems. But, as noted earlier, information technology also has the potential to cause errors. Therefore, attention to human factors and other aspects of system design is vital. Additional research is needed to explore the safety and effectiveness of, for example, decision support systems embedded in software, and other technical aspects of medical products.

ACTIONS::

- AHRQ and CDC will expand research efforts in the area of informatics to include initiatives aimed at developing and evaluating electronic systems to identify, track, and address patient safety concerns.
- CQuIPS at AHRQ, along with VA, DoD, FDA and other QuIC member agencies, will evaluate the effectiveness of automated physician order entry systems in hospitals.
- DoD, VA, and IHS will introduce electronic patient records to offer structured documentation and a common clinical lexicon for practitioners working throughout those systems. The QuIC will encourage other potential Federal participants to do likewise.

Action Items from QuIC Report

National Focus and Leadership

ACTIONS:

1

- AHRQ will establish the Center for Quality Improvement and Patient Safety (CQuIPS), which will replace and broaden the mission of AHRQ's Center for Quality Measurement and Improvement.
- CQuIPS will be used to coordinate with and complement other public and private sector initiatives to improve patient safety.
- QuIC will be used to coordinate Federal activities on patient safety, as it does on the broader quality agenda. This will include both regular meetings of the QuIC and use of its current structure to redirect QuIC workgroup efforts towards enhancing patient safety.
- AHRQ will sponsor a program to educate personnel of QuIC member agencies about patient safety, bringing them together with leading researchers on human factors analysis, systems design, error reporting, and quality improvement. This curriculum could serve as a model and be expanded for future educational activities with private sector partners.

Research Planning

ACTIONS:

2

- *Hold National Summits on Medical Error and Patient Safety Research* : AHRQ will lead the convening of conferences and expert meetings to review the information needs of those who wish to improve safety, assess the current state of patient safety research, set coordinated research agendas, and develop adequate reporting mechanisms. VA will lead a summit on lessons learned from its experiences in improving patient safety, and the FDA will lead a summit on drug errors.
- *Establish joint research solicitations (including partnerships between AHRQ, CDC, FDA, and VA):*
  - *Fundamental Research on Errors:* Investigate the role(s) of human factors, root causes analysis, informatics, and legal/judicial issues.
  - *Research on Reporting Systems:* Identify critical components of successful reporting systems used for learning, examine options for voluntary and mandatory reporting systems, implement and evaluate demonstration programs for reporting, evaluate existing State mandatory reporting systems, and investigate techniques and methods for analyzing and disseminating patient safety data (including integration into a National Healthcare Quality Report being prepared by DHHS under the leadership of AHRQ and CDC).
  - *Applied Research on Patient Safety:* Test the application of human factors knowledge to the design of health care products, processes, and systems; identify

best practices in reducing errors; fund patient safety "Centers of Research Excellence"; and support research and demonstrations on site, as well as level-of-care and cross-cutting research such as diagnostic accuracy, informatics applications, and systems re-engineering.

- *Develop tools for the public and private sector to support efforts to enhance patient safety including:*
  - — *Laboratories*: Identify tools and approaches from other industries that could be applied to the health care sector and develop community-based laboratories for error reduction through medical specialty societies, primary care networks, and integrated service delivery networks.
  - — *Measures*: Develop and evaluate data specifications for reporting on patient safety and work with the National Quality Forum and other private and public sector efforts on developing consensus around a core set of measures for patient safety
- *Finalize a QuIC Research Agenda on Working Conditions and Patient Safety:* The QuIC will finalize a research agenda to explore the relationship between health care workers' working conditions and the quality of patient care, including patient safety. CDC and AHRQ will coordinate this activity with VA and other agencies.

Learning from Errors

ACTIONS:

- The QuIC proposes that the new Center for Quality Improvement and Patient Safety (CQuIPS) at AHRQ identify existing State and Federal reporting systems (i.e., mandatory and voluntary), evaluate their suitability in helping to build a national system of errors reporting, and evaluate whether their data collection or enforcement efforts need to be enhanced to improve the value of those systems.
- QuIC will convene sponsors and users of external reporting systems to evaluate what works and does not work well in these systems.
- QuIC will work with the National Forum for Health Care Quality Measurement and Reporting to develop reporting criteria that assure that information can be pooled and shared as needed across organizations.
- The CQuIPS, working with the QuIC, will describe and disseminate information on characteristics of existing voluntary reporting programs associated with successful error reduction and patient improvement efforts. FDA, CDC, VA and NASA will provide expertise in the development of these nonpunitive systems
- Federal agencies, in partnership with others, will develop options for mandatory reporting systems that provide the public and purchasers with publicly available information about programs and procedures in place to reduce errors. This work will require the development of evidence-based, systems level measures.
- The QuIC will support evaluation of these systems, using a core list of measures developed in collaboration with the National Quality Forum, to determine the value of mandatory reporting of patient safety efforts. (Refer to Chapter 4 for more detailed information.)

- HCFA and its QuIC partners will work with the Quality Forum or similar entity to develop and define a finite list of "never" events with unambiguous definitions.
- HCFA, working with a State that already has an existing mandatory reporting requirement, will conduct a pilot of a mandatory reporting system of "never events." HCFA will publish the hospital rates for these events without patient identifiers.
- HCFA and its QuIC partners will evaluate whether consumers found this information valuable and what they understood about it, and the impact of such a system on a "penalty-free" confidential learning system. If successful, HCFA will move towards a national mandatory reporting system for publication for all hospitals participating in the Medicare program.

Reporting Systems

what about national database?

ACTIONS:

- Federal agencies, including the FDA, VA. DoD, CDC, HCFA and AHRQ, will integrate data from different sources and conduct and support analysis to identify error pronc procedures, products, and systems.
- AHRQ, in collaboration with other federal agencies, will develop strategies to provide effective feedback to clinicians and institutions on methods for improving patient safety.
- Federal agencies will assist health care providers to develop the skills necessary for analyzing adverse events and near misses (e.g. root cause analysis, trending, search tools). Federal agencies providing health care will develop internal systems to (1) identify and report errors to clinicians and other decision makers, and (2) learn from those errors and near misses in order to prevent future events.
- *Develop Joint Dissemination Activities*:

— *Outreach to Stakeholders*: QuIC will develop programs to foster the dissemination of research findings to end users through activities such as AHRQ's User Liaison Program; provide support to the Quality Forum to increase the national discussion on errors, their reduction, and standardized measures of errors; and fund collaborative agreements with health care professional organizations that foster education, track patient safety initiatives, provide input to the new patient safety research centers, and translate, disseminate, and promote adoption of research findings.

— *Patient Safety Clearinghouse*: AHRQ will develop a clearinghouse in partnership with other Federal agencies and *private* sector organizations to provide an objective source of state-of-the art information on patient safety, initiate a "National Morbidity & Mortality Conference" posting de-identified selected cases in a public forum via internet technology, and establish a Web site where patients can report incidents that will be analyzed to identify emerging problems.

Peer Review Protections

ACTIONS:

- The QuIC supports the extension of peer review protections to facilitate reporting of errors in a blame-free environment, and will propose considerations of confidentiality that will not undermine current mechanisms to address criminal activity or negligence.
- As part the development of the national reporting system, appropriate electronic protections (i.e., firewalls and encryption) will be constructed to ensure that the confidentiality of the clinician or institution providing the information is maintained, as is the patient's confidentiality, and that the information gathered will not be used for punitive purposes.

Patient Safety Programs

ACTIONS:

- Under the leadership of the CQuIPS, the QuIC will promote at the executive level the development and dissemination of evidence-based best patient safety practices to provider organizations.
- QuIC participants, including HCFA, VA, DoD, AHRQ, CDC, and FDA, will explore opportunities with private sector accreditation, purchaser, and provider organizations to develop organization-based patient safety models that could be evaluated, and if found effective, disseminated widely. In addition, these stakeholders will be engaged in a regular dialogue with QuIC participants to ensure that organizational needs are being met through federal research and reporting initiatives.
- Through its exemplary patient safety program, VA will continue to scrutinize its care provision for opportunities to improve safety, and develop and expand its reporting system.
- The DoD will complete development of a patient safety improvement program based on a reporting system modeled on VA's system.
- Other QuIC direct care providers will initiate patient safety programs (e.g., HRSA's community health care centers are investigating the most effective programs that can be implemented in their health care delivery systems).

What about purchasing power?

Safe Use of Drugs and Devices

ACTIONS:

The FDA will initiate programs to:

- Develop additional standards for proprietary drug names to avoid name confusion.
- Develop standards for packaging to prevent dosing and drug mix-ups.
- Lead in the development of new label standards for drugs, to highlight drug–drug interaction problems and other common errors related to medications.

- Improve the safety of transfusions by expanding mandatory reporting requirements for blood bank errors and accidents so that they apply to all registered blood establishments.
- Implement the Phase II pilot study of the Congressionally mandated Medical Product Surveillance Network (MedSUN).
- Intensify efforts to ensure manufacturers' compliance with FDA programs, specifically naming, labeling and packaging.
- Provide access to databases linked to health care systems and other sources of adverse-event and marketing data, and linking these to existing registries of product users.
- Complete the on-line Adverse Event Reporting Systems (AERS) for drugs and biologics
- Strengthen FDA's analytical and investigative capacities and
- Strengthen FDA outreach activities and collaboration with other government agencies and stakeholders.

Raising the Standards for Health Care Organizations

ACTIONS:

- HCFA will amend the Medicare hospital Conditions of Participation to require error reduction initiatives as a necessary component for certification and accreditation.
- HCFA will use its power as a purchaser and regulator to promote the use of effective error reduction initiatives in the health care institutions with which it deals.
- By 2002, OPM will follow the lead of selected private purchasers to raise the standard for participation by requiring that all health plans with which it contracts seek accreditation from and independent, national accrediting organization that includes evaluation of patient safety and programs to reduce errors in health care.

Raising the Standards for Health Care Professionals

ACTIONS:

The QuIC will:

- Develop and evaluate programs introducing health professionals to errors analysis and the challenges of practicing in a technically complex environment, explore the use and testing of simulators and automation as education tools, support training in errors research and evaluation, and develop patient safety expertise at the State level using the CDC's Epidemic Intelligence Service as a model.
- Convene a meeting of the accrediting, licensing and certifying bodies of the health professions to review information on medical errors in the context of current practice requirements and propose methods of strengthening health professions education in the areas of medical error prevention and medical error evaluation as a means of improving patient safety.
- Collaborate with the Federation of State Medical Boards and other entities to

encourage error reduction and prevention education be a provision for relicensing of health professionals.
- Collaborate in the planning, implementation, and evaluation of a national summit addressing patient safety and medical error reduction programs and producing directives for the future.
- QuIC agencies that provide care will provide training to encourage use of patient safety information and encourage enhanced reporting in partnership with private sector accreditors, purchasers, and providers.

Building Public Awareness of the Problem

ACTIONS:
- Through the QuIC's Patient and Consumer Information Work Group, led by OPM and HCFA, Federal agencies will develop and coordinate an information campaign for their constituencies/beneficiaries to increase their awareness of the problem of medical errors and patient safety.
- All QuIC agencies will include patient safety information on their web sites.
- AHRQ will develop generic material for the public on preventing medical errors that Federal agencies can disseminate, reprint, or adapt. This material will enable patients to become more involved in their care and more active participants in the decision making surrounding their care.
- AHRQ will develop a national patient safety bulletin board to allow individuals who believe a mistake has been made affecting them or a family member to report it in an anonymous fashion in the hope that others will not be subject to the same error. The bulletin board will also serve as a check on the pulse of the public concerning patient safety which could be used to target research supported by AHRQ.
- The CQuIPS will develop and test patient safety questions for inclusion in the provider level patient assessment of health care survey now being developed.
- HCFA will conduct formative research on how best to educate beneficiaries about medical errors.
- FDA will increase collaborative programs with patient and consumer groups regarding patient safety.
- FDA will enhance its interactions with the public through meetings with consumer and patient organizations and grass roots information meetings regarding patient needs and safe use of medical products, particularly for home use, and how to reach patients with important information on safe use of medical products through local networks and through use of electronic and print media.

Building Purchasers' Awareness of the Problem

ACTIONS:
- Building on existing relationships with purchasers and business coalitions, such as the National Business Coalition on Health, and the Washington (DC) and Midwest

Business Coalitions on Health, DOL, HCFA, OPM, and AHRQ will spearhead the QuIC's efforts to promote collaborative programs with other public- and private-sector partners to increase purchasers' and providers' awareness of the problem of medical errors, and steps that each can take to address the problem, including the issue of patients' health literacy skills.

- At the Federal Benefits Conference (June 2000), OPM will share information about patient safety with representatives from Federal agencies throughout the Nation.
- OPM will require that health plans describe their patient safety initiatives, will make patient safety information available in both print and electronic formats for the open enrollment period in Fall, 2000, and will expand its web site to include information about programs designed to reduce errors and enhance patient safety.

Working with Providers to Improve Patient Safety

ACTIONS:

- Through the QuIC, Federal agencies will leverage existing resources to promote collaborative patient safety programs with constituents, the health professional community, the public, academia, and other stakeholders, such as the American Medical Association, the American Nurses Association, NPSF, NPSP, and the Quality Forum.
- VA will develop and pilot patient safety education to medical residents and students.
- HCFA, in collaboration with FDA and AHRQ, will develop a strategy for incorporating patient safety into the pharmacy benefit managers program under an expanded Medicare drug benefit.

Using Decision Support Systems and Information Technologies

ACTIONS:

- AHRQ and CDC will expand research efforts in the area of informatics to include initiatives aimed at developing and evaluating electronic systems to identify, track, and address patient safety concerns.
- CQuIPS at AHRQ, along with VA, DoD, FDA and other QuIC member agencies, will evaluate the effectiveness of automated physician order entry systems in hospitals.
- DoD, VA, and IHS will finalize introduction of electronic patient records to offer structured documentation and a common clinical lexicon for practitioners working throughout those systems. The QuIC will encourage other potential federal participants to do likewise. by when?

Using Standardized Procedures, Checklists, and the Results of Human Factors Research

ACTIONS:

- CDC and FDA will work with the DHHS Advisory Committee on Blood Safety and Availability to help ensure the highest quality in blood collection and transfusion.
- FDA will work with manufacturers of medical products to explore incorporating standards, including human factors standards, into guidance to ensure that medical products are designed to minimize the chance of errors.
- NASA will be invited to become a participant in QuIC activities and bring its understanding and experience in redesigning processes and procedures to enhance safety. Linkages between NASA and the CQuIPS will be established through the NASA Medical Policy Board.
- AHRQ and CDC will develop a focused research initiative on worker safety, which will include an examination of the relationship between worker safety and patient safety.
- The QuIC will sponsor an educational program, noted in the section on research above, to increase the awareness of federal regulators and policymakers regarding patient safety, human factors, and systems based improvement.
- VA will continue to work with private sector organizations (e. g., the American Hospital Association and JCAHO) to explore the utility of its comprehensive error analysis and corrective action system.

Standards

ACTIONS:

- The QuIC and its member agencies will ask independent accrediting organizations to demonstrate how they are coordinating and strengthening their patient safety standards.
- AHRQ's CQuIPS, through its research agenda articulated above, will develop evidence based standards and measures integrating human factors and lessons from other industries.
- As with the DQIP measurement set, the QuIC will solicit formal adoption and use of common, validated, and standardized performance measures in the area of error reduction by member agencies. The QuIC will work with certifying boards for healthcare professionals to incorporate these measures into certification and re-certification programs where appropriate.
- QuIC agencies will encourage their private-sector partner organizations to support the implementation of more rigorous safety standards and will facilitate the ability of private sector partners to do so
- The QuIC will work through the Quality Forum, the NPSF, and the NPSP to collaborate with private-sector organizations, industry representatives, academic institutions, and scientific and health care professionals to examine issues related to standards, to test standards of performance measurement, and to establish a set of core standards.
- DOL will build on existing DOL/NAIC collaboration to exchange information between DOL, the States, employers, plans and individual patients on medical errors and safe, high-quality health care.

- OPM will participate with private-sector organizations in the development of standards and measures, will share the DQIP and other QuIC-adopted standards and measures with its health plans, and advocate the use of such standards and measures throughout plan networks.
- OPM will also begin collecting performance measurement data from its participating plans and will make performance information available to Federal Employees Health Benefits Program enrollees by 2003.
- Patient safety and reducing medical errors will be a featured topic at OPM's Fall 2000 annual health plan conference.

Data Integration

ACTIONS:

- The QuIC members will work with and support the Quality Forum in its identification of a core set of errors reporting data.
- AHRQ, working with its QuIC partners, will identify existing data sets such as the State mandatory errors reporting data that can be collected to enhance the Nation's knowledge and understanding of errors. Based upon experience with the HCUP and the CDC's data integration efforts, AHRQ will work with those entities that have the data to determine the feasibility of integrating the data and use such data to learn about opportunities to reduce errors and enhance patient safety.
- OPM will discuss with health plans and preferred provider organizations the development of strategies for focusing disease management programs and integrated data systems on the goal of avoiding errors and improving patient outcomes.
- In its call letter for the 2001 contract year, OPM will ask health plans to encourage their preferred hospitals to use automated prescription systems and other integrated data systems.
- OPM will encourage health plans to annotate PPO directories to indicate which hospitals and physicians offices use such automated programs.

Executive Office of the President of the United States
Office of Management and Budget

Office of Information and Regulatory Affairs
Human Resources and Housing Branch
New Executive Office Building
Room 10235
Washington, DC 20503

FAX TRANSMITTAL

FAX: 202-395-6974

DATE: 2/2/2000

TO: Deborah Adler

FROM: Allison Eydt

Total number of pages (Including Transmittal Sheet): 7 pgs.

Recipient's Fax Number: 6-5557

Recipient's Telephone Number:

Comments: Pursuant to phone message . . . Time Sensitive:

F.Y.I I have attached an HCFA change page pertaining to pending medical errors and excerpts from proposed Conditions of participation reg for Medicare rural clinics. If you have serious concerns, please let me know by 5:30 p.m. tomorrow. Thanks!

(We have had these rule for a while it needs to move . . . .)

oriented. Maybe, in the future, we will change all of part 491 to focus on outcomes.

A recent study of the Institute of Medicine (IOM) of the National Academies discussed medical errors as one of the nation's leading causes of death and injury. The study estimated that more people die from medical errors each year than from highway accidents, breast cancer, or autoimmune deficiency syndrome. We have been concerned about medical errors for some time and are exploring how to address this issue through our rulemaking process.

We want to make it clear that the requirements of QAPI set forth in this proposed rule for RHCs will address the issues of measuring and prioritizing the medical errors of underuse, overuse, and misuse. These issues are clearly concerns of the public, healthcare providers, and others, as highlighted by the IOM study. RHCs will be required to develop and implement programs that will foster continuous and proactive approaches to discovering and prioritizing opportunities to improve patiet outcomes. Medical errors would clearly be a priority area for improvement actions.

We are proposing to replace the current requirements in §491.11 with the proposed QAPI condition that contains three standards: the first addresses the components of a performance improvement program; the second addresses

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405 and 491

[HCFA-1910-P]

RIN 0938-AJ17

Medicare Program; Rural Health Clinics: Amendments to Participation Requirements and Payment Provisions; and Establishment of a Quality Assessment and Performance Improvement Program

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend our regulations to revise certification and payment requirements for Rural Health Clinics (RHCs) as required by the Balanced Budget Act of 1997 (BBA 1997). It would include new refinements of what constitutes a qualifying rural shortage area in which a Medicare RHC must be located; establish criteria for identifying RHCs essential to delivery of primary care services that can continue to be approved as Medicare RHCs in areas no longer designated as medically underserved; and limit waivers of certain nonphysician practitioner staffing requirements. It also would impose payment limits on provider-based RHCs and prohibit "commingling" the use of the space, equipment, and other resources of an RHC with another entity. Finally, the rule would require RHCs to establish a quality assessment and performance improvement program that goes beyond current regulations.

This proposed rule would make other revisions for clarity and uniformity and to improve program administration.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on **[OFR--insert 60 days after the date of publication in the Federal Register]**.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address:

Health Care Financing Administration,
Department of Health and Human Services,
Attention: HCFA-1910-P,
P.O. Box 26676,
Baltimore, MD 21207-0476.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 443-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201, or
Room C5-09-26,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

Comments may also be submitted electronically to the following e-mail address: HCFA1910P@hcfa.gov. For e-mail comment procedures, see the beginning of SUPPLEMENTARY INFORMATION. For further information on ordering copies of the **Federal Register**

* * * * *

(d) Temporary staffing waiver. (1) HCFA may grant a temporary waiver of the RHC staffing requirements in paragraphs (a)(1) and (a)(6) of this section for a 1-year period to a qualified RHC, if the RHC requests a waiver and demonstrates that it has been unable, despite reasonable efforts in the previous 90-day period, to hire a nurse midwife, nurse practitioner, or physician assistant to furnish services at least 50 percent of the time the RHC operates.

(2) If the RHC is not in compliance with the provisions waived under paragraph (a)(1) and paragraph (a)(6) of this section at the expiration of the waiver, HCFA terminates the RHC from participation in the Medicare program.

(3) The RHC may submit its request for an additional waiver of staffing requirements under this paragraph no earlier than 6 months after the expiration of the previous waiver.

5. Section 491.11 is revised to read as follows:

§491.11 Quality assessment and performance improvement.

The RHC must develop, implement, evaluate, and maintain an effective, ongoing, data-driven quality assessment and performance improvement (QAPI) program. The program must be appropriate for the level of complexity of the RHC's organization and services. The program should achieve, through ongoing measurement and intervention, demonstrable and sustained improvement in significant aspects of clinical care and nonclinical services.

(a) Standard: Components of a QAPI program.

(1) The RHC's QAPI program must include, but not be limited to, the use of objective measures to evaluate the following:

(i) Clinical effectiveness (for example, appropriateness of care, and prevention).

(ii) Access to care (for example, availability and accessibility of services, cultural competency, and emergency intervention).

(iii) Patient satisfaction.

(iv) Utilization of clinic services, including at least the number of patients served and the volume of services.

(2) Projects that focus on clinical areas should include, at a minimum, high-volume and high-risk services, the care of acute and chronic conditions, and coordination of care.

(3) Projects that focus on nonclinical services should include, at a minimum, criteria to measure convenience and timeliness of available services and grievances and complaints.

(b) Monitoring performance activities. For each of the areas listed in paragraph (a)(1) of this section, the RHC must adopt or develop performance criteria that reflect processes of care and RHC operations. The RHC must use those criteria to analyze and track its performance. These performance criteria must be shown to be predictive of desired patient outcomes or be the outcomes themselves.

(c) Program responsibilities. The RHC's professional staff, administrative officials, and governing body (if applicable) are responsible for ensuring that quality assessment and performance improvement efforts effectively address identified priorities. They are responsible for identifying or approving those priorities

and for the development, implementation, and evaluation of improvement actions.

2

Errors in Health Care: A Leading Cause of Death and Injury

Health care is not as safe as it should be. A substantial body of evidence points to medical errors as a leading cause of death and injury.

- Sizable numbers of Americans are harmed as a result of medical errors. Two studies of large samples of hospital admissions, one in New York using 1984 data and another in Colorado and Utah using 1992 data, found that the proportion of hospital admissions experiencing an adverse event, defined as injuries caused by medical management, were 2.9 and 3.7 percent,[1] respectively. The proportion of adverse events attributable to errors (i.e., preventable adverse events) was 58 percent in New York, and 53 percent in Colorado and Utah.[2]
- Preventable adverse events are a leading cause of death in the United States. When extrapolated to the over 33.6 million admissions to U.S. hospitals in 1997, the results of these two studies imply that at least 44,000 and perhaps as many as 98,000 Americans die in hospitals each year as a result of medical errors.[3] Even when using the lower estimate, deaths in hospitals due to preventable adverse events exceed the number attributable to the 8th leading cause of death.[4] Deaths due to preventable adverse events exceed the deaths attributable to motor vehicle accidents (43,458), breast cancer (42,297) or AIDS (16,516).[5]
- Total national costs (lost income, lost household production, disability, health care costs) are estimated to be between $37.6 billion and $50 billion for adverse events and between $17 billion and $29 billion for preventable adverse events.[6] Health care costs account for over one-half of the total costs. Even when using the lower estimates, the total national costs associated with adverse events and preventable adverse events represent approximately 4 percent and 2 percent, respectively, of national health expenditures in 1996.[7] In 1992, the direct and

indirect costs of adverse events were slightly higher than the direct and indirect costs of caring for people with HIV and AIDS.[8]

- In terms of lives lost, patient safety is as important an issue as worker safety. Although more than 6,000 Americans die from workplace injuries every year,[9,10] in 1993 medication errors are estimated to have accounted for about 7,000 deaths.[11] Medication errors account for one out of 131 outpatient deaths and one out of 854 inpatient deaths.
- Medication-related errors occur frequently in hospitals; not all result in actual harm, but those that do are costly. One recent study conducted at two prestigious teaching hospitals found that almost two percent of admissions experienced a preventable adverse drug event, resulting in average increased hospital costs of $4,700 per admission or about $2.8 million annually for a 700-bed teaching hospital.[12] If these findings are generalizable, the increased hospital costs alone of preventable adverse drug events affecting inpatients are about $2 billion for the nation as a whole.
- Hospital patients represent only a fraction of the total population at risk of experiencing a medication-related error. In 1998, nearly 2.5 billion prescriptions were dispensed by U.S. pharmacies at a cost of about $92 billion.[13] Numerous studies document errors in prescribing medications,[14,15] dispensing by pharmacists,[16] and unintentional nonadherence on the part of the patient.[17] Medication errors have the potential to increase as a major contributor to avoidable morbidity and mortality as new medications are introduced for a wider range of indications.

This chapter provides a summary of findings in the literature on the frequency and cost of health care errors and the factors that contribute to their occurrence.

INTRODUCTION

Although the literature pertaining to errors in health care has grown steadily over the last decade and some notable studies are particularly strong methodologically, we do not yet have a complete picture of the epidemiology of errors. Many studies focus on patients experiencing injury and provide valuable insight into the magnitude of harm resulting from errors. Other studies, more limited in number, focus on the occurrence of errors, both those that result in harm and those that do not (sometimes called "near misses"). More is known about errors that occur in hospitals than in other health care delivery settings.

Synthesizing and interpreting the findings in the literature pertaining to errors in health care is complicated due to the absence of standardized nomenclature. For purposes of this report, the terms error and adverse event are defined as follows:

> *An error is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning).*[18]

> *An adverse event is an injury caused by medical management rather than the underlying condition of the patient. An adverse event attributable to error is a "preventable adverse event."*[19] *Negligent adverse events represent a subset of preventable adverse events that satisfy legal criteria used in determining negligence (i.e., whether the care provided failed to meet the standard of care reasonably expected of an average physician qualified to take care of the patient in question).*[20]

When a study in the literature has used a definition that deviates from the above definitions, it is noted below.

Medication-related error has been studied extensively for several reasons: it is one of the most common types of error, substantial numbers of individuals are affected, and it accounts for a sizable increase in health care costs.[21, 22, 23] There are also methodologic issues: (1) prescription drugs are widely used, so it is easy to identify an adequate sample of patients who experience adverse drug events; (2) the drug prescribing process provides good documentation of medical decisions, and much of this documentation resides in automated, easily accessible databases; and (3) deaths attributable to medication errors are recorded on death certificates. There are probably other areas of health care delivery that have been studied to a lesser degree but may offer equal or greater opportunity for improvement in safety.

Efforts to assess the importance of various types of errors are currently hampered by the lack of a standardized taxonomy for reporting adverse events, errors, and risk factors.[24,25] A limited number of studies focus directly on the causes of adverse events, but attempts to classify adverse events according to "root causes" are complicated by the fact that several interlocking factors often contribute to an error or series of errors that in turn result in an adverse event.[26,27] In recent years, some progress toward a more standardized nomenclature and taxonomy has been made in the medication area, but much work remains to be done.[28]

The following discussion of the literature addresses four questions:

1. How frequently do errors occur?
2. What factors contribute to errors?
3. What are the costs of errors?
4. Are public perceptions of safety in health care consistent with the evidence?

HOW FREQUENTLY DO ERRORS OCCUR?

For the most part, studies that provide insight into the incidence and prevalence of errors fall into two categories:

1. *General studies of patients experiencing adverse events.* These are studies of adverse events in general, not studies limited to medication-related events. These studies are limited in number, but some represent large-scale, multi-institutional analyses. Virtually all studies in this category focus on hospitalized patients. With the exception of medication-related events discussed in the second category, little if any research has focused on errors or adverse events occurring outside of hospital settings, for example, in ambulatory care clinics, surgicenters, office practices, home health, or care administered by patients, their family, and friends at home.

2. *Studies of patients experiencing medication-related errors.* There is an abundance of studies that fall into this category. Although many focus on errors and adverse events associated with ordering and administering medication to hospitalized patients, some studies focus on patients in ambulatory settings.

Adverse Events

An adverse event is defined as an injury caused by medical management rather than by the underlying disease or condition of the patient.[29] Not all, but a sizable proportion of adverse events are the result of errors. Numerous studies have looked at the proportion of adverse events attributable to medical error. Due to methodologic challenges, far fewer studies focus on the full range of error—namely, those that result in injury *and* those that expose the patient to risk but do not result in injury.

The most extensive study of adverse events is the Harvard Medical Practice Study, a study of more than 30,000 randomly selected discharges from 51 randomly selected hospitals in New York State in 1984.[30] Adverse events, manifest by prolonged hospitalization or disability at the time of discharge or both, occurred in 3.7 percent of the hospitalizations. The proportion of adverse events attributable to errors (i.e., preventable adverse events) was 58 percent and the proportion of adverse events due to negligence was 27.6 percent. Although most of these adverse events gave rise to disability lasting less than six months, 13.6 percent resulted in death and 2.6 percent caused permanently disabling injuries. Drug complications were the most common type of adverse event (19 percent), followed by wound infections (14 percent) and technical complications (13 percent).[31,32]

The findings of the Harvard Medical Practice Study in New York have recently been corroborated by a study of adverse events in Colorado and Utah occurring in 1992.[33] This study included the review of medical records pertaining to a random sample of 15,000 discharges from a representative sample of hospitals in the two states. Adverse events occurred in 2.9 percent of hospitalizations in each state. Over four out of five of these adverse events occurred in the hospital, the remaining occurred prior to admission in physicians' offices, patients' homes or other non-hospital settings. The proportion of adverse events due to negligence was 29.2 percent, and the proportion of adverse events that

were preventable was 53 percent.[34] As was the case in the New York study, over 50 percent of adverse events were minor, temporary injuries. But the study in New York found that 13.6 percent of adverse events led to death, as compared with 8.8 percent in Colorado and Utah. In New York, about one in four negligent adverse events led to death, while in Colorado and Utah, death resulted in about 1 out of every 11 negligent adverse events. Factors that might explain the differences between the two studies include: temporal changes in health care, and differences in the states' patient populations and health care systems.[35]

Both the study in New York and the study in Colorado and Utah identified a subset of preventable adverse events that also satisfied criteria applied by the legal system in determining negligence. It is important to note that although some of these cases may stem from incompetent or impaired providers, the committee believes that many could likely have been avoided had better systems of care been in place.

Extrapolation of the results of the Colorado and Utah study to the over 33.6 million admissions to hospitals in the United States in 1997, implies that at least 44, 000 Americans die in hospitals each year as a result of preventable medical errors.[36] Based on the results of the New York study, the number of deaths due to medical error may be as high as 98,000.[37] By way of comparison, the lower estimate is greater than the number of deaths attributable to the 8th leading cause of death.[38]

Some maintain these extrapolations likely underestimate the occurrence of preventable adverse events because these studies: (1) considered only those patients whose injuries resulted in a specified level of harm; (2) imposed a high threshold to determine whether an adverse event was preventable or negligent (concurrence of two reviewers); and (3) included only errors that are documented in patient records.[39]

Two studies that relied on both medical record abstraction and other information sources, such as provider reports, have found higher rates of adverse events occurring in hospitals. In a study of 815 consecutive patients on a general medical service of a university hospital, it was found that 36 percent had an iatrogenic illness, defined as any illness that resulted from a diagnostic procedure, from any form of therapy, or from a harmful occurrence that was not a natural consequence of the patient's disease.[40] Of the 815 patients, nine percent had an iatrogenic illness that threatened life or produced considerable disability, and for another two percent, iatrogenic illness was believed to contribute to the death of the patient.

In a study of 1,047 patients admitted to two intensive care units and one surgical unit at a large teaching hospital, 480 (45.8 percent) were identified as having had an adverse event, where adverse event was defined as "situations in which an inappropriate decision was made when, at the time, an appropriate alternative could have been chosen".[41] For 185 patients (17.7 percent), the adverse event was serious, producing disability or death. The likelihood of experiencing an adverse event increased about six percent for each day of hospital stay.

Some information on errors can also be gleaned from studies that focus on inpatients who died or experienced a myocardial infarction or postsurgical complication. In a study of 182 deaths in 12 hospitals from three conditions (cerebrovascular accident, pneumonia, or myocardial infarction), it was found that at least 14 percent and possibly as many as 27 percent of the deaths might have been prevented.[42] A 1991 analysis of 203 incidents of cardiac arrest at a teaching hospital,[43] found that 14 percent followed an iatrogenic complication and that more than half of these might have been prevented. In a study of 44,603 patients who underwent surgery between 1977 and 1990 at a large medical center, 2,428 patients (5.4 percent) suffered complications and nearly one-half of these complications were attributable to error.[44] Another 749 died during the same hospitalization; 7.5 percent of these deaths were attributed to error.

Patients who died during surgery requiring general anesthesia have been the focus of many studies over the last few decades. Anesthesia is an area in which very impressive improvements in safety have been made. As more and more attention has been focused on understanding the factors that contribute to error and on the design of safer systems, preventable mishaps have declined.[45,46,47,48] Studies, some conducted in Australia, the United Kingdom and other countries, indicate that, today, anesthesia mortality rates are about one death per 200,000–300,000 anesthetics administered, compared with two deaths per 10,000 anesthetics in the early 1980s.[49] The gains in anesthesia are very impressive and were accomplished through a variety of mechanisms, including improved monitoring techniques, the development and widespread adoption of practice guidelines, and other systematic approaches to reducing errors.[50]

Lastly, some studies have relied on incident reporting systems to identify and analyze errors. For example, in Australia, 324 general practitioners participating voluntarily in an incident reporting system reported a total of 805 incidents during October 1993 through June 1995, of which 76 percent were preventable and 27 percent had the potential for severe harm.[51] These studies provide information on the types of errors that occur but are not useful for estimating the incidence of errors, because the population at risk (i.e., the denominator) is generally unknown.

Medication-Related Errors

Even though medication errors that result in death or serious injury occur infrequently, sizable and increasing numbers of people are affected because of the extensive use of drugs in both out-of-hospital and in-hospital settings. In 1998, nearly 2.5 billion prescriptions were dispensed in U.S. pharmacies at an estimated cost of about $92 billion.[52] An estimated 3.75 billion drug administrations were made to patients in hospitals.[53]

In a review of U.S. death certificates between 1983 and 1993, it was found that 7,391 people died in 1993 from medication errors (accidental poisoning by drugs, medicaments, and biologicals that resulted from acknowledged errors by

patients or medical personnel), compared with 2,876 people in 1983, representing a 2.57-fold increase.[54] Outpatient deaths due to medication errors rose 8.48-fold during the 10-year period, compared with a 2.37-fold increase in inpatient deaths.

Medication Errors in Hospitals

Medication errors occur frequently in hospitals. Numerous studies have assessed the incidence of adverse drug events (ADEs), defined as an injury resulting from medical intervention related to a drug.[55] Not all ADEs are attributable to errors. For example, a patient with no history of allergic reactions to drugs, who experiences an allergic reaction to an antibiotic, has suffered an ADE, but this ADE would not be attributable to error. However, an error would have occurred if an antibiotic was prescribed to a patient with a history of documented allergic reactions, because the medical record was unavailable or not consulted. We discuss only those studies of ADEs that identified the subset of ADEs determined to be preventable (i.e., attributable to errors).

In an analysis of 289,411 medication orders written during one year in a tertiary-care teaching hospital, the overall error rate was estimated to be 3.13 errors for each 1,000 orders written and the rate of significant errors to be 1.81 per 1,000 orders.[56] In a review of 4,031 adult admissions to 11 medical and surgical units at two tertiary care hospitals, Bates et al. identified 247 ADEs for an extrapolated event rate of 6.5 ADEs per 100 nonobstetrical admissions, and a mean number per hospital per year of approximately 1,900 ADEs.[57] Twenty-eight percent were judged preventable.

In a study of patients admitted to coronary intensive care, medical, surgical, and obstetric units in an urban tertiary care hospital over a 37-day period, the rate of drug-related incidents was 73 in 2,967 patient-days: 27 incidents were judged ADEs; 34, potential ADEs; and 12, problems orders.[58] Of the 27 ADEs, five were life threatening, nine were serious, and 13 were significant. Of the 27 ADEs, 15(56 percent) were judged definitely or probably preventable. In a study of prescribing errors detected and averted by pharmacists in a 631-bed tertiary care teaching hospital between July 1994 and June 1995, the estimated overall rate of errors was 3.99 per 1,000 medication orders.[59]

Children are at particular risk of medication errors, and as discussed below, this is attributable primarily to incorrect dosages.[60,61] In a study of 101,022 medication orders at two children's teaching hospitals, a total of 479 errant medication orders were identified, of which 27 represented potentially lethal prescribing errors.[62] The frequency of errors was similar at the two institutions, 4.9 and 4.5 errors per 1,000 medication orders. The error rate per 100 patient-days was greater in the pediatric intensive care units (PICUs) than in the pediatric ward or neonatal intensive care units, and the authors attribute this to the greater heterogeneity of patients cared for in PICUs and the broad range of drugs and dosages used. In a four-year prospective quality assurance study, 315

medication errors resulting in injury were reported among the 2,147 neonatal and pediatric intensive care admissions, an error rate of one per 6.8 admissions.[63] The frequency of iatrogenic injury of any sort due to a medication error was 3.1 percent—one injury for each 33 intensive care admissions.

Not surprisingly, the potential for medication-related error increases as the average number of drugs administered increases. In a prospective cohort study of 4,031 adult admissions to 11 medical and surgical units in two tertiary care hospitals (including two medical and three surgical ICUs), the rate of preventable ADEs and preventable potential ADEs in ICUs was 19 events per 1,000 patient-days, nearly twice the rate of non-ICUs.[64] When adjusted for the number of drugs used in the previous 24 hours or ordered since admission, there were no differences in error rates between ICUs and non-ICUs.

Current estimates of the incidence of medication errors are undoubtedly low because many errors go undocumented and unreported.[65,66,67,68] For example, in a study of patients admitted to five patient care units at a tertiary care hospital during a six month period in 1993, it was found that incident reports were filed with the hospital's quality assurance program or called into the pharmacy hotline for only three of the 54 people experiencing an adverse drug event.[69]

Some errors are also difficult to detect in the absence of computerized surveillance systems. In a study of 36,653 hospitalized patients, Classen et al. identified 731 ADEs in 648 patients, but only 92 of these were reported by physicians, pharmacists, and nurses.[70] The remaining 631 were detected from automated signals, the most common of which were diphenhydramine hydrochloride and naloxone hydrochloride use, high serum drug levels, leukopenia, and the use of phytonadione and antidiarrheals.

Medication Errors in Ambulatory Settings

There is evidence indicating that ADEs account for a sizable number of admissions to inpatient facilities, but we do not know what proportion of these ADE-related admissions are attributable to errors. One study found that between three and 11 percent of hospital admissions were attributable to ADEs.[71] A review of 14 Australian studies published between 1988 and 1996 reported that 2.4 to 3.6 percent of all hospital admissions were drug related, and between 32 and 69 percent were definitely or possibly preventable. Drug groups most commonly involved were cytotoxics, cardiovascular agents, antihypertensives, anticoagulants, and nonsteroidal anti-inflammatory drugs.[72]

ADEs also result in increased visits to physician offices and emergency departments. In an analysis of 1,000 patients drawn from a community, office-based medical practice who were observed for adverse drug reactions, adverse effects were recorded in 42 (4.2 percent), of which 23 were judged to be unnecessary and potentially avoidable.[73] In an analysis of 62,216 visits to an emergency department by patients enrolled in a health maintenance organization

(HMO), it was found that 1,074 (1.7 percent) were related to medication noncompliance or inappropriate prescribing.[74]

There is a sizable body of literature to document the incidence of patient noncompliance with medication regimens, but less is known about the proportion of noncompliance attributable to medical error (defined as accidental or unintentional nonadherence to a therapeutic program) as opposed to intentional noncompliance. In a meta-analysis of seven studies, Sullivan et al. estimate that 5.5 percent of admissions can be attributed to drug therapy noncompliance, amounting to 1.94 million admissions and $8.5 billion in hospital expenditures in 1986.[75] Similar results were obtained by Einarson in a meta-analysis of 37 studies published between 1966 and 1989, which found that hospital admissions caused by ADEs, resulting from noncompliance or unintentionally inappropriate drug use, ranged from 0.2 to 21.7 percent with a median of 4.9 percent and a mean of 5.5 percent.[76] Patient noncompliance is clearly an important quality issue, but it should be emphasized that we do not know the extent to which noncompliance is related to errors.

FACTORS THAT CONTRIBUTE TO ERRORS

Studies of Adverse Events

Patient safety problems of many kinds occur during the course of providing health care. They include transfusion errors and adverse drug events; wrong-site surgery and surgical injuries; preventable suicides; restraint-related injuries or death; hospital-acquired or other treatment-related infections; and falls, burns, pressure ulcers, and mistaken identity. Leape et al. have characterized the kinds of errors that resulted in medical injury in the Medical Practice Study as diagnostic, treatment, preventive, or other errors (see Box 2.1).

More than two-thirds (70 percent) of the adverse events found in this study were thought to be preventable, with the most common types of preventable errors being technical errors (44 percent), diagnosis (17 percent), failure to prevent injury (12 percent) and errors in the use of a drug (10 percent). The contributions of complexity and technology to such error rates is highlighted by the higher rates of events that occur in the highly technical surgical specialties of vascular surgery, cardiac surgery, and neurosurgery. In hospitals, high error rates with serious consequences are most likely in intensive care units, operating rooms and emergency departments.

Thomas et al., in their study of admissions to hospitals in Colorado and Utah experiencing adverse events found that about 30 percent were attributable to negligence.[77] The hospital location with the highest proportion of negligent adverse events (52.6 percent) was the emergency department. The authors note the complexity inherent in emergency medical care and point to the need to improve teamwork and standardize work procedures.

Other studies have made similar attempts to classify errors. Dubois and Brook studied 49 preventable deaths from 12 hospitals, and found that for those who died of a myocardial infarction, preventable deaths reflected errors in management; for cerebrovascular accident, most deaths reflected errors in diagnosis; and for pneumonia, some deaths reflected errors in management and some reflected errors in diagnosis[78]. In an analysis of 203 cardiac arrests at a teaching hospital, Bedell et al., found that of the half that might have been prevented, the most common causes of potentially preventable arrest were medication errors and toxic effects, and suboptimal response by physicians to clinical signs and symptoms[79].

Studies of Medication Errors

Ensuring appropriate medication use is a complex process involving multiple organizations and professionals from various disciplines; knowledge of drugs; timely access to accurate and complete patient information; and a series of interrelated decisions over a period of time. As shown in Box 2.2, errors can creep into this process at various points. Some errors are errors of commission (e.g., administration of improper drug), while others are errors of omission (e.g., failure to administer a drug that was prescribed).

BOX 2.1 Types of Errors

Diagnostic
- Error or delay in diagnosis
- Failure to employ indicated tests
- Use of outmoded tests or therapy
- Failure to act on results of monitoring or testing

Treatment
- Error in the performance of an operation, procedure, or test
- Error in administering the treatment
- Error in the dose or method of using a drug
- Avoidable delay in treatment or in responding to an abnormal test
- Inappropriate (not indicated) care

Preventive
- Failure to provide prophylactic treatment
- Inadequate monitoring or follow-up of treatment

Other
- Failure of communication
- Equipment failure
- Other system failure

SOURCE: Leape, Lucian; Lawthers, Ann G.; Brennan, Troyen A., et al. Preventing Medical Injury. Qual Rev Bull. 19(5):144–149. 1993.

BOX 2.2 Medication Use Processes

Prescribing

- Assessing the need for and selecting the correct drug
- Individualizing the therapeutic regimen
- Designating the desired therapeutic response

Dispensing

- Reviewing the order
- Processing the order
- Compounding and preparing the drug
- Dispensing the drug in a timely manner

Administering

- Administering the right medication to the right patient
- Administering medication when indicated
- Informing the patient about the medication
- Including the patient in administration

Monitoring

- Monitoring and documenting patient's response
- Identify and report adverse drug events
- Reevaluate drug selection, regimen, frequency and duration

Systems and Management Control

- Collaborating and communicating amongst caregivers
- Review and manage patient's complete therapeutic drug regimen

SOURCE: Nadzam, Deborah M., Development of medication-use indicators by the Joint Commission on Accreditation of Health Care Organizations. AJHP. 48:1925-1930, 1991.

Medication errors are often preventable, although reducing the error rate significantly will require multiple interventions. In the study of prescribing errors conducted by Lesar et al.[80], the most common factors associated with errors were decline in renal or hepatic function requiring alteration of drug therapy (13.9 percent); patient history of allergy to the same medication class (12.1 percent); using the wrong drug name, dosage form, or abbreviation (11.4 percent for both brand name and generic name orders); incorrect dosage calculations (11.1 percent); and atypical or unusual and critical dosage frequency considerations (10.8 percent). The most common groups of factors associated with errors were those related to knowledge and the application of knowledge regarding drug therapy (30 percent); knowledge and use of knowledge regarding patient factors that affect drug therapy (29.2 percent); use of calculations, decimal points, or unit and rate expression factors (17.5 percent); and nomenclature—for example incorrect drug name, dosage form, or abbreviations (13.4 percent).

Many studies have identified inappropriate prescribing as a particularly important factor in accounting for medication errors. In an analysis of 1987 Na-

tional Medical Expenditure Survey data, it was found that physicians prescribe potentially inappropriate medications for nearly a quarter of all older people living in the community.[81] In a study of 366 consecutive patients admitted to a department of cardiology, "definite" or "probable" drug events (i.e., adverse drug reactions and dose-related therapeutic failures) accounted for 15 admissions, of which five were judged to be due to error in prescription and another five judged to have been avoidable had appropriate measures been taken by prescribing physicians.[82] In an analysis of 682 children admitted to a Congenital Heart Disease Center at a teaching hospital in the United Kingdom, 441 medication errors were reported by nurses, doctors, and pharmacists, of which prescribing errors accounted for 68 percent, followed by administration errors (25 percent) and supply errors (seven percent).[83] In Burnum's[84] analysis of 1,000 patients drawn from a community office-based medical practice who experienced adverse drug reactions, 23 patients were judged to have experienced an "unnecessary and potentially avoidable" event, 10 of which were due to physician error (i.e., six due to administration of a drug not indicated and four to improper drug administration).

Physicians do not routinely screen for potential drug interactions, even when medication history information is readily available. In an analysis of 424 randomly selected visits to a hospital emergency department, 47 percent led to added medication, and in 10 percent of the visits in which at least one medication was added, the new medication added a potential adverse interaction.[85] In all cases, a medication history was recorded on the patients and available to the physicians.

Errors can occur in the dispensing of drugs by pharmacists. In a recent investigation of pharmacists, the Massachusetts State Board of Registration in Pharmacy estimated that 2.4 million prescriptions are filled improperly each year in Massachusetts.[86] Eighty-eight percent of the errors involved giving patients the wrong drug or the wrong strength.

Errors in the ordering and administration of medications are common in hospitals. Bates et al.[87], in an analysis of more than 4,000 admissions to two tertiary care hospitals, found that about 28 percent of 247 adverse drug events were preventable and most of these resulted from errors that occurred at the stages of ordering and administration. Davis and Cohen[88] in their review of the literature and other evidence on errors report an error rate of 12 percent to be common in the preparation and administration of medications in hospitals. In a study of medication orders at two children's teaching hospitals, Folli et al.[89] found that errors occurred in almost five out of every 1,000 orders and that the most prevalent error was overdose.

Patients make errors too. With greater emphasis on community-based long-term care, increased ambulatory surgery, shorter hospital lengths of stay, and greater reliance on complex drug therapy, patients play an increasingly important role in the administration of drugs. Greenberg et al.[90] found that 4.3 percent of the elderly enrolled in Medicare social HMOs required assistance with the administration of medications. The inability to manage complex drug therapies

explains why some elderly are in institutional rather than community-based long-term-care settings.[91]

Automated information and decision support systems are effective in reducing many types of errors. In an analysis of admissions to 11 medical and surgical units at two tertiary care hospitals, Leape et al.[92] identified 334 errors as the causes of 264 preventable ADEs and potential ADEs. About three out of four errors were caused by one of seven types of systems failures (drug knowledge dissemination, dose and identity checking, patient information availability, order transcription, allergy defense, medication order tracking, and interservice communication), and all could have been improved by better information systems that disseminate knowledge about drugs and make drug and patient information readily accessible at the time it is needed.

Computerized drug order entry systems have much potential to reduce errors. In a study of 379 consecutive admissions to three medical units at an urban tertiary care hospital, 10,070 medication orders were written and 530 medication errors were identified (5.3 errors per 100 orders). More than half of the medication errors involved at least one missing dose of a medication.[93] Of the 530 medication errors, five (0.9 percent) resulted in adverse drug events that were judged preventable, and another 35 represented potential adverse drug events (i.e., medication errors with the potential for injury but in which no injury occurred). Physician computer order entry could have prevented 84 percent missing dose medication errors, 86 percent of potential adverse drug events, and 60 percent of preventable adverse drug events. However, more sophisticated technology is not the only option; involving pharmacists in reviewing drug orders significantly reduced the potential harm resulting from errant medication orders.[94,95]

THE COST OF ERRORS

In addition to the unfortunate health consequences suffered by many as a result of medical error, there are direct and indirect costs borne by society as a whole as a result of medical errors. Direct costs refer to higher health care expenditures, while indirect costs include factors such as lost productivity, disability costs, and personal costs of care.

Based on analysis of 459 adverse events identified by reviewing the medical records of 14,732 randomly selected 1992 discharges from 28 hospitals in Colorado and Utah, Thomas et al., estimated the total costs (lost income, lost household production, disability and health care costs) to be nearly $662 million of which health care costs totaled $348 million.[96] The total costs associated with the 265 of the 459 adverse events that were found to be preventable were $308 million, of which $159 million represented health care costs. Based on extrapolation to all hospital admissions in the United States, the authors estimate the national costs of adverse events to be $37.6 billion and of preventable adverse events to be $17 billion. The total national costs associated with adverse events was approximately 4 percent of national health expenditures in 1996. In 1992,

the direct and indirect costs of adverse events were slightly higher than the direct and indirect costs of caring for people with HIV and AIDS.

It has been estimated that for every dollar spent on ambulatory medications, another dollar is spent to treat new health problems caused by the medication.[97] Studies of the direct costs of medication-related errors fall into three categories; (1) population-based studies of patients in a community or health plan; (2) studies of medication-related errors that occur in hospitals; and (3) studies of medication-related errors that occur in nursing homes.

One estimate places the annual national health care cost of drug-related morbidity and mortality in the ambulatory setting as high as $76.6 billion in 1994.[98] Not all drug-related morbidity and mortality is preventable, but numerous studies document errors in prescribing,[99,100] dispensing by pharmacists,[101] and unintentional nonadherence on the part of the patient.[102]

Medication-related errors occur frequently, most do not result in actual harm, but those that do are costly. One recent study conducted at two prestigious teaching hospitals found that almost two percent of admissions experienced a preventable ADE, resulting in an average increased length of stay of 4.6 days and an average increased hospital cost of nearly $4,700 per admission.[103] This amounts to about $2.8 million annually for a 700-bed teaching hospital, and if these findings are generalizable, the increased hospital costs alone of preventable adverse drug events affecting inpatients are about $2 billion for the nation as a whole.

In a matched case-control study of all patients admitted to a large teaching hospital from January 1990 through December 1993, it was found that adverse drug events complicated 2.43 admissions per 100.[104] Controls were matched to cases on primary discharge diagnosis related group (DRG), age, sex, acuity, and year of admission. The occurrence of an ADE was associated with an increased length of stay of 1.91 days and an increased cost of $2,262. The increased risk of death among patients experiencing an adverse drug event was 1.88.

Other studies corroborate the high cost of medication-related errors. One study conducted in a university-affiliated medical center hospital estimated that the annual costs of treating the 1,911 medication-related problems identified through the hospital's voluntary reporting system in 1994 totaled slightly less than $1.5 million.[105] Bloom has estimated that $3.9 billion was spent in 1983 to manage the preventable gastrointestinal adverse effects of nonsteroidal anti-inflammatory drugs.[106]

Medication-related errors also occur in nursing homes. For every dollar spent on drugs in nursing facilities, $1.33 is consumed in the treatment of drug-related morbidity and mortality, amounting to $7.6 billion for the nation as a whole, of which $3.6 billion has been estimated to be avoidable.[107]

PUBLIC PERCEPTIONS OF SAFETY

Although the risk of dying as a result of a medical error far surpasses the risk of dying in an airline accident, a good deal more public attention has been

focused on improving safety in the airline industry than in the health care industry. The likelihood of dying per domestic jet flight is estimated to be one in eight million.[108] Statistically, an average passenger would have to fly around the clock for more than 438 years before being involved in a fatal crash. This compares very favorably with a death risk per domestic flight of one in two million during the decade 1967–1976. Some believe that public concern about airline safety, in response to the impact of news stories, has played an important role in the dramatic improvement in safety in the airline industry.

The American public is aware that health care is less safe than some other environments, but to date, it has made few demands on the health care industry to demonstrate improvement. In a public opinion poll conducted by Louis Harris & Associates for the National Patient Safety Foundation, the health care environment was perceived as "moderately safe" (rated 4.9 on a scale of one through seven where one is not safe at all and seven is very safe).[109] Respondents viewed the health care environment as much safer than nuclear power or food handling, but somewhat less safe than airline travel or the work environment.

Americans have a very limited understanding of health care safety issues. When asked, What comes to mind when you think about patient safety issues in the health care environment? 28 percent of respondents did not mention anything, 20 percent mentioned exposure to infection, 13 percent cited the general level of care patients receive, and 11 percent cited qualifications of health professionals.[110] When asked about the main cause of medical mistakes, respondents most frequently cited carelessness or negligence (29 percent) of health care professionals, who are overworked, worried, or stressed (27 percent).

Most people learn about medical mistakes through anecdotes. More than four out of five respondents have heard about a situation in which a medical mistake was made.[111] When asked how they heard about the most recent medical mistake, 42 percent cited a friend or relative; 39 percent, television, newspaper, or radio; and 12 percent, personal experience.

Most people view medical mistakes as an "individual provider issue" rather than a failure in the process of delivering care in a complex delivery system. When asked about possible solutions to prevent medical mistakes, actions rated very effective by respondents were "keeping health care professionals with bad track records from providing care" (75 percent) and "better training of health care professionals" (69 percent).[112]

There are numerous factors that might contribute to the "disconnect" between public perceptions and actual health care error rates. The various accreditation and licensure programs for health care organizations and providers have been promoted as "Good Housekeeping Seals of Approval," yet they fail to provide adequate assurance of a safe environment. Reducing medical errors and improving patient safety are not an explicit focus of these processes. Even licensed and accredited organizations may have implemented only rudimentary systems and processes to ensure patient safety.

For the most part, media coverage has been limited to occasional reporting of anecdotal cases. The impact of anecdotal information on safety may also be

less effective in health care than in the nuclear waste or airline industries, where an individual event often impacts dozens or hundreds of people at a time.

Patient safety is also hindered through the liability system and the threat of malpractice, which discourages the disclosure of errors. The discoverability of data under legal proceedings encourages silence about errors committed or observed. Most errors and safety issues go undetected and unreported, both externally and within health care organizations.

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