

**DOING WHAT COUNTS FOR
PATIENT SAFETY:
FEDERAL ACTIONS TO REDUCE
MEDICAL ERRORS AND THEIR IMPACT**

**Report of the Quality Interagency Coordination
Task Force (QIIC)**

To the President

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Executive Summary and Actions

Doing What Counts for Patient Safety: Federal Actions 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 estimating 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 respond with a strategy to identify prevalent threats to patient safety and reduce medical errors. This report responds to the President's request and provides an action plan to implement Administration initiatives designed to help prevent mistakes in the Nation's health care delivery system.

A National Problem of Epidemic Proportion

It is clear that, although the United States provides some of the best health care in the world, the numbers of errors in health care are 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 tens of thousands. 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.

A wide body of research, including many studies funded by AHRQ, supports the IOM conclusions. The two seminal studies on medical error (Brennan, 1991; Thomas, 1999) have shown that adverse events occur to approximately 3–4 percent of patients. In another study (Leape, 1994), the average intensive care unit (ICU) patient experienced almost two errors per day. This translates to a level of proficiency of approximately 99 percent. One out of five of these errors were potentially serious or fatal. If performance levels of 99.9 percent—substantially better than those found in the ICU—applied to the airline and banking industries, it would equate to two dangerous landings per day at O'Hare International Airport and 32,000 checks deducted from the wrong account per hour (Leape, 1994).

Many of these adverse events are associated with the use of pharmaceuticals, and are potentially preventable. The IOM estimates the number of lives lost to preventable medication errors alone represents over 7,000 deaths annually—more than the number of Americans injured in the workplace each year. In addition, preventable medication errors are estimated to increase hospital costs by about \$2 billion nationwide. 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).

The Clinton-Gore Administration's Commitment to 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. Known as the Quality Forum, it is a broad-based, widely representative private body that establishes 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.

In accordance with its recent reauthorization, the AHRQ is the lead agency for the Federal government on quality in health care. It sponsors research examining the frequency and cause of medical errors and tests techniques designed to reduce these mistakes. It also examines issues generally related to health care quality, including overuse and underuse of services.

The Department of Defense (DoD) and the Department of Veterans Affairs (VA), serving over 11 million patients nationwide, have begun to implement computerized physician order entry systems, proven effective in reducing medical errors. In addition, Veterans

Affairs has implemented a computerized medical record in all their 172 hospitals, making it possible to reduce errors 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 began to use barcode technology to reduce medication errors.

The Health Care Financing Administration (HCFA), through its Peer Review Organizations (PROs), is working to reduce errors of omission for the 39 million Medicare beneficiaries. Under their current performance-based contracts, the PROs are working to prevent failures and delays in delivering services for breast cancer, diabetes, heart attack, heart failure, pneumonia, and stroke. These efforts have already decreased mortality for heart attack victims.

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) 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. CDC's National Nosocomial Infections Surveillance (NNIS) system is a hospital-based reporting system that monitors hospital-acquired infections that afflict more than two million patients every year. Among participating hospitals, bloodstream infection rates have decreased by more than 30 percent since 1990, and wound infections following surgery have decreased by 60 percent among high-risk patients. FDA receives approximately 100,000 reports per year of adverse events associated with medical devices and over 250,000 reports associated with pharmaceuticals. FDA estimates that over one-third of the adverse events associated with medical devices and pharmaceuticals are preventable.

In all of these efforts, the Administration has worked closely with the private sector and the States. Many States and members of the private sector are moving ahead with actions to reduce the number of medical errors. Currently, almost 20 States have implemented mandatory reporting systems to improve patient safety and hold health care organizations responsible for the quality of care they provide. The private sector has also taken large strides to address the issue of patient safety, most recently with the creation of the Leapfrog Group by executives of some of the Nation's biggest companies, including General Motors and General Electric. This group encourages all employers to make safe medicine a top priority of the health insurance they provide and to steer workers to the hospitals that make the fewest mistakes.

While both the public and private sectors have made notable contributions to reducing preventable medical errors, additional and aggressive efforts are needed in and outside of the Federal government to further reduce these mistakes.

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:

- Establish a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety.
- 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.
- Implement safe practices at the delivery level.

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 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.

The QuIC fully endorses 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.

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

IOM Recommendation: Creating a Center for Patient Safety. The IOM recommends that Congress fund a Center for Patient Safety within the Agency for Healthcare Research and Quality (AHRQ) that will set 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, disseminating grants for research on patient safety, 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 the President has included \$20 million in the Fiscal Year (FY) 2001 budget to support a Center for Quality Improvement and Patient Safety at the AHRQ, as part of the Agency's broader quality agenda. The Center will fund research on medical errors, principally through extramural grants and contracts. It will work with private-sector entities and

public sector partners, 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 patients, consumers, and health care providers about patient safety.

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. The IOM concludes that if States choose not to implement the mandatory reporting system, the Department of Health and Human Services (DHHS) should serve as the responsible entity.

Voluntary Reporting Systems. The IOM report does not propose the establishment of a national voluntary reporting system; rather, it 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 complement proposed mandatory reporting systems and can identify potential precursors to errors, thus preventing 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 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. Such an effort should establish important complementary approaches to both learning and accountability on errors. Well-designed patient safety programs include reporting systems that both hold health systems accountable for delivering high quality health care and provide important information to health care decision-makers that improves patient safety.

The QuIC agrees with the IOM that individuals should have access to information leading up to and including the occurrence of a preventable error that caused their serious injury or the death of a family member. 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 in conjunction with or prior to the implementation of mandatory or voluntary reporting systems.

It is important to note that the QuIC believes that any legislation or administrative intervention in this area should not undermine individuals' rights to redress for criminal activity, malpractice, or 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.

Mandatory Reporting Systems. The QuIC 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, and believes that the development of these systems are ultimately in the best interests of patients. We agree with the IOM that the scope of events targeted by mandatory reporting systems that contain public disclosure components should be limited to serious, preventable, and identifiable adverse events. By limiting required reporting systems to the most serious of errors—those causing life-long disability or death—this approach will most effectively target egregious problems and minimize the cost of operating such a system. The QuIC believes that, once mandatory systems are fully implemented, such information for each health system should be consolidated and made public, but that there should be no identification of patients or individual health care professionals. The QuIC believes that mandatory reporting systems that contain public disclosure components should not be used as a tool for punitive action by State and local authorities, but should be used as a mechanism to provide the public with information about the safety of its health systems and to highlight errors that can and should be prevented.

The IOM has a set of specific recommendations for the structure of a nationwide mandatory reporting system. The QuIC believes that there are a number of issues that need to be addressed prior to determining the best mechanism to ensure the establishment of State-based mandatory reporting systems. The Administration will work with the Congress to outline the appropriate Federal role in such a system. However, while these issues are being resolved, the Administration will take the following actions to demonstrate the importance of implementing mandatory reporting systems and to create an environment in which there is more widespread support for their use.

- *Implement a mandatory reporting system in the over 500 hospitals and clinics operated by the Department of Defense.* Beginning this spring, the Department of Defense will implement a new reporting system in its 500 hospitals and clinics serving approximately 8 million patients. This confidential reporting system will be modeled on the system in operation at the Department of Veterans Affairs and will be used to provide health care professionals and facilities with the information necessary to protect patient safety. This system will begin to be pilot tested in August of 2000, will collect information on adverse events, medication errors, close calls, and other patient safety issues. DoD providers will inform affected patients or their families when serious medical errors occur.

- *Expand mandatory reporting requirements for blood banks and establishments that deal with blood products nationwide.* By the end of the year, the Food and Drug Administration (FDA) will release regulations to improve the safety of blood transfusions by requiring the over 3,000 blood banks and establishments dealing with blood products to report errors and accidents, such as mistyping blood products and adverse events affecting donors, that affect patient safety. Currently, only 400 blood banks are required to report such errors.

In addition to Federal action to integrate mandatory reporting systems into Federal agencies delivering care and strengthen the mandatory systems that currently exist, there is a critical need for Federal leadership in the development of patient safety standards. To that end, the Federal government will:

- *Identify a set of patient safety measurements critical to the identification of medical errors.* The QuIC will ask the Quality Forum to identify a set of patient safety measurements that should be a basic component of any medical errors reporting system. Developing standardized measures lays the foundation for a uniform system of data collection and facilitates the development of these systems.
- *Identify a set of patient safety practices critical to prevention of medical errors.* The QuIC will ask the Quality Forum to identify, within 12 months, patient safety practices that should be adopted by all hospitals and health systems, and will undertake activities to encourage their widespread use. The QuIC suggests that mandatory reporting systems include information on whether hospitals and health systems' adopt these patient safety practices.
- *Identify issues related to the implementation of mandatory reporting for error reduction.* Using the Quality Forum's recommendations for medical error reporting, HCFA will develop a pilot project, through the PRO program, for up to 100 hospitals that volunteer to implement penalty-free, confidential, mandatory reporting systems. These pilot projects will assist hospitals in changing their medical delivery systems to reduce or eliminate errors. This pilot project will include a rigorous evaluation component and identify issues related to the implementation of medical error reporting systems.
- *Determine the most effective way to present information on the incidence of medical errors to the public.* HCFA, OPM, and AHRQ will lead a QuIC effort to work with the Quality Forum and States that have mandatory reporting systems to determine how data on medical errors can be collected, validated, and presented to the general public and local policy officials—and to determine the impact of providing such information. Since informing the public about the safety of their health care systems is a critical component of mandatory reporting systems, this pilot project will provide insights on presenting this information to the public.
- *Examine existing mandatory reporting systems.* The Center for Quality Improvement and Patient Safety, in collaboration with other QuIC agencies, 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 such systems or that currently have existing systems, to help them design effective reporting systems likely to improve patient safety.

The QuIC believes that these actions will encourage States to begin implementing their own mandatory reporting systems for preventable adverse events, with the goal that all 50 States have mandatory reporting systems for preventable adverse events within 3 years. This time frame will enable the Federal government, working with the Congress and other private-sector stakeholders, to conclusively resolve outstanding implementation issues. If all states have not implemented mandatory reporting systems within three years, the QuIC will deliver recommendations to the President that assure all health care institutions are reporting serious, preventable adverse events.

Although currently the QuIC believes that moving towards a mandatory reporting system is the appropriate course of action, if research conducted by AHRQ and other agencies indicates that the implementation of these systems does not enhance (or detracts from) patient safety, these results will be reported to the QuIC. Special emphasis will be placed on efforts to determine whether making information public serves to hold health systems accountable and reduce preventable errors, or whether it only stifles reporting.

Voluntary Reporting Systems. The QuIC agrees with the IOM that voluntary reporting systems are a critical component of a national strategy to reduce errors. Information from voluntary reporting systems is usually gathered by an independent entity and is used to identify patterns of errors. The QuIC proposes to integrate existing Federal voluntary reporting systems with data collection efforts by States and private organizations. The QuIC agrees with the IOM that these programs should be confidential to protect the privacy of patients, institutions, and providers reporting errors and close calls. Experience in other industries demonstrates that confidentiality encourages reporting. In order to encourage the development of voluntary reporting systems, the Administration will:

- *Implement a voluntary reporting system nationwide for veterans' hospitals.* The VA currently operates a mandatory reporting system. By the end of the year, the VA will implement a voluntary reporting system for both adverse events and close calls nationwide. Information will be collected by an independent external entity, analyzed, and disseminated to all VA health care networks to help prevent medical errors. Implementing this system is likely to lead to a richer database of information, as incidents are reported on a de-identified basis, and will allow researchers to compare the effectiveness of identified systems to de-identified ones.
- *Examine existing voluntary systems.* The Center for Quality Improvement and Patient Safety, with its QuIC partners, will evaluate the effectiveness of existing voluntary reporting systems at the Federal and State levels and develop recommendations to improve them. This study will demonstrate which entity or entities would be best to

collect, analyze, and disseminate information on frequently occurring errors and the best interventions to prevent them.

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:

- *Assuring that all hospitals participating in the Medicare program implement patient safety programs.* The Health Care Financing Administration intends to publish regulations this year requiring the over 6000 hospitals participating in the Medicare program to have ongoing medical error reduction programs that would include, among other interventions, mechanisms to reduce medication errors. To comply with this new regulation, most hospitals are likely to implement systems such as automated pharmacy order-entry systems and automatic safeguards against harmful drug interactions and other adverse events.
- *Requiring the almost 300 health plans in the Federal Employees Health Benefits Program to implement patient safety programs.* In its annual call letter, to be issued this April, the Office of Personnel Management will announce that, beginning in 2001, all health plans participating in the program will be required to implement patient safety initiatives. OPM will encourage health plans to collaborate with their providers to reduce errors and improve the quality of care.
- *Working with private-sector employers and employees to incorporate patient safety into purchasing decisions.* 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.

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 they appropriately fall under State jurisdiction and oversight. However, the QuIC agencies will provide technical assistance to State or professional agencies seeking to ensure a basic level of knowledge for health care providers on patient safety issues, promote model patient safety programs that include evidence-based best patient safety practices to provider organizations, or help agencies encourage the cultural change necessary to make reporting systems a success.

IOM Recommendation: FDA should increase attention to the safe use of drugs. Both pre- and postmarketing processes should be improved to maximize safe drug 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, and is pleased that the President is committing \$33 million, an increase of 65 percent over last year's funding level, in his FY 2001 budget to prevent medical errors associated with drugs and medical devices. Among other things, 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 interactions and dosage errors related to medications.

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 actions:

The Department of Veterans Affairs. The VA is considered one of the Nation's leaders in patient safety, having instituted patient safety programs in all of its health care facilities serving 3.8 million patients nationwide. This year, the VA will invest over \$47.6 million to increase the requirement for patient safety training for staff from 15 to 20 hours a year, provide "VA Quality Scholars" fellowships for 10 physicians, implement a patient safety awards program, and place "patient safety checklists" in operating rooms in every hospital nationwide.

The Department of Defense. Beginning this fall, the Department of Defense will invest \$64 million in FY 2001 to begin the implementation of a new computerized medical record, including an automated entry order system for pharmaceuticals, that makes all relevant clinical information on a patient available when and where it is needed. It will be phased in at all DoD facilities over 3 years.

The QuIC Task Force. This summer, the QuIC member agencies, including DoD, VA, AHRQ, and HCFA, will begin a collaborative project with the QuIC Task Force and the Institute for Healthcare Improvement to reduce errors in "high hazard areas," such as emergency rooms, operating rooms, intensive care units, and labor and delivery units.

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

QuIC Response. The QuIC endorses this recommendation. This year, VA will invest \$75.1 million to complete the implementation of an automated order entry system in all of its health care facilities, along with a barcoding system for blood transfusions and medication administration. A 1999 evaluation of this system indicates that it has reduced medication errors by 67 percent since its implementation. The Department of Defense will invest \$12 million to implement an integrated pharmacy system that creates a single profile for all the medications a patient takes, regardless of whether the prescriptions were filled at military and private pharmacies serving DoD beneficiaries worldwide by the end of 2000.

In addition, to comply with the new proposed requirement that hospitals participating in the Medicare program have error reduction programs, hospitals are likely to implement programs such as automated pharmacy order-entry systems. Furthermore, as highlighted in the prescription drug provisions in the President's Medicare reform initiative, any outpatient drug benefit for Medicare beneficiaries should require private contractors administering the program to use the latest patient safety techniques, including drug utilization review and patient counseling.

Additional Federal Actions to Improve Patient Safety

The President asked the QuIC to identify additional strategies to reduce medical errors and ensure patient safety in Federal health care programs. This report includes several additional recommendations, including an emphasis on the application of information

systems and computer-based initiatives to improve patient safety. The President has requested \$20 million in his FY 2001 budget to develop a consistent structure for health care information technology that incorporates strong privacy protections for patients and providers. Investments in information technology are one of the most effective and efficient ways to improve the quality of health care. This Health Informatics Initiative will address the problem of medical errors as a part of the Administration's efforts to improve health care quality through enhanced information technology.

Conclusion

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 IOM's recommendations can be addressed individually by specific agencies, the majority of the proposed actions require joint effort. 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.

Compendium of Action Items

National Focus and Leadership

Center for Patient Safety

- AHRQ will take immediate action to 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 coordinate with and complement other public- and private-sector initiatives to improve patient safety.
- QuIC will 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 working group 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 will serve as a model and be expanded for future educational activities with private-sector partners.
- QuIC agencies such as OPM, HCFA, DoD, and VA will demonstrate their national leadership as purchasers and providers of care, developing model programs that use information on errors to improve patient safety.
- Federal agencies and other bodies, including AHRQ, FDA, CDC, and HCFA, will collaborate to provide national leadership in developing and testing systems of mandatory reporting for public accountability.

Research Planning

- 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. These summits will take place within 1 year
- Establish joint research solicitations (including partnerships between AHRQ, CDC, FDA, and VA) for:
 - *Fundamental Research on Errors*: Investigate root causes analysis, informatics, the role(s) of human factors, 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 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 in diagnostic accuracy, informatics applications, and systems re-engineering.
- Develop tools for the public and private sector to support efforts to enhance patient safety, including:
 - *Applications*: Identify tools and approaches from other industries that could be applied to the health care sector and develop community-based settings that can serve as 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 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.

Identifying and Learning From Errors

Accountability

- The QuIC will ask the Quality Forum to define unambiguously, within 12 months, a set of egregious errors that are preventable and should never occur. These measures will serve as criteria for a HCFA-sponsored mandatory reporting demonstration project with a State that already has an existing mandatory reporting requirement. 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. Based on these results, HCFA will move towards a national mandatory reporting system, with publication of findings, for all hospitals participating in Medicare.
- Federal agencies, in partnership with other organizations, 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 in collaboration with the Quality Forum.

- OPM will require that health plans have error reduction plans and will report on its web site whether the health plans have reliable patient safety initiatives in place.
- QuIC will ask the Quality Forum to identify, within 12 months, patient safety practices that institutions should undertake and urges that information about whether the measures are in place be made available to the public.
- FDA will report to the public on the safety of drugs, devices, and biologic products.
- QuIC proposes that State and Federal mandatory reporting systems, as well as those of private accrediting and other oversight groups, be evaluated to determine the ways in which they are helpful in assuring public accountability for patient safety, and that these results be used to develop future reporting systems.
- AHRQ will include information on patient safety in the National Quality Report it is developing in collaboration with other agencies, in particular, the National Center for Health Statistics.
- 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.
- OPM will encourage health plans to annotate Preferred Provider Organization (PPO) directories to indicate which hospitals and physicians' offices use automated information systems.
- FDA will 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.

Learning from Errors

- The new Center for Quality Improvement and Patient Safety (CQuIPS) at AHRQ will identify existing State and Federal reporting systems (both mandatory and voluntary), evaluate their suitability in helping to build a national system of errors reporting, and evaluate how their data collection or enforcement efforts can be enhanced to improve the value of those systems.
- QuIC will work with the Quality Forum to develop reporting criteria that assure that information can be pooled and shared as needed across organizations.
- CQuIPS, working with the QuIC, will describe and disseminate information on characteristics of existing voluntary reporting programs associated with successful error reduction and patient safety improvement efforts. FDA, CDC, and NASA will provide expertise in the development of these nonpunitive systems.
- Within six months, HCFA, working 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.
- 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 prone procedures, products, and systems.

- By August 2000, the DoD will complete development of a patient safety improvement program based on a reporting system modeled on that of the VA.
- VA will establish a voluntary reporting system to supplement its existing mandatory system.
- AHRQ, in collaboration with other Federal agencies, will investigate, develop and test 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 to prevent future events.
- 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.
- AHRQ will initiate a "National Morbidity & Mortality Conference" posting selected cases (stripped of identifying information) 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

- 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.

Setting Performance Standards and Expectations for Safety

Raising the Standards for Health Care Organizations

- 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.
- HCFA will publish regulations this year requiring hospitals participating in the Medicare Program to ongoing medical error reduction programs.
- 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 an independent, national accrediting organization that includes evaluation of patient safety and programs to reduce errors in health care.
- 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.

Raising the Standards for Health Care Professionals

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 that 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 in producing directives for the future.
- Provide training within the QuIC agencies that provide care to encourage use of patient safety information and encourage enhanced reporting in partnership with private-sector accreditors, purchasers, and providers.
- Provide technical assistance to State or professional agencies seeking to ensure a basic level of knowledge for health care providers on patient safety issues.

Safe Use of Drugs and Devices

Within 1 year, 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.
- Develop new label standards for drugs, highlight drug–drug interactions, potential dosing errors, and address other common errors related to medications.
- 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 link 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.
- Strengthen FDA outreach activities and collaboration with other Government agencies and stakeholders.

Implementing Safety Systems in Health Care Organizations

- 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 the stakeholders' 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.
- VA will invest \$47.6 million this year to increase patient safety training for staff (details in Chapter 3).
- DoD will invest \$64 million in FY 2001 to begin implementation of a new computerized medical record system, including an automated order entry system for pharmaceuticals (details in Chapter 3).
- 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).

- QuIC member agencies will begin a collaborative project this summer with the Institute for Healthcare Improvement to reduce errors in high-hazard health care delivery settings.

Building Public Awareness of Medical Errors

- Through the QuIC's Enhancing Patient and Consumer Information Working Group, led by OPM and HCFA, Federal agencies will develop and coordinate an information campaign for their constituencies and beneficiaries to increase their awareness of the problem of medical errors and patient safety.
- 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 to be more active participants in the decisionmaking surrounding their care.
- The CQuIPS will develop and test patient safety questions for inclusion in the patient survey now being developed for provider-level assessment of health care.
- HCFA will conduct research aimed at shaping programs to educate beneficiaries about medical errors.
- Within 1 year, 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 through grass-roots informational meetings. The meetings will focus on patient needs and the safe use of medical products, particularly for home use. The meetings will also discuss how to reach patients with important information on safe use of medical products—including through the use of local networks, the Internet, and electronic and print media. This will occur within 1 year.
- Patient safety and reducing medical errors will be a featured topic at OPM's Fall 2000 annual health plan conference.

Building Purchasers' Awareness of the Problem

- 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 medical errors as a health care problem and of steps that each can take to address this problem, such as addressing 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.

Working with Providers to Improve Patient Safety

- Through the QuIC, Federal agencies will take advantage of existing resources to promote collaborative patient safety programs involving agency constituents, the health professions 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 run pilot patient safety education programs for medical residents and students.

Using Decision-support Systems and Information Technologies

- 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.

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

- CDC and FDA will work with the DHHS Advisory Committee on Blood Safety and Availability to help ensure that the highest quality standards are met in blood collection and transfusion.
- Within 1 year, FDA will begin working 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.
- 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

- 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 the research agenda articulated above, will develop evidence-based measures that integrate human factors and lessons from other industries.
- As with the DQIP measurement set, the QuIC will solicit formal adoption and use by member agencies of common, validated, and standardized performance measures in the area of error reduction. The QuIC will work with certifying boards for healthcare professionals to incorporate these measures into certification and recertification programs where appropriate.
- QuIC agencies will encourage their private-sector partner organizations to support the implementation of more rigorous safety standards and will act to facilitate the ability of private-sector partners to do so.
- The QuIC will work through the Quality Forum, the NPSF, and the NPSF 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 an existing collaboration with the National Association of Insurance Commissioners (NAIC) 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 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 beneficiaries of the Federal Employees Health Benefits Program.
- Patient safety and reducing medical errors will be a featured topic at OPM's Fall 2000 annual health plan conference.

Data Integration

- 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 brought together 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 pooling

the data and using this resource 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 medical errors and improving patient outcomes.
- HCFA, in collaboration with FDA and AHRQ, will develop a strategy for incorporating initiatives to increase patient safety into the pharmacy benefit managers program under an expanded Medicare drug benefit.

Introduction

Errors: Part of a Broader Quality Agenda

“Mistakes are a fact of life. It's the response to the error that counts.”
—Nikki Giovanni (American poet, 1943-)

For years, experts have recognized that medical errors exist and compromise health care quality, but the response to the November 30, 1999, release of the Institute of Medicine's (IOM) report, *To Err is Human: Building a Safer Health System*, brought medical errors to the forefront of public attention. The report's estimate that 44,000 to 98,000 Americans die each year as a result of adverse events has captured the public's concern and resulted in a sense of urgency about increased attention to safety in the health care system. On December 7, 1999, one week after the IOM report's release, the President directed the Quality Interagency Coordination Task Force (QuIC) to evaluate the recommendations in *To Err is Human* and report to him through the Vice President within 60 days “with recommendations to improve health care through the prevention of medical errors and enhancements of patient safety.”

The QuIC was established by the President in the spring of 1998. Its goals are to ensure that all Federal agencies involved in purchasing, providing, studying, or regulating health care services are working in a coordinated way toward the common goal of improving the quality of care; to provide beneficiaries with information to assist them in making choices about their care; and to develop the infrastructure needed to improve the health care system, including knowledgeable and empowered workers, well-designed systems of care, and useful information systems. The participating Federal agencies include the Departments of Health and Human Services, Labor, Defense, Veterans Affairs, and Commerce; the Office of Personnel Management, the Office of Management and Budget, the U.S. Coast Guard, the Federal Bureau of Prisons, the National Highway Transportation and Safety Administration, and the Federal Trade Commission. The QuIC is co-chaired by Secretary of Health and Human Services Donna Shalala and Secretary of Labor Alexis Herman. John Eisenberg, Director of the Agency for Healthcare Research and Quality, serves as Operating Chair of the QuIC.

The QuIC believes that the IOM report has performed an important service in drawing national attention to the problems of patient safety, showing how preventable errors cause an immense burden for patients and the Nation's health care system. The Federal agencies that are members of the QuIC are working actively to reduce this burden through their roles as purchasers (i.e., buyers of health care services through private insurers or health maintenance organizations), program funders, research agencies, regulators, patient advocates, and providers of care. Some of the QuIC participants are already recognized as leaders in error recognition and prevention, and all are committed to improving the health care that Americans receive.

The QuIC agencies are aware of several challenges, many of which were dealt with in the IOM report, that must be addressed if there is to be a substantial increase in patient safety. This report addresses those issues, recognizing that the improvement of patient safety will require coordinated actions from a wide array of individuals and organizations involved in health care, including public and private-sector purchasers, providers, and oversight bodies, as well as patients. This report discusses ways the Federal Government, in collaboration with its partners in the private sector and in State and local government, can uncover the root causes of errors, identify best practices to avoid them, accelerate the widespread adoption of these best practices, and ensure that the public can be assured that the health care delivery systems on which their lives depend are operating safely.

The IOM emphasized that errors should not be studied in isolation from other health care issues. Rather, the IOM report *To Err is Human* is part of a larger project on quality in health care that is investigating ways to redesign the delivery system, realign financial incentives to reward high quality care, and use information technology as a tool for measuring and understanding quality. Because the QuIC also has a broad quality mandate, member agencies are already working in these areas and believe that progress in the broad domain of health care quality is essential to the more specific but compelling need to reduce errors.

The IOM Report

In addition to documenting the need for attention to the issue of patient safety, the IOM report makes specific recommendations for actions to galvanize the health care industry into action to improve safety. In brief, the key recommendations of the IOM report include:

Establish a Center for Patient Safety at the Agency for Healthcare Research and Quality (AHRQ). The IOM recommends that a center be established within AHRQ with responsibility for promoting the development of knowledge about errors and to encourage the sharing of strategies for reducing errors. The IOM committee recommends substantial budget increases over the next several years.

Promote voluntary and mandatory reporting of errors. First, the IOM recommends that *voluntary* reporting systems should focus on errors that result in little or no harm to patients, and should be encouraged by AHRQ. Second, a *mandatory* reporting system should be established to allow State governments to collect standardized information on adverse events resulting in death or serious harm.

Protect reporting systems from being used in litigation. The IOM urges Congress to pass legislation extending peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for purposes of improving safety and quality.

Make patient safety the focus of performance standards for health care organizations and professionals. Regulators and accreditors should require health care organizations to have meaningful patient safety programs. Purchasers are also encouraged to provide incentives for patient safety programs. The IOM suggests that professional licensing organizations periodically reexamine and relicense professionals based, in part, on their knowledge of patient safety. Licensing organizations also need to develop more effective means of identifying unsafe practitioners and taking actions against them. It also suggests that professional societies should promote patient safety education.

Increase FDA attention to safety in pre- and postmarket reviews of drugs. The IOM specifically suggests developing standards for safe packaging and labeling; testing of drug names to prevent sound-alike and look-alike errors; and working with doctors, pharmacists, and patients to identify and rectify problems in the post-marketing phase.

Encourage health care organizations to make a commitment to improving patient safety and to implement safe medication practices. Health care organizations should develop a culture of safety and implement nonpunitive systems for reporting and analyzing errors. These organizations should also follow recommendations for safe medication practices as published by professional and collaborative organizations interested in patient safety.

The President's Directive

In response to the IOM report, the President directed the QuIC to prepare a set of recommendations for specific actions to improve health care outcomes and prevent medical errors. These recommendations were to include specific actions in both the public and private sectors, and be consistent with the strong privacy protections proposed by the Administration. Specifically, the President requested that the QuIC report:

- Identify prevalent threats to patient safety and medical errors that can be prevented through the use of decision-support systems, such as patient monitoring and reminder systems.
- Evaluate the feasibility and advisability of the recommendations provided by the Institute of Medicine's Quality of Health Care in America Committee on Patient Safety.
- Identify additional strategies to reduce medical errors and ensure patient safety in Federal health care programs.

- Evaluate the extent to which medical errors are caused by misuse of medications and medical devices, and consider steps to strengthen the Food and Drug Administration's surveillance and response system to reduce their incidence and
- Identify opportunities for the Federal Government to take specific action to improve patient safety and health care quality nationwide through collaboration with the private sector, including through the National Forum for Health Care Quality Measurement and Reporting (the Quality Forum).

The President requested that the recommended actions serve as a foundation for a national system that prevents adverse medical events.

The QuIC has prepared this response to the President's directive with several principles in mind. First, it agrees with the IOM and with private-sector experts that medical errors are generally due to systemic flaws in health care rather than individual incompetence or neglect. Bad care givers are sometimes a problem, but most errors are the result of weaknesses in the organization of the health care system and its component services. Thus, the QuIC agrees with the IOM emphasis on systemic solutions and avoidance of the assignment of blame.

Second, the QuIC agrees with the IOM and other experts that errors are one of a number of problems in the health care system that compromise patient safety and quality and endanger large numbers of patients in ways that can be avoided. These include under-treatment, excessive treatment, and widespread deviations in practice that cannot be explained scientifically.

Third, the QuIC shares the belief of many experts that errors can be reduced and safety enhanced in health care by applying lessons from successful efforts in other American industries to improve quality. Now is the time to use these lessons in health care.

Fourth, the QuIC recognizes that errors occur in all sectors of health care, not just hospitals, and in all types of care, including prevention, diagnosis, drug therapy, anesthesia, surgery, and others.

Fifth, the Nation's response to errors should emphasize opportunities to learn from errors in order to avoid future errors. The QuIC believes that Government can assist health care institutions to develop appropriate systems for capturing such knowledge, which will require some degree of confidentiality to operate effectively.

Sixth, Federal and State governments have the responsibility to ensure, through mandatory public reporting, that the Nation can determine whether health care institutions have met an adequate standard of patient safety. Public reporting of both certain types of errors and the use of proven error-reduction techniques would provide the Nation with information that is needed to make choices about where to seek health care.

Finally, the QuIC agrees with the IOM on the importance of launching patient safety initiatives within the context of the roles of the Federal Government in health care quality, as purchasers, program funders, research agencies, regulators, patient advocates, and providers of care.

This report to the President focuses on the roles that the Federal Government can and should play in the development and implementation of systemic solutions for avoiding medical errors. The Federal Government, in partnership with State and local governments and the private sector, can lead the way toward reaching this goal.

The following chapters describe the steps that QuIC's member agencies are taking to assure patient safety. These steps can serve as a framework for developing a national strategy to reduce errors and variations in health care practices so that Americans not only get the best health care in the world, but the best health care possible.

Understanding Medical Errors

Growing Concerns About Medical Errors

The IOM's release of *To Err is Human* brought medical errors and patient safety the attention it has long needed but never had. The information presented in the report is not new. Indeed, many studies, some as early as the 1960s, showed that patients were frequently injured by the same medical care that was intended to help them (Schimmel, 1964). While evidence of medical error has existed for some time, the report succeeded in capturing the public's attention by revealing the magnitude of this pervasive problem and presenting it in a uniquely compelling fashion. The IOM estimates that medical errors cause between 44,000 and 98,000 deaths annually in the United States. Using the more conservative figure, medical errors rank as the eighth leading cause of death, killing more Americans than motor vehicle accidents, breast cancer, or AIDS. In addition to this extraordinary human toll, medical errors result in annual costs of \$17 to \$29 billion in the United States (Institute of Medicine, 1999). Additionally, fear of becoming a victim of medical error may lead patients to delay obtaining potentially beneficial medical care, which may allow their illnesses to worsen.

Experiencing harm as a result of receiving health care is a growing concern for the American public. Front-page articles in newspapers, television exposes, and cover stories in magazine have provided the stark details of the latest and most dramatic examples of medical errors. Until recently, the perception of medical errors among health care providers and the public has been shaped by these anecdotes, and remedies have focused on fixing blame on individual providers, including health plans, hospitals, doctors, pharmacists, nurses, and other caregivers. That approach, however, has proven ineffective in addressing patient safety, as documented by the ongoing problems noted in the IOM report. The IOM's recommended alternative approaches and other ways in which the Federal agencies can work to reduce medical errors are described in this report.

Definitions and Context

The lack of standardized nomenclature and a universal taxonomy for medical errors complicates the development of a response to the issues outlined in the IOM report. A number of definitions have been applied to medical errors and patient safety. In *To Err is Human*, the IOM adopted the following definition:

An error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.

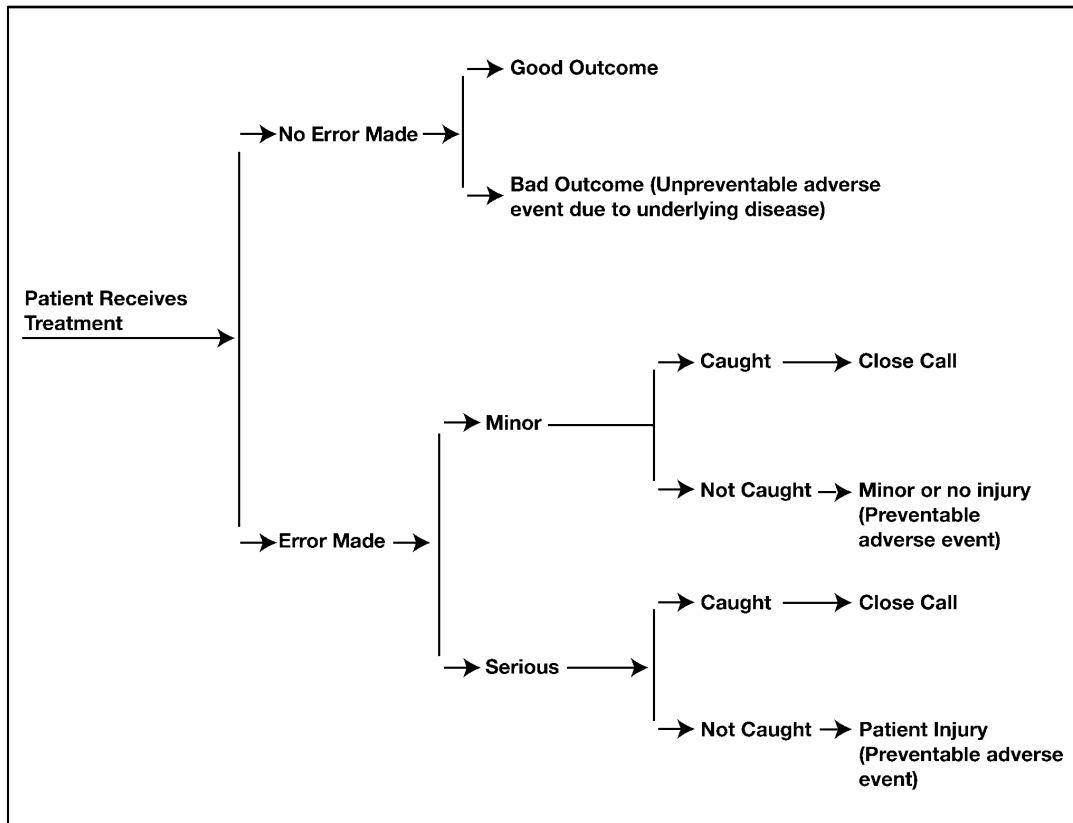
In an effort to thoroughly consider all of the relevant issues related to medical errors, the QuIC expanded of the IOM definition, as follows:

An error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems.

The explicit acknowledgment of the broad scope of errors reflected in this definition respects the responsibilities and capabilities of the Government agencies and departments contributing to this report. The term “patient safety” as used here applies to initiatives designed to prevent adverse outcomes from medical errors. The enhancement of patient safety encompasses three complementary activities: preventing errors, making errors visible, and mitigating the effects of errors.

It is critical to recognize that not all bad outcomes for patients are due to medical errors. Patients may not be cured of their disease or disability despite the fact that they are provided the very best of care. Additionally, not all adverse events that are the result of medical care are, in fact, errors. An adverse event is defined broadly as an injury that was caused by medical management and that resulted in measurable disability (Leape, 1991). Some adverse events, termed “unpreventable adverse events,” result from a complication that cannot be prevented given the current state of knowledge. Many drugs, even when used appropriately, have a chance of side effects, such as nausea from an antibiotic. The occurrence of nausea would be an adverse event, but it would not be considered a medical error to have given the antibiotic if the patient had an infection that was expected to respond to the chosen antibiotic. Medical errors are adverse events that are preventable with our current state of medical knowledge. Figure 1 shows this set of possible outcomes of medical care.

Figure 1: Framework for Identifying Errors



In this report, the consideration of errors is broadened beyond preventable adverse events that lead to actual patient harm to include “near misses,” sometimes know as “close calls.” A “near miss” is an event or situation that could have resulted in an accident, injury, or illness, but did not, either by chance or through timely intervention. Experience in other industries, including aviation, manufacturing, and nuclear energy, demonstrates that there is as much to learn from close calls as there is from incidents leading to actual harm.

It is also important to situate medical errors within the broader context of problems in health care quality. These can be classified under three categories: overuse (the service is unlikely to have net benefit), underuse (a potentially beneficial service is withheld), and misuse (a service is inappropriately used) (Chassin, 1998). The majority of medical errors fall into the category of misuse, but some problems with overuse (e.g., when an unnecessary therapy is prescribed, leading to harm) or underuse (e.g., when an error in diagnosis leads to the failure to apply timely treatment) blur these distinctions. These are related quality problems and may be addressed, in part, by using some of the same approaches. In some cases, however, distinct approaches may be required. That is why the IOM has chosen to deal with the issue of errors separately in its report and plans to issue future reports on underuse and overuse quality problems. Our report will also focus

exclusively on errors. Nevertheless, the QuIC participants recognize that the improvements made in patient safety will lay the foundation for, and may encourage, other quality improvements.

A Framework for Thinking About Errors

There are many possible ways to categorize medical errors, but no universally accepted taxonomy. Classifications have included:

- Type of health care service provided (e.g., classification of medication errors by the National Coordinating Council for Medication Error Reporting and Prevention).
- Severity of the resulting injury (e.g., sentinel events, defined as “any unexpected occurrence involving death or serious physical or psychological injury” by the Joint Commission on Accreditation of Healthcare Organizations [JCAHO]).
- Legal definition (e.g., errors resulting from negligence [Institute of Medicine, 1999]).
- Type of setting (e.g., outpatient clinic, intensive care unit), and
- Type of individual involved (e.g., physician, nurse, patient).

Implicit in the current variety of classifications is the understanding that different types of medical errors are likely to require different solutions and preventive measures. A single approach to error reduction will fail because it does not account for important differences in types of errors. For example, for the Food and Drug Administration (FDA), product risk category may be a crucial dimension for shaping regulatory policy, but a health care provider may see this dimension as a minor consideration in shaping its error-control methods.

An “ideal” classification of errors would need to be well suited to the purpose to which it is being applied, but there is no single classification system that could be successfully applied to the full set of IOM recommendations being addressed by the QuIC. A framework for reporting may include considerations of the level of reporting (Federal versus State versus organizational), the reasons for which the reporting is being done (learning versus accountability), or the level of injury (near-miss versus minor versus severe). A framework for developing a research agenda may require more focus on the populations involved, available data, and research tools that can be applied to the problem. The experience with the Aviation Safety Reporting System (ASRS), which relies on narrative reporting without a formal framework, demonstrates that rigorous classification may not be necessary at all for some purposes.

The QuIC recommends that the framework for analysis of errors in health care include considerations of how to measure and improve patient safety. As a result, the framework will evolve with each of the initiatives outlined in this report, and the development of classifications to deal with specific purposes will be part of the ongoing work of the QuIC in addressing the IOM recommendations.

Lessons From Other Industries

As noted in the IOM report, health care is “a decade or more behind other high-risk industries in its attention to ensuring basic safety” (Institute of Medicine, 1999; p. 4). Other sectors of the economy have made remarkable progress in error reduction and safety assurance during the latter part of the 20th century, much of which is attributable to industry’s attention to quality management and improvement. In 1986, Motorola instituted a strategy called “Six-Sigma Quality,” whose name refers to the Greek letter used to represent standard deviation from the mean of any normally distributed curve (Chassin, 1998). A company which has six-sigma quality experiences only 3.4 defects or errors per million products or events. This is the equivalent of seeing only one misspelled word in about six typical mystery novels or one fumble in 1,600 football games.

Through the six-sigma quality strategy, Motorola, General Electric, and others have substantially reduced their error rates. These companies have systems in place to monitor and report errors and defects so that proper action can be taken, and it is no surprise that these companies are the leaders in their respective industries. Although originally devised for reducing defects in manufacturing plants, the application of the six-sigma quality approach has provided benefits to service industries as well (Chassin, 1998). Service industries have used the six-sigma strategy to analyze, for example, the number of customer complaints that go unanswered after 2 days (per million complaints) or the excess waiting time over 5 minutes a customer encounters before being served (per million customers).

In another example, the aviation industry has adopted quality improvement, safety assurance, and error reduction as its core mission. Currently, airline safety is operating at a five-sigma level (Chassin, 1998). The Federal Aviation Administration (FAA) strategic plan targets a further 80 percent reduction in the airline accident death rate, which would place it close to the six-sigma level. The cornerstone of the FAA’s safety initiative has been the ASRS, which was established in 1975. Although the ASRS is funded by the FAA, it is administered by the National Aeronautics and Space Administration (NASA). Many believe that this separation of control over the reporting function to improve safety from the enforcement function is a critical factor in its success. It gives credibility and a sense of safety to the system in the eyes of the many users, particularly those being asked to report their errors and near misses. The ASRS is a vital link between those who observe or experience errors and defects and investigators who have the ability to research and disseminate information regarding these errors. In January 2000 the President signed an executive order providing further protections to reporters under the aviation safety system to enhance information collection. The aviation community (as well as nuclear power and the military communities) has demonstrated the importance of looking critically at human factors and interface design practices in preventing accidents and increasing operating efficiency (Rouse, Kober, and Mavor, 1997).

A review of the experience in non-health-care industries offers some lessons that may be applicable to reducing medical errors. Characteristics of error-reducing industries include:

- Not tolerating high error rates, and setting ambitious targets for error reduction initiatives.
- Developing tracking mechanisms that expose errors.
- Relying on the abundant reports of errors and “near misses.”
- Thoroughly investigating errors, including a root causes analysis.
- Applying to error reduction a systems approach that embraces a wide array of human factors, technical, and organizational remedies.
- Focusing on systems solutions that do *not* seek to find individual fault and blame.
- Changing the organizational culture so that it enhances safety and error reduction.
- Allocating adequate resources to error prevention initiatives and the development of the knowledge base to support them and
- Recognizing that solutions often come from unexpected sources, “out of the box” thinking, and new combinations of disciplines (e.g., human factors psychology with aeronautical engineering).

The QuIC, in reviewing the IOM report as well as these experiences in other industries, has concluded that there is no single “magic bullet” approach to reducing errors, but there is a generalizable approach (that includes the strategies listed above) which, when applied vigorously, is likely to yield favorable outcomes.

Unique Aspects of Health Care Errors

Research, much of it sponsored by AHRQ’s predecessor, the Agency for Health Care Policy and Research, documents that the rate of health care errors is far higher than the error rate in other industries. In one study of intensive care units, the correct action was taken 99.0 percent of the time, translating to 1.7 errors per day. One out of five of these errors was serious and/or potentially fatal. If performance levels even substantially better than those found in the ICU (for example, 99.9%, a 10-fold reduction in errors) were applied to the airline and banking industries, it would still equate to two dangerous landings per day at O’Hare International Airport and 32,000 checks deducted from the wrong account per hour (Leape, 1994). In these industries, such error rates would not be tolerated.

Health care shares a number of characteristics with these other industries. They all rely on systems which include the interaction of humans and technology to perform a number of functions leading to an outcome (e.g., a safe transcontinental flight, a check correctly deducted from the right account, a patient’s recovery from breast cancer). However, health care is distinct in its complexity. For example, a patient in an intensive care unit is the recipient of an average of 178 different activities performed per day that rely on the interaction of monitoring, treatment, and support systems (Leape, 1994). One observer noted that many medical errors can be attributed to the simple fact that the knowledge

base to effectively and safely deliver health care exceeds the storage capacity of the human brain (Millenson, 1997).

The decentralized and fragmented nature of the American health care industry contributes to the problem of errors, and will make it a challenge to institute the kind of comprehensive strategy to reduce errors and increase patient safety that the IOM recommends in its report. The work of federally-sponsored researchers such as Lucian Leape and David Bates has illustrated the importance of focusing on the systems of health care delivery in efforts to reduce medical errors. Prescription and delivery of medications provides a dramatic example. It requires the successful completion of at least five interdependent steps: ordering, transcribing, dispensing, delivering, and administering. Inattention to system design leads to numerous opportunities for error in any one of these steps. One study on adverse drug events showed that 78 percent of adverse drug events were due to system failures (Leape, 1995).

Organizational factors are also a distinct challenge in addressing medical errors. Within many hospitals, departments are only loosely linked, and communications between primary care doctors and medical specialists are notoriously poor. As a result, information on problems, as well as improved practices to reduce errors and enhance safety, in one department or one facility do not migrate quickly to others. The variety of settings in which health care is provided (including hospitals, nursing homes, clinics, ambulatory surgery centers, private offices, and patients' homes) and the transitions of patients and providers among them provide additional challenges.

Errors may be particularly difficult to recognize in health care because variations in an individual's response to treatment is expected. In addition, medical professionals may not recognize that a particular product or procedure may have contributed to or caused the problem because the patient is already ill, the product is not expected to work perfectly at all times, or the event appears unrelated to the product or procedure. Lack of recognition of a service's role in adverse events reduces reporting of the association and the opportunity to learn from previous experiences with the product. Because medical errors usually affect only a single patient at a time, they are treated as isolated incidents, and little public attention is drawn to these problems when compared with aviation or nuclear power accidents. Health care errors are also underreported due to liability and confidentiality concerns. These factors explain, in part, the ongoing "invisibility" of medical errors despite the existence of research which has documented their high prevalence.

Impact of Organizational and Professional Culture

Although the complexity of health care delivery systems is one of the factors distinguishing health care from other industries, the professional culture may pose an even greater challenge than does complexity to improving patient safety. The "naming, blaming, and shaming" approach to dealing with errors has hindered medical error reduction, yet it is the most commonly used approach to addressing errors in health care.

In fact, this traditional approach has proven counterproductive—it has driven the patient safety problem underground, leading to an implicit “conspiracy of silence” where problems and close calls are not discussed due to fear of reprisal (Koop, 1999).

Adverse medical events have existed since the beginning of organized medical practice, but may not have been recognized at the time of their occurrence. Bloodletting and toxic “therapies,” such as mercurials, led to premature deaths, but these deaths were seen as a reflection of the patient’s underlying illness rather than of harmful practice. To some extent, that culture still persists in health care. Although advances in medical technology and knowledge have eliminated these historic practices, errors and mistakes continue to occur at an unacceptably high rate in the delivery of health care. Contrary to popular expectations, doctors, nurses, and other health care professionals are inherently fallible—as are all humans.

The IOM report notes that the majority of medical errors today are not produced by negligence, lack of education, or lack of training. Rather, errors occur in our health care systems due to poor systems design and organizational factors, much as in any other industry. Health care workers are placed in systems and settings where errors are bound to happen. That is, the systems are designed to achieve a particular set of goals, but inadvertently produce a certain level of errors. For example, health care workers are sometimes expected to work 24-hour shifts to ensure patients are cared for and have some continuity of care, although it is known that overwork and fatigue lead to decreased mental concentration and alertness. These caregivers are expected to function in an environment that is not ergonomically designed for optimal work performance. They are expected to rely on their memories and deliver safe care without substantial investments in information technology or even the simple application of checklists. They often deliver care through a set of complex processes, although industry has shown that the probability of performing a task perfectly decreases as the number of steps in the process increases. Finally, they are expected to work in a climate where one error, even if not preventable, may mean a catastrophe or the end of a career. By not improving the systems in which medicine is practiced, the health care industry as a whole has not advocated a culture of safety and is not well organized to tackle the challenge of improving patient safety. Only when the entire industry is able to make patient safety and the reduction of medical errors its first priority will errors in medical practice be reduced.

A Global Challenge

The medical errors epidemic is a global problem. The United Kingdom, for example, has had some well-publicized difficulties with pediatric surgery outcomes in Bristol. British authorities estimate that 40,000 hospitalized patients die annually as a result of errors, which translates to a 3.7 percent overall rate of errors. The Australian Review of Professional Indemnity Arrangements for Health Care Professionals (Commonwealth Department of Human Services and Health, 1995) also found error to be a serious cause of morbidity and mortality. Australia, the United Kingdom, and Sweden are among the countries that have begun to address this issue. The British Ministry of Health is in the

process of making funds available to researchers to investigate medical errors, and is re-engineering its clinical governance programs to provide mechanisms to improve patient safety. Australia has included medical errors as part of its focus on quality, and is initiating a national system for error reduction with enhanced reporting mechanisms. However, efforts to actually translate the limited research available into practice are still at an early stage, at best. Approaches are likely to vary across nations because of differences in health care organization, attitudes toward regulation, and views on patient information and confidentiality. The evidence informing those approaches, however, is likely to be more universal. As a global leader, the United States has a responsibility to the many countries that do not have the resources to devote to the study of this issue.

Evidence of Errors

The Epidemiology of Medical Errors

Errors and other adverse events occur regularly in health care settings, but the causes, frequency, severity, preventability, and impact of these events on patient outcomes are not completely understood. A few studies have found an alarmingly high prevalence of adverse events and medical errors in some hospitals. In two large studies of hospital admissions, one in New York using 1984 data and another in Colorado and Utah using 1992 data, the proportions of admissions in which there were adverse events (defined as injuries caused by medical management) were 2.9 and 3.7 percent, respectively (Leape, 1991; Gawande, 1999). In the New York study, errors (defined as avoidable “mistakes in performance or thought”) were determined to have caused more than half of the adverse events. However, the absence of standardized definitions of medical error, the lack of coordination and integration of systems to report and monitor errors, and the difficulty in distinguishing preventable errors from currently unavoidable adverse events hamper our understanding of this problem. It is unlikely that we can ever know the precise frequency with which errors occur in health care settings because we must rely on people to recognize that errors were made, to distinguish them from bad outcomes of appropriate treatment, and then to report them.

Adverse Events and Medical Products Use or Misuse

Preventable injuries and deaths from pharmaceutical drugs are a growing problem that, according to some studies, represents a leading cause of death and patient harm in the United States (American Hospital Association, 1999; Centers for Disease Control and Prevention, 1999; Leape, 1991). Although the methods used to measure the rate of errors associated with the use of drugs have significant limitations, researchers have estimated that more than 50 percent of prescriptions are used incorrectly (Porter and Jick, 1977). 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).

In the Harvard Medical Practices Study of adverse medical events (Leape, 1991), which was based on 30,195 randomly selected records from 51 hospitals in New York State, the researchers found that drug complications represented 19 percent of all adverse events. The researchers concluded that 58 percent of injuries and deaths due to drug reactions were preventable, and 27.6 percent of such complications were due to negligence. According to this study, antimicrobial drugs were the class of agents most commonly associated with adverse drug events. Misuse of antimicrobial drugs not only exposes individual patients to an increased risk of a poor treatment outcome, but also leads to the emergence and spread of drug-resistant microorganisms, which may place other patients and health care workers at risk of infection.

The specific problem of medication errors has drawn considerable public attention, since all such errors are preventable. Medication errors—mistakes in writing prescriptions, dispensing or administering drugs—are a subset of the larger category of errors involving drugs. In a case-control study covering a 4-year period at a single hospital, it was determined that there was an almost 2-fold increase in the risk of death attributable to such errors. In the previously cited Harvard Medical Practice Study, 19.4 percent of all disabling adverse events were caused by drugs, of which 45 percent were due to medication errors. In that study, 30 percent of those with drug-related injuries died.

In addition to drug-related injuries and deaths that occur in hospitals, information is available indicating that preventable, drug-related injuries also occur at a high frequency among out-patients. In a study of 1,000 ambulatory patients drawn from a community, office-based medical practice (Burman, 1976), the researchers noted side effects from drugs in 42 patients (4.2 percent), including 23 who experienced preventable side effects. Well-understood drug-drug interactions are preventable, but there is evidence that physicians do not routinely screen for them, even when a patient's medication history is readily available. In a study of 424 randomly selected visits to a hospital emergency department (Beers, 1990), 47 percent of visits resulted in the patient receiving a prescription for a medication. In 10 percent of these instances, the new medication could potentially harm the patient due to an avoidable drug-drug interaction. In all of these cases, a medication history had been recorded and available to the prescribing physicians.

Thus, it can be seen that preventable and avoidable injuries due to drugs constitute a significant public health concern. The increasing use of drugs, the growing fragmentation of health care delivery, and the competing demands of an overburdened health care delivery system will, undoubtedly, accentuate these problems.

Current Programs to Prevent Errors

Local Performance Measurement and Performance Improvement Systems. In the past decade, health care facilities and health plans have placed an increasing emphasis on improving health care quality. The impetus has come, at least in part, from patients,

purchasers, accreditation agencies, and regulators determined to obtain the best value for the Nation's health care dollars. Today, virtually all health care organizations have programs to measure and/or improve health care quality.

Many hospitals and health plans collect and monitor data relevant to specific events (e.g., patient falls, failure to appropriately administer beta-blockers after myocardial infarction) or health outcomes (e.g., anesthesia mortality, length of stay after total hip replacement), which may or may not reflect medical errors. Hospitals commonly use these data for performance measurement or continuous quality improvement. Decisions about what will be monitored are usually based on the nature, severity, and importance of perceived problems at the local level, the feasibility of accessing data and formulating a response, and related incentives (e.g., meeting standards required for accreditation, anticipated cost-savings). Similarly, some hospital departments (e.g., pharmacy, nursing) use performance measurement to target treatment errors and other adverse events.

Performance measurement and quality improvement programs are less common and often less extensive outside of acute-care hospitals. Programs in risk management as well as more recently developed programs in what has been called "disease management" or "outcomes management," although aimed at improving health outcomes, generally have not specifically included error reduction in their scope. Occupational health or employee health programs, in addressing risks to health care workers, may also impact patient safety and quality of care. Overall, the degree to which these local programs address medical errors or other preventable adverse events and, more importantly, the extent to which they motivate changes that improve the overall health status of patients, are not known. Part of the research agenda will be to see if market forces favor those health care organizations that improve patient safety.

Programs of infection prevention and control provide long-standing and successful examples of health care programs specifically designed to prevent adverse health events. These programs have been shown to reduce morbidity and mortality due to health care-associated infections. For this reason, infection control programs are mandated as a condition of accreditation for health care facilities. In hospitals, accreditation standards require a minimum number of trained infection control personnel and delineate specific program components. Such programs usually include ongoing monitoring (surveillance) of infection rates by trained infection control personnel using standardized case definitions, analysis of data with adjustment for facility and patient characteristics known to affect risk, comparison of local rates to aggregate benchmark data, prompt feedback of infection rates and trends to providers and decisionmakers, and targeted interventions that address specifically identified problems. This approach parallels that used in industrial continuous quality improvement programs and in industrial quality control. In nonhospital facilities, accreditation standards are less rigorous, and the composition and quality of infection control program is variable.

Regional and National Programs. Some regional and national external reporting systems to monitor errors and adverse health events already exist. FDA operates systems monitoring adverse events associated with drugs, medical devices, vaccines (co-managed

with CDC), and blood and blood products. CDC's NNIS monitors health care-associated infections. Some State health agencies (e.g., those of New York, Massachusetts, Florida) also monitor targeted health events. Nongovernmental agencies (e.g., JCAHO and the U.S. Pharmacopeia, through their Sentinel Events and Medication Errors Reporting Programs, respectively) also operate error reporting systems.

Such external programs motivate local efforts to recognize and address problems, provide norms to which local efforts can be compared, and identify emerging problems (e.g., adverse drug events or manufacturing errors) that may require governmental or other system-wide response. For example, reported errors related to medical products can lead FDA to require changes in package inserts and promotional materials, modifications in product packaging, and widespread dissemination of information through letters to health professionals and published alerts.

Most reporting systems have little or no enforcement authority to assure that reporting of errors is occurring consistently and completely. A recent report from the Department of Health and Human Service's (DHHS) Inspector General found that there is widespread underreporting to FDA's drug adverse event reporting system, despite the fact that more than 270,000 incidents are reported annually. In addition, even though these programs—some of which may be considered mandatory—may promise the opportunity to report errors and near-misses confidentially, those who submit reports (e.g., clinicians and hospitals) have expressed concern about their legal vulnerability in these reporting systems. Another reason for low rates of reporting in some systems is that information on how to prevent similar errors in the future is not fed back to the reporters. Therefore, these reporters see little benefit in completing and submitting reports.

Accomplishments of Programs to Prevent Medical Errors

Despite the strikingly high incidence of medical errors documented in the IOM report, and the difficulties in obtaining reports on errors and near misses, there are remarkable examples of successful efforts to improve patient safety. Surgical anesthesia, which once had an error rate of 25 to 50 per million patients, reduced its error rate nearly 7-fold. (Orkin, 1993). The first step in reducing surgical anesthesia error rates was the collection of data that permitted a systems analysis of errors, rather than a hunt for “responsible” individuals. Through teamwork, practice guidelines, automation, procedure simplification, and standardization of many functions, anesthesiologists demonstrated that a properly designed system can either prevent mistakes or prevent mistakes from doing harm.

Another example of success is the advances in patient safety that have been achieved in the Department of Veterans Affairs (VA), through its Veterans Health Administration. For instance, a hand-held, wireless bar-coding system was introduced into VA and has reduced medication errors by 70 percent at relatively low cost (Gebhart, 1999). It is particularly interesting that this approach was adopted from a completely different industry—from observation of how Avis checked in returned rental cars. Similar

behavioral and cultural changes must occur in other segments of the health care industry in order to address the patient safety issue fully.

Many Federal agencies have learned that the creation of a comprehensive knowledge base, rich in textual description of all aspects of errors occurrence, must be developed if preventive efforts are to be targeted and effective. One hopeful sign has been the development of private-sector organizations, such as the National Patient Safety Foundation (NPSF), the National Coordinating Council for Medication Error Reporting and Prevention, and JCAHO, which are promoting research and improvement initiatives focused on systems approaches to error reduction.

The occupational health field has demonstrated that human factors engineering can identify ergonomic concepts to prevent injuries to both patients and workers. Examples include curving the design of hallway corners to reduce the risk of injury from collisions, using mechanical lifts to prevent patient falls and employee back injuries, and reducing the number of scheduled work hours in a rotating shift to minimize the likelihood of errors resulting from fatigue and sleep deprivation.

Insufficiency of Existing Programs

Effective error prevention systems need to be built on a foundation of locally directed and managed programs within health care organizations, complemented by coordinated, external support and guidance from Federal, State, and nongovernmental agencies and organizations. Within this framework, a comprehensive approach to error reduction would require specifically designated personnel working in or consulting with each health care setting to:

- 1) Identify and monitor the occurrence of errors in targeted patient populations at greatest risk, and understand their root causes, especially those that are preventable.
- 2) Analyze, interpret, and disseminate data to clinicians and other stakeholders.
- 3) Implement error reduction strategies based on reanalysis and reworking of health care systems.
- 4) As necessary, call upon experts with clinical, epidemiologic, and management training and experience for technical support and to conduct on-site investigations.
- 5) Evaluate the impact of these programs on patient safety.

A number of factors reduce the effectiveness of existing programs to prevent medical errors. Performance measurement and improvement programs within health care organizations do not directly address the problem of medical errors. Programs that have been specifically developed to prevent medical errors often operate in isolation. In addition, programs such as infection control and employee health and safety typically receive low priorities within health care centers.

Efforts by external organizations to monitor errors also face limitations. A number of different programs exist to detect adverse health events, although no one system is designed to detect the full scope of medical errors.

Passive surveillance systems, such as the National Notifiable Diseases Surveillance System—in which health care providers and laboratories report incident cases of diseases (mostly infectious) to the State health department—while broad in scope and coverage, are often hampered by collection of incomplete data. Each State determines the diseases that are reportable, resulting in some differences across States. Furthermore, health care providers must remember which diseases are reportable, and take the time to report them.

Active surveillance, on the other hand, means soliciting case reports in a timely manner directly from potential reporting sources. Examples of this type of reporting include HIV/AIDS reporting, in which CDC provides funding to State and local health departments to support the surveillance process. These active surveillance systems provide more complete and accurate information, but are expensive to implement and maintain. Systems designed to hold organization or individual accountable for bad outcomes are commonly limited by underreporting of adverse events.

Although quality improvement programs within health care organizations could be enhanced or adapted to address errors, obstacles remain. The more serious are:

- 1) Lack of awareness that a problem exists.
- 2) A traditional medical culture of individual responsibility and blame
- 3) The lack of protection from legal discovery and liability, which causes errors to be concealed.
- 4) The primitive state of medical information systems, which hampers efficient and timely information collection and analysis.
- 5) Inadequate allocation of resources for quality improvement and error prevention throughout the health care system.
- 6) Inadequate knowledge about the frequency, cause and impact of errors, as well as about evidence of effective methods for error prevention.
- 7) Lack of understanding of systems-based approaches to error reduction (such as those used in aviation safety or manufacturing) and the perceived difficulty of adapting those approaches to the health care sector.

There are even greater barriers to error reduction in nonhospital settings, where the general absence of organized surveillance systems and lack of adequate personnel hinder local data collection, feedback, and improvement.

Lack of awareness. As stated earlier, the existence of medical errors has been known for some time. However, the fact that there has been very little success in reducing errors suggests that a general lack of awareness or alarm about errors is a factor in this failure. The awareness of the problem of medical errors and any subsequent solutions must be improved, not only among physicians, nurses, pharmacists, dentists, and other health care providers, but also among patients, policymakers, and the many other stakeholders of the health care community.

Barriers to partnership. The punitive and pejorative connotations of “error” as the object of investigation pose a potential barrier to the unfettered cooperation and collaboration of health care providers in establishing and managing effective error control programs. A cultural change needs to occur that will enable health care providers and leaders, as well as the public, to talk about errors and recognize that they are, in large measure, a result of faulty systems and faulty system design, not of individual failures.

Legal barriers. A system which supports learning from errors is dependent upon reporting, but fear of reprisal or legal action will dissuade many potential reporters. Assurances that the identity of reporters will be masked or never collected at all have been shown to enhance reporting in other industries (e.g., the ASRS). Disclosure of the individuals or organizations involved in an incident could also discourage reporting. There will remain instances, however, where criminal or negligent acts demand appropriate disclosure. The legal issues surrounding patient safety will have to be examined carefully to determine the best mechanisms to promote learning from errors while protecting the public.

Information systems and technical problems. To be practical, error prevention will need to rely on sophisticated management and clinical information systems, both as sources of data on adverse events and as a component of interventions to reduce errors, such as through the adoption of computer-based decision-support for health care providers. However, information systems in most health care organizations are neither sufficiently integrated nor flexible enough to serve either of these purposes. Technical support and research into information system design will be required to address this problem.

Cost and structural concerns. Although considerable cost savings could be realized by effective reduction in medical errors, instituting such programs will require a substantial initial investment. In addition, the relative autonomy of departments within some health care institutions is a potential barrier to rapid organizational change and the adoption of new models and procedures needed to prevent errors.

Deficiencies in knowledge and understanding. The epidemiology of errors is not well understood. Standardized definitions of errors and adverse events need to be developed and the methods of collecting meaningful data require further study. Research is needed to help distinguish between adverse events due to errors, unavoidable consequences of treatment, and complications caused by a patient’s underlying disease. The current paucity of fundamental and applied research on medical errors limits the tool kit of effective interventions that can enhance patient safety.

Lack of appropriate collaboration among disciplines. Because of the nature of medical errors, an effective response requires an integration of efforts across traditional occupational and scientific boundaries. The nature of the patient safety challenge requires synergy among scientific and technical disciplines, from human factors psychology to product design and delivery. This collaboration is needed at all stages of the effort to

reduce errors and enhance patient safety—from research on its causes and remedies to implementation and partnership in its reduction and elimination. The response to medical errors by the health care system is hindered by the traditional focus of single disciplines on individual providers or on products, and even by poorly coordinated efforts among Government agencies and with the private sector.

Failure to apply a coherent strategy. The variety of medical errors and the multidimensional nature of the patient safety challenge demand a variety of approaches for improvement. Experience from other industries demonstrates, however, that successful interventions to address different types of errors can consistently result from the application of a coherent strategy that includes intolerance of high rates of error, development of tracking mechanisms, root cause analysis, the application of innovative resources and relationships to address the problem, and an institutional devotion to error prevention.

The QuIC concludes that systems designed to facilitate quality improvement through error reduction can generate effective, useful reporting if those individuals who report are assured of confidentiality, protected from legal liability resulting from the report, provided with timely feedback on data from the system, and are not unduly burdened by the effort involved in reporting.

Federal Response to the IOM Report

In this chapter, the QuIC responds to recommendations from the IOM report and describes how the Federal Government can act on the issues of medical error and patient safety. This includes responses by the QuIC, as an interagency coordinating organization, as well as responses by individual agencies of the QuIC.

National Focus and Leadership

Center for Patient Safety

IOM Recommendation

Congress should create a Center for Patient Safety within the Agency for Health Care Policy and Research. This Center should:

- *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.*
- *Develop knowledge and understanding of errors in health care 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 (IOM; 1999, page 6).*

QuIC Response

The IOM's recommendations build upon AHRQ's focus on health care quality, its expertise, and its track record in funding research, training, and dissemination activities. AHRQ will take immediate action to expand the mission of the Center for Quality Measurement and Improvement, creating the Center for Quality Improvement and Patient Safety (CQuIPS), which will provide leadership in reducing medical error and improving patient safety. Integration of the patient safety agenda within AHRQ's existing quality improvement efforts reflects an approach similar to that used by the IOM, in which its work on patient safety was included within a broader "Quality in America" framework.

The formation of CQuIPS explicitly recognizes that patient safety and quality improvement are complementary activities with great potential for synergy. Furthermore, establishing the Center takes advantage of AHRQ's current infrastructure, which includes a center focusing on quality improvement and a task force that advises the Director on matters related to patient safety and medical errors. The Center will develop initiatives in these areas and facilitate communication between the Agency and external organizations.

In the Center's first year, the President has proposed a budget of an additional \$20 million to be spent on research.

The Center will:

- 1) Conduct and provide grants and contracts for extramural research on patient safety and the causes of medical errors, and on the effectiveness of programs to reduce them.
- 2) Include patient safety within the broader focus of quality measurement and improvement.
- 3) Bring together individuals and groups from the public and private sectors with an interest in patient safety.

Because the Center's role will not include regulatory, payer, or provider functions, it is well positioned to share information from both the private and public sectors (e.g., pooling and analyzing results of State mandatory error reporting systems). Additionally, patient safety will be integrated into the activities of other organizational units within AHRQ.

The Center's functions will be coordinated with and complementary to other private-sector and Federal initiatives focused on error reduction and improved patient safety. For example, VA, CDC, HCFA, FDA, DoD, the National Patient Safety Foundation (NPSF), the National Patient Safety Partnership (NPSP), and professional societies all have expertise relevant to identifying and reducing medical errors and improving patient safety. Their collaboration via the QuIC will enhance the Center's functions. One example of such collaboration will be the Center's development of a curriculum for QuIC participants on reducing medical errors that can be used as a model and expanded by other public- and private-sector organizations.

ACTIONS:

- AHRQ will take immediate action to 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 coordinate with and complement other public- and private-sector initiatives to improve patient safety.
- QuIC will 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 working group 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 will serve as a model and be expanded for future educational activities with private-sector partners.

- QuIC agencies such as OPM, HCFA, DoD, and VA will demonstrate their national leadership as purchasers and providers of care, developing model programs that use information on errors to improve patient safety.
- Federal agencies and other bodies, including AHRQ, FDA, CDC, and HCFA, will collaborate to provide national leadership in developing and testing systems of mandatory reporting for public accountability.

Research Planning

IOM Recommendation

Develop a research agenda, conduct and fund intramural and extramural research to assess the magnitude of errors and the role of human factors, and test and evaluate approaches for preventing errors.

QuIC Response

A substantial research program is central to the overall effort to improve patient safety and reduce medical errors. Without the evidence base that research provides, efforts to reduce errors and improve safety are unlikely to be fully productive, and may even be harmful. An example of an event with potential for harm is the automation of health care processes without due consideration of system design and human–technology interfaces. Automating a flawed system may invite errors and further mask their occurrence.

Research also is needed on the role of patients in helping to reduce errors. While much is known about the power of patient participation in helping to improve overall patient outcomes and satisfaction, research is sparse regarding the patient’s role in error reduction (e.g., wrong-site surgery, medication errors). In general, further research is needed on how best to measure medical errors, explore options for reporting them, understand why they occur, and test the success and cost-effectiveness of various approaches to improving safety, including the patient’s role in helping to prevent errors.

A number of research activities are currently underway in Federal agencies and departments. In December 1999, AHRQ released a request for grant applications to research the effectiveness of the transfer and application of “best practices” to reduce medical errors that are frequent, serious, and preventable. AHRQ also is supporting a project conducted by the NPSF that identifies and gathers information on public- and private-sector agencies and organizations funding research on medical errors and patient safety. This effort helps to coordinate research initiatives, prevent overlaps, and identify research gaps.

Other agencies and departments also have research projects underway. VA is evaluating grant applications focused on mitigating adverse drug events and has established four Patient Safety Centers of Inquiry to develop innovative solutions to critical challenges in patient safety. HCFA is funding the Study of Clinically Relevant Indicators for

Pharmacologic Therapy (SCRIPT) to develop and test a core set of measures that can be used to evaluate and improve medication use associated with significant morbidity, mortality, and unnecessary cost. The FDA is strengthening its understanding of the impact of pre- and postmarket risk management decisions, which includes exploring the association between errors and medical products, human factors and pharmaceutical name confusion, patient communication, exposure to risk, and improved methods for extracting information from both large reporting databases and patient medical records.

Federal agency collaborative efforts also are underway. For example, in 1999 AHRQ funded four Centers for Education and Research on Therapeutics (CERTs). Established as part of the FDA Modernization Act of 1997 and administered by AHRQ in collaboration with the FDA, the CERTs examine the benefits and risks of new drugs, biologics, and medical devices. Under the aegis of the QuIC, several agencies and departments will implement a project in 2000 focused on identifying and reducing medical errors in high-hazard health care environments.

While important and timely, however, these initiatives fall short of meeting the ambitious research agenda described in the IOM report.

The QuIC proposes a broad research initiative aimed at developing evidence-based approaches to reducing medical error and improving patient safety, but it will require substantial additional funding. With coordination, direction, and input through AHRQ's new CQuIPS, this initiative will include setting a coordinated research agenda, supporting research and demonstrations, evaluating programs, developing tools and training initiatives, and disseminating findings. Potential components of this initiative are outlined below.

ACTIONS:

- 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. These summits will take place within 1 year
- Establish joint research solicitations (including partnerships between AHRQ, CDC, FDA, and VA) for:
 - *Fundamental Research on Errors*: Investigate root causes analysis, informatics, the role(s) of human factors, 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 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 in diagnostic accuracy, informatics applications, and systems re-engineering.
 - Develop tools for the public and private sector to support efforts to enhance patient safety, including:
 - *Applications*: Identify tools and approaches from other industries that could be applied to the health care sector and develop community-based settings that can serve as 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 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.

Identifying and Learning From Errors

IOM Recommendations

- *A nationwide mandatory reporting system should be established that provides for the collection of standardized information by State governments about adverse events that result in death or serious harm. Reporting should initially be required of hospitals and eventually be required of other institutional and ambulatory care delivery settings. Congress should:*
 - *Designate the Forum for Health Care Quality Measurement and Reporting as the entity responsible for promulgating and maintaining a core set of reporting standards to be used by States. Reporting standards should include a nomenclature and taxonomy.*
 - *Require all health care organizations to report standardized information on a defined list of adverse events.*
 - *Provide funds and technical expertise for State governments to establish or adapt their current error reporting systems to collect the standardized information, analyze it, and conduct followup action as needed with health care organizations. Should a State choose not to implement the mandatory reporting system, the Department of Health and Human Services should act as the body responsible for data collection and analysis. Further, the Center for Patient Safety should be designated to:*

- (1) *Convene States to share information and expertise, and evaluate alternative approaches taken for implementing reporting programs, identify best practices for implementation, and assess the impact of State programs and*
- (2) *Receive and analyze aggregate reports from States to identify persistent safety issues that require more intensive analysis and/or a broader based response (e.g., designing prototype systems or requesting a response by agencies, manufacturers or others).*

The development of voluntary reporting efforts should be encouraged. The Center for Patient Safety should:

- *Describe and disseminate information on external voluntary reporting programs to encourage greater participation in them and track the development of new reporting systems as they form.*
- *Convene sponsors and users of external reporting systems to evaluate what works and what does not work in the programs and ways to make them more effective.*
- *Periodically assess whether additional efforts are needed to address gaps in information to improve patient safety and to encourage health care organizations to participate in voluntary reporting programs and*
- *Fund and evaluate pilot projects for reporting systems, both within individual health care organizations and within collaborative efforts among health care organizations.*

QuIC Response

The IOM report states that to decrease the incidence of errors in the health care system, it is necessary to have and use information. The IOM's recommendations reflect two important information needs that are vital to efforts to improve safety. First, the public expects and has a right to information that will demonstrate that the health care delivery system is as safe as possible. Second, there is the need for data and information in support of efforts to learn why errors occur and what changes are effective in preventing errors or minimizing their effects. Both needs can be met only through the development of effective data collection systems. Additionally, accountability and learning will only be achieved if the data are analyzed and information is fed back to the users.

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 policymakers, 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. As appropriate, the QuIC supports the extension of peer review protections to encourage reporting. Details of these extensions are given in “Peer Review Protections,” below.

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 that the Quality Forum identify those patient safety practices that health care organizations have adopted and that have been proven through research to be effective in reducing errors. The QuIC anticipates that the Quality Forum will encourage health care organizations to adopt these practices and inform the public of their use.

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.

While information on what programs are in place will be useful, it may not be sufficient to ensure the public is able to make the decisions it wants to make about its health care. Therefore, the QuIC proposes to look at how to provide useful information on errors to the public. This examination will consist of two separate parts.

First, AHRQ will lead a QuIC effort to examine the existing State reporting systems that have been designed for public accountability, to learn what their common characteristics are, how effective they have been in providing information to the public, and what have been the most successful elements of those programs. This information will be shared with the States that currently operate error reporting systems and others that are considering developing such systems, as a means of encouraging improvement and expansion of State reporting. The goal would be for all States to have a reporting system for errors within 3 years. If, at the end of 3 years, all States have not implemented reporting systems, the QuIC will recommend options to the President so that all health care institutions are reporting serious errors.

Second, HCFA will experiment with creating its own program for collecting and reporting publicly on medical errors that result in significant harm to patients and are preventable, given the current state of knowledge. Examples of such events are: surgery on the wrong body part, surgery on the wrong patient, and suicide while the patient is being watched to prevent a suicide. HCFA proposes to conduct a pilot study of such a mandatory reporting system for these events in collaboration with a State. It will work with the Quality Forum or similar entity to develop a finite list of events to be reported, and will ensure they have unambiguous definitions. In addition, HCFA will ask the Quality Forum or other entity to advise it on how best to report the information to the public to ensure it is understandable and useful.

HCFA will work with the chosen State to require that such events are reported by all hospitals in the State and published on a hospital-by-hospital basis. The published data will be stripped of all information that might jeopardize patient confidentiality. In the course of the pilot study, HCFA will refine any definitions and work out the operational issues of enforcement and reporting mechanics with the State Survey and Certification agency. HCFA and its QuIC partners will evaluate whether consumers found this information valuable and what they understood about it, and how they used it. Finally, HCFA and its QuIC partners will evaluate the impact of such a system on confidential reporting for learning from errors.

If successful, based on the results and evaluation of the pilot study by HCFA and its QuIC partners, HCFA will move towards a national mandatory reporting system for all hospitals participating in the Medicare program, with the intent of making the data publicly available.

Serious errors and accidents also occur during the collection, testing, and administration of human blood. On January 27, 2000, the DHHS Advisory Committee on Blood Safety and Availability recommended, among other things, facilitating development of technology to prevent misidentification of blood products and/or recipients. By the end of the year, FDA will release regulations to improve the safety of blood transfusions by requiring the over 3,000 blood banks and establishments dealing with blood products to report errors and accidents, such as mistyping blood products and adverse events affecting donors, that affect patient safety. Currently, only 400 blood banks are required to report such errors.

In addition to broad public accountability, the IOM asserted that providers have the responsibility to provide information to affected individuals and their families about mistakes that cause serious injury or death. The QuIC agrees with this recommendation. However, subsequent investigations by the health care organization into the causes of error need not be shared.

ACTIONS:

- The QuIC will ask the Quality Forum to define unambiguously, within 12 months, a set of egregious errors that are preventable and should never occur. These measures will serve as criteria for a HCFA-sponsored mandatory reporting demonstration project with a State that already has an existing mandatory reporting requirement. 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. Based on these results, HCFA will move towards a national mandatory reporting system, with publication of findings, for all hospitals participating in Medicare.
- Federal agencies, in partnership with other organizations, 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 in collaboration with the Quality Forum.

- OPM will require that health plans have error reduction plans, and will report on its web site whether the health plans have reliable patient safety initiatives in place.
- QuIC will ask the Quality Forum to identify, within 12 months, patient safety practices that institutions should undertake and urges that information about whether the measures are in place be made available to the public.
- FDA will report to the public on the safety of drugs, devices, and biologic products.
- QuIC proposes that State and Federal mandatory reporting systems, as well as those of private accrediting and other oversight groups, be evaluated to determine the ways in which they are helpful in assuring public accountability for patient safety, and that these results be used to develop future reporting systems.
- AHRQ will include information on patient safety in the National Quality Report it is developing in collaboration with other agencies, in particular, the National Center for Health Statistics.
- 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.
- OPM will encourage health plans to annotate Preferred Provider Organization (PPO) directories to indicate which hospitals and physicians' offices use automated information systems.
- FDA will 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.

Learning from Errors

To learn from errors, the aviation industry experimented with different models, but found it most useful to have a large national database of information that can be analyzed for patterns of underlying causes of mistakes. This ensures that data from events that rarely occur, but which have dire consequences, can be more readily identified. At the moment, no comprehensive system of data collection exists that will drive the Nation's efforts to learn from medical errors.

To inform its thinking about how such a system should be constructed, the QuIC reviewed data collection systems that have been designed to support learning systems in other industries. Successful reporting programs possess the following common characteristics:

Table. Characteristics of an Ideal Reporting System for Learning

- The intent and goal of the reporting system are clear to all interested parties.

- Active leadership support is ensured at all levels.
- Reports are accepted from all interested parties.
- Reports are confidential and identifying information has been removed.
- Reports are used for prevention, not punishment.
- Reports are analyzed by technically expert peers, from multiple perspectives.
- Reporting is easy to do and captures rich detail.
- Reporters and larger interested communities receive timely feedback.
- Pilot testing and prototyping of the system takes place before large scale roll-out occurs.

Currently, several databases exist that collect information on specific types or errors, such as CDC's hospital acquired infections reporting systems, FDA's adverse drug and device event reporting systems, and the JCAHO's sentinel event system. Others exist that collect information on errors that occur in a particular health care system, such as VA's error reporting system. As previously mentioned, some States have data collection systems for the facilities within their boundaries.

The QuIC believes that the fastest way to create a useful and analyzable data set would be to integrate the data from these existing databases and from any others that exist. AHRQ has experience in creating such harmony from disparate data collections. Within its Healthcare Cost and Utilization Project (HCUP), AHRQ currently employs cooperative agreements with 22 States to ensure the collection of a core set of administrative data from hospital discharges that are then aggregated. These data are then made available for research and analysis, in a way that protects patient and provider identities. The QuIC proposes that a similar method should be used to create an errors database that can be used to provide important insights into the causes and effective methods for prevention of errors. AHRQ will lead an effort to gather information from those who run the existing error data-collection systems, including the Federal, State and private-sector systems. This evaluation of existing systems will be used to determine whether they can be aggregated into a single database.

The aviation reporting system, which the IOM and others have suggested as a model that health care should emulate, depends on the collection of as much information as possible about close calls (which are sometimes called near misses) as well as errors that actually resulted in harm. To encourage people to report errors and speed the availability of information, the aviation system protects the identity of those who report and those who are involved in the incident. The QuIC will encourage States and others to include sufficient protections on the information to ensure that providers will report errors. This issue is discussed more fully below in the section on Peer Review Protections.

A common set of core measures is necessary to integrate a broad array of data collected through different reporting systems. The Quality Forum can ably undertake the creation of a common set of core measures for a national errors database. The QuIC agencies would support such an effort by the Quality Forum or other appropriate private-sector body.

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

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.

Beginning this spring, the Department of Defense will implement a new reporting system in its 500 hospitals and clinics, which serve approximately 8 million patients. This reporting system will be modeled on the system in operation at the Department of Veterans Affairs and will be used to provide health care professionals and facilities with the information necessary to protect patient safety. This system will begin to be pilot tested in August of 2000, will collect information on adverse events, medication errors, close calls, and other patient safety issues. Under this system, patients or their families are notified when a serious medical mistake has been made.

The VA currently operates a mandatory reporting system. By the end of the year, the VA will implement a voluntary reporting system for both adverse events and close calls 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. Implementing this system is likely to lead to a richer database of information, as incidents are reported on a de-identified basis, and will allow researchers to compare the effectiveness of identified systems to de-identified ones.

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.

ACTIONS:

- The new Center for Quality Improvement and Patient Safety (CQuIPS) at AHRQ will identify existing State and Federal reporting systems (both mandatory and voluntary), evaluate their suitability in helping to build a national system of errors reporting, and evaluate how their data collection or enforcement efforts can be enhanced to improve the value of those systems.
- QuIC will work with the Quality Forum to develop reporting criteria that assure that information can be pooled and shared as needed across organizations.
- CQuIPS, working with the QuIC, will describe and disseminate information on characteristics of existing voluntary reporting programs associated with successful error reduction and patient safety improvement efforts. FDA, CDC, and NASA will provide expertise in the development of these nonpunitive systems.
- Within six months, HCFA, working 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.
- 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 prone procedures, products, and systems.
- By August 2000, the DoD will complete development of a patient safety improvement program based on a reporting system modeled on that of the VA.
- VA will establish a voluntary reporting system to supplement its existing mandatory system.
- AHRQ, in collaboration with other Federal agencies, will investigate, develop and test 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 to prevent future events.
- 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.
- AHRQ will initiate a "National Morbidity & Mortality Conference" posting selected cases (stripped of identifying information) 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.

Analysis and Feedback

On pages 85 and 86, the IOM report summarizes two important points: 1) caution must be exercised when calculating rates from any type of adverse event reporting system; and 2) the goal of reporting systems is not to count the number of reports.

Successful error reporting systems are analysis and feedback systems. The key to their success starts with a highly visible ability to properly analyze cases and recommend changes to those who are empowered to implement them. Experts in the field of patient safety report that understanding the "root" of the problem and the "contributing" factors are winning strategies; counting errors and comparing performance are not.

Feedback to key decision makers and those who report is the second part of all successful error reporting systems. The CDC and FDA have found that lack of feedback was one of two main reasons for failed "mandatory" systems. Other activities contributing to success include: 1) training for those with reporting responsibilities; and 2) free software and generic data to aid internal analysis.

Experience with other reporting systems for improving safety demonstrates the importance of closing the feedback loop. Timely and usable feedback is crucial in making the system useful to those who report. Therefore, reporting formats should include both free-text narrative and standardized information as well as indicate how those who report can use the feedback.

Peer Review Protections

IOM Recommendation

Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality.

QuIC Response

As noted throughout the IOM report, solutions unique to one individual are essentially irrelevant. It is the system-wide, generalizable approach that is the cornerstone to success. The question “Who did it?” is not important. However, it is critical to find out what happened, why it happened, and how it can be prevented in the future.

Basic tenets of a successful reporting system are that those who report must feel safe in doing so and that their confidentiality must be protected. Reporting systems in which these factors are missing are generally unsuccessful in obtaining data, inaccurate, and incomplete. The experience of the aviation industry speaks to the importance of a confidential, blame-free reporting environment. The FAA and others have found major increases in reporting by removing the identity of the institution submitting the report.

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.

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.

Setting Performance Standards and Expectations for Safety

Raising the Standards for Health Care Organizations

IOM Recommendation

Performance standards and expectations for health care organizations should focus greater attention on patient safety.

- *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

Several QuIC member organizations are involved with regulation and accreditation. Some are also health care purchasers. A major purchaser of health care, HCFA, intends to require hospitals in the Medicare program to have an effective internal error reporting system and an effective evidence-based error reduction program for all patients as necessary components for certification and accreditation. The State survey agencies, acting as HCFA's contractors, and the hospital accreditation organizations, will monitor whether activities to reduce medical errors are occurring in Medicare participating hospitals. Enforcement actions will be taken only if such activities are not occurring.

HCFA will conduct research and pilot studies or demonstrations in nursing homes, where experience with error measurement is more limited but the need may be equally great.

The current Conditions of Participation (CoP) for hospitals participating in Medicare require that the hospitals meet State laws, which includes error reduction systems. Thus, Medicare rules support existing State requirements for confidential reporting, whether voluntary or mandatory.

The Health Care Financing Administration will publish regulations this year requiring the over 6,000 hospitals participating in the Medicare program to have ongoing medical error reduction programs that would include, among other interventions, mechanisms to reduce medication errors. In order to comply with this new regulation, hospitals may choose to implement automated pharmacy order entry systems, include automatic safeguards against harmful drug interactions and other adverse side effects built into the treatment process, or institute decision-support systems.

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 evaluation of patient safety programs in their accreditation process.

ACTIONS:

- 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.
- HCFA will publish regulations this year requiring hospitals participating in the Medicare Program to ongoing medical error reduction programs.
- 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 an independent, national accrediting organization that includes evaluation of patient safety and programs to reduce errors in health care.
- 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.

Raising the Standards for Health Care Professionals

IOM Recommendation

Performance standards and expectations for health professionals should focus greater attention on patient safety.

- *Health professional licensing bodies should:*
 - *Implement periodic re-examination and relicensing of doctors, nurses, and other key providers, based on both competence and knowledge of safety practices and*
 - *Work with certifying and credentialing organizations to develop more effective methods to identify unsafe providers and take action.*
- *Professional societies should make visible commitment to patient safety by establishing a permanent committee dedicated to safety improvement. This committee should*
 - *Develop a curriculum on patient safety and encourage its adoption into training and certification requirements and*
 - *Disseminate on a regular basis information on patient safety to members through special sessions at annual conferences, journal articles and editorials, newsletters, publications, and Web sites;*

QuIC Response

The QuIC proposes that the Federal Government take a lead role in fostering patient safety efforts through a concerted program in support of error reduction and improved safety. HRSA, HCFA, VA, DoD, OPM, and all other Federal agencies that provide or sponsor health services will collaborate in a five-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 clinical training programs and the use of CDC's Epidemic Intelligence Services (EIS) as a model.
- 4. Licensing and Certification:** The QuIC will convene a meeting of accrediting, licensing, and certifying bodies to propose, investigate, and evaluate educational methods to improve analysis, understanding, and prevention of medical errors. This will also include collaboration with the Federation of State Medical Boards and others to encourage education in these areas as a component of relicensing. HRSA, in coordination with State governments and other agencies involved with licensing and certification bodies, will assist licensing bodies to assure continuing competence among practitioners and to take appropriate actions to protect against unsafe providers. This will include provision for error-prevention education as part of the relicensure process.
- 5. Technical Assistance:** The QuIC will provide technical assistance to State or professional agencies seeking to ensure a basic level of knowledge for health care providers on patient safety issues, promote model patient safety programs that include evidence based best patient safety practices to provider organizations, or help agencies implement the cultural change necessary to make reporting systems a success.

Priority components of such a four-part program include community quality measures, infrastructure development, health professional training, and licensing and certification measures. These programs will be carried out cooperatively by involved public- and private-sector institutions.

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 that 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 in producing directives for the future.
- Provide training within the QuIC agencies that provide care to encourage use of patient safety information and encourage enhanced reporting in partnership with private-sector accreditors, purchasers, and providers.
- Provide technical assistance to State or professional agencies seeking to ensure a basic level of knowledge for health care providers on patient safety issues.

Safe Use of Drugs and Devices

IOM Recommendation

The Food and Drug Administration (FDA) should increase attention to the safe use of drugs in both pre- and postmarketing processes through the following actions:

- *Develop and enforce standards for the design of drug packaging and labeling that will maximize safe use.*
- *Require pharmaceutical companies to test (using FDA-approved methods) proposed drug names to identify and remedy potential sound-alike and look-alike confusion with existing drug names.*
- *Work with physicians, pharmacists, consumers, and others to establish appropriate responses to problems identified through postmarketing surveillance, especially for concerns that are perceived to require immediate response to protect the safety of patients.*

QuIC Response

The FDA works to ensure the safety and effectiveness of medical products, including drugs, medical devices, and biological products such as human blood. In May 1999 the FDA published a report, *Managing the Risks from Medical Product Use*, that evaluated its role in medical safety and discussed options for further improvements. The report emphasized the systems nature of medical safety and the role of the many stakeholders in the safety chain.

FDA is responsible, in conjunction with Institutional Review Boards, for oversight of patient and volunteer safety in clinical trials of investigational medical products. To this end, FDA reviews clinical protocols conducted under Investigational New Drug Applications and Investigational Device Applications, monitors the adverse events

occurring in trials—reporting adverse events is mandatory for investigators and trial sponsors—and requires modification or cessation of trials when patient safety is an issue.

FDA has promulgated extensive safety criteria that medical products must meet prior to marketing. Drug, devices, and biological products must undergo laboratory and clinical testing and meet safety standards before approval. In addition to toxicological and human safety testing, these criteria include design controls and human factors testing for medical devices, and requirements for naming, packaging, and labeling pharmaceuticals. Strengthening criteria aimed at reducing name confusion, dosage errors, and device misuse, or improving comprehension of the product information, would reduce product-related errors. Improving product safety requirements will require additional research and collaboration with health care delivery systems, health care professionals, Government agencies, and manufacturers. Additional work could be done to implement human factors testing in the evaluation of medical devices, and to institute such testing for pharmaceuticals.

Threats to patient safety from medical products can arise from unsafe products or from unsafe use of medical products. Despite extensive premarket safety evaluation, unanticipated errors do occur as medical products are used in the health care system. Although FDA is extensively involved in the detection and prevention of such errors, many more steps can be taken to increase the safe use of these products. For example, FDA has completed Phase I of implementing the Congressionally mandated Medical Product Surveillance Network (MedSuN), an active reporting network. FDA now wants to implement a large-scale Phase II study that will allow the dissemination of data regarding emerging device problems to health care professionals and the public.

Although FDA engages in numerous outreach efforts, more safety information, in a more useful form, needs to be provided to users of medical products. Similar opportunities for increased efforts exist in the areas of risk detection, data analysis, risk management, and risk communication. The FDA, as outlined in the action items below, will take steps to increase its capacity to detect errors, investigate and understand them, and prevent further occurrences. The knowledge gained in these investigations can also be incorporated into premarket review activities, thus preventing repetition of errors with new medical products.

ACTIONS:

Within 1 year, 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.
- Develop new label standards for drugs, highlight drug–drug interactions, potential dosing errors, and address other common errors related to medications.
- 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 link 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.
- Strengthen FDA outreach activities and collaboration with other Government agencies and stakeholders.

Implementing Safety Systems in Health Care Organizations

IOM Recommendations

Health care organizations and the professionals affiliated with them should make continual improvement in patient safety a declared and serious aim by establishing patient safety programs with defined executive responsibility. Patient safety programs should:

- *Provide strong, clear, and visible attention to safety.*
- *Implement nonpunitive systems for reporting and analyzing errors within their organizations.*
- *Incorporate well-understood safety principles, such as standardization and simplification of equipment, supplies, and processes.*
- *Establish interdisciplinary team-training programs for providers that incorporate proven methods of team training, such as simulation.*

Health care institutions should implement proven medication safety practices.

QuIC Response

Extensive “hands-on” communication is critical in building trust in the population from whom reports are expected. Systems perceived as punitive or exposing individuals or institutions to legal liability have proven to be much less effective than desired. For example, JCAHO has experienced significant difficulty in securing hospitals’ participation in its “sentinel events” reporting system because of worries surrounding legal vulnerabilities or punitive actions.

Another factor influencing the success of safety programs is the level at which organizational responsibility is established. Experts suggest that safety programs within individual organizations or institutions are most effective when reporting is at the level of the chief executive officer. Responsibility and reporting at the level of the CEO makes the issue of organizational accountability clear. It ensures that patient safety has the attention of the highest levels of the organization. It sends a clear message throughout the organization that safety is a priority, and it helps remove the inherent conflicts of interest that may occur if the reporting occurs at lower levels.

Several Federal agencies have already undertaken the task of creating meaningful patient safety systems within their health care delivery organizations. VA has an exemplary patient safety program, and the DoD is developing one that is modeled after that of VA. The National Institutes of Health's Clinical Center has a long standing "Occurrence Reporting System" to report unanticipated patient care events. Further refinements of each system will be made.

This summer, the QuIC will be working with the Institute for Healthcare Improvement (IHI) to create an initiative that will test several strategies for rapidly reducing the number of errors committed. Our effort will be targeted specifically at health care delivery settings where patients are in need of urgent assistance and decisions have to be made rapidly, which we are calling "high-hazard environments." These would include emergency departments, operating rooms, intensive care units, and on-site rescue operations. This is the first such initiative targeted at error reduction in these high hazard environments. Based on the results of previous IHI initiatives, it is hoped that some sites will be able to achieve reductions of 25–30 percent in the number of errors within 12 to 15 months. The findings from this Federal effort will be shared broadly to help other organizations reduce errors in their own health care delivery settings.

Information technology offers other opportunities for the reduction of medical errors and is discussed in Chapter 3.

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 the stakeholders' 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.
- VA will invest \$47.6 million this year to increase patient safety training for staff (details in Chapter 3).
- DoD will invest \$64 million in FY 2001 to begin implementation of a new computerized medical record system, including an automated order entry system for pharmaceuticals (details in Chapter 3).

- 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).
- QuIC member agencies will begin a collaborative project this summer with the Institute for Healthcare Improvement to reduce errors in high-hazard health care delivery settings.

APPENDIX

FRAMEWORK FOR REPORTING SYSTEMS		
A. Purpose: Data collected for one purpose are not easily used for another.	B. Reporting¹: Need clear definitions, easy mechanisms for reporting, system capable of using data for intended purpose.	
	<i>Mandatory</i>	<i>Voluntary</i>
Learning	<ul style="list-style-type: none"> • Need incentive (e.g., return of valuable information) to ensure reporting. • Data need to be protected from discovery. • Could include near misses likely to lead to major adverse event. 	<ul style="list-style-type: none"> • Reporter must see it in self-interest to report. • Completeness of database contingent upon willingness to report. • Could include near misses likely to lead to major adverse event.
Accountability	<ul style="list-style-type: none"> • Accountability aspect could be the review (i.e., audit) of the safety and error analysis process. • Many systems already exist for high interest/high profile adverse events. • Works best for events that are difficult to overlook. 	<ul style="list-style-type: none"> • Not applicable because no one would agree that something truly voluntary is a basis for accountability.

¹ Any criminal act identified through reporting systems will be handled with appropriate mechanisms.

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. 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

Well-informed patients are key participants in the effort to enhance the quality and safety of American health care. The right question from a patient at the right time may be the intervention that averts an error. As the IOM report recognizes, the public largely believes that it is protected from errors and safety problems. For instance, the public assumes that licensure and accreditation confer a “Good Housekeeping Seal of Approval” on practitioners and institutions (Institute of Medicine, 1999). Thus, the public assumes that they can implicitly trust those professionals and facilities to do the right thing in the right way. Despite health professionals’ best attempts to make patients’ assumptions a reality, the available evidence about medical errors suggests that reality falls short. In that respect, patients’ understanding of the medical errors situation is not substantially different from their understanding of other confusing aspects of the health care system. For example, the Employee Benefit Research Institute (EBRI) reports that only 21 percent of managed care participants know they are in this type of plan. Instituting a national patient safety electronic bulletin board, as indicated in “Learning from Errors” in Chapter 2, will not only enable patients to report errors that they see or experience, but will also aid in improving the public’s general understanding of patient safety.

Although some members of the public are aware that the health care environment itself is less safe than previously assumed, they have made few demands for improvement of the system. A 1997 survey by the National Patient Safety Foundation found that many people view errors as a problem that can be fixed by getting rid of bad providers, rather than as the consequence of delivering care within a complex delivery system.

Clearly, an ongoing, aggressive public information and education effort is needed to increase all Americans' understanding of both how medical errors occur and what steps they can take to prevent such errors. This campaign must carefully address the tension between the need for increasing general awareness with the competing need of ensuring that patients are not afraid of receiving necessary care.

The QuIC agencies, working in close collaboration with private-sector organizations, can develop consistent patient safety messages and themes that can be used by Federal agencies and private-sector employers, health care purchasers, and others to disseminate a powerful and consistent message to individuals about their role in ensuring the quality of their own health care. The QuIC has established the Enhancing Patient and Consumer Information working group with the specific intent of providing the public with clearer and more consistent information about health care quality—and patient safety is a key part of that information. The QuIC agencies see this work group as a foundation for strengthening the effectiveness of the actions that agencies might have otherwise taken independently.

In particular, Federal agencies that provide or purchase health care have a responsibility to work with their constituencies to increase awareness of patient safety issues and the role their constituents can play in improving safety. For instance, part of HCFA's and OPM's mission in purchasing health care is to provide information to enrollees that will help them choose their health coverage. These agencies are exploring how to educate enrollees so that they can understand and evaluate issues related to medical errors and take appropriate actions. HCFA and OPM also lead the QuIC working group on patient and consumer information, which provides a natural vehicle for extending the messages to other Federal beneficiaries and the public.

A number of other mechanisms exist to extend the work of this work group to more people. It is possible to use public–private partnerships to communicate the patient safety message to a variety of audiences through recently developed mechanisms. These partnerships include the NPSF, NPSF, and the Quality Forum, and are summarized in the “Actions” section that follows.

ACTIONS:

- Through the QuIC's Enhancing Patient and Consumer Information Working Group, led by OPM and HCFA, Federal agencies will develop and coordinate an information campaign for their constituencies and beneficiaries to increase their awareness of the problem of medical errors and patient safety.
- 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 to be more active participants in the decisionmaking surrounding their care.
- The CQuIPS will develop and test patient safety questions for inclusion in the patient survey now being developed for provider-level assessment of health care.

- HCFA will conduct research aimed at shaping programs to educate beneficiaries about medical errors.
- Within 1 year, 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 through grass-roots informational meetings. The meetings will focus on patient needs and the safe use of medical products, particularly for home use. The meetings will also discuss how to reach patients with important information on safe use of medical products—including through the use of local networks, the Internet, and electronic and print media. This will occur within 1 year.
- Patient safety and reducing medical errors will be a featured topic at OPM's Fall 2000 annual health plan conference.

Building Purchasers' Awareness of the Problem

Just as with Federal purchasers of health care, it is critical that employers who sponsor group health plans understand that quality, not just cost, is a factor to be considered in selecting health care providers for their employees. In 1998, the DOL's Pension and Welfare Benefits Administration (PWBA) issued a letter making clear that, where the selection involves the disposition of employee benefit plan assets, taking quality into account is part of a plan decisionmaker's responsibility under the Employee Retirement Income Security Act (ERISA).

To assist employers in meeting this obligation, the DOL launched the Health Benefits Education Campaign in December 1998. One of the goals of the Campaign, a coalition of the DOL with both public- and private-sector partners, is to inform employees about issues of quality and safety under their employer-provided health benefits so that they can make informed health benefits decisions. The Campaign further seeks to inform employers of the value of providing quality and affordable health benefits to their employees. It provides a forum for sharing with the private sector the information learned from other QuIC agencies on quality care, setting and implementing standards, developing and implementing data integration techniques, and effectively communicating with consumers.

A number of employers and employer health care coalitions are already taking the initiative of making safe medical practice an important criterion in selecting the health insurance they provide to their workers. For example, the National Business Coalition on Health (NBCH), a Campaign partner, is developing a set of standards that employers can voluntarily use to evaluate safety and quality in health plans. The Business Roundtable, another Campaign partner, has allocated funds for the Leapfrog Group, an organization of eight executives of some of the Nation's biggest companies and health care purchasers, including OPM, to encourage all employers to make safety and quality in health care a top priority. DOL will, through the Campaign, work with plans, employers, and participants to advance the provision of safe, high-quality health benefits. Some of the work that is being done is summarized in the "Actions" section that follows.

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 medical errors as a health care problem and of steps that each can take to address this problem, such as addressing 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.

Working With Providers to Improve Patient Safety

In addition to information for patients and purchasers, information is needed for health professionals, facilities, and systems of care to ensure that they understand the scope of the medical errors problem and its impact. Results from surveys and focus groups conducted by VA, involving both VA and private-sector facilities, have shown that a substantial portion of doctors, nurses, and others working in health care facilities do not believe that medical errors present a significant threat to patients. If they believe that medical errors and issues of patient safety are isolated, random events, efforts to reduce the current incidence of preventable errors will not be successful.

The public's perception is that the health professional credentialing and institutional accreditation processes provide meaningful assurances of the quality of care. It is crucial that professional societies, accrediting bodies, and licensure organizations use their roles to promote patient safety by ensuring that those whom they credential and accredit are knowledgeable about issues of safety and implement procedural changes that have been shown to reduce the likelihood of error. Help by these organizations is paramount in fostering awareness and understanding of issues about medical errors and patient safety.

The QuIC agencies will work collaboratively with professional societies to promote awareness of the medical errors problems and to identify ways to improve the education, credentialing and accrediting processes to rigorously examine safety knowledge and practices. AHRQ will work with private-sector groups, such as NPSF, NPSP, and the Quality Forum to educate providers and purchasers about improving patient safety.

ACTIONS:

- Through the QuIC, Federal agencies will take advantage of existing resources to promote collaborative patient safety programs involving agency constituents, the health professions 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 run pilot patient safety education programs for medical residents and students.

Using Decision-Support Systems and Information Technologies

The Federal Government has played a pivotal role in the application of information technology to health care. The predecessor of AHRQ funded some of the earliest research on computerized patient records, studies evaluating the impact of computer reminder systems on laboratory testing errors, and research on the effect of computers on drug ordering. VA and DoD are recognized national leaders in the implementation of electronic medical records and decision-support tools. They have recently joined in partnership with the Indian Health Service (IHS) to develop a prototype for a computerized medical record system. In addition, many private-sector leaders in health care informatics, such as Intermountain Healthcare and the Brigham and Women's Hospital, have used Federal grants to develop and test their systems. The President has also requested \$20 million in the FY 2001 Budget for the Health Informatics Initiative, which includes support for strategies to address the problem of medical errors through enhanced information technology.

Although the success of health care informatics models is well documented and their applicability to patient safety is clear, they have not been widely adopted. A Federal effort to further knowledge about the application and effectiveness of these technologies to patient safety improvement and to promote the appropriate adoption of these tools would build on a strong foundation of prior work and put health care technologies to use in improving the quality of care for Americans.

One example of where the QuIC could have an impact through its participants' activities is in the area of electronic records and order entry. Most health care providers currently work with handwritten patient notes, which are often difficult to read, not readily available, incomplete, and prone to alteration, destruction, and loss. Electronic medical records and interactive decision-support tools have the potential to allow health care providers timely knowledge of a patient's health history and improve clinical care. Electronic access to a patient's chart removes uncertainties regarding the patient's health history. Further, well-designed electronic systems can give physicians, nurses, and other providers essential access to the most current results of consultations, laboratory tests, x-rays and other studies, and to previous test results. Structured, electronic order entry systems that require complete data entry remove ambiguities that arise from incomplete information or illegible writing.

Moreover, real-time decision support constitutes a powerful technology that can help address the significant problem of medication errors. Decision-support systems can intercept errors, such as interactions between incompatible medications and the prescription of drugs to which the patient's electronic medical record notes an allergy. Patient factors relevant to the dosing of particular medications can also be evaluated electronically; drug overdosing or underdosing can be corrected by accounting for a patient's age, weight, and kidney function. Taken further, better choices of medications for a particular condition can be recommended, such as the most diagnosis-appropriate antibiotic. Finally, bar-coding of medications and use of robotics in dispensing medications can ensure that the appropriate medication is provided to the appropriate patient at the appropriate time.

Health care organizations can more easily and reliably aggregate their electronic records to look for trends and provide data for research on patient safety issues without relying on costly chart reviews. Provider profiles can be used to provide helpful feedback to clinicians and to identify needs for training and system changes. Health care organization profiles can be developed for any level of the organization to look for systemic problems and evaluate interventions.

However, there is a real need to involve clinicians and other users in the design of systems at an early stage to optimize usability. Increased emphasis on design controls for manufacturers is needed to ensure that usability testing occurs throughout development, especially in the premarket design phase of medical device development. Continued development, taking into account knowledge of human factors and results of usability testing, is needed. Use of human factors standards, such as nationally or internationally accepted standards for products and the human factors standards used by NASA and DoD, could aid in that process.

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.

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

Embedding checklists and standardized procedures in medical devices (as has been done with anesthesia gas machines) needs to be expanded to many more medical devices to protect patient safety. The American National Standards Institute (ANSI) is leading an effort to develop U.S. national standards for medical device alarms and human factors-based engineering designs of medical devices. The Association for the Advancement of Medical Instrumentation is developing human factors standards for medical devices. The development of standard operating procedures can also help. For example, the Occupational Safety and Health Administration's (OSHA's) Bloodborne Pathogens Standard requiring proper disposal of contaminated sharps and needles ensures a safer environment for both workers and patients. The DHHS Advisory Committee on Blood Safety and Availability has issued recommendations to prevent errors and accidents in the collection and administration of blood.

FDA's Quality Systems Regulation, which governs the design process for medical devices, provides manufacturers with guidance on human factors design principles and information on how to conduct a risk assessment to qualify their design, and serves as a model for other programs. The internationally recognized expertise in human factors research of NASA, DoD, and FAA could be applied to the improvement of patient safety with the establishment of appropriate links to the QuIC participants.

Additionally, recognizing that many problems are not detected until after a product has been marketed, FDA believes that strengthening its premarket activities, including those related to human factors, will aid in reducing problems that users may encounter with medical products in clinical use. For example, premarket testing of standardized procedures for operation and maintenance of products, user instructions, and labels would aid in detecting and preventing errors associated with the use of medical products. FDA proposes to encourage manufacturers to explore human factors issues through the use of premarket focus groups as well as through user testing of the product in its intended environment.

Health care organizations need to develop staff awareness of the need for continuous improvement of quality, processes, and performance as another critical component of error reduction. The Federal health care delivery systems have been providing meaningful quality improvement training to personnel at their delivery sites for several years. Error reduction has been a strong focus for some programs, such as those at VA. For example, quality improvement training led to concentrated potassium chloride

containers being removed from patient care settings. This kind of information can be shared broadly with other health care providers to emulate VA's success.

ACTIONS:

- CDC and FDA will work with the DHHS Advisory Committee on Blood Safety and Availability to help ensure that the highest quality standards are met in blood collection and transfusion.
- Within 1 year, FDA will begin working 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.
- 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.

CHAPTER 4

Working With the Private Sector and State Governments

The agencies that constitute the QuIC have longstanding relationships with the private sector, including professional organizations, purchasers and purchaser coalitions, business groups, independent accrediting entities, quality measurement and consumer information experts, researchers, medical product manufacturers, hospitals, group practices, health systems and health plans. Working collaboratively, the QuIC agencies can make use of these relationships to help reduce medical errors and increase patient safety, thereby improving the quality of care for all Americans.

Federal agencies working with the private sector can use a systems approach to help bring a level of organization to the Nation's systems of health care. They can:

- Develop, articulate, and encourage clear lines of accountability through measures and standards.
- Improve reporting and identification of errors through data integration.
- Provide clear, consistent information and educate patients to be more responsible for their own care and safety.
- Reach out to others in the health care industry and increase support for efforts to reduce medical errors and improve patient safety.

Together, Federal agencies and the private sector can bring patient safety to the forefront of the national agenda and help the Nation achieve greater safety and quality in its health care system.

The QuIC member agencies represent health care purchasers, providers, policymakers, regulators, researchers, and patient advocates. These agencies—working together with their private-sector counterparts—can define, demand, recognize, and reward quality. Specifically, they can capitalize on the current consensus for action in the areas of standards and data integration, improve the knowledge base about errors, learn from errors, and encourage the dissemination of information on patient safety to the public—issues that were addressed earlier in this report.

State government plays a critical role in a number of patient-safety related activities, such as the authority for licensure of health care providers. Importantly, over 20 States have existing mandatory reporting programs related to patient safety. State and local governments can also have a significant impact on patient safety in their roles as health care purchasers, providers, and regulators. These activities could be enhanced by partnership with both Federal agencies and the private sector. For example, the collection of protected State reporting data—that has also been stripped of identifying information—through the coordination of the CQuIPS at AHRQ will provide a national

resource for learning more about the occurrence of errors and developing strategies to reduce them. The CDC has programs, including the Epidemic Intelligence Service, that could serve as a model for coordinated Federal-State efforts to improve patient safety. The Department of Labor's PWBA has also developed a valuable collaborative relationship with the National Association of Insurance Commissioners (NAIC) and individual State insurance regulators to foster a better understanding of ERISA's health benefits provisions among the public and the regulated community. Many of the actions proposed by the QuIC will benefit from building upon existing Federal-State Government partnerships.

Despite these encouraging and productive collaborations between the Federal Government's agencies involved in health care quality and both the private sector and State governments, the IOM report emphasizes how much more can be done to reduce the rate of medical errors and to enhance patient safety. The QuIC and its member agencies are committed to implementing additional cooperative and collaborative programs, especially in the areas of standards and data integration.

Standards

In the health care industry, standards, broadly defined, are reflected in two areas: accreditation programs and performance measures (or measurement sets). Accreditation programs for health plans offer a powerful vehicle to enhance quality and safety. Such programs not only assess the structural capacity of organizations to meet critical standards, but also increasingly incorporate performance measures into the accreditation process. By working with independent accrediting organizations, such as JCAHO, the American Accreditation Health Care Commission/URAC, and the National Committee for Quality Assurance (NCQA), and by encouraging or requiring accreditation of health plans, QuIC agencies that purchase or provide health care can raise the bar for quality across the industry.

The QuIC will send a clear and consistent message about the desirability of appropriate measures and standards by encouraging its member agencies to participate in development efforts, disseminate information, adopt or encourage adoption of measures and standards related to patient safety, and require reports and performance improvement, as appropriate. The QuIC will assure that individual agency efforts are communicated, coordinated, and cohesive in terms of what is being asked of the health care industry and its providers. By doing so, the QuIC will directly impact the quality of care available to Americans.

For example, under HCFA's leadership, a group of public- and private-sector partners developed the DQIP measurement set. The measures were developed based on research sponsored by QuIC agencies and translated into performance measures by collaborating Federal agencies. QuIC agencies have endorsed and will use the DQIP measurement set. Similarly, NCQA, one of the DQIP partners, has adopted the measurement set for testing in 2000. The result of these DQIP-related activities will be better care for Americans with

diabetes. QuIC agencies, in partnership with accreditation organizations and others, will undertake similar collaborative efforts in other areas to improve standards and measures related to patient safety and the reduction of medical errors.

In another effort, Federal agencies have launched a public-private sector initiative with over 50 participating organizations or agencies to reduce medication errors in the outpatient setting. The Study of Clinically Relevant Indicators for Pharmacologic Therapy (SCRIPT) project will result in development and field testing of performance measures for medication management and error reduction in several common and costly diseases or conditions (diabetes, coronary artery disease, congestive heart failure, hypertension, hyperlipidemia, and atrial fibrillation) and should be completed this year.

Few health care purchasers, either private or Federal, deal directly with providers. However, purchasers can encourage their health plans to endorse and facilitate sound provider practices. They can require that health plans encourage their networks to implement accountability systems and ensure that sound practices are noted and rewarded. For instance, Federal agencies, such as HCFA, that contract with health plans will provide oversight of health plan arrangements for hospital and practitioner services to help create a patient-safe hospital environment (i.e., requirements for medical error reduction systems, including approaches to producing appropriate results over a specified period of time). In addition, health plans can encourage their network providers to participate in nonpunitive error reporting that facilitates the identification and correction of systemic problems. Health plans can make a major contribution to patient safety and quality of care in response to clearly articulated and achievable purchaser expectations.

Federal agencies also can work with other health care purchasers to support the development and implementation of provider-level programs for accrediting organizations and encourage the incorporation of more rigorous safety standards into existing programs. While much good work has already been completed, much more needs to be done to establish and enforce adequate credentialing standards for physicians, hospitals, and preferred provider organizations. Under the auspices of the QuIC, VA is leading an effort to identify a core set of credentialing elements across different agencies and departments. This effort will establish a model for interorganizational collaboration that the private sector may choose to adopt. As part of its research effort on medical errors, the QuIC will collaborate with certifying boards for health care professionals to develop measures of patient safety appropriate for inclusion in certification and recertification programs.

As mentioned earlier, the health care industry has much to learn from other industries that have more impressive safety records. The CQuIPS in AHRQ will identify successful safety programs, assessing the evidence that they are, indeed, “best practices,” and sharing information on their techniques and their adaptability to health care. QuIC agencies can use their influence to incorporate those strategies and encourage private-sector purchasers to do likewise. For example, there is considerable potential for error reduction through the use of automated systems to enter and process prescription orders and to monitor for risks of adverse drug events. The use of and advocacy for such

systems by Federal purchasers and providers could accelerate their use. Similarly, Federal agencies could create demand for the use of electronic prescription ordering systems at physicians' offices by encouraging their colleagues in the pharmaceutical industry, including pharmacy benefits managers and others, to support and facilitate the use of such systems by health care providers. Adherence to recommended protocols (e.g., beta-blockers following heart attack) is another aspect of care that can be monitored to reduce errors. QuIC agencies and their partners should institute programs of quality assurance and quality improvement focused on error reduction.

Finally, Federal agencies have been involved in the creation of performance standards used in development of medical products for many years. The FDA plays a central role in collaborating with the private sector by helping to develop industry standards for medical products. For example, FDA works with representatives from the medical industry, health and technical professionals, and consumer and patient organizations to identify and develop new standards for medical products that use emerging and complex technologies. In addition, the QuIC recommends that Federal agencies should, in partnership with the Quality Forum, establish a consortium of private-sector organizations, industry representatives, academic institutions, and scientific and health care professionals to examine issues related to medical product standards, such as addressing human factors early in the development of new medical products.

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 the research agenda articulated above, will develop evidence-based measures that integrate human factors and lessons from other industries.
- As with the DQIP measurement set, the QuIC will solicit formal adoption and use by member agencies of common, validated, and standardized performance measures in the area of error reduction. The QuIC will work with certifying boards for health care professionals to incorporate these measures into certification and recertification programs where appropriate.
- QuIC agencies will encourage their private-sector partner organizations to support the implementation of more rigorous safety standards and will act to 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 an existing collaboration with the National Association of Insurance Commissioners 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, share 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 beneficiaries of the Federal Employees Health Benefits Program.
- Patient safety and reducing medical errors will be a featured topic at OPM's Fall 2000 annual health plan conference.

Data Integration

At present, the challenge of improving patient safety with an inadequate evidence base is compounded by the fragmentation of information regarding errors. The QuIC can play an important role in bringing together information from disparate sources to create comprehensive information resources that could further the development of research and practice related to patient safety. For example, FDA could use the databases developed by pharmaceutical benefits managers to learn about frequent errors and near misses. QuIC members can play an important role by insisting on data integration among providers such as pharmacy benefits managers, physicians, hospitals, and laboratories.

The CQuIPS, working with the QuIC and its member agencies (e.g., CDC, DoD, FDA, OPM, VA), State and local governments, providers, and health plans, should develop and maintain a national program to collect information abstracted from reports on errors and incidents, to share the lessons learned from these error-reporting systems, and to promote action to reduce errors and near misses. AHRQ's existing Healthcare Cost and Utilization Project (HCUP) provides a relevant model for this task. HCUP pools hospital discharge data (that has been stripped of identifying patient information) from the States, and integrates that data into a single resource for researchers and decisionmakers. The HCUP database thus provides an opportunity for States to compare themselves to other States. The CDC also has relevant experience in integrating data from the States for learning purposes that will help guide this effort.

An additional opportunity for QuIC agencies (especially HCFA, FDA, and AHRQ) to work together through data integration would be provided by the development of an expanded drug benefit program for Medicare beneficiaries. Combining data stripped of patient identifiers from the PBMs (pharmaceutical benefits managers) into a single resource could provide a valuable tool for enhancing patient safety. This could build on work being done by AHRQ's CERTs and the work of the FDA, as well as on models already being used by VA and DoD. Through collaborations with the private sector, the QuIC agencies could develop a plan for reducing medication errors in an expanded Medicare drug benefit program. OPM can also use its relationship with health plans and preferred provider organizations to encourage the adoption of data integration by those providers as well.

This effort, as envisioned by the IOM, requires that a coordinated set of core information on errors be collected across all of the participating reporting systems. The IOM suggested that the Quality Forum be given the task of identifying that core set of information. Given the mission of the Quality Forum and its existence as a public-private partnership, the QuIC believes that this recommendation is entirely appropriate, and QuIC agencies are committed to working with the Quality Forum on the development of this set of data requirements. Methods for integrating, analyzing, and disseminating patient safety data will also be developed as part of the National Healthcare Quality Report effort being led by AHRQ and the CDC.

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 brought together 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 pooling the data and using this resource 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 medical errors and improving patient outcomes.
- HCFA, in collaboration with FDA and AHRQ, will develop a strategy for incorporating initiatives to increase patient safety into the pharmaceutical benefits managers program under an expanded Medicare drug benefit.

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Organization and Acronym Guide

Agency for Health Care Policy and Research	AHCPR
Agency for Healthcare Research and Quality	AHRQ
American National Standards Institute	ANSI
Area Health Education Center Program.....	AHEC
American Hospital Association	AHA
American Medical Association.....	AMA
American Nurses Association.....	ANA
Association for the Advancement of Medical Instrumentation.....	AAMI
Aviation Safety Reporting System	ASRS
Centers for Disease Control and Prevention	CDC
Centers for Education and Research on Therapeutics	CERTs
Center for Quality Improvement and Patient Safety	CQuIPS
Conditions of Participation	CoP
Department of Defense	DoD
Department of Health and Human Services	DHHS
Department of Labor	DOL
Department of Veterans Affairs	VA
Diabetes Quality Improvement Project	DQIP
Employee Benefit Research Institute	EBRI
Employee Retirement Income Security Act	ERISA
Epidemic Intelligence Service	EIS
Federal Aviation Administration	FAA
Federation of State Medical Boards	FSMB
Fiscal Year	FY
Food and Drug Administration	FDA
Health Benefits Education Campaign	
Healthcare Cost and Utilization Project	HCUP
Health Care Financing Administration	HCFA
Health Resources and Services Administration	HRSA
Indian Health Service	IHS
Institute of Medicine	IOM
Intensive care unit	ICU

Joint Commission on Accreditation of Healthcare Organizations	...JCAHO
National Aeronautics and Space AdministrationNASA
National Association of Insurance CommissionersNAIC
National Business Coalition on HealthNBCH
National Committee for Quality AssuranceNCQA
National Coordinating Council for Medication Error Reporting and PreventionNCCMERP
The National Forum for Health Care Quality Measurement and ReportingQuality Forum
National Health Care SurveyNHCS
National Nosocomial Infections SurveillanceNNIS
National Patient Safety FoundationNPSF
National Patient Safety PartnershipNPSP
National Practitioner Data BankNPDB
Occupational Safety and Health AdministrationOSHA
Office of Personnel ManagementOPM
Operating roomOR
Pension and Welfare Benefits AdministrationPWBA
Quality Assessment/Performance ImprovementQAPI
Quality Interagency Coordination Task ForceQuIC
Study of Clinically Relevant Indicators for Pharmacologic TherapySCRIPT
Veterans Health AdministrationVHA
Washington (DC) Business Group on HealthWBGH

Glossary of Terms

Adverse event: an injury that was caused by medical management and that results in measurable disability.

Error: the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems.

Unpreventable adverse event: an adverse event resulting from a complication that cannot be prevented given the current state of knowledge.

Medical error: an adverse event or near miss that is preventable with the current state of medical knowledge.

Near miss: an event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention.

System: a regularly interacting or interdependent group of items forming a unified whole.

Systems error: an error that is not the result of an individual's actions, but the predictable outcome of a series of actions and factors that comprise a diagnostic or treatment process.