An Approach to Medical Errors and Patient Safety in Laboratory Services

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Abstract

The Institute of Medicine (IOM) reports, *To Err Is Human* and *Crossing The Quality Chasm* have focused attention on medical errors, patient safety, and the quality of care. Quality can be defined and measured and improved. Examples of quality improvement programs include the accreditation programs of the Joint Commission for Accreditation of Health Care Organizations, the Centers for Medicaid and Medicare Services quality improvement program for Medicare, the National Committee for Quality Assurance's HEDIS measures for managed care organizations, the Veterans Administration's promotion of a culture of patient safety, and the Anesthesia Patient Safety Foundation's research and education programs.

Studies have documented inappropriate utilization of laboratory tests and interventions are effective in improving the utilization of laboratory tests. Laboratory practice uses many methods to reduce errors, assure patient safety, and improve quality including quality control procedures, quality assurance programs, certification of education programs, licensing of laboratory professionals, accreditation of laboratories, and federal regulation of laboratory practices. Although errors still occur through all phases of the testing cycle, the proportion of errors in the analytic phase of testing is lower than the proportion of errors in the pre-analytic and post-analytic phase of testing. This suggests that collectively the methods to reduce errors are a laboratory medicine practice have been effective and that further efforts to reduce errors and assure patient safety will require partnerships with providers.

There are important implications of the recommendations of the IOM reports for laboratory medicine. Successful quality improvement activities have previously benefited from national reports on the state of health-care quality, the development of indicators of the quality of care, and the establishment of ongoing organizations with specific missions to reduce errors, improve patient safety, and improve quality of care. A National Report on The Quality of Laboratory Services with indicators of the quality of laboratory services and the creation of Quality Institute for laboratory services have great potential to further reduce errors in the use of laboratory services, assure patient safety, and improve the quality of laboratory services.

1 Introduction

"Making the Laboratory a Partner in Patient Safety"

The Center for Disease Control and Prevention's (CDC) Division of Laboratory Systems, along with 39 partner organizations, has convened a national conference in April 2003 on patient safety and laboratory services. The theme of the conference is "Making the Laboratory a Key Partner in Patient Safety." The conference provides an opportunity for practitioners of laboratory medicine to meet with others in the health care system to plan an approach to improve patient safety and laboratory services. Conference attendees will consider: 1) the development of a national report on the quality of health laboratory services; 2) the identification of indicators for the quality of laboratory services; and 3) the establishment of a Quality Institute to improve patient safety and enhance the quality of laboratory services. The following overview of data on medical errors and patient safety and current programs that address quality, medical errors and patient safety is provided to foster consideration of policies, organizations, programs, and activities that could improve quality, assure patient safety and reduce error in laboratory services. Opportunities for laboratory medicine professionals to contribute their knowledge and experience in reducing error and improving services to the overall efforts to improve patient safety and the quality of the health care system are also discussed.

The Evolving US Health Care System: Cost, Access, and Quality

Health care in the United States (US) is provided by well-trained specialists from many disciplines in many settings in a mixture of public and private organizations. The US health care system has evolved with incremental changes and has generally been resistant to large-scale reform. In recent years, horizontal and vertical integration of health care organizations, capitation and other changes in payment for health care and managed care programs have developed in response to efforts to control health care costs. Health care costs continue to rise due in part to the development of new drugs and technologies, the aging of the population, continued expansion of health care services, and increased complexity in the organization and financing of health care. Access to health care and lack of health insurance are increasing concerns. Studies of health care services have documented wide variations in the use of services, inappropriate use of some services, under use of necessary services, and surprisingly high prevalence of medical errors and medical injuries. National reports on medical errors have focused attention on the quality of health care services and have resulted in a growing public and governmental interest in patient safety and quality of care.

The Quality of Health Care Can be Defined and Measured

Quality of health care can be defined and measured. Patients and their families, physicians and other providers of care, managers, and payers have different definitions and emphasize different aspects of quality. However, there is often strong agreement about specific instances of poor quality of care, especially when care results in injury, disability, or death. The Institute of

Medicine (IOM) formulated the most recent widely accepted definition of quality of health care as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[1] The quality of health care can be assessed using information on the structure of health care, the process of care, and the outcomes of care.[2]

Quality of care can be improved by changing the behavior of participants in the health care system. Several methods have been used to change behavior: education, feedback, participation in changing practice behavior, administrative rules, financial incentives, and financial penalties. Performance reports that provide risk-adjusted outcomes and permit physicians and hospitals to compare performance with that of peers can be useful in improving quality of care. Administrative interventions including computerized ordering and decision support systems can reduce medication errors and improve the use of antibiotic medications. Although many are skeptical about efforts to improve the quality of care, a growing body of evidence suggests that a variety of methods can improve the quality of care. However, a recent RAND review of studies on the quality of care in the US found that there was surprisingly little systematic knowledge on the quality of care in the US. The dominant finding from the available studies is that a large gap exists between the care that patients should receive and the care that they do receive. This appears true for both overuse and under use of services, across different types of health insurance, age groups, and geographic regions.[3]

2 Medical Errors, Medical Injuries and Patient Safety

Epidemiology of Medical Error

Three major studies have provided insight into adverse medical events: the Harvard Medical Practice Study (HMPS) which used New York state hospital admissions,[4-6] the Quality of Australian Health Care Study (QAHS),[7] and the Colorado and Utah Study.[8] The two US studies of medical injury served as the basis for the estimates of the number of deaths due to medical errors reported in the IOM report, *To Err Is Human.*[9] The major findings in the studies were similar. Errors in prevention, diagnosis, and drug treatment occurred. Among errors in diagnosis, 50 percent were in failure to use indicated tests, 32 percent were failure to act on results of test or findings, and 55 percent involved avoidable delay in diagnosis.[5] Medical malpractice litigation was not found to necessarily promote high-quality medical care, and the rate of claims data seems to have limited value as an indicator of the quality of care being provided.[6]

To Err is Human

In 1999, the IOM report, *To Err Is Human: Building A Safer Health System* was released.[9] This report used information from the Colorado and Utah and the New York State studies of adverse events to estimate the number of Americans who die each year as result of medical errors. The studies suggest that at least 44,000 and many as 98,000 Americans die each year due to medical error. These numbers exceed the eighth leading cause of death, and suggested more people die in a given year as result of medical errors than from motor vehicle accidents, breast cancer, or AIDS. The report contained four approaches to reducing medical error: 1) establishing a

national focus to create leadership, research, tools and protocols to enhance knowledge about safety; 2) identifying and learning from errors through immediate mandatory reporting efforts, as well as encouraging voluntary efforts aimed at making sure the health care system is safer for patients; 3) raising standards and expectations for improvement on safety by actions of oversight organizations, group purchasers, and professional groups; and 4) creating safety systems inside health care organizations through the implementation of safe practices at the delivery level. The recommendations of *To Err is Human* are summarized in Table 1.

Crossing the Quality Chasm

In 2001, The Committee on Quality of Health Care in America of the IOM issued a report entitled *Crossing the Quality Chasm: a New Health System for the 21st Century*.[10] This report called for redesigning the 21st century health-care system in the following ways: 1) commitment by all health care constituencies, including policy makers, purchasers, regulators, health professionals, health care trustees and management, and consumers to a national statement of purpose for the health care system as a whole and to a shared agenda of improvement; 2) principles for clinicians, patients, and health care organizations that support care delivery to guide the redesign of care processes; 3) priority setting by The Department of Health and Human Services to identify conditions upon which to focus initial efforts and provision of resources to stimulate innovation, and to initiate the change process; 4) support by health care organizations in design and implementation of more effective processes to make change in the delivery of care possible; 5) creation of an environment that fosters and rewards improvement by supporting evidence-based practice, facilitating the use of information technology, aligning payment incentives, and preparing the workforce to better serve patients in a world of expanding knowledge and rapid change. The agenda proposed six aims for improvement: 1) Safety; 2) Effectiveness; 3) Patient-centeredness—providing care that is respectful of and responsive to individual patient preferences, needs, and values to ensure that patient values guide all clinical decisions; 4) Timeliness; 5) Efficiency; and 6) Equity. The recommendations of *Crossing the Quality Chasm* are summarized in Table 2. Don M. Berwick, MD, a member of the IOM Committee on the Quality of Health Care in America prepared a "user's manual" for the *Crossing the Quality Chasm* report. The manual provided a framework for understanding the recommendations of the report within the US health care system.[11]

Criticism of *To Err is Human*

The IOM reports have been critically reviewed, and concern has been expressed about the accuracy of estimates of the magnitude of medical errors and preventable injuries, the reliability of methods used to identify medical errors and medical injuries, the approach to patient safety (systems versus individuals, errors versus injuries) and evidence for the effectiveness of patient safety practices. It is appropriate to consider whether the IOM estimate of the number of deaths due to medical errors is accurate. Few studies directly measured errors and there are no studies of the reliability of measurements of errors. No studies directly evaluated the relationship of medical errors to adverse events.[12] Investigators have not been able to confirm the estimates of the number of preventable deaths in the IOM report using published data.[13] Two recent articles in the *Journal of the American Medical Association* address the controversy of whether the IOM estimates of the number of deaths due to medical errors were exaggerated. One noted that the

estimates were based on the flawed assumption that eliminating preventable adverse events would eliminate deaths and that there was no information regarding the baseline expected rate of death among the patients who were involved in potential adverse events.[14] In response a member of the IOM committee on Quality of Health Care in America indicated that the IOM estimates of medical errors are not exaggerated and noted that reviews of medical errors underestimate medical errors since many medical errors are not recorded in the medical record, that errors occurring in the ambulatory setting are excluded from most studies, and that prospective studies report higher rates of errors than studies that use implicit review of medical records.[15] Regardless of the accuracy of the estimates of medical error and injury, important problems in the quality of health care seem to exist and indicate a need for increased efforts to reduce injury, disability, and death due to medical error.

An Approach to Patient Safety

Patient safety can be improved by efforts to reduce medical errors and by efforts to prevent medical injuries. However, many medical errors do not result in medical injury and many medical injuries are not the result of a medical error. Proponents of focusing on reducing medical errors emphasize the need to look beyond the person or persons who made the mistake to the underlying root cause or core causes at the system level.[16] Proponents of a focus on medical injury emphasize the difficulty of reliably identifying medical errors and the value of an approach that reduces the impact of injuries whether or not the injuries are due to error.[17]

Recommendations have been made that: 1) health care organizations adopt proven medication safety practices; 2) the Agency for Healthcare Quality and Research (AHRQ) and private foundations convene workshops to identify, adopt, and implement state-of-the-art approaches to patient safety and improving the quality of health care; 3) care processes be redesigned based on best practices; 4) that information technologies be used to improve access to clinical information and to support clinical decision-making; 5) efforts be made to enhance knowledge and skills management, the development of effective teams, and improve the coordination of care across patient conditions and services and settings over time; and 6) performance and outcome measurements be used for improvement and accountability (Tables 1 and 2).

Patient safety research is particularly challenging because many practices cannot be subject to double-blind studies, capturing all relevant outcomes including "near misses" is difficult, many effective practices are multidimensional, and many patient safety problems are uncommon, which makes it difficult to demonstrate statistically significant improvement. Of interest to laboratory medicine professionals are two systematic reviews of evidence on interventions to reduce errors in health care delivery.[18, 19] The majority of published evidence on patient safety do not address laboratory tests. Two issues were identified that are highly relevant to laboratory medicine: 1) the prevention of misidentifications of patients and specimen using bar coding and 2) the transfer of information to care providers about abnormal results. This suggests that there are many potential opportunities to improve patient safety in the process of laboratory testing.

Impact of the Institute of Medicine Reports

The IOM reports have had a broad impact on patients, the press, policymakers, payers, and providers. Unfortunately, for many patients the report on the occurrence of medical errors was consistent with their own personal experience with the health care system. For the press, the estimates were newsworthy. For policymakers, the news that the health care system was a source of injury and harm required prompt response to identify the source of the problems and protect patients from injury. For payers, estimates that adverse events cost between $38 and $50 billion and that preventable adverse events cost between $17 billion to $29 billion raised concerns about the quality of care they were purchasing. Providers were concerned about the accuracy of estimates of the number of deaths due to medical errors while also acknowledging the importance of assuring patient safety. Payers began to focus attention on measures of quality and patient safety in their decisions to contract with providers. These efforts have been limited by a paucity of information on medical errors and quality of care.

The federal government's response has been formation of the Quality Interagency Coordination Task Force (QuIC), to coordinate efforts to improve quality and to respond with a strategy to identify prevalent threats to patient safety and a strategy to reduce medical errors. The IOM reports have mobilized the Executive Branch of the federal government, through the QuIC, to implement recommendations not requiring new legislation. In addition, a bill called The Patient Safety and Quality Improvement Act (H.R. 663) has been introduced in the House, which was unanimously passed on February 12, 2003 by the House Energy and Commerce Committee. H.R. 663 would create a voluntary and confidential medical errors reporting system. The medical error information would be stored in a national database for use in patient safety and quality improvement research.

Medical error and patient safety has become an important theme of medical conferences, professional society meetings, and activities of academic medical centers, healthcare organizations, and professional organizations. The National Patient Safety Foundation initiated a National Patient Safety Awareness Week. Peer review journals such as New England Journal of Medicine, Journal of American Medical Association, and Annals of Internal Medicine published articles on medical errors, patient safety, and quality of care. Other developments include the AHRQ initiated web-based online journal and forum on patient safety and health care quality to educate health care providers about medical errors in an engaging and blame-free environment. Activity on patient safety and medical error reduction is also occurring within several states.

Implication of *To Err is Human* for Pathology

The implications of the IOM report *To Err Is Human* for pathology have been reviewed.[20] Over the years the College of American Pathologists (CAP) has developed numerous quality standards to assure high-quality practice. The review of the IOM report stressed the importance of establishing a culture of safety, the need for leadership, and the need to understand safety, error reduction, and nature of error. The report identified the components of a culture of safety, and tasks for leaders of pathology professional societies, accrediting bodies, and individual pathology departments. The report described the complexity of the nature of error in pathology, need to understand underlying sources of variability, and the need to develop error reduction strategies

such as redundancy, standardized report protocols, reducing reliance on human memory, and task simplification.

The Joint Commission on Accreditation of Health Care Organizations (JCAHO)

The Joint Commission for Accreditation of Health Care Organizations (JCAHO) was founded in 1951. JCAHO's current mission is to continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations. Accreditation is a method of improving quality and assuring patient safety by establishing standards for the structure and processes of care and granting accreditation to organizations that meet these standards. If the standards are valid indicators of high-quality performance, then organizations that receive accreditation can improve patient safety by reducing the risk of adverse outcomes. JCAHO accredits more than 16,000 health care organizations including general, psychiatric, children's, and rehabilitation hospitals; critical access hospitals; health care networks; home care organizations; nursing homes and long-term care facilities; assisted living facilities; ambulatory care providers; and clinical laboratories, including independent or freestanding laboratories, blood transfusion and donor centers, and public health laboratories.

The JCAHO has several goals, standards, policies and programs that promote patient safety. In July 2002, JCAHO approved six national patient safety goals with 11 related specific recommendations for improving the safety of patient care in health care organizations. These goals address accurate patient identification before taking blood samples, administering medications or blood products, or prior to surgical invasive procedures; improving the effectiveness of communication among caregivers with verification of verbal or telephone orders; improving the safety of certain "high alert" medications; the elimination of wrong-site, wrong-patient, and wrong-procedure surgery; improving the safety of infusion pumps, and improving the effectiveness of clinical alarm systems. The JCAHO has multiple standards that directly relate to patient safety; in addition, standards address organizational leadership to create a culture of safety, the implementation of patient safety programs, response to adverse events when they occur, the prevention of accidental harm through prospective analysis to redesign vulnerable patient systems, and hospital responsibility to inform patients of errors and the outcomes of care.

JCAHO has established a sentinel event policy and a sentinel events reporting system. The sentinel events policy encourages organizations to report to JCAHO on a voluntary basis sentinel events that have resulted in death or serious injury. JCAHO provides a format for evaluating their root causes and identifying related preventive actions. JCAHO publishes a newsletter summarizing specific sentinel events, their common underlying causes and steps to prevent future recurrences.

The Joint Commission Resources (JCR) a not-for-profit affiliate organization provides services, seminars, programs, publications, training, education and consultation on patient safety. JCAHO is also involved in advocating for legislation to improve patient safety. JCAHO networks with patient safety coalitions including the National Council on Medication Error Reporting and Prevention, National Patient Safety Foundation, the National Patient Safety Partnership, and the

National Quality Forum. JCAHO is involved in patient safety and quality of laboratory services directly through its accreditation of laboratories as well as its role in accrediting the organizations where the pre-analytic and post-analytic phases of the testing cycle are reviewed as part of the organizations accreditation.

Quality Improvement in the Medicare Program

The Center for Medicare and Medicaid Services (CMS) initiated a program to measure and track quality of care to its beneficiaries using a voluntary, collaborative, and nonpunitive educational strategy. This program tracks 24 performance measures on a periodic basis. Most of the measures are process of care measures, rather than outcome measures. Process of care measures were selected because there is more consensus on processes of care; process measures generally do not require risk adjustment; it is easier to improve processes of care rather than to determine why outcomes are not optimal; many outcomes take years to occur; and generally smaller sample sizes are needed to demonstrate improvement in processes rather than improvement in outcomes. The clinical topics for which performance measures were identified include acute myocardial infarction, heart failure, stroke, pneumonia treatment and prevention, breast cancer screening, and diabetes mellitus – all measures that rely to some extent on the quality of laboratory service. The CMS approach to quality improvement uses established Quality Improvement Organizations (QIO's) with a specific mission to improve quality, indicators for the quality of care, and periodic national reports.[21-23]

Quality Improvement in Managed Care: the National Committee for Quality Assurance

The National Committee for Quality Assurance (NCQA), an organization that accredits managed care organizations, has effectively used performance measures and national reports of performance to stimulate improved quality of care. NCQA has developed the Health Plan Employer Data and Information Set (HEDIS®), a set of over 60 performance measures that address a range of conditions including asthma medication use, control of blood pressure, use of beta-blocker treatment after heart attack, and breast cancer screening. HEDIS measures are selected based on: (1) relevance, (2) scientific soundness, and (3) feasibility. The majority of the HEDIS measures are process measures. Only a few of the HEDIS performance measures address conditions for which laboratory tests would serve as indicators (cervical cancer screening, chlamydia screening, cholesterol management after acute cardiovascular events, and comprehensive diabetes care). NCQA provides health plan specific data that permits the alignment of financial incentives with the promotion of the delivery of higher quality care. NCQA issues an annual report on the state of health care quality focused primarily on the performance of the managed care industry. The NCQA, with its performance indicators and annual reports serves as an example of the potential value of the creation of an independent, ongoing organization devoted to improving quality in health-care that could serve as a model for approaching the problem of medical errors in the quality of laboratory services.

Veterans Health Administration Establishes a Culture of Safety

The veteran's health care system (VHA) is the largest organized health-care delivery system in the United States. The VHA has created a culture of safety by adopting a systems approach to

the reduction of medical errors and establishing a National Center for Patient Safety.[24] The National Center for Patient Safety provides educational resources, a VHA virtual learning center, a Web site, and a patient safety handbook. Directors of the 22 VA networks are held accountable for specific performance measurements. The VHA developed a VHA Patient Safety Event Registry and a mandatory reporting system that catalogs adverse events. They also conduct systematic reviews of adverse events and report the results to regional and national leadership of the VA. The VHA also supports the development of a national reporting system for medical errors that is voluntary and anonymous. This externally managed, independent entity is designed to accommodate the future addition of other public or private health care systems. The VHA also initiated specific activities to improve patient safety including computerized medical record, bar coding of medications, bar-coding of blood products, standardization of heparin dosing, use of double check systems to ensure accuracy of mixing intravenous solutions, and protocols for high-risk populations.

The Anesthesia Patient Safety Foundation

Anesthesiology is a leading medical specialty in addressing patient safety. The Anesthesia Patient Safety Foundation (APSF) undertakes educational programs and sponsors research to improve the safety of anesthesia administration and reduce adverse events. Factors associated with the success of the specialty of anesthesia in addressing patient safety include: publications, critiques in the peer reviewed literature of the methodological quality of published studies, critical analysis of a series of anesthesia mishaps, public media that addressed concerns and fears about patient safety in anesthesia, development of common definitions, the establishment of APSF, an ongoing foundation to support research and educational missions, an analysis of malpractice claims, an understanding of the role of human factors in accidents and mishaps, and the development of new technology, evidence-based guidelines, and protocols for anesthesia care. The APSF has expressed concern about two IOM recommendations, mandatory reporting and removal of "unsafe providers," and one issue not mentioned in the *To Err Is Human* report: patient safety of complex surgery and invasive procedures in the office setting, which is a completely unregulated setting. The APSF endorsed voluntary reporting and emphasized the need for legislation to assure peer review protection for patient safety data. The APSF recommended that professional societies be given flexibility to address their specific problems.

3 Medical Errors and Patient Safety in Laboratory Services

The Scope and Volume of Laboratory Services

Laboratory medicine specialties include clinical chemistry, hematology, microbiology, genetics, anatomic pathology, and transfusion medicine. Each year over 7 billion laboratory tests are performed in the U.S., influencing an estimated 70% of medical decisions. Laboratory services play a central role in both individual and population based health care. Therefore, changes in policies and programs designed to improve patient safety and the quality of health care services will inevitably have an impact on laboratory services. Even a low incidence of laboratory testing mistakes in the ordering, performance, or interpretation of laboratory tests among 7 billion tests could have important public heath and patient safety ramifications. The fact that laboratory services are delivered by over 180,000 laboratories certified by the federal government to offer

laboratory services and that the workforce is very diverse complicates an analysis of the incidence and impact of laboratory testing mistakes.

Laboratory services are delivered in a wide variety of settings for many purposes. Like other areas of health care, new technology is emerging that offers the opportunity to improve patient care, but could raise the costs of health care delivery and could result in uneven access to care. New challenges include the pressure to provide testing at the point of care, to provide patients with direct access to testing, and to ensure that all newborns have access to a basic set of tests to screen for hereditary conditions. One important feature of laboratory service is that these services are currently being delivered both closer to and farther from patients than ever before. The location of service has important implications not only for access to and cost of testing, but also for what factors influence the kinds of errors that might occur in the process of testing. Another important feature of laboratory services is that the type of testing offered and its location are often out of the control of the laboratory. Often which tests will be performed, where they are performed, and how often they are performed is dictated by care providers, health insurance coverage, or government mandates. As a consequence, the providers of laboratory services may be left out of the decision–making process when basic considerations of which tests to have available, where, and when are being made. Leaving the laboratory out of the decision-making process can result in them being left out of health care improvement, which would be unfortunate since the laboratory industry has been a leader in process control. Many of the concepts about quality assurance and quality control that are just being considered within the health care system have long been features of laboratory service delivery.

The Total Testing Process

An important framework for patient safety in laboratory services is the Total Testing Process. In this cyclical process a patient or physician initiates testing to answer a clinical or public health question. The laboratory test is ordered, the patient is identified and the specimen is collected, transported, and prepared for analysis. The specimen is then analyzed and the results are interpreted and reported to the physician or person who ordered the tests. Action is taken based on the user's interpretation of the test results. In practice, the laboratory's involvement in the steps in the total testing process varies based on the setting, type of test, and type of laboratory. Laboratories often refer to a simplified three-phase framework for the Total Testing Process -- a pre-analytic phase before an analysis occurs, an analytic phase, and a post-analytic phase after the analysis to describe issues related to the quality of laboratory services. Participation by laboratory medicine professionals is often minimal in test ordering and in test interpretation, two steps in the total testing process where there is a high potential for error. In delivery of laboratory services, mistakes often occur before the laboratory actually does the test (pre-analytic) or after the test has been performed.[25] Many of the mistakes in the process of laboratory testing are referred to as laboratory error, but are actually due to poor communication, actions by others involved in the testing process, or poorly designed processes outside of the laboratory's control.

Quality of Laboratory Services

The quality of laboratory services needs to be considered within the context of access, cost, and quality of all health care services. With over 40 million uninsured persons in the United States, lack of health insurance is a major factor in access to health care services. Most laboratory services are covered by most insurance plans, but uninsured patients may have decreased access to these services. Although the costs of health care continue to rise, laboratory services are only a small component of the increase in health care costs. Efforts to contain health care costs, however, have been focused on decreasing the use of laboratory services, especially where there is good evidence of no benefit or no evidence of benefit. The quality of laboratory services must address the appropriate use of laboratory tests. There are large variations in the estimates of inappropriate laboratory use.[26] Inappropriate laboratory use estimates range from 11 to 70 percent for general biochemistry and hematology tests, 5 to 95 percent for urine screens and microbiology, 17.4 to 55 percent for cardiac enzymes and thyroid function tests, and 4.5 percent to 82.5 percent for therapeutic drug monitoring. The tests with the highest inappropriate utilization included prothrombin time, calcium, cerebrospinal fluid analysis for the VDRL test, and antiepileptic drug monitoring. Inappropriate testing can increase health care costs, initiate a cascade of subsequent, potentially harmful testing, and may delay diagnosis and initiation of appropriate therapy. Inappropriate laboratory use may increase the risk of medical errors and injury. A large number of studies have been conducted on interventions to reduce the overuse and inappropriate use of laboratory tests.[27, 28] Interventions included education and feedback. Combinations of interventions are more effective than single interventions. The overall results of these studies show modest improvement, which does not persist after the intervention is withdrawn.

Errors in Laboratory Medicine

A recent review of errors in laboratory medicine concluded that there is a need for better definition of laboratory error and the causes of laboratory errors.[25] Within the laboratory, error reduction over time has occurred due in part to training and qualification of personnel, the adoption of rules for defining allowable error in quality control procedures, and the use of proficiency testing. It is important to relate laboratory errors to real or potential effects on patients. A standard terminology for laboratory error detection and reporting needs to be defined. Accurate analysis of risk of error in the clinical laboratory needs to be further studied. The review of studies of errors in laboratory medicine concluded that it is important to define ways to reduce laboratory-testing error and possibly completely avoid errors that have significant negative effects on patients' outcomes. Appropriate error detection programs and adequate measures to quantify the effects of these programs and to evaluate whether the reduction can be considered satisfactory seem to be critical. Finally, there is a need to establish a culture in which risk and injury prevention is recognized as the responsibility of everyone in the health care system.

Need for Partnerships with Providers

An approach to error reduction in the use of laboratory services must address the total testing process, and an important need is the reduction of the errors that occur before and after the

laboratory conducts the analysis. A study of problems in laboratory testing in primary care identified the largest proportion of errors occurring in the pre-analytic and the post-analytic phases of testing.[29] Errors after analysis extend beyond the reporting of the laboratory results of the ordering physician. Ideally this includes physicians' reporting the test results to the patient. A recent study suggests problems in patient notification and follow-up of abnormal test results and highlights an area where there is potential of increased risk of medical error and patient injury.[30] Test ordering and test interpretation are not viewed by all as a shared responsibility between the laboratory and the user of the laboratory results. Thus laboratory medicine professionals must work in partnership with physicians and other providers to effectively reduce errors in test ordering and test interpretation. Other areas where improvement is needed include lost specimen and test orders, and charting of laboratory results.

Lessons from the Laboratory to Assure Quality

Laboratory medicine practice includes several measures to assure high quality laboratory services. Laboratories routinely use quality control methods and have quality assessment programs. Laboratory medicine professionals are highly trained and many are licensed by states. Laboratories are subject to federal and state regulations. Transfusion errors are subject to FDA reporting requirements. The observation that more errors occur before or after testing than in the analysis itself suggests that collectively these programs have been effective in reducing medical error and improving patient safety. Currently, studies of errors indicate that the proportion of errors in the analytic phase of testing is lower than in the pre-analytic and the post-analytic phases of testing. Quality has been a hallmark of the analytic phase of laboratory services. However, the importance of their quality management procedures is often underappreciated. As a result, these activities are sometimes cut to reduce costs. An extension of some of these quality enhancement procedures to address mistakes in the delivery of laboratory services is much needed. Some assert that quality can be engineered into testing, others that it can be inspected into testing, and still others feel that these long-standing methods are no longer necessary. However, these methods have allowed the laboratory to produce reliable results in difficult environments, with sometimes poorly trained analysts, using methods that were less than optimal.

Clinical and public health laboratories which report patient results must be certified as having met the requirements of the Clinical Laboratory Improvement Amendments (CLIA). In addition to this federally mandated requirement, some states and certain professional organizations have requirements that meet or exceed the federal requirements. Professional organizations, NCCLS, and the International Organization for Standardization (ISO) and others have established a wide variety of voluntary guidelines for laboratory testing and practice, that have become the standard of good laboratory practice. Under CLIA laboratory tests are classified by complexity (high complexity, moderate complexity, waived tests, and provider performed microscopy). Laboratories that perform moderate and high complexity tests must have quality control programs, quality assurance programs, proficiency testing, and are subject to personnel requirements. Laboratories performing waived tests must register and follow manufacturers' instructions.

The College of American Pathologists Q-Probes and Q-Tracks Programs

The College of American Pathologists (CAP) has a long-standing commitment to improving the quality of laboratory services and patient safety. In 1989 the CAP initiated the Q-Probes program to move beyond traditional laboratory analytic quality assurance. The Q-Probes program is an inter-institutional quality improvement program to evaluate factors that affect laboratory performance and to benchmark quality indicators for all phases of the testing cycle.[31] Over 100 Q-Probe studies have been published in the peer-reviewed literature and as many as 1600 institutions voluntarily participated in the Q-Probes program each year.[32] The Q-Probes program provides reports to participating organizations on their own performance, and allows the identification of practices and factors associated with best performance defined as in the top quartile. The Q-Probe studies are essentially cross-sectional studies in which participating organizations provide data and receive information on their own performance and benchmarks for their performance. Thus in addition to the individual benefit to participating organizations, the practice of laboratory medicine benefits by the identification and dissemination of information on best practices.

Q-Probes has addressed all phases of the total testing cycle. Studies have addressed the pre-analytic phase of testing with measures of specimen collection (phlebotomy, specimen acceptability, timing of specimen acquisition, blood culture contamination) and order accuracy. Studies of the post-analytic phase of testing studies have addressed errors in reporting laboratory results, the accuracy timeliness and adequacy of surgical pathology and autopsy reports, and the process of telephone inquiry for reporting laboratory results. The timeliness of laboratory services was addressed in several studies of turnaround time (cerebrospinal fluid specimens, specimens originating in emergency department, and routine laboratory testing). Studies of autologous blood transfusion address the efficiency of laboratory services. Studies have also addressed nosocomial infection, a well-recognized patient safety area in which the laboratory has a central role. The Q-Probes measures can serve as the basis for indicators for the quality of laboratory services in future patient safety and quality improvement programs, and the Q-Probe methods and procedures can be adapted for future studies of quality of laboratory services.

The CAP recently developed the Q-Tracks program, which it built upon Q-Probes by introducing longitudinal tracking of performance over time.[32] The Q-Tracks program is a voluntary program. Participating hospitals provide monthly data on one or more indicators and receive information on their own performance within six weeks for a period of one year. A wide range of hospitals and hospital laboratories by size, geographic distribution and teaching status participated. The recent report of the Q-Tracks programs identified significant improvement in 4 of the 6 indicators studied (wrist band identification, specimen acceptability, blood wastage, intra-operative frozen section consultation), and no improvement in the 2 other indicators (PAP cytology-histopathology correlation and blood culture contamination). Improvement was greater for laboratories and hospitals with two consecutive years of participation than for hospitals that only participated for one year. The program also identified several practices associated with high-performance that can be adopted by other laboratories.[32] Q-Probes and Q-Tracks address patient safety and a wider range of issues in the quality of laboratory services. Q-Probes and Q-Tracks can be expanded to serve a broader range of laboratories and laboratory services and can serve as a useful model for an approach to patient safety for other clinical specialties.

The CDC Division of Laboratory Systems

The mission of the CDC Division of Laboratory Systems is to improve the quality of laboratory practices by providing global leadership, fostering partnerships, and collaborating with stakeholders in support of the continuous improvement of the public's health. The Division conducts research and surveillance on laboratory practices, develops and promotes standards and guidelines for good laboratory practice, assesses new and emerging technologies and their applications, disseminates information to the laboratory community, and provides training and education to laboratory staff and to individuals who utilize laboratory services. The Division strategies include improving the science base for health laboratory practice through partnerships with recognized scientific experts and organizations, and conducting research and development to improve laboratory performance and practice. The reduction of errors in laboratory services and assuring patient safety is central to the Division's mission and strategic goals.

4 Patient Safety for Laboratory Medicine: Next Steps

The health care system is dependent on reliable laboratory services. Therefore patient safety concerns provide an opportunity to develop policies and programs to improve the quality of laboratory services and assure patient safety. Recommendations from *To Err Is Human* and *Crossing the Quality Chasm* have potential implications for laboratory services. Several recommendations are especially relevant to laboratory services because many measures of health status and outcome involve both the care providers and the laboratory working together to produce accurate information. These recommendations include an annual report, service quality indicators, involvement of all health care professionals in development of common goals, mandatory reporting of deaths and serious injuries, voluntary reporting of errors, issues concerning unsafe providers, and implications regarding certification, licensing, training, accreditation, and standard setting organizations. In addition, the forthcoming National Report on Quality of Health Care will include conditions that are defined largely on the basis of laboratory tests and, therefore, input from laboratory medicine professionals is needed. Other issues where laboratory medicine could make a contribution to patient safety and error reduction include advising about legislation on patient safety, mandatory versus voluntary reporting of errors, the role of autopsy in patient safety, direct access to laboratory services, duplication of tests, appropriate use of home testing and near patient testing and genetic testing.

A National Report on the Quality of Laboratory Services

A specific recommendations in both of the IOM reports, *To Err is Human* and *Crossing the Quality Chasm* was to develop a national annual report to the President and Congress on the Quality of Health Care in the US. The National Report on the Quality of Health Care is being prepared by the Agency for Healthcare Research and Quality (AHRQ) and should be available in 2003. A companion report on Health Care Disparities is also being prepared by AHRQ and will also likely be released in 2003. There are many precedents for national reports on health and health policy topics to influence policy makers, public and private organizations, and the public. The IOM reports aptly illustrate the potential power of national reports to focus attention on

important issues. *Healthy People 2010,* the most recent of a series of decennial reports on health status of Americans in relation to achievable objectives for health is an excellent example of the value of national reports, goals or objectives, and indicators that can be tracked to assess progress in meeting goals for delivery of health services, processes of care, and health outcomes. National reports have great potential in focusing policies, resources, and programs to achieve goals of improving health. An important issue for laboratory medicine is whether the National Report on the Quality of Health Care in the United States will adequately address the issues of patient safety related to laboratory medicine or whether a separate report is needed. Reasons against a separate report include a concern that a separate report may appear to compete or conflict with the National Report on Quality of Health Care Services, and that a separate report may not get the attention needed. There are several advantages and potential benefits in preparing a separate report on the quality of laboratory services. First, a separate report could be more responsive to potential areas where laboratory medicine has special expertise. A separate report could include a framework, such as the Total Testing Process and indicators for quality of service that may be more applicable to the provision of laboratory services. A separate report could also include more specific recommendations that could focus on additional opportunities for error reduction and patient safety in the analytic phase of testing. A related issue is the need for additional information on the occurrence, nature, and impact of errors in laboratory medicine on health care.

The Content of a National Report on the Quality of Laboratory Services

The content for a National Report on the Quality of Laboratory Services could address several areas relevant to medical errors and patient safety in laboratory services as well as broader areas related to the quality of laboratory services. At the least it should contain demographic information about the US clinical and public health laboratories, the laboratory workforce, and the tests being offered. Depending on the intended audience the content could vary. Elements of the report might include: quality of test ordering; quality of analytic performance, clinical validity of certain tests; quality of reporting and test interpretation; patient safety; and workforce preparedness. The report could be developed in several ways. The National Report of the Quality of Laboratory Services could be a central mission of a newly established Quality Institute. Alternatively, it could be developed by the CDC's Division of Laboratory Services, an ad hoc group of laboratory medicine professionals and representatives of other stakeholders, or by one or more existing laboratory professional organizations. If a report is prepared, additional issues that must be addressed include authorship, whether separate versions should be prepared for different audiences, what method should be used for dissemination (print, electronic media, etc.), and whether the report should be periodically or continuously updated. One vision would be an ongoing, virtual report, with information being available from many sources through a single web-site that provides links to key data sources on other sites.

Indicators of Quality of Laboratory Services

Progress in achieving the goals of improving the quality of health care services, reducing medical errors and injuries, and assuring patient safety requires a set of definitions and standards for measurements or indicators of error and injuries, data sources, and procedures for data collection, analysis and dissemination. Again there are precedents for development of indicators.

The IOM report on *Access to Health Care in America* proposed indicators of access to health care such as "ambulatory care sensitive conditions." The IOM has also addressed issues in measuring the quality of care for patients with cancer. AHRQ has developed an instrument for consumer assessment of health plans (CAHPS) and a National CAHPS Benchmarking Database (NCDB). AHRQ has indicators of the quality of ambulatory care and indicators of the quality of hospital care and has recently developed indicators for patient safety for use in analysis of the Health Care Utilization (HCUP) data. Quality measures for long term care ("nursing homes") have been developed and are included in the minimum data set (MDS) and are accessible to consumers on the World Wide Web for direct comparison of long term care facilities (http://www.medicare.gov/NHCompare/home.asp). NCQA has developed the HEDIS indicators for assessing quality of care provided by managed care plans. CMS has developed indicators for specific conditions to assess the quality of care provided to Medicare beneficiaries.

Goal of Indicators

A key issue for laboratory medicine is the overall goals for developing indicators. The goal may be broadly defined as the role of laboratory services in the quality of health care, or may be directed at the quality of laboratory services, or may be more narrowly defined as laboratory tests as indicators of the quality of health care. The first formulation might encompass and emphasize necessary and appropriate use of laboratory services; the second formulation might emphasize the total testing process, and the third formulation might be restricted to specific conditions such as diabetes, cardiovascular disease, infectious diseases or cancer. A related issue is whether indicators should be developed for the quality of laboratory services, patient safety in laboratory services, or errors in laboratory services. While only a few indicators for the quality of health care services currently use laboratory data, the central role of laboratory results in medical-decision making suggest that indicators for the quality of laboratory services will be useful. For some conditions, such as hypercholesterolemia a laboratory test is already a criterion standard and for some infectious diseases the laboratory test results define the disease. In the future, genetic tests may become the basis for diagnosis for many conditions, and it is reasonable to expect a growing role for laboratory tests. Therefore, laboratory tests will increasingly be used as indicators of processes and outcomes of health care throughout the life cycle. However, the use of laboratory tests as indicators for the quality of health care services only partly addresses the need for indicators of the quality of laboratory services.

Need for Criteria, Definitions, and Standards in Establishing Indicators

It will be necessary to develop a set of definitions, standards and measures for indicators of the quality of laboratory services. These indicators may reflect the processes used in providing laboratory services, the accuracy of laboratory tests, and whether error has occurred in the Total Testing Process. Criteria for these indicators need to be developed, such as their importance in delivery of quality laboratory service, the scientific soundness of the measures, and the feasibility of the measures. The entire set of measures should be balanced, comprehensive, and robust. Indicators should permit an assessment of trends, of progress toward goals, and should achieve balance between process measures and outcomes. It will therefore be essential that these issues be addressed in a manner that is relevant to laboratory medicine and to unique aspects of laboratory services. Indicators may reflect overall processes of laboratory testing such as turn

around time (TAT), accuracy of laboratory tests, or more specific aspects of the parts of the Total Testing Process such as how often specimens are adequate, how often they are lost, how often critical test reports do not reach the care provider's attention, the frequency of revised test results, patient notification of test results, and receipt of appropriate follow-up care based on the laboratory test result.

Indicators: Format, Data Sources, Data Collection, Analysis and Access

Several related issues should be considered in developing indicators of the quality of laboratory services. Clearly others involved in the health care system will need to participate in the development of and application of these measures for the quality of laboratory services. It is important to have indicators that reflect quality, error reduction, and patient safety at a national and state level. Indicators could be developed for the steps in the Total Testing Process, or the phases of testing, by the type of test, CLIA complexity, geographic setting, or demographic characteristics of a population receiving services. Other issues are data sources, cost of data collection, access to data for analysis, methods of analysis, archiving and retrieval of data, and dissemination of data or indicators of quality of laboratory services. The relationship of data on quality of laboratory service to data on medical errors obtained from existing and proposed reporting systems for serious adverse events or other medical errors will need to be considered. Data collection will need to occur within the legal framework of malpractice, discovery of evidence, and protection of patient privacy and within the scope of quality processes designed to reduce medical errors and medical injury.

A Quality Institute for Laboratory Services

On the question of whether to form a Quality Institute the first issue is related to the need for an ongoing, sustained effort to reduce medical errors, improve patient safety and improve quality of care by improving laboratory services. It will be important to consider whether existing organizations are sufficient to address this issue or not. There are several arguments against establishing a new entity, a Quality Institute for laboratory medicine. Laboratory medicine already includes multiple methods to assure high quality laboratory services and routinely uses quality management tools and has quality assessment programs. The observation that errors in analytic phase of the total testing cycle are lower than other areas of testing suggests that collectively these programs have been effective in reducing medical error and improving patient safety.

However, there are several reasons to consider establishing an ongoing Quality Institute with the mission to reduce medical errors, assure patient safety, and increase the quality of laboratory services. First, there is substantial evidence of continued overuse and inappropriate use of laboratory tests and substantial residual error in the Total Testing Process. Second, while laboratory medicine professional organizations have led successful efforts to reduce error in the analytic phase of testing, errors in test ordering and test reporting and interpretation will require effective partnership with providers to improve test ordering and test interpretation. Third, recently recognized national priorities to reduce medical errors will require additional efforts directed at these problems. Fourth, laboratory medicine must effectively coordinate an approach to patient safety with the approach that will be developed by the Center for Patient Safety in the

AHRQ. Fifth, there is a need to develop a framework for patient safety that will be consistent with the framework in the National Report on the Quality of Healthcare. Finally, the ongoing missions of existing laboratory professional organizations may compete for personnel, funding, time, space, and other resources to establish their own patient safety missions; and patient safety organizations outside of laboratory medicine may not address the unique issues in laboratory medicine that have implications for patient safety. Error reduction and improving patient safety, two important issues in the quality of care, will require sustained effort by multiple stakeholders for success.

There are precedents for establishing independent organizations to address patient safety. There is the newly established Center for Patient Safety in AHRQ. While the mission of the Center for Patient Safety may meet some of the needs of laboratory medicine, its broader mission and limited resources may not permit it to focus on issues that reflect the priorities of laboratory medicine practice. For example, medication errors are common and are associated with substantial morbidity and cost. These errors may be viewed as more urgent or higher priority for the Center for Patient Safety than errors in laboratory medicine. Also a center in the federal government will be subject to federal government policies, budgeting, and administrative procedures that may limit its ability to reflect the interests of laboratory medicine or to move rapidly in initiating programs to reduce errors in laboratory practice or in use of laboratory services. NCQA with its accreditation programs for managed care organizations, HEDIS measures and national report can serve as a model for private sector organization with an ongoing mission to improve quality of managed care services. The Anesthesia Patient Safety Foundation (APSF) is perhaps the best model of a professional discipline establishing an organization devoted to error reduction and patient safety. Other organizations with a patient safety mission include the National Patient Safety Foundation (NPSF), and Institute for Safe Medical Practices (ISMP), among others. The Washington Clinical Laboratory Initiative is a collaboration of diverse stakeholders that identified common objectives, created an administrative infrastructure and established a set of programs and procedures to improve the quality of laboratory services.[33] The Washington Clinical Laboratory Initiative could serve as a model for patient safety activities for laboratory medicine.

Mission of a Quality Institute

The core mission of a Quality Institute would include research and education. The research mission of a Quality Institute could include developing a research agenda, identifying sources of research funding, providing research funding for investigators and other organizations, conducting research, administering research programs, evaluation of research proposals, and monitoring the conduct of patient safety research. The APSF has a research mission and has effectively leveraged limited funding to have a broad impact on patient safety in anesthesia practices. Laboratory medicine professionals and their representative organizations could help identify a research agenda for patient safety in laboratory medicine. Patient safety research could include research into potential advances in technologies that may reduce error, research concerning organizational structures that foster patient safety, and human factors research to identify methods to increase patient safety. The in vitro diagnostic medical device industry and market forces may provide adequate private sector funding for technologies to advance patient safety. However, private sector funding may not be sufficient to develop an adequate base of research on organizational and human factors for patient safety. Research in the private sector

and the experience and practices used in industry, may, however, be effectively adapted for use in laboratory medicine practice. Laboratory medicine professional organizations and the federal government have important roles in fostering research into organizational factors and human factors that may increase patient safety.

Education in patient safety should also be an initiative of the Quality Institute. Many laboratory professional organizations have educational programs and the Quality Institute need not duplicate these activities. The Quality Institute, however, could develop a database of effective practices that have been shown to reduce errors in the testing cycle and reduce injuries to patients from errors in use of laboratory services. The Quality Institute could serve as a clearinghouse for effective patient safety practices in laboratory medicine and the use of laboratory tests in patient care. In addition, the Quality Institute could have a more "active" education mission and assume a mission of dissemination of the best practices throughout laboratories in United States.

Quality Institute: Organization, Funding, Location, and Relation to Other Organizations

An independent, private sector, not-for-profit organization with broad representation on the Board of Directors from multiple stakeholders -- including government and laboratory medicine professionals, laboratory medicine professional organizations, industry, providers, payers, regulators, and other stakeholders -- should be considered for the Quality Institute. Such an organization could receive funds from a variety of sources, conduct research, education and other activities, and distribute resources to other organizations and programs as needed to effectively achieve its mission and goals. Startup funds for a Quality Institute might be obtained from a variety of sources including government grants, private foundations, industry, laboratory medicine professional organizations, and other sources. The geographic location of a Quality Institute need not be an important factor in assuring the success of a Quality Institute meeting its mission. Potential locations may include Washington, D.C. for its proximity to the federal government and other private policy organizations; Atlanta, GA for its proximity to the CDC's Division of Laboratory Systems; or other locations.

The Quality Institute will have to interact effectively with federal government agencies and programs concerned with laboratory medicine and patient safety including the Center for Patient Safety, the Division of Laboratory Systems in the Centers for Disease Control and Prevention, the Quality Inter Agency Coordinating Committee (QuIC) Task Force of the federal government, the Food and Drug Administration, and the Centers for Medicare and Medicaid Services (CMS) and the Department of Health and Human Services and the VA and other state government agencies. The Quality Institute will have to have effective interaction with laboratory medicine professional organizations, with others patient safety organizations involved in the health care system, and with patients and their advocacy groups to be successful.

5 Summary and Recommendations

Laboratory medicine plays an important role in the delivery of health care services. Therefore, any effort to enhance patient safety and improve health care outcomes must include the providers of laboratory services. The formation of a Quality Institute for Laboratory Medicine has the opportunity to improve the coordination and collaboration between all participants in the health

care system by providing a focal point for the improvement of the delivery of laboratory services. The Quality Institute, by focusing on the development of better ways to measure the effectiveness of laboratory service (quality indicators) and by holding the laboratory service industry publicly accountable (national report) for achieving these goals could lead to substantial improvements in patient safety and in the quality of laboratory services. It would keep laboratory medicine at the forefront in ensuring quality in the health care industry. The benefits of having a coalition that addresses major policy questions and offers solutions to issues before legal or regulatory action is required, and which acts as a clearinghouse for information could protect patient safety while dealing effectively with the important issue of access, cost, and quality of laboratory services.

Table 1. *To Err is Human:* Recommendations
Congress should create a Center for Patient Safety within the Agency for Healthcare Research and Quality. 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; and 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 of activities to improve patient safety.
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.
The development of voluntary reporting efforts should be encouraged. Specific recommendations for the Center for Patient Safety were made to encourage voluntary reporting systems.
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.
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.
Performance standards and expectations for health professionals should focus greater attention on patient safety. Health professional licensing bodies should implement periodic re-examinations and re-licensing 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 a visible commitment to patient safety by establishing a permanent committee dedicated to safety improvement. Specific recommendations were made of patient safety committee responsibilities.
The Food and Drug Administration (FDA) should increase attention to the safe use of drugs in both pre-and post-marketing processes
Health care organizations and the professionals affiliated with them should make continually improved patient safety a declared and serious aim by establishing patient safety programs.
Health care organizations should implement proven medication safety practices.

Table 2. *Crossing the Quality Chasm*: Recommendations
All health care organizations, professional groups, and private and public purchasers should adopt as their explicit purpose to continually reduce the burden of illness, injury, and disability, and to improve the health and functioning of the people of the United States.
All health care organizations, professional groups, and private and public purchasers should pursue six major aims; specifically, health care should be safe, effective, patient-centered, timely, efficient, and equitable.
Congress should continue to authorize and appropriate funds for, and the Department of Health and Human Services should move forward expeditiously with the establishment of, monitoring and tracking processes for use in evaluating the progress of the health system in pursuit of the above-cited aims of safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. The Secretary of the Department of Health and Human Services should report annually to Congress and the President on the quality of care provided to the American people.
Recommendation 4: Private and public purchasers, health care organizations, clinicians, and patients should work together to redesign health care processes in. accordance with ten rules to enhance the effectiveness of microsystems.
The AHRQ should identify at least 15 priority conditions, convene stakeholders, and develop strategies, goals, and action plans for achieving substantial improvements in quality in the next 5 years for each of the priority conditions.
Congress should establish a Health Care Quality Innovation Fund to support projects targeted at (1) achieving the six aims of safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity; and/or (2) producing substantial improvements in quality for the priority conditions..
AHRQ and private foundations should convene a series of workshops to identify, adapt, and implement state-of-the-art approaches to: redesign of care processes based on best practices; use of information technologies to improve access to clinical information and support clinical decision making, knowledge and skills management; development of effective teams; coordination of care across patient conditions, services, and settings over time, incorporation of performance and outcome measurements for improvement and accountability
The Secretary of the Department of Health and Human Services should be given the responsibility and necessary resources to establish and maintain a comprehensive program aimed at making scientific evidence more useful and accessible to clinicians and patients.
Congress, the executive branch, leaders of health care organizations, public and private purchasers, and health informatics associations and vendors should make a renewed national commitment to building an information infrastructure to support health care delivery, consumer health, quality measurement and improvement, public accountability, clinical and health services research, and clinical education.
Private and public purchasers should examine their current payment methods to remove barriers that currently impede quality improvement, and to build in stronger incentives for quality enhancement.

The Health Care Financing Administration and the Agency for Healthcare Research and Quality, with input from private payers, health care organizations, and clinicians, should develop a research agenda to identify, pilot test, and evaluate various options for better aligning current payment methods with quality improvement goals.
A multidisciplinary summit of leaders within the health professions should be held to discuss and develop strategies for (1) restructuring clinical education (2) assessing the implications provider credentialing programs, funding, and sponsorship of education programs for health professionals.
The AHRQ should fund research to evaluate how the current regulatory and legal systems (1) facilitate or inhibit the changes needed for the 21st-century health care delivery system, and (2) can be modified to support health care professionals and organizations

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