

Institute of Medicine's Quality Chasm series

**To Err Is Human: Building a Safer Health System 287 pages (2000)
9 Recommendations.**

**Crossing the Quality Chasm: A New Health System for the 21st Century
364 pages (2001) 13 Recommendations.**

**Leadership by Example: Coordinating Government Roles in Improving
Health Care Quality 206 pages (2002) 8 Recommendations.**

**Health Professions Education: A Bridge to Quality 192 pages (2003)
10 Recommendations.**

**Priority Areas for National Action: Transforming Health Care Quality
160 pages (2003) 6 Recommendations.**

**Patient Safety: Achieving a New Standard for Care 528 pages (2004)
7 Recommendations.**

53 Total Recommendations

To Err Is Human
Building a Safer Health System
9 Recommendations

RECOMMENDATION 4.1 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 activities to improve patient safety.

RECOMMENDATION 5.1 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 National 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, including a nomenclature and taxonomy for reporting;
- 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 follow-up 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 be designated as the responsible entity; and
- Designate the Center for Patient Safety to:
 - 1) Convene states to share information and expertise, and to 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).

RECOMMENDATION 5.2 The development of voluntary reporting efforts should be encouraged. The Center for Patient Safety should

- Describe and disseminate information on existing 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 well 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 collaborative efforts among health care organizations.

RECOMMENDATION 6.1 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.

RECOMMENDATION 7.1 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.

RECOMMENDATION 7.2 Performance standards and expectations for health professionals should focus greater attention on patient safety.

- Health professional licensing bodies should
 - 1) Implement periodic reexaminations and relicensing of doctors, nurses, and other key providers, based on both competence and knowledge of safety practices; and
 - 2) 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. This committee should
 - 1) Develop a curriculum on patient safety and encourage its adoption into training and certification requirements;
 - 2) Disseminate information on patient safety to members at special sessions at annual conferences, journal articles and editorials, newsletters, publications and websites on a regular basis;
 - 3) Recognize patient safety considerations in practice guidelines and in standards related to the introduction and diffusion of new technologies, therapies, and drugs;
 - 4) Work with the Center for Patient Safety to develop community-based, collaborative initiatives for error reporting and analysis and implementation of patient safety improvements; and
 - 5) Collaborate with other professional societies and disciplines in a national summit on the professional's role in patient safety.

RECOMMENDATION 7.3 The Food and Drug Administration (FDA) should increase attention to the safe use of drugs in both pre and post-marketing processes through the following actions.

- Develop and enforce standards for the design of drug packaging and labeling that will maximize safety in 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; and
- Work with physicians, pharmacists, consumers and others to establish appropriate responses to problems identified through post-marketing surveillance, especially for concerns that are perceived to require immediate response to protect the safety of patients.

RECOMMENDATION 8.1 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 with a defined executive responsibility. Patient safety programs should: (1) provide strong, clear, and visible attention to safety; implement non-punitive systems for reporting and analyzing errors within their organizations; (2) incorporate well-understood safety principles, such as, standardizing and simplifying equipment, supplies, and processes; and (3) establish interdisciplinary team training programs, such as simulation, that incorporate proven methods of team management.

RECOMMENDATION 8.2 Health care organizations should implement proven medication safety practices.

Crossing The Quality Chasm

A New Health System for the 21st Century

13 Recommendations

Recommendation 1: 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.

Recommendation 2: 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.

Recommendation 3: 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 the following rules:

1. Care based on continuous healing relationships. Patients should receive care whenever they need it and in many forms, not just face-to-face visits. This rule implies that the health care system should be responsive at all times (24 hours a day, every day) and that access to care should be provided over the Internet, by telephone, and by other means in addition to face-to-face visits.
2. Customization based on patient needs and values. The system of care should be designed to meet the most common types of needs, but have the capability to respond to individual patient choices and preferences.
3. The patient as the source of control. Patients should be given the necessary information and the opportunity to exercise the degree of control they choose over health care decisions that affect them. The health system should be able to accommodate differences in patient preferences and encourage shared decision making.
4. Shared knowledge and the free flow of information. Patients should have unfettered access to their own medical information and to clinical knowledge. Clinicians and patients should communicate effectively and share information.
5. Evidence-based decision making. Patients should receive care based on the best available scientific knowledge. Care should not vary illogically from clinician to clinician or from place to place.
6. Safety as a system property. Patients should be safe from injury caused by the care system. Reducing risk and ensuring safety require greater attention to systems that help prevent and mitigate errors.

7. The need for transparency. The health care system should make information available to patients and their families that allows them to make informed decisions when selecting a health plan, hospital, or clinical practice, or choosing among alternative treatments. This should include information describing the system's performance on safety, evidence-based practice, and patient safety satisfaction.
8. Anticipation of needs. The health system should anticipate patient needs, rather than simply reacting to events.
9. Continuous decrease in waste. The health system should not waste resources or patient time.
10. Cooperation among clinicians. Clinicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care.

Recommendation 5: The Agency for Healthcare Research and Quality should identify not fewer than 15 priority conditions, taking into account frequency of occurrence, health burdens, and resource use. In collaboration with the National Quality Forum, the agency should convene stakeholders, including purchasers, consumers, health care organizations, professional groups, and others, to develop strategies, goals, and action plans for achieving substantial improvements in quality in the next 5 years for each of the priority conditions.

Recommendation 6: 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. The fund's resources should be invested in projects that will produce a public-domain portfolio of programs, tools, and technologies of widespread applicability.

Recommendation 7: The Agency for Healthcare Research and Quality and private foundations should convene a series of workshops involving representatives from health care and other industries and the research community to identify, adapt, and implement state-of-the-art approaches to addressing the following challenges:

- 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

Recommendation 8: 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. In developing this program, the Secretary should work with

federal agencies and in collaboration with professional and health care associations, the academic and research communities, and the National Quality Forum and other organizations involved in quality measurement and accountability.

Recommendation 9: 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. This commitment should lead to the elimination of most handwritten clinical data by the end of the decade.

Recommendation 10: 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.

Recommendation 11: 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.

Recommendation 12: A multidisciplinary summit of leaders within the health professions should be held to discuss and develop strategies for (1) restructuring clinical education to be consistent with the principles of the 21st-century health system throughout the continuum of undergraduate, graduate, and continuing education for medical, nursing, and other professional training programs; and (2) assessing the implications of these changes for provider credentialing programs, funding, and sponsorship of education programs for health professionals.

Recommendation 13: The Agency for Healthcare Research and Quality 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 that seek to accomplish the six aims set forth in Chapter 2.

Leadership by Example

Coordinating Government Roles in Improving Health Care Quality

8 Recommendations

Recommendation 1: The federal government should assume a strong leadership position in driving the health care sector to improve the safety and quality of health care services provided to the approximately 100 million beneficiaries of the six major government health care programs. Given the leverage of the federal government, this leadership will result in improvements in the safety and quality of health care provided to all Americans.

Recommendation 2: The federal government should take maximal advantage of its unique position as regulator, health care purchaser, health care provider, and sponsor of applied health services research to set quality standards for the health care sector.

Specifically:

- a. Regulatory processes should be used to establish clinical data reporting requirements applicable to all six major government health care programs.
- b. All six major government health care programs should vigorously pursue purchasing strategies that encourage the adoption of best practices through the release of public domain comparative quality data and the provision of financial and other rewards to providers that achieve high levels of quality.
- c. Not only should health care delivery systems operated by the public programs continue to serve as laboratories for the development of innovative 21st-century care delivery models, but much greater emphasis should be placed on the dissemination of findings and, in the case of information technology, the creation of public-domain products.
- d. Applied health services research should be expanded and should emphasize the development of knowledge, tools, and strategies that can support quality enhancement in a wide variety of settings.

Recommendation 3: Congress should direct the Secretaries of the Department of Health and Human Services (DHHS), Department of Defense (DOD), and Department of Veterans Affairs (VA) to work together to establish standardized performance measures across the government programs, as well as public reporting requirements for clinicians, institutional providers, and health plans in each program. These requirements should be implemented for all six major government health care programs and should be applied fairly and equitably across various financing and delivery options within those programs. The standardized measurement and reporting activities should replace the many performance measurement activities currently under way in the various government programs.

Recommendation 4: The Quality Interagency Coordination (QIAC) Task Force should promulgate standardized sets of performance measures for 5 common health conditions in fiscal year (FY) 2003 and another 10 sets in FY 2004.

- a. Each government health care program should pilot test the first 5 sets of measures between FY 2003 and FY 2005 in a limited number of sites. These pilot tests

- should include the collection of patient-level data and the public release of comparative performance reports.
- b. All six government programs should prepare for full implementation of the 15-set performance measurement and reporting system by FY 2008. The government health care programs that provide services through the private sector (i.e., Medicare, Medicaid, the State Children's Health Insurance Program (SCHIP), and portions of DOD (TRICARE) should inform participating providers that submission of the audited patient-level data necessary for performance measurement will be required for continued participation in FY 2007. The government health care programs that provide services directly (i.e., the Veterans Health Administration (VHA), the remainder of DOD TRICARE, and the Indian Health Services (IHS) should begin work immediately to ensure that they have the information technology capabilities to produce the necessary data.

Recommendation 5: The federal government should take steps immediately to encourage and facilitate the development of the information technology infrastructure that is critical to health care quality and safety enhancement, as well as to many of the nation's other priorities, such as bioterrorism surveillance, public health, and research.

Specifically:

- a. Congress should consider potential options to facilitate rapid development of a national health information infrastructure, including tax credits, subsidized loans, and grants.
- b. Government health care programs that deliver services through the private sector—Medicare, Medicaid, the State Children's Health Insurance Program (SCHIP), and a portion of Department of Defense (DOD) TRICARE—should adopt both market-based and regulatory options to encourage investment in information technology. Such options might include enhanced or more rapid payments to providers capable of submitting computerized clinical data, a requirement for certain information technology capabilities as a condition of participation and direct grants.
- c. The Veterans Health Administration (VHA), DOD TRICARE, and the Indian Health Service (IHS) should continue implementing clinical and administrative information systems that enable the retrieval of clinical information across their programs and can communicate directly with each other. Whenever possible, the software and intellectual property developed by these three government programs should rely on Web-based language and architecture and be made available in the public domain.

Recommendation 6: Starting in FY 2008, each government health care program should make comparative quality reports and data available in the public domain. The program should provide for access to these reports and data in ways that meet the needs of various users, provided that patient privacy is protected.

Recommendation 7: The government health care programs, working with the Agency for Healthcare Research and Quality (AHRQ), should establish a mechanism for pooling performance measurement data across programs in a data repository. Contributions of

data from private-sector insurance programs should be encouraged provided such data meet certain standards for validity and reliability. Consumers, health care professionals, planners, purchasers, regulators, public health officials, researchers, and others should be afforded access to the repository, provided that patient privacy is protected.

Recommendation 8: The government health care programs should work together to develop a comprehensive health services research agenda that will support the quality enhancement processes of all programs. The Quality Interagency Coordination (QulC) Task Force (or some similar interdepartmental structure with representation from each of the government health care programs and the Agency for Healthcare Research and Quality (AHRQ) should be provided the authority and resources needed to carry out this responsibility. This agenda for fiscal years (FY) 2003-2005 should support the following:

- a. Establishment of core sets of standardized performance measures
- b. Ongoing evaluation of the impact of the use of standardized performance measurement and reporting by the six major government health care programs
- c. Development and evaluation of specific strategies that can be used to improve the federal government's capability to leverage its purchaser, regulator, and provider roles to enhance quality.
- d. Monitoring of national progress in meeting the six national quality aims (safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity)

Health Professions Education

A Bridge to Quality

10 Recommendations

Recommendation 1: DHHS and leading foundations should support an interdisciplinary effort focused on developing a common language with the ultimate aim of achieving consensus across the health professions on a core set of competencies that includes patient-centered care, interdisciplinary teams, evidence-based practice, quality improvement and information.

Recommendation 2: DHHS should provide a forum and support for a series of meetings involving the spectrum of oversight organizations across and within the disciplines. Participants in these meetings would be charged with developing strategies for incorporating a core set of competencies into oversight activities, based on definitions shared across the professions. These meetings would actively solicit the input of health professions associations and the education community.

Recommendation 3: Building upon previous efforts, accreditation bodies should move forward expeditiously to revise their standards so that programs are required to demonstrate – through process and outcome measures – that they educate students in both academic and continuing education programs in how to deliver patient care using a core set of competencies. In so doing, these bodies should coordinate their efforts.

Recommendation 4: All health professions boards should move toward requiring licensed health professionals to demonstrate periodically their ability to deliver patient care – as defined by the five competencies identified by the committee – through direct measures of technical competence, patient assessment, evaluation of patient outcomes, and other evidence-based assessment methods. These boards should simultaneously evaluate the different assessment methods.

Recommendation 5: Certification bodies should require their certificate holders to maintain their competence throughout the course of their careers by periodically demonstrating their ability to deliver patient care that reflects the five competencies, among other requirements.

Recommendation 6: Foundations, with support from education and practice organizations, should take the lead in developing and funding regional demonstration learning centers, representing partnerships between practice and education. These centers should leverage existing innovative organizations and be state-of-the-art training settings focused on teaching and assessing the five core competencies.

Recommendation 7: Through Medicare demonstration projects, the Center for Medicare and Medicaid Services (CMS) should take the lead in funding experiments that will enable and create incentives for health professionals to integrate interdisciplinary approaches into educational or practice settings with the goal of providing a training ground for students and clinicians that incorporates the five core competencies.

Recommendation 8: The Agency for Healthcare Research and Quality (AHRQ) and private foundations should support ongoing research projects addressing the five core competencies and their association with individual and population health, as well as research related to the link between the competencies and evidence-based education. Such projects should involve researchers across two or more disciplines.

Recommendation 9: AHRQ should work with a representative group of health care leaders to develop measures reflecting the core set of competencies, set national goals for improvement, and issue a report to the public evaluating progress toward these goals. AHRQ should issue the first report, focused on clinical educational institutions, in 2005 and produce annual reports thereafter.

Recommendation 10: Beginning in 2004, a biennial interdisciplinary summit should be held involving health care leaders in education, oversight processes, practice, and other areas. This summit should focus on both reviewing progress against explicit targets and setting goals for the next phase with regard to the five competencies and other areas necessary to prepare professionals for the 21st century health system.

Priority Areas for National Action Transforming Health Care Quality 6 Recommendations

Recommendation 1: The committee recommends that the priority areas collectively:

- Represent the U.S. population's health care needs across the lifespan, in multiple health care settings involving many types of health care professionals.
- Extend across the full spectrum of health care, from keeping people well and maximizing overall health; to providing treatment to cure people of disease and health problems as often as possible; to assisting people who become chronically ill to live longer, more productive and comfortable lives; to providing dignified care at the end of life that is respectful of the values and preferences of individuals and their families.

Recommendation 2: The committee recommends use of the following criteria for identifying priority areas:

- Impact – the extent of the burden – disability, mortality, and economic costs – imposed by a condition, including effects on patients, families, communities, and societies.
- Improvability- the extent of the gap between current practice and evidence-based best practice and the likelihood that the gap can be closed and conditions improved through change in an area; and the opportunity to achieve dramatic improvements in the six national quality aims identified in the Quality Chasm report (safety, effectiveness, patient-centeredness, timeliness, efficiency and equity).
- Inclusiveness – the relevance of an area to a broad range of individuals with regard to age, gender, socioeconomic status, and ethnicity/race (equity); the generalizability of associated quality improvement strategies to many types of conditions and illnesses across the spectrum of health care (representativeness); and the breadth of change effected through such strategies across a range of health care settings and providers (reach).

Recommendation 3: The committee recommends that DHHS, along with other public and private entities, focus on the following priority areas for transforming health care:

- Care coordination (cross-cutting)
- Self-management/health literacy (cross-cutting)
- Asthma – appropriate treatment for persons with mild/moderate persistent asthma
- Cancer screening that is evidence-based – focus on colorectal and cervical cancer
- Children with special health care needs
- Diabetes – focus on appropriate management of early disease
- End of life with advanced organ system failure – focus on congestive heart failure and chronic obstructive pulmonary disease
- Frailty associated with old age – preventing falls and pressure ulcers, maximizing function, and developing advanced care plans
- Hypertension – focus on appropriate management of early disease
- Immunization – children and adults

- Ischemic heart disease – prevention, reduction of recurring events, and optimization of functional capacity
- Major depression – screening and treatment
- Medication management – preventing medication errors and overuse of antibiotics
- Nosocomial infections – prevention and surveillance
- Pain control in advanced cancer
- Pregnancy and childbirth – appropriate prenatal and intrapartum care
- Severe and persistent mental illness – focus on treatment in the public sector
- Stroke – early intervention and rehabilitation
- Tobacco dependence treatment in adults
- Obesity (emerging area)

Recommendation 4: The committee recommends that the Agency for Healthcare Research and Quality (AHRQ), in collaboration with other private and public organizations, be responsible for continuous assessment of progress and updating of the list of priority areas. These responsibilities should include:

- Developing and improving data collection and measurement systems for assessing the effectiveness of quality improvement efforts.
- Supporting the development and dissemination of valid, accurate, and reliable standardized measures of quality.
- Measuring key attributes and outcomes and making this information available to the public.
- Revising the selection criteria and the list of priority areas.
- Reviewing the evidence base and results, and deciding on updated priorities every 3 to 5 years.
- Assessing changes in the attributes of society that affect health and health care and could alter the priority of various areas.
- Disseminating the results of strategies for quality improvement in the priority areas.

Recommendation 5: The committee recommends that data collection in the priority areas:

- Go beyond the usual reliance on disease – and procedure-based information to include data on the health and functioning of the U.S. population.
- Cover relevant demographic and regional groups, as well as the population as a whole, with particular emphasis on identifying disparities in care.
- Be consistent within and across categories to ensure accurate assessment and comparison of quality enhancement efforts.

Recommendation 6: The committee recommends that the Congress and the Administration provide the necessary support for the ongoing process of monitoring progress in the priority areas and updating the list of areas. This support should encompass:

- The administration costs borne by AHRQ.
- The costs of developing and implementing data collection mechanisms and improving the capacity to measure results.

- The costs of investing strategically in research aimed at developing new scientific evidence on interventions that improve the quality of care and at creating additional accurate, valid, and reliable standardized measures of quality.

Patient Safety

Achieving a New Standard for Care

7 Recommendations

Recommendation 1. Americans expect and deserve safe care. Improved information and data systems are needed to support efforts to make patient safety a standard of care in hospitals, in doctors' offices, in nursing homes, and in every other health care setting.

All health care organizations should establish comprehensive patient safety systems that:

- Provide immediate access to complete patient information and decision support tools (e.g., alerts, reminders) for clinicians and their patients.
- Capture information on patient safety – including both adverse events and near misses – as a by-product of care and use this information to design even safer care delivery systems.

Recommendation 2. A national health information infrastructure – a foundation of systems, technology, applications, standards, and policies – is required to make patient safety a standard of care.

- The federal government should facilitate deployment of the national health information infrastructure through the provision of targeted financial support and the ongoing promulgation and maintenance of standards for data that support patient safety.
- Health care providers should invest in electronic health record systems that possess the key capabilities necessary to provide safe and effective care and to enable the continuous redesign of care processes to improve patient safety.
- Clinical terminologies. The federal government should move expeditiously to identify a core set of well-integrated, non-redundant clinical terminologies for clinical care, quality improvement, and patient safety reporting. Revisions, extensions, and additions to the codes should be compatible with, yet go beyond, the federal government's initiative to integrate all federal reporting systems.
 - AHRQ should undertake a study of the core terminologies, supplemental terminologies, and standards mandated by the Health Insurance Portability and Accountability Act to identify areas of overlap and gaps in the terminologies to address patient safety data requirements. The study should begin by convening domain experts to develop a process for ensuring comprehensive coverage of the terminologies for the 20 IOM priority areas.
 - The National Library of Medicine should provide support for the accelerated completion of RxNORM2 for clinical drugs. The National Library of Medicine also should develop high-quality mappings among

the core terminologies and supplemental terminologies identified by the CHI and NCVHS.

- Knowledge representation. The federal government should provide support for the accelerated development of knowledge representation standards to facilitate effective use of decision support in clinical information systems.
 - The National Library of Medicine should provide support for the development of standards for evidence-based knowledge representation.
 - AHRQ, in collaboration with the National Institutes of Health, the Food and Drug Administration, and other agencies, should provide support for the development of a generic guideline representation model for use in representing clinical guidelines in a computer-executable format that can be employed in decision support tools.

Recommendation 3. Congress should provide clear direction, enabling authority, and financial support for the establishment of national standards for data that support patient safety. Various government agencies will need to assume major new responsibilities and additional support will be required. Specifically:

- The Department of Health and Human Services (DHHS) should be given the lead role in establishing and maintaining a public-private partnership for the promulgation of standards for data that support patient safety.
- The Consolidated Health Informatics (CHI) initiative, in collaboration with the National Committee on Vital and Health Statistics (NCVHS), should identify data standards appropriate for national adoption and gaps in existing standards that need to be addressed. The membership of NCVHS should continue to be broad and diverse, with adequate representation of all stakeholders, including consumers, state governments, professional groups, and standard-setting bodies.
- The Agency for Healthcare Research and Quality (AHRQ), in collaboration with the National Library of Medicine and others, should (1) provide administrative and technical support for the CHI and NCVHS efforts; (2) ensure the development of implementation guides, certification procedures, and conformance testing for all data standards; (3) provide financial support and oversight for development activities to fill gaps in data standards; and (4) coordinate activities and maintain a clearinghouse of information in support of national data standards and their implementation to improve patient safety.
- The National Library of Medicine should be designated as the responsible entity for distributing all national clinical terminologies that relate to patient safety and for ensuring the quality of terminology mappings.

Recommendation 4. The lack of comprehensive standards for data to support patient safety impedes private-sector investment in information technology and other efforts to improve patient safety. The federal government should accelerate the adoption of standards for such data by pursuing the following efforts:

- Clinical data interchange standards. The federal government should set an aggressive agenda for the establishment of standards for the interchange of clinical data to support patient safety. Federal financial support should be provided to accomplish this agenda.

- After ample time for provider compliance, government health care programs should incorporate into their contractual and regulatory requirements standards already approved by the secretaries of DHHS, the Veterans Administration, and the Department of Defense (i.e., the HL7 version 2.x series for clinical data messaging, DICOM for medical imaging, IEEE 1073 for medical devices, LOINC for laboratory test results, and NCPCP Script for prescription data).
- AHRQ should provide support for (1) accelerated completion (within 2 years) of HL7 version 3.0; (2) specifications for the H7 Clinical Document Architecture and implementation guides; and (3) analysis of alternative methods for addressing the need to support patient safety by instituting a unique health identifier for individuals, such as implementation of a voluntary unique health identifier program.

Recommendation 5. All health care settings should establish comprehensive patient safety programs operated by trained personnel within a culture of safety. These programs should encompass (1) case finding – identifying system failures, (2) analysis – understanding the factors that contribute to system failures, and (3) system redesign – making improvements in care processes to prevent errors in the future. Patient safety programs should invite the participation of patients and their families and be responsive to their inquiries.

Recommendation 6. The federal government should pursue a robust applied research agenda on patient safety, focused on enhancing knowledge, developing tools, and disseminating results to maximize the impact of patient safety systems. AHRQ should play a lead role in coordinating this research agenda among federal agencies (e.g., the National Library of Medicine) and the private sector. The research agenda should include the following:

- Knowledge generation
 - High-risk patients – Identify patients at risk for medication errors, nosocomial infections, falls, and other high-risk events.
 - Near-miss incidents – Test the causal continuum assumption (that near misses and adverse events are causally related), develop and test a recovery taxonomy, and extend the current individual human error/recovery models to team-based errors and recoveries.
 - Hazard analysis – Assess the validity and efficiency of integrating retrospective techniques (e.g., incident analysis) with prospective techniques.
 - High-yield activities – Study the cost/benefit of various approaches to patient safety, including analysis of reporting systems for near misses and adverse events.
 - Patient roles – Study the role of patients in the prevention, early detection, and mitigation of harm due to errors.
- Tool development
 - Early detection capabilities – Develop and evaluate various methods for employing data-driven triggers to detect adverse drug errors, nosocomial

- infections, and other high-risk events (e.g., patient falls, decubitus ulcers, complications of blood product transfusions).
- Prevention capabilities – Develop and evaluate point-of-care decision support to prevent errors of omission or commission.
 - Data mining techniques – Identify and develop data mining techniques to enhance learning from regional and national patient safety databases. Apply natural language processing techniques to facilitate the extraction of patient safety-related concepts from text documents and incident reports.
 - Dissemination – Deploy knowledge and tools to clinicians and patients.

Recommendation 7. AHRQ should develop an event taxonomy and common report format for submission of data to the national patient safety database. Specifically:

- The event taxonomy should address near misses and adverse events, cover errors of both omission and commission, allow for the designation of primary and secondary event types for cases in which more than one factor precipitated the adverse event, and be incorporated into SNOMED CT.
- The standardized report format should include the following:
 - A standardized minimum set of data elements.
 - Data necessary to calculate a risk assessment index for determining prospectively the probability of an event and its severity.
 - A free-text narrative of the event.
 - Data necessary to support use of the Eindhoven Classification Model – Medical Version for classifying root causes, including expansions for (1) recovery factors associated with near-miss events, (2) corrective actions taken to recover from adverse events, and (3) patient outcome/functional status as a result of those corrective actions.
 - A free-text section for lessons learned as a result of the event.
 - Clinical documentation of the patient context.
- The taxonomy and report format should be used by the federal reporting system integration project in the areas for basic domain, event type, risk assessment, and causal analysis but should provide for more extensive support for patient safety research and analysis (Department of Health and Human Services, 2002).