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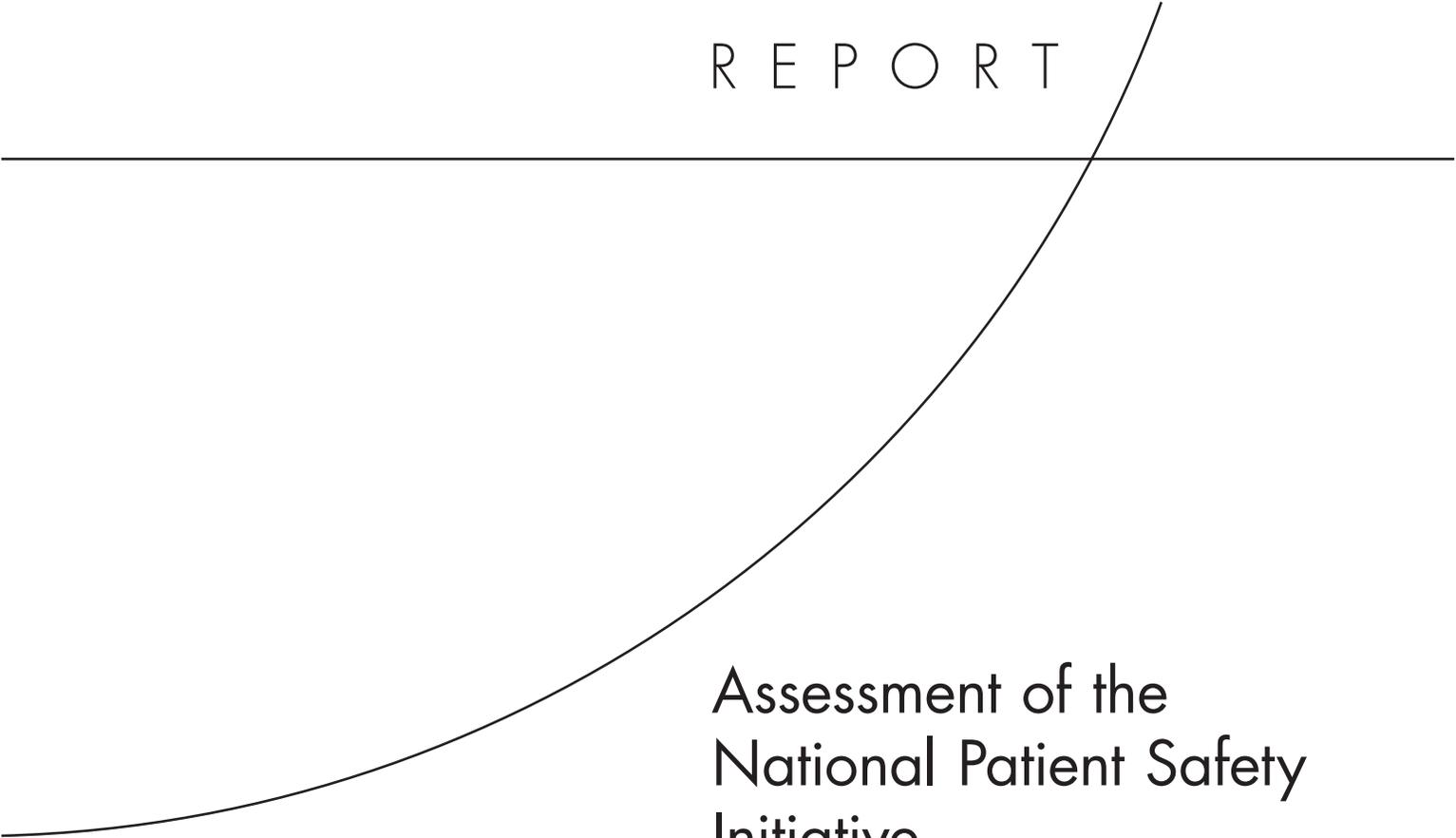
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R E P O R T

Assessment of the National Patient Safety Initiative

Context and Baseline Evaluation Report I

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PREFACE

The Agency for Healthcare Research and Quality (AHRQ), an agency within the Department of Health and Human Services (DHHS), is fulfilling its congressional mandate to establish a patient safety research and development initiative to help health care providers reduce medical errors and improve patient safety. In September 2002, AHRQ entered into a four-year contract with the RAND Corporation to serve as the evaluation center for its national patient safety initiative. The evaluation center is responsible for performing a longitudinal evaluation of the full scope of AHRQ's patient safety activities and for providing regular feedback to support the continuing improvement of this initiative over the four-year project period.

This report is the first of what will be four annual reports that RAND will prepare during the course of the formative evaluation for submittal to AHRQ in September of each year. It assesses the context and goals that were the foundation for the AHRQ patient safety initiative and documents the baseline status of the activities being undertaken in the initiative. Implications of these early findings for future policy, programming, and research are discussed, and suggestions for subsequent AHRQ activities are presented. This report will be of interest to national and state policy makers, health care organizations and clinical practitioners, patient advocacy organizations, health researchers, and others with responsibilities for ensuring that patients are not harmed by the health care they receive.

The contents and format of the report are designed to provide a stable conceptual framework for the longitudinal evaluation, within which results of each year's assessment will be reported to develop a cumulative record of program evolution. The second and third reports will focus on findings from the process evaluation regarding activities and progress in implementing the patient safety initiative, and the final report will focus on findings regarding effects of the initiative on patient safety improvements as well as on the various stakeholders involved in these activities.

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EXECUTIVE SUMMARY

Congress has placed a high priority on making a safer U.S. health care system. It has given a mandate to the Agency for Healthcare Research and Quality (AHRQ), an agency within the Department of Health and Human Services (DHHS), to establish a patient safety research and development initiative. This mandate holds AHRQ accountable for helping health care providers reduce medical errors and improve patient safety. AHRQ, in turn, is committed to improving patient safety in the U.S. health care system by ensuring that the extensive work supported by AHRQ and other organizations (1) addresses the many aspects of achieving safe health care practices; (2) identifies and fills gaps in knowledge on patient safety epidemiology and practices, and (3) is focused on effective identification and dissemination of successful patient safety practices.

AHRQ contracted with RAND in September 2002 to serve as the evaluation center for the patient safety initiative. The evaluation center is responsible for performing a longitudinal evaluation of the full scope of AHRQ's patient safety activities and providing regular feedback to support the continuing improvement of this initiative. The evaluation also is to assess overall initiative impacts, outcomes, and adoption diffusion using both qualitative and quantitative assessment approaches.

This report is the first of what will be four annual reports prepared during the course of the longitudinal, formative evaluation, which are scheduled to be submitted to AHRQ in September of each year. This report presents findings on the history leading to the AHRQ patient safety initiative, the start-up of the initiative, and early activities through September 2003. By design, the initial evaluation focuses on assessing the context and goals that were the foundation for the patient safety initiative and developing baseline information for the process evaluation. The contents and format are designed to provide a stable conceptual framework for the longitudinal evaluation, within which results of each year's assessment will be reported to develop a cumulative record of program evolution. In concurrent work, the evaluation continues to gather and assess information on the activities and evolution of the initiative, the results of which will be presented in subsequent annual reports.

EVALUATION FRAMEWORK

The Policy Context

In early 2000, the Institute of Medicine (IOM) published the report entitled *To Err is Human: Building a Safer Health System*, which mobilized national efforts to improve the safety of the U.S. health care system (IOM, 2000). The IOM called for leadership from the DHHS in reducing medical errors, identifying AHRQ as the focal point for patient safety research and practice improvements. In response to the IOM report, the Quality Interagency Coordination Task Force (QuIC), a collaborative effort among federal agencies,[1] issued a report in February 2000 – *Doing What Counts for Patient Safety, Federal Action to Reduce Medical Errors and Their Impact*. This report laid out a strategy of more than 100 actions designed to create a

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national focus on reducing errors, strengthen the patient safety knowledge base, ensure accountability for safe health care delivery, and implement patient safety practices.

When the U.S. Congress established patient safety as a national priority and gave AHRQ the mandate to lead federal patient safety improvement activities, it provided AHRQ with funding to support related research and implementation activities. The AHRQ patient safety work is one of numerous and important patient safety initiatives being undertaken by a variety of organizations across the country. AHRQ's leadership can provide motivation and guidance for the activities of others, and by integrating its work with that of other organizations in both public and private sectors, the agency can leverage finite resources and achieve synergy through collaboration.

The CIPP Evaluation Model

Through this longitudinal evaluation, which includes an annual reporting cycle, lessons from the current experiences of AHRQ and its funded projects can be used to strengthen subsequent program activities. As specified by AHRQ in the evaluation contract, the overall evaluation design is based on the CIPP evaluation model, which is a well-accepted strategy for improving systems that encompasses the full spectrum of factors involved in the operation of a program (Stufflebeam, et al., 1971; Stufflebeam, et al., 2000). The core model components are represented in the CIPP acronym:

- *__Context evaluation__* assesses the circumstances stimulating the creation or operation of a program as a basis for defining goals and priorities and for judging the significance of outcomes.

- *__Input evaluation__* examines alternatives for goals and approaches for either guiding choice of a strategy or assessing an existing strategy against the alternatives, including congressional priorities and mandates as well as agency goals and strategies. Stakeholders also are identified and their perspectives on the patient safety initiative are assessed.

- *__Process evaluation__* assesses progress in implementation of plans relative to the stated goals for future activities and outcomes. Activities undertaken to implement the patient safety initiative are documented, including any changes made that might alter its effects, positively or negatively. Three questions are addressed in this evaluation phase: (1) is the initiative reaching the target population(s), (2) are delivery and support functions consistent with program design, and (3) are positive changes occurring as a result of these activities?

- *__Product evaluation__* identifies consequences of the program for various stakeholders, intended or otherwise, to determine effectiveness and provide information for future program modifications.

A Framework for the Process Evaluation

To provide a cohesive framework for the process evaluation, we identified five system components that work together to bring about improved practices and a safer health care system for patients (see Figure 1.1). AHRQ is engaged in all of these system components, as are numerous other key organizations. The five system components are: (1) monitoring progress and maintaining vigilance; (2) knowledge of epidemiology of patient safety risks and hazards; (3) development of effective practices and tools; (4) building infrastructure for effective practices; and (5) broader adoption of effective practices.

For this evaluation, we adopt a national perspective, with the goal of assessing the progress of the AHRQ initiative in helping to achieve a safer health care system. Accordingly, our examination recognizes AHRQ as one of the leaders in the large and growing field of patient safety improvement. The exploration of particular aspects of patient safety activities or new practices or information is conducted within the broader context of the health care system. Similarly, the assessment of the effects of AHRQ activities and those of other federal agencies includes consideration of their contributions to the larger patient safety system.

FINDINGS FROM THE CONTEXT AND INPUT EVALUATIONS

Context Evaluation

The context evaluation documents the historical events that led to and framed the formation of the AHRQ patient safety initiative and identifies consequences for the AHRQ patient safety initiative. The following consequences were identified:

- *AHRQ leadership* – a clear mandate by Congress for AHRQ to provide leadership in effecting change in patient safety practices

- *Balance research and implementation* – the need for AHRQ to balance its traditional role of funding health services research with new activities to serve as a catalyst for bringing about changes that improve patient safety in the health care system.

- *Resource constraints* –appropriation of funding that is small relative to the work to be done, including research to strengthen knowledge and actions to bring that knowledge to the health care community and increase adoption of safer practices.

- *Accountability for results* – high expectations by Congress that AHRQ demonstrate progress in improving patient safety practice and reduction of harm to patients.

- *Coordination of multiple activities* – a diversity of patient safety activities being undertaken by multiple public and private organizations, which requires a coordination role for AHRQ to achieve synergy among them and to encourage consistent standards of practice.

Input Evaluation

In this evaluation cycle, the input evaluation documents and assesses the start-up and initial operations of the AHRQ patient safety initiative. In general, both external leaders and the AHRQ staff believe the agency has done an impressive job in starting the patient safety initiative and has taken a productive approach for spending the $50 million on research to generate new knowledge. The initiative serves as a model for building multiyear budgets based on a trajectory of research and for explicitly linking investments in knowledge development in early years to translational and practice improvement activities in later years. Evaluation research also is an integral part of the initiative.

In FY2000 and FY2001, AHRQ awarded patient safety grants for 81 research and demonstration projects, as well as other contracts and grants for other work for the patient safety initiative. A total of $160 million was obligated over the life of the multiyear projects. Of this total, $141.6 million was obligated for the 81 grants in seven project groups: Systems-Related Best Practices, Clinical Informatics, Centers of Excellence, Developmental Centers, Dissemination and Education, Reporting Demonstrations, and Working Conditions. The Systems-Related Best Practices grants were awarded in FY2000 before the first patient safety

appropriation was enacted. The remaining groups of grants were awarded in FY 2001 using the FY 2001 patient safety funding. (See Appendix A for summaries of the project groups.)

In addition, AHRQ and the Health Resources and Services Administration (HRSA) have collaborated to enhance opportunities for exchange of information and synergy among the researchers for the AHRQ-funded grants and five HRSA-funded patient safety projects. The HRSA-funded grantees participated in patient safety conferences and other cross-grantee interactions.

In the AHRQ reauthorization, Congress established an expanded role for AHRQ that encompasses not only its traditional role of supporting health care research but also the new role of stimulating changes in health care delivery practices. This new mandate has created ongoing tension between AHRQ's research and implementation functions, within the constraints of a finite budget. AHRQ is a small agency, and although the patient safety budget is small relative to its mandate to achieve a safer health care system, it is large relative to AHRQ's overall budget. Some concerns were raised in our stakeholder interviews that the patient safety initiative could crowd out the other programs for which AHRQ is responsible.

ISSUES AND SUGGESTED AHRQ ACTIONS FROM THE PROCESS EVALUATION

Monitoring Progress and Maintaining Vigilance

The ability to measure patient safety events and monitor progress in practice improvements is the lynchpin to achieving safer health care in this country. It is essential to have an effective national patient safety data repository that can aggregate data from a diversity of participating organizations using consistent national standards to (1) provide the feedback and accountability to stimulate practice improvements by health care organizations, and (2) enable AHRQ to fulfill its accountability to Congress for achieving patient safety improvements. As a federal agency, AHRQ is in an excellent position to bring together the key stakeholders and facilitate decision making processes for establishing national data standards that would provide the foundation for a national data repository.

Design and execution of such a national data resource is likely to be the most difficult challenge of the patient safety initiative, because it requires both technical expertise and successful collaboration across numerous levels and types of organizations. AHRQ's strategy acknowledges the multiplicity of organizations and activities involved in patient safety measurement and reporting. It aims for collaboration in crafting a data system, using an incremental approach that leverages its initially funded projects into subsequent development of a national data capability.

Ongoing work by AHRQ, the National Quality Forum (NQF), and others has yielded a growing number of patient safety measures. Substantial overlap in the measures developed by different organizations suggests there is convergence in thinking about the priority items. However, more work is needed to establish measures for services provided in a variety of settings, including ambulatory care, outpatient diagnostic and treatment services, long-term care, and home care.

Suggestions for AHRQ Action

- AHRQ should actively facilitate development work toward establishment of a national patient safety data repository, using a structured consensus process to select national

measures, develop the data standards and specifications, and delineate procedures for operation of the reporting network.

- In identifying candidate measures, AHRQ should ensure that the most important safety aspects of the patient's health care experience are identified and represented by the measures.

- The process used by University of California at San Francisco (UCSF) and Stanford University to select the Healthcare Cost and Utilization Project (HCUP) patient safety indicators should be adapted by AHRQ for selection and definition of the broader set of national patient safety measures.

- AHRQ should place a priority on the synthesis it plans to prepare of the knowledge, products, and newly tested reporting systems that will begin to emerge from the Reporting Demonstration projects during FY2004.

- AHRQ should invite accreditation and credentialing organizations and insurers to be actively involved in the process for establishing national patient safety measures and designing a reporting network, with the goal of their adopting the measures as standards in their accreditation processes.

Knowledge of Epidemiology of Patient Safety Risks and Hazards

Our scan of the available data on the epidemiology of patient safety issues confirms that systematic or consistent estimates of the current incidence and severity of medical errors or adverse events do not yet exist. Numerous published papers report this information for specific issues, health care settings, and geographic locations, but the information has not been synthesized in a way that enables conclusions to be drawn about the country's current patient safety status and the priority issues that merit attention.

The projects in the patient safety portfolio are generating important new information on the epidemiology and causes of patient safety risks and hazards for a broad range of issues across a variety of patient care areas and settings. This new information has the potential to contribute substantially to the current state of knowledge of patient safety epidemiology. However, even when the epidemiological information generated from the patient safety projects is synthesized and interpreted, the synthesis is not expected to produce national-level estimates of the epidemiology of patient safety issues. The absence of standards for defining medical errors and adverse events, and for the measurement of these events, will preclude quantitative synthesis for many of the study results. The successful establishment of a national patient safety data repository would help provide such a capability.

Suggestions for AHRQ Action

- AHRQ should ensure that the results of epidemiological studies by the patient safety projects are summarized in usable forms for a variety of stakeholders and for future decisions on patient safety priorities.

- Definitions and standards for measurement methods should be established by AHRQ as the basis for valid and consistent epidemiologic estimates for patient safety issues.

- AHRQ should fund the development of a review report that summarizes the current state of knowledge on patient safety epidemiology and presents the best available estimates of the incidence and severity of errors and adverse events.

- Future AHRQ funding for research on patient safety epidemiology should focus on topics that have been addressed least frequently thus far, placing a priority on areas that are high risk for patient harm.

Development of Effective Practices and Tools

Our review of the patient safety projects indicates that they are well positioned to expand the scientific evidence on the effectiveness of practices for improving patient safety, including issues of importance to vulnerable populations, specific practices that the patient safety evidence report identified as in need of further research, and substantial numbers of practices not rated by the evidence report. The preliminary information from our assessment is encouraging because it confirms that new ground is being covered, and it identifies several areas where further practice development and testing are needed. A full assessment of the contributions of the patient safety projects to the evidence base cannot be made until the projects publish their research results. AHRQ and other stakeholders should focus future research funding on the practices for which the need for more evidence is greatest.

Suggestions for AHRQ Action

- As the AHRQ-funded patient safety projects and other research generate new evidence on the effective practices, AHRQ should update the evidence report on patient safety to incorporate this evidence and should make the evidence information readily available to users through web-based and other communication media.

- AHRQ should commit resources to define the standards of evidence that should apply for assessing the effectiveness of patient safety practices, and to determine methods for prioritizing which practices should be implemented.

- Future AHRQ research funding should focus on testing patient safety practices that are promising, but for which evidence regarding their effects on safety outcomes is lacking or insufficient.

- AHRQ should support work to document the costs, cost effectiveness, and return on investment of promising patient safety practices to make the business case for their adoption in the field.

- To support health care organizations in adopting evidence-based patient safety practices, AHRQ should collaborate with users to establish implementation guides and tools with practical "how to" information that reduce barriers to implementation progress.

Building Infrastructure for Effective Practices

AHRQ has made tangible progress in developing infrastructure to support patient safety implementation activities. Virtually all of the groups of patient safety projects are addressing infrastructure issues, and two of the groups have infrastructure development as a primary goal. Two survey instruments will soon be ready for use by health care organizations to assess their patient safety culture and the extent to which hospitals are using adverse-event reporting

systems. Development of several components of a national data repository is underway in an incremental process, with more work planned in the near future.

Strategic partnerships among AHRQ, researchers, federal and state agencies, private sector entities, and professional organizations will serve as the infrastructure for an initiative to support transformation of patient safety research findings into safer practice. However, as a federal agency, AHRQ is not in a position to "build" a patient safety infrastructure alone. A better metaphor might be that AHRQ is "seeding" patient safety infrastructures. AHRQ's research network programs are impressive examples of "seeding" infrastructure by facilitating and funding creative partnerships among entities in the private sector that will ultimately become self-perpetuating.

Suggestions for AHRQ Action

- AHRQ should undertake a variety of partnerships with public and private sector organizations to explore creative ways for putting tested new patient safety products and knowledge into practice in the health care system.

- AHRQ should pursue a focused strategy to integrate the patient perspective into activities to improve patient safety performance, including relevant research, consumer reporting on their experiences with care, and consumer involvement in activities by health care organizations.

- AHRQ should explore mechanisms for establishing contingency financing of dissemination and implementation activities to provide flexibility to respond to needs or opportunities identified in the field.

- Continued funding support should be provided for DCERPS and other projects that are beginning to build patient safety research infrastructure in order to enable them to become self-sustaining.

- AHRQ should expand its efforts to take full advantage of its already established network infrastructures to serve as testing grounds for new patient safety interventions.

Achieving Broader Adoption of Effective Practices

The process of bringing new patient safety knowledge and products into widespread practice in the health care system requires both creativity and persistence. The primary players in adoption of improved patient safety practices are health care providers and other stakeholders with influence over them, including purchasers, insurers, accreditation and credentialing organizations, and consumers. By serving as a facilitator and technical resource for their activities, AHRQ has the opportunity to build synergy that will hasten the adoption of new practices for patient safety improvements. AHRQ will need to choose its initiatives strategically to leverage its limited resources for the greatest possible return on investment.

The dissemination of findings and products from the patient safety projects represents an intersection of two challenges for AHRQ. The first is a structural challenge – the large number of projects that will be generating results, which the current system of health care publications does not have ready capacity to absorb. The second is a process challenge – the need for a creative and comprehensive dissemination strategy that will enable AHRQ and its grantees to effectively move the project output into the hands of a diverse mix of users and stakeholders. As AHRQ continues to develop and adjust its strategy, it can learn from its experience with the

dissemination process and draw upon the expertise and resources of public and private sector partners.

<u>Suggestions for AHRQ Action</u>

- AHRQ should design and carry out a cohesive strategy to disseminate the new knowledge and products of the patient safety projects to the broad spectrum of stakeholders that will put them into practice in the delivery of safer health care.

- AHRQ should identify and test alternative strategies for AHRQ to serve as a catalyst that motivates and supports initiatives by health care organizations to implement new patient safety practices.

- AHRQ should develop a monitoring process to measure the effects of individual implementation initiatives on patient safety practices and outcomes, as well as the cumulative effects of all the patient safety activities on key outcome measures.

FUTURE DIRECTIONS AND PRIORITIES

In the first year of the evaluation, we have observed, documented, and assessed the operations of the patient safety initiative, learning from participants and other stakeholders about the activities and interactions involved in the process. These individuals also have shared with us their concerns and ideas for future work. Drawing upon our assessments of the program context, inputs, and processes, we have identified four priorities that we believe in the aggregate will have the strongest positive impact on the future of the patient safety initiative.

Accountability and Patient Safety Goals

The high expectations initially set forth for achieving a 50 percent reduction in errors in five years have been replaced with recognition among participants and observers that the goal was both incorrect and unrealistic, especially given the relatively limited funding appropriated for the patient safety initiative. While setting a goal of low tolerance for errors and patient risk may be useful for establishing performance accountability, interim objectives must also be designed to pull the health care system toward that goal incrementally. In particular, there should be a realistic match between the objectives defined and the financial resources allocated for programming to achieve them.

A National Patient Safety Data Repository

The ability to measure patient safety issues and monitor progress in practice improvements nationally is one of the key components of a strategy for achieving safer health care in this country. An effective monitoring and measurement capability based on consistent national standards is essential to (1) provide the feedback and accountability to stimulate practice improvements by health care organizations and (2) enable AHRQ to fulfill its accountability to Congress for achieving patient safety improvements. We encourage AHRQ to continue to move actively on this aspect of the initiative, adjusting strategy as opportunities arise, and dedicating resources to the work. In particular, AHRQ can use its position as a federal agency to facilitate a consensus process with the goal of enhancing participation from multiple stakeholders across the country.

The Role of AHRQ in Making Practice Changes Happen

As a federal agency, AHRQ operates in a unique external environment of legislative oversight and regulatory requirements. The conditions imposed by this environment create both advantages and constraints that influence AHRQ's ability to stimulate and support improved patient safety practices in the nation's health care system. While congressional requirements (e.g., procedural rules for funding projects, OMB approval requirements for survey data collection) provide important protections for the people of this country, they can also involve time-consuming procedures that slow down progress toward patient safety goals or discourage private sector participation. The aspect of the AHRQ patient safety initiative that may be most vulnerable to the federal bureaucracy is the translation of new knowledge into improvements in patient safety practices in the field. This mission involves AHRQ's participation in active public-private partnerships, supporting health care organizations in their implementation activities. In this process, AHRQ and other participating organizations should make strategic use of the respective assets of the government and the private sector.

Balancing Research and Adoption Activities

During FY2004, the AHRQ patient safety initiative is entering a period of transition, as the existing projects conclude their research, the Patient Safety Improvement Corps (PSIC) enters the field, new Patient Safety Challenge Grants begin their work, and other activities move ahead to bring new knowledge and practices to end-users. During this process, AHRQ will be balancing internal staff activities and workload and deciding how best to use the new funding in the FY2004 budget. One could argue for applying more resources to implementation activities in order to achieve greater progress in the advancement of safer health care practices. However, AHRQ is unique as a funder of research, and reduction of AHRQ funding for priority research topics might well lead to some of them going unfunded. Relatively more of the resources of other federal or state agencies and the private sector might be used to undertake or support implementation initiatives, leveraging the funding available from AHRQ for this work. While there are no "correct" answers to this question, we encourage AHRQ to deliberate carefully to seek the optimal use of its finite resources, both human and financial.

ACRONYMS

AHA	American Hospital Association
AHCPR	Agency for Health Care Policy and Research
AHRQ	Agency for Healthcare Research and Quality
AMA	American Medical Association
CDC	Centers for Disease Control and Prevention
CERT	Center for Education and Research on Therapeutics
CHCS2	Composite Health Care System
CIPP	Context, Input, Process, Product Evaluation
CLIPS	Clinical Informatics to Promote Patient Safety
CMS	Centers for Medicare and Medicaid Services
CoE	Center of Excellence in Patient Safety
CPRS	Computerized Patient Record System
CQuIPS	Center for Quality Improvement and Patient Safety
DCERPS	Developing Centers of Excellence in Patient Safety
DHHS	Department of Health and Human Services
DoD	Department of Defense
EPC	Evidence-based Practice Center
FDA	Food and Drug Administration
GPRA	Government Performance and Results Act
HCUP	Healthcare Cost and Utilization Project
HEDIS	Health Plan Employer Data and Information Set
HRN	HIV Research Network
HRSA	Health Resources and Services Administration
IDSRN	Integrated Delivery Systems and Research Network
IOM	Institutes of Medicine
IRB	Internal Review Board
JCAHO	Joint Commission on Accreditation of Health Care Organizations
MEPS	Medical Expenditure Panel Survey
NAC	National Advisory Council
NASA	National Aeronautics and Space Administration
NCC MERP	National Coordinating Council on Medication Error Reporting and Prevention
NCHS	National Center for Health Statistics
NCQA	National Committee for Quality Assurance
NNIS	National Nosocomial Infections Surveillance System
NPSF	National Patient Safety Foundation
NQF	National Quality Forum
NQMC™	National Quality Measures Clearinghouse
OMB	Office of Management and Budget

OPM	Office of Personnel Management
PBRN	Practice-Based Research Networks
PSIC	Patient Safety Improvement Corps
PSO	Patient Safety Organization
PSRS	Patient Safety Reporting System
QAPI	Quality Assessment and Performance Improvement
QuIC	Quality Inter-Agency Coordination Task Force
RFA	Request for Application
ROI	Return on Investment
SBIR	Small Business Innovative Research
SRPB	Systems-Related Best Practices
TRIP	Translating Research into Practice
UCD	University of California Davis
UCSF	University of California San Francisco
ULP	User Liaison Program
URAC	American Accreditation HealthCare Commission
VA	Department of Veterans' Affairs
V*ISTA*	Veterans Health Information Systems and Technology

ACKNOWLEDGEMENTS

CHAPTER 1. INTRODUCTION

Congress has placed a high priority on making a safer U.S. health care system. It has given a mandate to the Agency for Healthcare Research and Quality (AHRQ), an agency within the Department of Health and Human Services (DHHS), to establish a patient safety research and development initiative. This mandate holds AHRQ accountable for helping health care providers reduce medical errors and improve patient safety. AHRQ, in turn, is committed to improving patient safety in the U.S. health care system by ensuring that the extensive work supported by AHRQ and other organizations (1) addresses the many aspects of achieving safe health care practices; (2) identifies and fills gaps in knowledge on patient safety epidemiology and practices, and (3) is focused on effective identification and dissemination of successful patient safety practices.

AHRQ contracted with RAND in September 2002 to serve as the evaluation center for its patient safety initiative. The evaluation center is responsible for performing a longitudinal evaluation of the full scope of AHRQ's patient safety activities and providing regular feedback to support the continuing improvement of this initiative. AHRQ specified that the evaluation is to develop baseline information on the context and antecedent conditions that led to establishment of AHRQ's patient safety initiative, use formative evaluation procedures to monitor progress at meeting the objectives of the initiative, and make recommendations for improvement. The evaluation also is to assess overall initiative impacts, outcomes, and adoption diffusion using both qualitative and quantitative assessment approaches.

This report is the first of what will be four annual reports prepared during the course of the longitudinal, formative evaluation, which are scheduled to be submitted to AHRQ in September of each year. This report presents findings on the history leading to the AHRQ patient safety initiative, the start-up of the initiative, and early activities through September 2003. By design, the initial evaluation focuses on assessing the context and goals that were the foundation for the patient safety initiative and developing baseline information for the process evaluation. From this information, we discuss implications for future policy and research, and offer suggestions for strengthening subsequent AHRQ activities. In concurrent work, the evaluation continues to gather and assess information on the activities and evolution of the initiative, the results of which will be presented in subsequent annual reports.

The contents and format of the report are designed to provide a stable conceptual framework for the longitudinal evaluation, within which results of each year's assessment will be reported to develop a cumulative record of program evolution. We will attempt to track patterns and trends in patient safety activities and effects, and we will examine adjustments made to the initiative by AHRQ or others in response to previous evaluation findings or other factors.

EVALUATING THE PATIENT SAFETY INITIATIVE

The Policy Context

In early 2000, the Institute of Medicine (IOM) published a report entitled *To Err is Human: Building a Safer Health System*, which mobilized national efforts to improve the safety of the U.S. health care system (IOM, 2000). This report estimated that between 44,000 and 98,000 people die each year in hospitals from medical errors, and it called for "a comprehensive

and strong response to this most urgent issue facing the American people." The IOM called for leadership from the DHHS in reducing medical errors, identifying AHRQ as the focal point for patient safety research and practice improvements.

In response to the IOM report, the Quality Interagency Coordination Task Force (QuIC), a collaborative effort among Federal agencies,[2] issued a report in February 2000 – *Doing What Counts for Patient Safety, Federal Action to Reduce Medical Errors and Their Impact*. This report laid out a strategy of more than 100 actions designed to create a national focus on reducing errors, strengthen the patient safety knowledge base, ensure accountability for safe health care delivery, and implement patient safety practices.

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[2] The QuIC is composed of members representing the Departments of Commerce, Defense, Health and Human Services, Labor, State, and Veterans Affairs; Federal Bureau of Prisons; Federal Trade Commission; National Highway Transportation and Safety Administration; Office of Management and Budget; Office of Personnel Management; and the U.S. Coast Guard.

- ***Product evaluation*** identifies consequences of the program for various stakeholders, intended or otherwise, to determine effectiveness and provide information for future program modifications.

The sequence of the four stages of the CIPP program evaluation process for the patient safety initiative is listed in Table 1.1. The activities covered in this first evaluation report are shown in the shaded column in the table. These include performance of the context and input evaluations and establishment of baseline information for the process evaluation. The report does not contain a chapter for the product evaluation because this work will begin in the second evaluation year.

Table 1.1
Timeline for Reporting Results from the Longitudinal Evaluation
of the AHRQ Patient Safety Initiative

	Contents and Time Periods of Evaluation Reports			
	Report 1: History- Sept 2003	Report 2: Oct 2003- Sept 2004	Report 3: Oct 2004- Sept 2005	Report 4: Oct 2005- Sept 2006
Context Evaluation				
Initial assessment of context	X			
Updates on context changes		X	X	X
Input Evaluation				
Assessment of goals and strategy established for the initiative	X			
Updates on changes in goals or strategy		X	X	X
Process Evaluation				
Baseline documentation patient safety activities related to the initiative	X			
Assessment of contributions by AHRQ-funded patient safety projects to patient safety knowledge and patient safety practices	X	X	X	X
Assessment of other mechanisms used by AHRQ to strengthen patient safety practices		X	X	X
Assessment of dissemination of new knowledge to stakeholders in the field		X	X	X
Assessment of progress in adoption of effective patient safety practices		X	X	X
Product Evaluation				
Initial identification of potential outcome measures and data sources		X		
Development of data sources when feasible			X	X
Documentation of baseline trends for selected measures			X	X
Assessment of impacts of the patient safety initiative on selected measures				X
Establishment of infrastructure for AHRQ to continue and expand monitoring impacts			X	X

During the second and third years of the evaluation, the process evaluation will be the primary evaluation focus, while work also will proceed on preparing measures and data for the product evaluation. The fourth evaluation year will focus on product evaluation to assess the impacts of the patient safety initiative on various stakeholders, while the process evaluation also will be completed.

Major Stakeholder Groups Addressed

We have identified the following major stakeholder groups for the patient safety initiative, for which effects should be assessed:

- *Patients* – who receive health care services and bear the impact of adverse health care events, have a direct stake in the occurrence of those events.

- *Providers* – including physicians, nurses, and the organizations that employ them, also have a stake in the occurrence of adverse events, as well as in the adoption of clinical and organizational practices designed to promote safety.

- *States* – which license health care providers and (in many instances) operate adverse-event reporting systems, have a stake in tracking adverse events, and in promoting remediation efforts by providers.

- *Patient safety organizations* – organizations that are working to promote best practices, education, and technology adoption in patient safety, and have a stake in building collaborations in order to achieve these ends.

- *Federal government* – agencies in the federal government, in particular AHRQ and other DHHS agencies, that are involved in patient safety activities.

A Framework for the Process Evaluation

To provide a cohesive framework for the process evaluation, we identified five system components that work together to bring about improved practices and a safer health care system for patients. This system framework, which is presented graphically in Figure 1.1, can represent the components of an effective system at either the national level or a more local level. At the national level, AHRQ is engaged in all of these system components, as are numerous other key organizations. Each system component is defined as follows:

Monitoring Progress and Maintaining Vigilance. Establishment and monitoring of measures to assess performance improvement progress for key patient safety processes or outcomes, while maintaining continued vigilance to ensure timely detection and response to issues that represent patient safety risks and hazards.

Knowledge of Epidemiology of Patient Safety Risks and Hazards. Identification of medical errors and causes of patient injury in health care delivery, with a focus on populations that are vulnerable because they are compromised in their ability to function as engaged patients during health care delivery.

Development of Effective Practices and Tools. Development and field testing of patient safety practices to identify those that are effective, appropriate, and feasible for health care organizations to implement, taking into account the level of evidence needed to assess patient safety practices.

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Building Infrastructure for Effective Practices. Establishment of the health care structural and environmental elements needed for successful implementation of effective patient safety practices, including an organization's commitment and readiness to improve patient safety (e.g., culture, information systems), hazards to safety created by the organization's structure (e.g., physical configurations, procedural requirements), and effects of the macro-environment on the organization's ability to act (e.g., legal and payment issues).

Achieving Broader Adoption of Effective Practices. The adoption, implementation, and institutionalization of improved patient safety practices to achieve sustainable improvement in patient safety performance across the health care system.
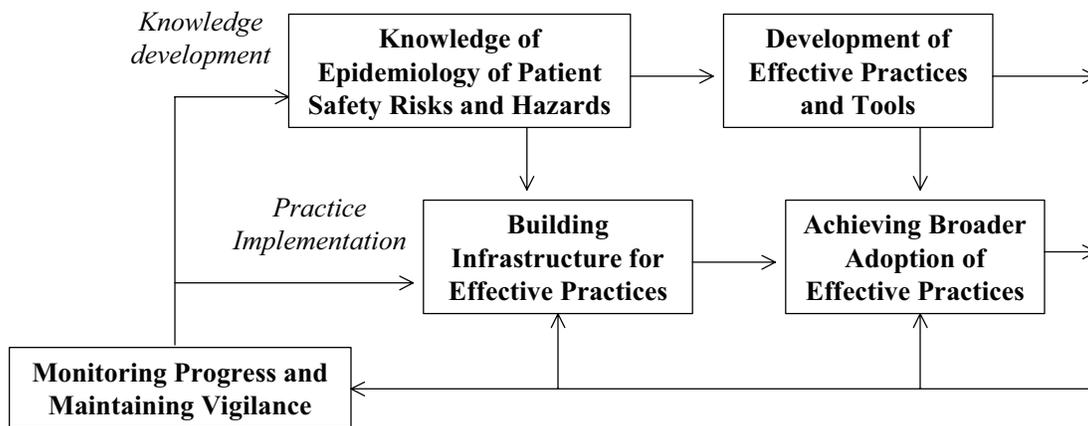
Figure 1.1 A Framework for an Effective Patient Safety System

The component for monitoring progress and maintaining vigilance is identified first and placed on the left side of the figure, reflecting the need for early data on patient safety issues to help guide intervention choices. This function then continues to provide routine feedback regarding progress in developing knowledge and implementing practice improvements. The top row of the figure contains the two components that contribute to knowledge development regarding patient safety epidemiology and effective practices and tools. This knowledge is then used in the remaining two model components that contribute to practice implementation – building infrastructure and adoption of effective practices (in the second row of the figure).

We note that this model is quite similar to the one defined by AHRQ in its Interim Report to Congress, entitled *AHRQ's Patient Safety Initiative: Building Foundations, Reducing Risk* (AHRQ, 2003). In the AHRQ model, the infrastructure and adoption components are combined into one component for teaching, dissemination, and implementation of effective patient safety practices.

EVALUATION APPROACH AND METHODS

This evaluation adopts a national perspective, with the goal of assessing the progress of the AHRQ patient safety initiative in helping to achieve safer health care for the United States. Our assessment recognizes AHRQ as one of the leaders in the large and growing field of patient safety improvement across the country. We examine AHRQ's contributions to patient safety activities in the context of those of other organizations across the overall health care system.

The evaluation design allows for both a national-level evaluation of the overall AHRQ patient safety initiative and a local-level evaluation of the contributions of the patient safety projects funded by AHRQ. At the national level, AHRQ is building a coordinated initiative from which the collective activities and knowledge generated can be applied to improve patient safety practices across the country. AHRQ is funding projects, developing patient safety outcome measures and monitoring processes, disseminating information on best practices and other research findings to the health care community, and working with public and private organizations to put the knowledge and practices to work in the health care system.

At the local level, we can learn from the experiences of the groups of patient safety projects funded by AHRQ. Some projects are doing research that is generating new knowledge on patient safety epidemiology or developing new practices to prevent errors and adverse events. Others are testing new practices under field conditions, in preparation for adoption of successful practices by health care providers.

Another component of the patient safety initiative is the Patient Safety Research Coordinating Center (hereafter called the Coordinating Center), which AHRQ established to serve as a facilitator of interactions among the patient safety grantees. The Coordinating Center serves as an administrative extension of the agency staff to help achieve the synergy that would make "the whole initiative greater than the sum of its parts."

For the first evaluation cycle, which covers the initiative history through September 2003, we used published materials as the source of factual information on the components of the patient safety initiative. We also conducted interviews with numerous individuals, both AHRQ staff and others external to the agency, who participated in the start of the patient safety initiative, currently work in it, or otherwise are stakeholders. These interviews provided information on the dynamics and issues relevant to the formation and operation of the program.

To obtain information specific to the individual funded projects, five data sources were used: (1) the patient safety project database provided by AHRQ; (2) proposals prepared by the research teams operating the patient safety projects that are part of the initiative; (3) updated information on the projects collected by the Coordinating Center; (4) focus groups conducted with each project group; and (5) individual interviews conducted with the principal investigator of each patient safety project.

ABOUT THIS REPORT

This initial evaluation report presents a formative evaluation of the status of the AHRQ patient safety initiative as of September 2003 in the context of relevant current activities of other key organizations across the country. We also offer suggestions for AHRQ action that focus on actions to help enhance AHRQ's future strategy and activities.

The remaining eight chapters are organized according to the context, input, and process components of the CIPP evaluation model. Chapters 2 and 3 focus on the context and input components of the evaluation respectively. Chapters 4 through 8 present the information developed in the first cycle of our process evaluation on the baseline status of the AHRQ patient safety initiative, which is organized according to the five-component patient safety system framework presented in Figure 1.1. Chapter 9 concludes with a summary of the current status of the AHRQ patient safety initiative, and presents a set of directions and priorities that we believe will have the strongest positive impact on the future of the patient safety initiative. It also

describes the next steps in our longitudinal evaluation, including preparation for the product (effects assessment) component of the CIPP evaluation model.

Each of the process evaluation chapters (4 through 8) begins with a summary of the relevant recommendations of the IOM report, *To Err Is Human*, and the strategy and actions defined in the QuIC report in response to the IOM report. These are followed by a summary of the related patient safety strategy and activities being undertaken by AHRQ. Although the guidance from the IOM and QuIC provides a policy context for the AHRQ activities, in some cases AHRQ has chosen to pursue different approaches. Such differences in approach are to be expected, as AHRQ and its collaborators learn from each step in the implementation process. We present this information to highlight consistencies and differences in policy approaches and priorities, which are perspectives that can contribute to future policy formation.

CHAPTER 2. CONTEXT EVALUATION

This chapter provides an overview of the historical context and sequence of events that led to and framed the formation of the AHRQ patient safety initiative. Table 2.1 presents a timeline of these events, with additional detail provided in the chapter narrative. These events continue to influence the strategy and activities of AHRQ and other federal agencies as they fulfill their roles to help improve patient safety practices. Our understanding of the history has been informed by factual information in documents and web sites and by information and viewpoints shared by the stakeholders we interviewed. We conclude with a brief discussion of the consequences of these contextual issues for the AHRQ patient safety activities.

Table 2.1
Timeline of Activities in Establishing the AHRQ Patient Safety Initiative

Year	Patient Safety Activities
1996	First Annenberg Conference on patient safety; formation of the National Patient Safety Foundation by the American Medical Association
Late 1990s	Department of Veterans Affairs patient safety initiative; sentinel event reporting policy established by Joint Commission on Accreditation of Healthcare Organizations
December 1999	The Healthcare Research and Quality Act of 1999 passed by Congress, reauthorizing the Agency for Healthcare Research and Quality and giving it the patient safety mandate
December 1999	Publication by AHRQ of the request for application (RFA) for patient safety Systems-Related Best Practices grants
January 2000	Publication of *To Err Is Human* by the Institute of Medicine (release in December 1999)
February 2000	Release of *Doing What Counts for Patient Safety* by the Federal Quality Improvement Coordination Task Force in response to the IOM report
2000	FY2000 funding awarded by AHRQ for six Systems-Related Best Practices patient safety demonstrations
2000	Appropriation by Congress of $50 million for FY2001 for the AHRQ patient safety initiative
2001	Patient safety grants awarded by AHRQ to 81 grantees in six groups of grants; contract awarded by AHRQ for the Patient Safety Research Coordinating Center
2002	Contract awarded by AHRQ for the Patient Safety Evaluation Center

ANTECEDENTS TO THE AHRQ PATIENT SAFETY INITIATIVE

Status of Early Patient Safety Work

Individuals we interviewed characterized the patient safety situation through the 1990s as problematic, with hospital systems being woefully inadequate to prevent errors and in need of redesign. However, the health care community tended to be resistant to early research that revealed the frequency and severity of medical errors and adverse events (Brennan et al., 1991; Leape et al., 1991). Momentum for patient safety activities picked up in 1996 with the Annenberg I conference and the American Medical Association's (AMA) announcement of the formation of the National Patient Safety Foundation (NPSF). The Department of Veterans' Affairs (VA) began focusing heavily on patient safety during this period, and the Joint

Commission on Accreditation of Healthcare Organizations (JCAHO) established its policy for voluntary reporting of sentinel events.

The most visible patient safety activity of the federal government during this period was the work of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, which served as a catalyst for the subsequent IOM report on patient safety and led to the formation of the federal QuIC Task Force. At the Annenberg II conference in fall 1998, the director of AHRQ publicly expressed AHRQ's interest in continuing to fund patient safety work, indicating that AHRQ was aware, supportive, and ready to push the patient safety agenda.

The IOM Report: Bringing Patient Safety to the Forefront

The IOM report, *To Error Is Human: Building a Safer Health System,* was the catalyzing force that made patient safety a visible and important issue not only for the health care community, but also for the general public, the news media, and the U.S. Congress (IOM, 2000). The report outlined a four-tiered strategy for improving patient safety practices and outcomes: (1) a national focus to create leadership, research, tools and protocols to enhance knowledge about safety; (2) identifying and learning from errors through immediate and strong reporting efforts and encouragement of voluntary reporting efforts to make the system safer for patients; (3) raising standards and expectations for improvements in safety through actions of oversight organizations, group purchasers, and professional groups; and (4) creating safety systems inside health care organizations through implementation of safe practices at the delivery level – the ultimate target. It also presented numerous recommendations for building the system components needed to carry out this strategy.

LEGISLATIVE PROCESSES FOR REAUTHORIZATION AND FUNDING

Two independent legislative processes were involved in establishing and funding the patient safety initiative at AHRQ. The first was the legislation for reauthorization of the agency, entitled the Healthcare Research and Quality Act of 1999. The second was the FY2001 appropriations legislation with provisions for funding the patient safety initiative.

The Reauthorization Process

Congress reviewed AHRQ for reauthorization in 1998 and 1999, holding hearings on AHRQ's mission and performance. The controversial history of the agency was discussed in these hearings, with diverging opinions about its future. Previously, AHRQ had received criticism for taking on what some observers felt were policy-making roles that exceeded its authority. A new agency director was appointed shortly after this low point in its history, and by the time patient safety rose to prominence, the agency leadership had begun redefining its purpose and rebuilding its credibility with Congress.

The Healthcare Research and Quality Act of 1999 was signed into law on December 6, 1999, reauthorizing the agency and changing its name from the Agency for Health Care Policy and Research to the Agency for Healthcare Research and Quality (AHRQ). This legislation virtually coincided with the release of the IOM patient safety report. The act defined AHRQ's mission as follows:

"To enhance the quality, appropriateness, and effectiveness of health care services, and access to such services, through the establishment of a broad base of scientific

research and through the promotion of improvements in clinical practice, patient safety, and in the organization, financing, and delivery of health care services."

The authorization also specified that the director of AHRQ was to conduct and support research, to build private-public partnerships for identifying the causes of patient safety problems, and pursue strategies for improving patient safety throughout the health care industry.

The Patient Safety Appropriation Process

In discussions with Congress during the reauthorization process, AHRQ leaders were focused on developing a five-year patient safety initiative with $20–30 million in initial funding as recommended by the IOM. The AHRQ patient safety appropriation established by Congress was $50 million for FY2001. The appropriation legislation specified that $23 million of this funding was to be spent for research on reporting of medical errors and adverse events, and another $2 million was to be spent on other data collection activities.

Many of those we interviewed believed that this limited funding was not in accordance with the magnitude of the patient safety problem (e.g., compared to responses to cancer or AIDS), and that the funding limits have constrained the ability of the federal agencies to respond to the issue. Some also had concerns that the congressionally mandated allocation for reporting systems research over emphasized this aspect of a patient safety strategy, and that not enough attention was paid to human factors and system design issues.

AHRQ Activities During the Legislative Process

Months before the IOM report was released, AHRQ had begun to develop a request for application (RFA) for patient safety Systems-Related Best Practices grants with $2 million in funding. The RFA was published in December 1999, two weeks after the IOM report was released.

The White House focused on patient safety very soon after the IOM report was published, with the President requesting the Quality Interagency Coordination Task Force (QuIC) to prepare an assessment of the report's implications. Staff from AHRQ, the Department of Veterans Affairs (VA), Department of Defense (DoD), Centers for Medicare and Medicaid Services (CMS), the Office of Personnel Management, and other agencies contributed expertise on diverse aspects of safety. The participants determined that an adequate patient safety knowledge base did not yet exist, and that the level of funding provided would not be sufficient to generate the scope of information needed. The QuIC report, entitled *Doing What Counts for Patient Safety, Federal Action to Reduce Medical Errors and Their Impact,* was released in February 2000, within 60 days of the President's December 13 announcement (QuIC, 2000).

How AHRQ Got the Patient Safety Program

Two factors contributed to the decision by Congress to designate AHRQ as the agency with lead responsibility for the patient safety initiative. One of these was the recommendation of the IOM Committee that a Center on Patient Safety be established within AHRQ. A second factor was the initiative taken by AHRQ leadership leading up to and following the issuance of the IOM report. Little additional funding was given to other federal agencies for patient safety work.

OVERVIEW OF PATIENT SAFETY EFFORTS

Figure 2.1 depicts the government departments and agencies involved in patient safety activities. The left side of the chart identifies the QuIC and Patient Safety Task Force and lists the departments and agencies participating in them. The QuIC is a federal government-wide task force with participation by agencies having involvement in health care and related policy functions. The Patient Safety Task Force was established by the Department of Health and Human Services (DHHS). Also shown is the DHHS standardized federal patient safety data systems project that is designed to develop front-end integration for the data systems of the participating agencies. The right side of the chart provides information on the components and activities of AHRQ's patient safety program. See Appendix A for brief descriptions of key federal organizations involved in the patient safety initiative.

Federal Departments and Agencies

Quality Inter-Agency Coordination Task Force (QuIC)

Department of Commerce
Department of Defense
Department of Health and Human Services
Department of Labor
Department of State
Department of Veterans Affairs
Federal Bureau of Prisons
Federal Trade Commission
National Highway Administration
Office of Management and Budget
Office of Personnel Management
U.S. Coast Guard

DHHS Patient Safety Task Force

Agency for Healthcare Research & Quality
Federal Drug Administration
Centers for Disease Control & Prevention
Centers for Medicare & Medicaid Services

Standardized Federal Patient Safety Data Systems

Summit Conferences

AHRQ National Advisory Council

Agency for Healthcare Research & Quality

Grantee Steering Committee

Patient Safety Research Coordinating Center

Funded Projects for Patient Safety RFAs

Systems Best Practices
Reporting Demonstrations
Health Informatics
Working Conditions
Centers of Excellence
Developmental Centers
Dissemination, Education

Patient Safety Evaluation Center

Funded projects for Patient Safety Support Capability

Figure 2.1 Government Participants in Patient Safety Activities, 2003

Quality Interagency Coordination Task Force

The QuIC was established in March 1998 with the goal of ensuring that all federal agencies involved in purchasing, providing, studying, or regulating health care services are working in a coordinated way toward improving quality of care. Technical and administrative support for the QuIC is provided by AHRQ staff. QuIC's first patient safety activities were to prepare an assessment of and response to the IOM report, and to sponsor the National Summit on Medical Errors and Patient Safety Research held in September 2000. The QuIC report describes more than 100 actions that the QuIC and its participating agencies planned to take, either alone or with the private sector or state governments (QuIC, 2000). These actions comprise a fourfold strategy to (1) create a national focus on reducing errors; (2) develop a knowledge base for

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learning about the causes of errors and effective error prevention; (3) ensure accountability for safe health care delivery; and (4) guarantee that patient safety practices are implemented.

Department of Health and Human Services (DHHS)

The responsibility for federal leadership in the patient safety initiative resides in the DHHS, and AHRQ is the DHHS agency designated to provide leadership for inter-agency collaboration on patient safety issues. In addition, the Health Resources and Services Administration (HRSA) funded a group of patient safety projects that address multidisciplinary patient safety training for medical and nursing students.

Patient Safety Task Force

The Patient Safety Task Force was established by the Secretary of DHHS in April 2001 with a mission to integrate existing data collection on medical errors and adverse events, coordinate research and analysis efforts, and collaborate on reducing the occurrence of injuries that result from medical errors. AHRQ staff have provided a leadership role for the Task Force operation and the projects it has sponsored. The Task Force concentrated its initial efforts on the integration of federal reporting systems, involving data users from both a reporting and analysis standpoint. The National Summit on Patient Safety Data Collection and Use, held in April 2001, established priorities for a national patient safety data repository, giving primary consideration to input from user and stakeholder organizations, such as the American Hospital Association (AHA), AMA, state departments of health, and risk managers.

Activities and Collaborations in the Private Sector

An enormous amount and variety of patient safety activities are also being led by an array of private sector organizations and state-level patient safety coalitions. Numerous national-level organizations are providing policy and technical leadership to support improved patient safety practices in the thousands of health care organizations across the country. These include the AHA, AMA, IOM, JCAHO, the Leapfrog Group, the National Committee for Quality Assurance (NCQA), the National Coordinating Council on Medication Error Reporting and Prevention (NCC MERP), the NPSF, and the National Quality Forum (NQF). Currently, patient safety coalitions are in operation in 11 states (Conrow and Rosenthal, 2002). AHRQ and other federal agencies are working with many of these organizations in carrying out the patient safety initiative.

PENDING PATIENT SAFETY ORGANIZATION LEGISLATION

The proposed Patient Safety and Quality Improvement Act (H.R. 663 and S. 720, respectively) was passed by the house in March 2003 and placed on the Senate Legislative calendar in November 2003. These bills address a core issue of the need for legal protections for reporting patient safety errors and adverse events, without which reporting will remain incomplete and opportunities to take corrective actions will be lost. The proposed legislation would create new protections for adverse-event reporting systems in health care, and would help foster a national reporting scheme in which hospitals, nursing homes, and physicians could report medical errors to new, private patient safety organizations. These organizations would then analyze the submitted reports and provide feedback. Event reporting under either of these bills would be voluntary, and would be entitled to protection from discovery in civil litigation. If passed, this legislation would be implemented by the DHHS, and AHRQ would likely be given a substantial or lead role in managing the program.

CONSEQUENCES FOR THE AHRQ PATIENT SAFETY INITIATIVE

In assessing the history and policy context, we found that this context has created the following consequences for AHRQ's efforts to implement the patient safety initiative:

- *AHRQ leadership* – a clear mandate by Congress for AHRQ to provide leadership in effecting change in patient safety practices

- *Balance of research and implementation* – the need for AHRQ to balance its traditional role of funding health services research with newly mandated activities to serve as a catalyst for bringing about changes that improve patient safety in the health care system.

- *Resource constraints* –appropriation of funding that is small relative to the work to be done, including research to strengthen knowledge and actions to bring that knowledge to the health care community and increase adoption of safer practices.

- *Accountability for results* – high expectations by Congress that AHRQ demonstrate progress in improving patient safety practice and reduction of harm to patients.

- *Coordination of multiple activities* – a diversity of patient safety activities being undertaken by multiple public and private organizations, which requires a coordination role for AHRQ to achieve synergy among them and to encourage consistent standards of practice.

CHAPTER 3. INPUT EVALUATION

This chapter examines AHRQ's overall strategy and goals, structure, and approaches with respect to its patient safety activities and assesses the existing strategy against the alternatives. This aspect of our evaluation has been informed by factual information in documents and web sites, and by information and viewpoints shared by the stakeholders we interviewed. In this review, we describe the patient safety activities and how they fit into the broader AHRQ organization, the processes involved in starting up the initiative, and related budgets. The effects of the policy and environmental context on AHRQ activities, as discussed in the previous chapter, are also considered.

THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

Figure 3.1 depicts the organizational structure of AHRQ that was established through an agency reorganization in May 2003. The Office of the Director directs the activities of the agency to ensure that its strategic objectives are achieved. AHRQ also has a National Advisory Council, on which external national-level policy experts serve as members. This Council, which is staffed by the agency Director, provides policy guidance for design and execution of the agency's program of work.
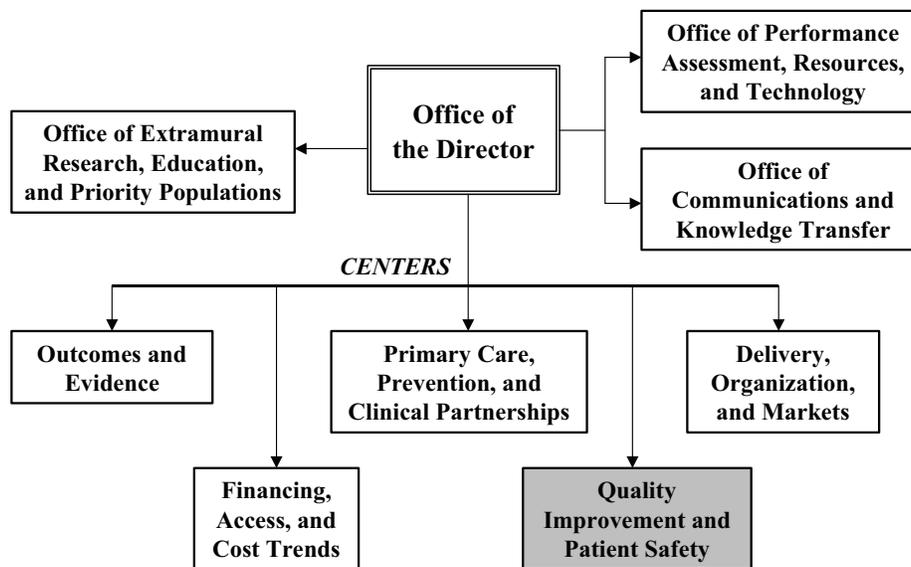
Source: AHRQ web site, Revised July 2003

Figure 3.1 Organization Chart of the Agency for Healthcare Research and Quality

The agency has five centers that have responsibility for the agency's program operation (AHRQ, July 2003):

- *Center for Quality Improvement and Patient Safety*—works to improve the quality and safety of our health care system through research and implementation of evidence. This center (highlighted in Figure 3.1) is the lead for the patient safety initiative.

- *Center for Outcomes and Evidence*—conducts and supports research and assessment of health care practices, technologies, processes, and systems.

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- *Center for Primary Care, Prevention, and Clinical Partnerships*—expands the knowledge base for clinical providers and patients and assures the translation of new knowledge and systems improvement into primary care practice.
- *Center for Delivery, Organization, and Markets*—provides a locus of leadership and expertise for advances in health care delivery, organization, and markets through research.
- *Center for Financing, Access, and Cost Trends*—conducts, supports, and manages studies of the cost and financing of health care and access to health care services and related trends; also develops data sets to support policy and behavioral research and analyses.

Three offices work with the Director's Office to provide support across these centers: the Office of Performance Assessment, Resources and Technology; the Office of Extramural Research, Education, and Priority Populations; and the Office of Communications and Knowledge Transfer. While the Center for Quality Improvement and Patient Safety (CQuIPS) has primary responsibility for overall management of the patient safety initiative, all of the centers are involved in the patient safety initiative to varying degrees.

AHRQ PATIENT SAFETY STRATEGY AND GOALS

AHRQ's overall approach to funding research, development, and intervention projects has been based on the concept of "the research pipeline" in which funded activities collectively build infrastructure, tools, and knowledge for practice improvements (AHRQ, 2002). The agency's long-range plan for patient safety is based on a four-element model, as specified in its Interim Report to Congress (AHRQ, 2003): (1) identifying threats to patient safety; (2) identifying and evaluating effective patient safety practices; (3) teaching, disseminating, and implementing effective patient safety practices; and (4) maintaining vigilance.

The Government Performance and Results Act (GPRA), passed in 1993, requires federal departments and agencies to submit annual performance plans to Congress with the annual budget to enhance the accountability of federal programs. Each year, AHRQ develops a performance plan that specifies its own strategic goals and GPRA goals, as well as actions that will be undertaken to achieve them. Listed in Table 3.1 are AHRQ's FY2003 strategic goals and GPRA goals for health care costs, quality, and outcomes, including patient safety.

Table 3.1
AHRQ and GPRA Goals for Health Care Costs, Quality, and Outcomes, FY2003

AHRQ Strategic Goal	GPRA Goal
1. Strengthen quality measurement and improvement	To have measurable improvement in the quality and safety of health care for Americans.
2. Support improvements in health outcomes	To have measurable improvement in the type of delivery system or processes by which care is provided and their effects on health care outcomes.
3. Identify strategies to improve access, foster appropriate use, and reduce unnecessary expenditures	To develop the evidence base for policy makers and health systems to use in making decisions about what services to pay for, how to structure those services, and how those services are accessed.

AHRQ PATIENT SAFETY INITIATIVE

Mandates and Expectations Placed on the AHRQ Initiative

Congressional expectations for patient safety mirrored those Congress had for AHRQ in general; specifically, the agency was to support effective research that will lead to improvements in practice. The initiative was started when Congress appropriated $50 million to AHRQ for patient safety activities for FY2001, and an additional $7 million for working conditions was appropriated soon thereafter. Half of the $50 million funding was earmarked by Congress for evaluating demonstrations on reporting of errors and adverse events. AHRQ's approach to obligating the remaining portion was guided by the research agenda that emerged from the National Summit on Patient Safety Research convened by the QuIC in September 2000.

In its response to the IOM report, the QuIC report included the goal recommended by the IOM to achieve a 50 percent reduction in medical errors in five years. However, many informed observers believed that this goal was the wrong one and it would be unachievable, even with optimal funding. There has been growing agreement that the focus should be on reducing patient harm (i.e., adverse events) through more complete reporting of errors followed by practice improvements designed to reduce error rates.[3] In addition, the funding appropriated for patient safety fell short of the amounts recommended by the IOM. By FY2003, AHRQ's patient safety portfolio had increased to approximately $60 million, whereas the IOM report recommended that it be $100 million by that time.

Increasingly, the Office of Management and Budget (OMB) is expecting to see outcome effects from government programs, and it is cutting budget for functions that are not performing. As a result, AHRQ has included more information in its congressional budget justifications on how AHRQ is making a difference. The stakeholders we interviewed expressed differing views regarding such expectations for AHRQ's role, in particular with respect to whether implementation is AHRQ's proper role and whether a research agency should be held accountable for achieving measurable change in the field, especially when traditional standards of evidence (e.g., randomized controlled trials) are difficult to apply to practice improvement.

Defining a Vision for the Initiative

A core AHRQ leadership team, with advice from its National Advisory Council, defined the vision that guided the initial organization and operation of the patient safety initiative. The vision was to place a focus on patient safety as core to AHRQ's business, strive for cross-center synergy and collaboration within AHRQ for patient safety activities, and engage in partnerships within and outside the agency to make safety improvements.

Building an Organizational Structure

Although the IOM report recommended that a Patient Safety Center be established within AHRQ, Congress did not act on that recommendation. In the absence of a congressional mandate, soon after its reauthorization, AHRQ took action internally and changed the Center for

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[3] Actual error rates are extremely difficult to estimate because errors need to be observed and reported before they can be counted. Increasing the rates of reporting for errors or near misses is an essential step in reducing patient harm, by identifying where problems exist in the system so these problems may be corrected.

Quality Measurement and Improvement to the Center for Quality Improvement and Patient Safety (CQuIPS), where it placed the leadership for the patient safety initiative.

At the same time, it was decided that all of the AHRQ centers would participate in the initiative, and project officers in other centers as well as CQuIPS staff were given patient safety projects to manage. This decision was made for several reasons. First, leaders in other centers had a deep interest in being involved in patient safety for its intellectual promise and policy relevance. Second, placing the entire patient safety portfolio in one center would have isolated the rest of the agency from growth in patient safety knowledge and expertise, much of which is transferable to other quality of care issues and translating research into practice. Third, moving all the patient safety activities into one center would have required hiring of new staff for that center, which was not possible due to budget constraints. Finally, involving staff from other centers in the patient safety work would promote strengthening of cross-center collaboration.

Moving the Patient Safety Funding into Research

AHRQ's basic strategy was to fund new patient safety research through a series of RFAs, with all funding decisions under any of the RFAs made through the standard peer-review process. Its first patient safety RFA was for Systems-Related Best Practices demonstration grants, and five grants were funded in FY2000, before Congress appropriated the FY2001 patient safety funding in response to the IOM report, *To Err Is Human*. The FY2001 $50 million appropriation was enacted late, so AHRQ had to balance competing pressures for getting the money obligated on schedule and developing strong requests for applications (RFA). AHRQ issued six RFAs, awarding grants for different types of projects grouped under each RFA. These grants were followed in FY2003 by a set of Challenge Grants, which focused on implementation of proven patient safety practices and risk assessment techniques.

Facilitating Interactions Among Grantees and Between Grantees and AHRQ

AHRQ established the Patient Safety Research Coordinating Center (hereafter called the Coordinating Center) to serve as a stimulus and facilitator of interactions among the grantees, helping to achieve the synergy that would make "the whole initiative greater than the sum of its parts." The three-year Coordinating Center contract was awarded to Westat, a private research and consulting firm, effective October 2001.

AHRQ defined the following tasks for the Coordinating Center: serve as a liaison for interactions between the Reporting Demonstrations and other components of the patient safety initiative; provide technical assistance on methods, analytic mechanisms, dissemination, and evaluation approaches; provide information to assist AHRQ project officers in monitoring the projects; assist with the preparation of AHRQ reports to Congress; facilitate communication and sharing of ideas among projects; disseminate information on project activities and results both among the patient safety researchers and to a broader audience; and consult with AHRQ on trends and developments resulting from the research activities.

In 2002, the Coordinating formed its Center Grantee Steering Committee to provide a vehicle for coordination among the grantee RFA groups and communication with the Coordinating Center. A representative from each grantee group sits on the Steering Committee. As of September 2003, the Steering Committee was developing a strategy for dissemination of project results.

CURRENT GROUPS OF PATIENT SAFETY PROJECTS

As shown in Table 3.2, AHRQ has obligated a total of $160 million over the life of the multiyear grants for projects designated as official components of the patient safety initiative. The patient safety projects funded by AHRQ under the RFAs issued in FY2000 and FY2001 constitute the initial groups of projects in the patient safety initiative, but they represent only part of the patient safety research funded by AHRQ. The names of the groups of projects, as defined by the separate RFAs under which they were funded, are listed in Table 3.2, along with their funding. A total of $141.6 million has been obligated for these grants. Additional detail on these project groups is provided in Appendix A. (We use the term "RFA groups" to refer to these project groups throughout this report.) The minority supplements represent additional funding awarded to the patient safety grants to support research by minority researchers. AHRQ also has funded several contracts and it continues to fund investigator-initiated projects on patient safety issues, as well as patient safety projects performed by the integrated delivery systems and research networks (IDSRNs) and other research networks. A total of $18.4 million has been obligated for these additional grants and contracts.

Table 3.2
Total AHRQ Funding for the Patient Safety Initiative, Obligated in FY2000 and FY2001

Types of Projects	Number of Projects	Total Budget (all project years)	Percentage of FY2001 Grants
Systems-Related Best Practices	6	$ 6,433,099	
FY2001 patient safety projects:		134,887,202	100.0%
Clinical Informatics	11	11,440,770	8.5
Centers of Excellence	3	19,547,890	14.5
Developmental Centers	18	10,019,601	7.4
Dissemination and Education	6	4,923,856	3.7
Reporting Demonstrations	16	68,199,607	50.6
Working Conditions	21	20,755,478	15.4
Minority Supplements	4	315,850	
Total grant project funding	85	141,636,151	
Other patient safety contracts		18,363,849	
Total patient safety funding	230	160,000,000	

Source: Patient safety database provided by CQuIPS, 2003.

In addition, AHRQ and HRSA have collaborated to include five HRSA-funded patient safety projects in the patient safety initiative to enhance opportunities for exchange of information and synergy among the researchers. The HRSA projects began in September 2001, with $2.4 million in funding to develop and test methods for interdisciplinary training on patient safety for medical and nursing students. Two principal investigators for the HRSA projects also have AHRQ-funded patient safety projects.

FINANCIAL RESOURCES AND BUDGETS

The addition of the patient safety funding to the AHRQ budget had predictable effects on its financial profile. As shown in Figure 3.2, patient safety funding has been stable or increasing since the start of the initiative. It increased from 18.4 percent of the AHRQ budget in FY2001 to 24.0 percent in FY2003. Under AHRQ's proposed FY2004 budget, patient safety would become

30.1 percent of the total AHRQ budget. This growth contrasts with declining budgets for other AHRQ research areas.
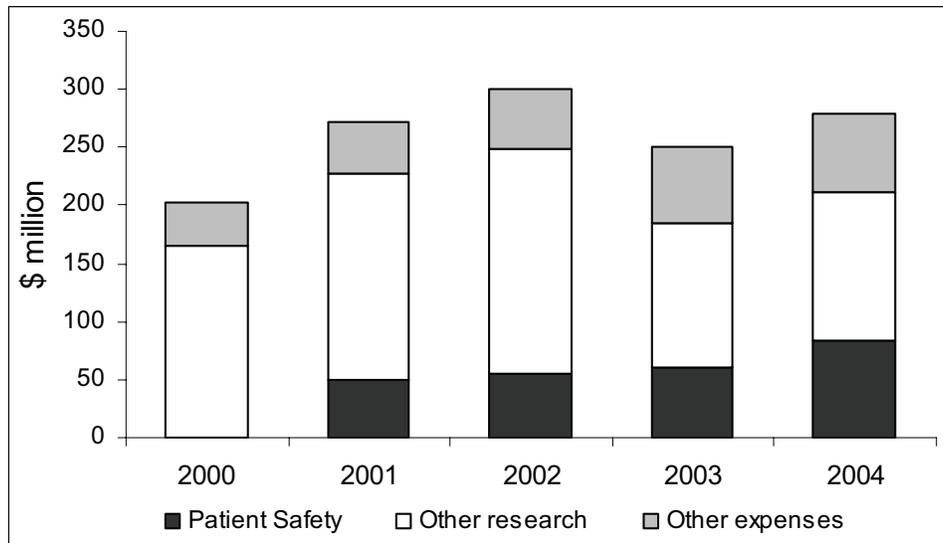
Note: Other research areas include Translating Research Into Practice (TRIP), Consumer Assessment of Health Plans (CAHPS), HCUP, and other quality, cost-effectiveness and intramural research. Other functions include Medical Expenditures Panel Surveys (MEPS), Current Population Survey, and program support.

Figure 3.2 Trends in AHRQ Budgets for Patient Safety and Other Functions, FY2000-2004

The patient safety budget will change markedly in FY2004, when funding for most of the existing patient safety projects ends. The proposed $84 million for FY2004 is intended to fund an entirely new set of patient safety priorities. The emphasis on information technology in the proposed budget extends beyond the $50 million specifically earmarked for hospital-based technology investment to include another $13 million for accelerating diffusion of information ($10 million) and continued work on the Patient Safety Task Force integrated data system ($3 million). Only $16 million remains available for funding of work on the variety of other patient safety issues.

ISSUES TO CONSIDER

In general, both external leaders and the AHRQ staff believe the agency has done an impressive job in starting the patient safety initiative and has taken a productive approach for spending the $50 million on research to generate new knowledge. The patient safety initiative serves as a model for explicitly linking investments in knowledge development in early years to translational and practice improvement activities in later years. Evaluation also is an integral part of the projects funded under the initiative, to assess the effects of patient safety interventions.

In the AHRQ reauthorization, Congress established an expanded role for AHRQ that encompasses not only its traditional role of supporting health care research but also the new role of stimulating changes in health care delivery practices. This new mandate has created ongoing tension between AHRQ's research and implementation functions, within the constraints of a finite budget. As AHRQ increasingly focuses on stimulating the adoption of proven patient safety practices, needed patient safety research is at risk of decline. AHRQ is a small agency, and although the patient safety budget is small relative to its mandate to achieve a safer health care system, it is large relative to AHRQ's overall budget. Some concerns were raised in our stakeholder interviews that the patient safety initiative could crowd out the other programs for which AHRQ is responsible.

The new patient safety information technology grants to be funded in FY2004 will be managed by the Center on Primary Care, Prevention, and Clinical Partnerships. With the rest of the patient safety initiative housed in CQuIPS, this shift in leadership has the potential to integrate cross-center activities across the patient safety initiative. With guidance from the AHRQ leadership to encourage and facilitate cross-center activities, this new component of the patient safety initiative can contribute further to building synergy.

CHAPTER 4. PROCESS EVALUATION:
MONITORING PROGRESS AND MAINTAINING VIGILANCE

> *Establishment and monitoring of measures to assess performance improvement progress for key patient safety processes or outcomes, while maintaining continued vigilance to ensure timely detection and response to issues that represent patient safety risks and hazards.*

For any system to be effective in minimizing risk of harm to patients receiving health care services, it must have the capability to measure and monitor performance on patient safety measures. A well-designed and well-executed monitoring system provides data that can be used for problem identification and assessment as well as for tracking progress in improving patient safety practices.

In this chapter, we review the status of patient safety measures and data as of September 2003, which provides a baseline for tracking future development and monitoring efforts through our process evaluation. We also review the status of patient safety monitoring activities, and we examine how efforts by AHRQ, its funded patient safety projects, the Patient Safety Task Force, and other federal agencies and organizations are helping to strengthen our ability to identify and respond to patient safety issues.

Our evaluation addresses the following research questions with respect to monitoring and vigilance, for which we will continue to track progress during the remainder of the longitudinal evaluation:

- Have generally accepted sets of measures for patient safety events or outcomes been established for health care services in a range of service settings?

- Has a consistent set of standards for patient safety reporting systems, public or private, been established for use by both government agencies and health care providers?

- What is the status of the use of generally accepted patient safety measures for assessing performance as part of accreditation or other credentialing processes?

- To what extent are national-level data available regarding the performance of our health care system on patient safety measures?

- What additional steps need to be taken to move toward achievement of the capability for effective monitoring of patient safety performance?

POLICY CONTEXT

IOM Report

The IOM report, *To Err Is Human*, recommended the establishment of a nationwide system of medical error and adverse-event reporting that includes both mandatory and voluntary components (IOM, 2000). A nationwide mandatory reporting system should provide for the collection of standardized information by state governments about serious adverse events that result in death or serious harm, and should be linked to systems of accountability and made available to the public. The IOM also recommended that more research be conducted to

determine the best way to develop voluntary reporting systems. Such systems would help identify potential precursors to errors, and thus complement proposed mandatory reporting systems. The IOM recommended that Congress extend peer-review protections to data collected through such voluntary reporting systems.

QuIC Response

The QuIC supported the development of a nationwide mandatory reporting system, but identified a number of issues that needed to be addressed before determining the best mechanism for establishment of such a system (QuIC, 2000). The QuIC defined the following actions for creating an environment in which state reporting systems would have more widespread support:

- Evaluate the suitability of existing state and federal reporting systems (both mandatory and voluntary) for helping to build a national system of error reporting, and assess how data collection or enforcement efforts can be enhanced to improve the value of those systems.

- Request the NQF to identify a set of patient safety measures that should be a basic component of any medical error reporting system, laying the foundation for a uniform system of data collection.

- Using the NQF's recommendations for medical error reporting, develop a pilot project through the Medicare Quality Improvement Organization (QIO) program, with up to 100 hospitals volunteering to implement mandatory reporting systems.

- Work with the NQF and states that have mandatory reporting systems to determine how data on medical errors can be collected, validated, and presented to the general public and local policy officials, and to determine the impact of providing such information.

- Describe and disseminate information on characteristics of existing voluntary reporting programs associated with successful error reduction and patient safety improvement efforts.

- Integrate data from different sources and conduct and support analyses to identify error prone procedures, products, and systems.

- Implement a mandatory reporting system in hospitals and clinics operated by the DoD.

- Implement a voluntary reporting system nationwide for VA hospitals for less severe errors and adverse events, all of which already have a mandatory reporting system for severe events.

AHRQ Strategy and Actions

In addressing patient safety reporting and monitoring issues, AHRQ has been pursuing four activities. First, in FY2001, it funded three-year Reporting Demonstration grants (16 grants) that have been evaluating the development and testing of a variety of patient safety reporting systems. Second, AHRQ has been serving as the lead agency for the work of the Patient Safety Task Force to integrate existing federal agency data collection on medical errors and adverse events. Third, AHRQ funded an IOM study on patient safety data standards that is intended to provide the basis for establishment of national measurement and reporting standards for patient safety issues. Finally, AHRQ has supported several projects for the development of patient safety measures, which would be candidates for use by various organizations in monitoring performance of the health care system.

AVAILABILITY OF PATIENT SAFETY MEASURES

At the current time, the health care community has not yet agreed upon a standard set of patient safety measures. This is a difficult task, especially in a new field that has not yet reached general agreement on the scope of the problem, definitions of basic terms, or which measures best represent the most important patient safety issues. Several agencies and private organizations, including AHRQ, have developed various sets of measures that apply to some health care sectors, many of which can be measured with available data. However, little work has been done on development of measures for several key settings, such as ambulatory care and long-term care. Nor has work been done to establish priorities regarding which aspects of patient safety are most critical for patient protection, which would guide selection of measures to monitor performance and progress.

Patient safety measures have been defined as specific quality measures that focus on aspects of patient safety, screening for problems that patients experience as a result of exposure to the health care system and that are likely to be amenable to prevention by changes at the system or provider level (McDonald et al., 2002). We summarize below the various measures and data collection efforts that currently exist and could be integrated into a platform for developing a national data repository.

Patient Safety Measures Developed by AHRQ

AHRQ has supported the development of a set of patient safety indicators using readily available hospital inpatient administrative data, and building upon AHRQ's larger Healthcare Cost and Utilization Project (HCUP) that is measuring the quality of hospital inpatient care and the frequency of patient safety events. These indicators were developed by the Evidence-based Practice Center (EPC) at UCSF and Stanford University, with collaboration from the University of California Davis (UCD) (McDonald et al., 2002). The indicators are intended to serve as a screening tool for further analysis to reduce potentially preventable errors through system or process changes. As of September 2003, it is not known whether states and other health care entities have begun to use the indicators, or how they have used them.

As called for in the 1999 AHRQ reauthorization legislation, AHRQ prepared its first annual report on the quality of health care in the United States in late 2003, working in collaboration with numerous other federal agencies and data sources. Patient safety measures were included as a subset of the quality measures. The patient safety measures were drawn from the HCUP-based patient safety indicators, the Centers for Disease Control and Prevention (CDC) National Nosocomial Infections Surveillance (NNIS) system, and the Medical Expenditure Panel Survey (MEPS).

Sponsored by AHRQ, the National Quality Measures Clearinghouse (NQMC™) is a database and web site that provides information on evidence-based health care quality measures and measure sets, including some measures that address patient safety issues. The NQMC builds on several of AHRQ's previous quality measurement initiatives.

National Quality Forum (NQF) Patient Safety Measures

In May 2003, the NQF issued a report entitled *Serious Reportable Events in Healthcare*, which was prepared in response to a request from QuIC with funding from AHRQ and CMS. The objective was to establish agreement on a set of serious preventable adverse events that could form the basis for a national mandatory state-based reporting system. The NQF consensus

document recommended that a list of 27 serious events, many of which coincide with JCAHO sentinel events, be reported by all licensed health care facilities.

Measures to Monitor Adoption of Safe Practices

In addition to measures of the occurrence or consequences of errors, work has been done on developing measures to monitor the adoption of safe practices, which in turn should yield improvements in outcomes. Two leading examples of these activities are the NQF's set of best practices and the Leapfrog Group patient safety indicators. The NQF best practices, published in its report *Safe Practices for Better Healthcare* (NQF, 2003), draw on information presented in the July 2001 patient safety evidence report and other sources. In addition, the Leapfrog Group established three other measures of patient safety practices for hospitals, and it tracks adoption of these measures by hospitals in an annual survey of hospitals in 22 geographic markets participating in the Leapfrog consortium.

STANDARDS FOR PATIENT SAFETY DATA SYSTEMS

A comprehensive national data repository would coordinate and integrate data on patient safety activities that now is collected and maintained separately in federal, state, and organizational data systems. Goals of this work are to enhance tracking across the country of valid and reliable measures of patient safety processes and outcomes and to eliminate the proliferation of independent reporting systems that providers find burdensome. The formation of such a system depends on having national consistency in data system structures and definitions for events (medical errors, near misses, adverse events).

As discussed in Chapter 3, Thomas and Petersen (2003) suggest that a comprehensive monitoring system should include a combination of measurement methods. They make a distinction between active errors and latent errors, in which an active error is a mistake made in the delivery of care and a latent error is a system defect (e.g., inadequate staffing, poor technology design) that contributes to the occurrence of an active error. Measurement methods such as incident reporting, claims analysis, and morbidity and mortality conferences, are more useful for identifying latent errors, whereas direct observation and clinical surveillance are more useful for identifying active errors and adverse events. Only some of the data generated by health care providers would be candidates for transmission to an external data system.

To be effective, a national repository should have the capability to receive data from several types of sources, which together provide an information base that can detect a larger fraction of errors, near misses, or adverse events than could be detected by any one source alone. Three key types of data have been identified as providing needed "triangulation" to maximize the identification of patient safety events: active reporting of events (e.g., to state reporting systems), analysis of secondary data (e.g., encounter data or health insurance claims), and triggers identified from health records (e.g., data from electronic health records).

AHRQ's strategy has been to move incrementally toward this goal of developing a national data repository capability. It has begun the process by funding two projects on data standards and system integration. The first project, which is being performed by the IOM, is establishing data standards for consistent collection, coding, and classification of patient safety information. The second project is the work of the Patient Safety Task Force, which was charged to establish front-end integration of the patient safety databases of the participating federal agencies. As discussed in Chapter 3, AHRQ has been providing leadership and funding for this project. With

technical work being performed by an outside contractor, the initial focus of the project was to develop an integrated patient safety reporting capability for the FDA and CDC data systems. In addition to these focused projects, 50 percent of the FY2001 funds appropriated for the AHRQ patient safety research portfolio are supporting demonstrations for development and testing of patient safety reporting systems in diverse settings.

USE OF MEASURES IN ACCREDITATION OR CREDENTIALING

Because accreditation and credentialing organizations set standards and measures for performance of health care providers, they can build synergy toward adoption of national patient safety measures and data standards by providing consistent policy direction to providers. Therefore, it is important for these organizations to be active participants in the development of consensus on national measures and standards, and ultimately, to adopt them for their accreditation or credentialing processes. Although many of these organizations already have established patient safety standards for their processes, each has taken a different approach and has used different measures. We summarize below the current status of several organizations that together have a substantial influence on the practices of health care organizations via their accreditation or credentialing processes.

Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

The JCAHO has addressed patient safety in its accreditation process since 1996, when it established its Sentinel Event Policy. It subsequently crafted a comprehensive patient safety policy comprising seven components: establishing National Patient Safety Goals, setting state-of-the-art standards, enforcing its Sentinel Event Policy, issuing *Sentinel Event Alerts*, monitoring sentinel event responses, providing educational resources, and supporting safety-related legislative initiatives.

JCAHO reports that almost 50 percent of its standards are directly related to safety. Additional patient safety standards for hospitals went into effect in July 2001, and for behavioral health care and long-term care organizations in January 2003. Others for ambulatory care and home care organizations were expected in January 2004. Patient safety standards are also being developed for health care networks and assisted living programs.

National Committee on Quality Assurance (NCQA)

NCQA offers accreditation for managed care organizations, managed behavioral health care organizations, preferred provider organizations, disease management programs, new health plans, and other organizations. As of 2001, managed care organizations were required to provide a comprehensive description of how they are addressing patient safety issues. At this time, NCQA's Health Plan Employer and Data Information Set (HEDIS) measures do not include any that directly address patient safety. In 2002, NCQA partnered with the American Medical Group Association and Pharmacia on a Joint Recognition Program to Improve Patient Safety for medical groups.

URAC (also known as the American Accreditation HealthCare Commission)

URAC is a nonprofit accreditation and certification organization that offers 16 different accreditation programs for health care organizations. URAC has a set of core standards that all organizations must meet. The standards say that the organization must have a process in place to respond to any urgent patient safety problems. However, URAC does not have specific

guidelines to make sure that organizations meet that requirement. Additionally, HMOs and PPOs are required to track if individual providers are meeting patient safety requirements, and to have a process in place to remedy problems with individual providers (e.g., revoking privileges). URAC does not track how this is done, only that the organization does it. At this time, URAC does not appear to have specific patient safety measures or standards in its accreditation processes.

Medicare Program Requirements

Conditions of Participation are the requirements that hospitals, other institutional providers, and health plans must meet to participate in Medicare. The Conditions are intended to protect patient health and safety and to ensure that high quality care is provided to all patients. Effective March 2003, a new Condition of Participation was established that requires hospitals participating in Medicare to develop and implement a Quality Assessment and Performance Improvement (QAPI) program that identifies patient safety issues and reduces medical errors.

Performance Standards Set by Other Major Insurers

There is little summary information available about the actions of health insurers to address patient safety issues and performance as part of their contracts with providers in their service networks. To the extent that they are using specific measures to monitor provider performance or are expecting providers to address patient safety measures in their quality improvement activities, fragmentation of expectations is likely. A well-tested set of patient safety measures that represents a consensus in the health care community would help insurers strengthen their expectations for provider performance in patient safety, while enabling providers to work toward consistent standards of performance.

DATA AVAILABILITY ON PATIENT SAFETY PERFORMANCE

Our preliminary scan of organizations and their patient safety data bases highlights the diversity of potential data resources for patient safety monitoring. However, few of these data resources offer representative national-level data on a regular basis, which is needed to be able to track trends consistently over time. Furthermore, organizations with state- or regional-level data systems typically collect data for different measures or define measures in different ways, thus limiting the ability to aggregate data across the systems. We describe here some well-known examples of patient safety data systems.

Statewide Patient Safety Reporting Systems

Fewer than 20 states have established adverse-event reporting systems, virtually all of which were in place before the IOM *To Err Is Human* report was published (Rosenthal et al., 2000; IOM, 2000). These systems contain potentially rich information, most of which does not appear to be used as a resource for estimating incident rates and severity of patient safety risks and consequences. However, the systems vary widely in the sets of measures they track.

The states have identified a number of barriers to maintaining effective adverse-event reporting systems. Measurement issues include variations in incidents being reported across institutions and over time, under-reporting, and differing measurement methods. Two issues with implications for any efforts to achieve cross-state comparisons are (1) incompatibility in definitions of events (e.g., occurrence, incident, serious injury, sentinel event) and (2) conflicts between the need for data specificity to calculate incidence rates and legal requirements to

aggregate data to protect privacy. There also has been a weak focus on improving performance following the events reported by both states and health care providers. The reporting systems themselves are vulnerable due to tight and shrinking budgets as well as political opposition.

Data Systems of Federal Agencies

The DoD Patient Safety Center, in collaboration with several other DoD offices, has developed a Patient Safety Registry to serve as a database for the DoD patient safety program. The registry gathers standardized, clinically relevant information about adverse events and close calls, which will be used to identify and provide feedback on systemic patterns of practices that place patients at risk across the three military services. The DoD reporting system is reportedly operating at 440 facilities worldwide. Staff involved in developing the registry reported that it was a major challenge to implement the program around the world and across the three services. They have not yet been able to fully evaluate the completeness and quality of reporting, and they are unsure whether changes in results from year to year are due to changes in levels of patient safety or levels of reporting. The DoD is also completing development of its new Composite Health Care System (CHCS2), which supports its clinical care processes. CHCS2 will establish electronic medical records for all DoD beneficiaries that can be accessed no matter where they are deployed. When this system is fully operational, the electronic clinical data will substantially enhance the DoD capability for quality and patient safety monitoring.

The VA is operating and continuing to develop the Veterans Health Information Systems and Technology Architecture (V*IST*A)—an automated environment that supports day-to-day operations at local VA health care facilities, including ambulatory and inpatient care. V*IST*A was significantly enhanced in 1997 with the addition of the Computerized Patient Record System (CPRS), which provides a single interface for health care providers to review and update a patient's medical record and to place orders. V*IST*A Imaging is also operational at most VA medical centers, providing a multimedia, online patient record that integrates traditional medical chart information with medical images. The VA formed an agreement with the National Aeronautics and Space Administration (NASA) in May 2000 to jointly develop a Patient Safety Reporting System (PSRS) for their health care facilities. The PSRS is a learning program with guiding principles of voluntary participation, confidentiality protection, and non-punitive reporting that will identify vulnerabilities.

ISSUES AND ACTION OPPORTUNITIES

The ability to measure patient safety events and monitor progress in practice improvements is the lynchpin to achieving safer health care in this country. An effective monitoring and measurement capability based on consistent national standards is essential to (1) provide the feedback and accountability to stimulate practice improvements by health care organizations, and (2) enable AHRQ to fulfill its accountability to Congress for achieving patient safety improvements. Thus, an important task for AHRQ and its partners is to establish a national patient safety data repository that uses consistent sets of measures and data standards, enabling the aggregation of data from a diversity of participating organizations. Design and execution of such a national data resource also is likely to be the most difficult challenge of the patient safety initiative, as it requires both technical expertise and successful collaboration across numerous levels and types of organizations.

In selecting a strategy for moving toward a national patient safety data repository, AHRQ has chosen to acknowledge the multiplicity of organizations and activities involved in patient

safety measurement and reporting, and to craft a data system that leverages these efforts. AHRQ is taking an incremental, multi-pronged approach, with the first projects funded focusing on definition of data standards, evaluation of reporting system demonstrations, development of patient safety measures, and integration of federal agency reporting systems. The groundwork fashioned by these efforts can be used as the basis for further development work, with the goal of ultimately establishing a national data repository for use by multiple health care participants. We agree that both the strategy of building upon existing systems and the incremental approach to implementation are sound approaches that offer the best potential for timely success at reasonable costs.

Issues to Consider

Because the development of a national reporting and monitoring capability is still in its initial stages, our assessment of early progress has focused on documenting the activities undertaken thus far in carrying out the planned work, and identifying issues and considerations to be addressed as the work continues.

Two key structural barriers to an effective patient safety data repository are incompatibility among multiple versions of both patient safety measures (data definitions) and reporting systems (information technology infrastructure). While there are calls by stakeholders for guidance on standards for monitoring and reporting, there is also reluctance by many to change existing reporting systems or to compromise in the design of new ones to comply with national standards.

Because the development of a national data repository is, by definition, a multi-organizational endeavor, this effort should have sponsorship that extends beyond AHRQ alone. As one of the federal agencies, however, AHRQ is in an excellent position to bring together the key stakeholders and to stimulate and facilitate the decision making processes for establishing the needed national standards. With many approaches to choose from and no clear mandate for imposing order, consensus methods should be used to bring stakeholders together on developing common standards and approaches that integrate data across different systems.

Ongoing work by AHRQ, the NQF, and others has yielded a growing number of patient safety measures. Substantial overlap in these measures suggests convergence in thinking about the priority items. However, we still are short of achieving consensus on one set of measures that can serve as the standard basis for measurement of patient safety issues. More work remains to be done on defining and reaching consensus on measures for services provided in other non-hospital settings, including ambulatory care, outpatient diagnostic and treatment services, long-term care, home care, and others.

The various projects that are contributing to technical design of a patient safety data system are completing their work, including the IOM data standards project, the Patient Safety Task Force project to integrate federal agency data systems, and the patient safety reporting demonstrations. As results emerge from these projects, AHRQ and its collaborators will face the challenge of integrating multiple definitions and design options. The IOM standards can serve as an important foundation for integrating patient safety issues into the larger set of quality issues, but we anticipate incompatibilities between the IOM specifications and those now being used in the field. Standards for the integrated federal agency data systems also may have to be modified to incorporate design requirements from other organizations.

Suggestions for AHRQ Action

- **AHRQ should actively facilitate development work toward establishment of a national patient safety data repository, using a structured consensus process to select national measures, develop the data standards and specifications, and delineate procedures for operation of the reporting network.**

AHRQ already has taken the lead in funding and guiding several aspects of work to define measures and build the core of a national patient safety data repository. From this start, AHRQ is beginning to seek collaborations with other public and private organizations to advance the development of a national patient safety data repository. This effort will need to address the diverse needs and priorities by multiple organizations, which are likely to make the consensus process a challenging one. However, a major barrier that could lead to failure is concern by providers that they would have medical liability exposure if they reported data on errors and adverse events to external organizations. This barrier would be removed by the protections provided by the proposed "Patient Safety and Quality Improvement Act," which remained pending in the Congress as of September 2003.

Continued leadership by AHRQ in facilitating the consensus process and design decisions will be essential to successful development of a national data repository. Existing processes, such as the NQF consensus mechanism, might be applied to this development effort. We suggest that AHRQ take the following actions to establish a collaborative approach:

- o Initiate a structured consensus-building process for selection of a set of national patient safety measures. Encourage use of existing sets of measures on which there is consensus, and include them in the process for selecting the full set of patient safety measures.
- o Using a similar consensus approach, establish principles to guide development of a database capability for the national patient safety data repository.
- o Consult with participating organizations to gain an understanding of what will motivate them to report data into a national repository and to identify concerns that might cause them to not participate.
- o Collaboratively define procedures and mechanisms by which health care organizations will submit data into the national repository, and what reports will be generated from the database for use by the public or health care organizations.
- o Prepare agreements with the key stakeholders that define an effective mix of roles of AHRQ, other federal agencies, and private organizations.

- **In identifying candidate measures, AHRQ should ensure that the most important safety aspects of the patient's health care experience are identified and represented by the measures.**

Measures based on the patient's health care experience can be developed by (1) selecting measures that address the key interactions that pose the greatest potential patient safety risks as a patient experiences a need for health care and then moves through the health care system, and (2) obtaining self-reported information from patients about errors or events they have experienced and their perceptions about these events.

- **The process used by UCSF and Stanford University to select the HCUP patient safety indicators should be adapted by AHRQ for selection and definition of the broader set of national patient safety measures.**

The UCSF-Stanford measure development process used clinical judgment, scientific evidence, and technical analysis to select a set of indicators. We suggest that a modified version of this process be used by adding a consensus-building step that allows for additional involvement by diverse stakeholder groups. Selected measures should have face validity from the perspectives not only of clinicians, but also of patients, health plans, various health care organizations, and insurers. The NQF developed its list of 27 serious patient safety events using a consensus process that was supported by AHRQ and CMS. This mechanism also might be used to select the full set of patient safety measures.

- **AHRQ should place a priority on the synthesis it plans to prepare of the knowledge, products, and newly tested reporting systems that will begin to emerge from the Reporting Demonstration projects during FY2004.**

As discussed in Chapter 8, AHRQ is preparing to synthesize the results emerging from the FY2000 and FY2001 patient safety projects, to make the new knowledge developed by the projects available to the health care end-users. Findings of the Reporting Demonstrations are planned to be synthesized as part of this process. Because the Reporting Demonstrations were funded at the same time as the IOM data standards project and a year before the federal agency integrated data system project, the demonstration research teams had to proceed in the absence of national standards for measures or data systems. Therefore, each project's reporting system will be unique, although the systems will share some characteristics. Their results will need to be integrated quickly into the design of the larger national patient safety data repository.

- **AHRQ should invite accreditation and credentialing organizations and insurers to be actively involved in the process for establishing national patient safety measures and designing a reporting network, with the goal of their adopting the measures as standards in their accreditation processes.**

Accreditation and credentialing organizations have an important influence on patient safety practice improvements by holding the accredited health care providers accountable for effective practices. The JCAHO has defined comprehensive patient safety standards in its approval processes, and several other organizations are also developing policies and standards.

CHAPTER 5. PROCESS EVALUATION:
KNOWLEDGE OF EPIDEMIOLOGY OF PATIENT SAFETY RISKS

Identification of medical errors and causes of patient injury in health care delivery, with a focus on populations that are vulnerable because they are compromised in their ability to function as engaged patients during health care delivery.

The overall goals for patient safety epidemiology are to develop the capability to examine levels and variation in incidence rates of errors and adverse events across settings, institutions, regions, and populations, and to track changes in rates over time. Two factors are essential for understanding the epidemiology of patient safety. These are (1) a common understanding of issues that fall under the umbrella of medical errors and patient safety; and (2) scientifically sound methods to measure errors and their causes. Currently, neither of these conditions exists, but progress is being made on both fronts.

This chapter examines what is currently known about the epidemiology of patient safety risks, and how the AHRQ-funded research is contributing to that knowledge base. Our starting point for assessing the current state of knowledge is the epidemiology information presented in the IOM *To Err Is Human* report (2000) and in the UCSF-Stanford evidence report on patient safety practices (Shojania et al., 2001). Next we examine the contribution of papers published more recently in the scientific literature, specifically reviews or databases that offer systematic estimates of the incidence and severity of patient safety risks or adverse events. We use this information to identify gaps in knowledge that require additional research and data collection. Drawing on this information as context, we then examine the extent to which the work of the AHRQ-funded patient safety projects is developing epidemiological information on patient safety issues, and assess its potential for addressing the identified gaps in epidemiological knowledge.

The following key questions are examined this year, and will be revisited in subsequent years of the evaluation:

- What are the priority needs for additional knowledge regarding the epidemiology of errors and adverse events across populations and health care settings?

- In which areas are AHRQ-funded research projects contributing to strengthening the evidence base?

- What additional work is needed to strengthen the evidence regarding epidemiology of errors and adverse events and priorities for interventions to reduce adverse outcomes?

As this four-year evaluation proceeds, this chapter of the report will describe what knowledge is being generated by the AHRQ-funded patient safety projects currently underway. It will also describe progress made toward developing a common taxonomy of consistent terms for patient safety measurement and reporting.

POLICY CONTEXT

IOM Report

In its 2000 report, *To Err Is Human*, the IOM asserted that medical errors are primarily the result of system problems rather than incompetence by individual clinicians. As the first step in achieving reductions in patient safety risks and adverse events, the IOM recommended that AHRQ develop a research agenda, conduct and fund research to assess the magnitude of medical errors, and identify the role of human factors in causing errors. It also recommended testing and evaluating approaches to prevent errors and maintaining a "core set of reporting standards to be used by states, including a nomenclature and taxonomy for reporting" (IOM, 2000).

QuIC Response

The QuIC report stated that the first step in developing a comprehensive approach to error reduction is the identification and monitoring of occurrences of errors in targeted patient populations at greatest risk, followed by development of an understanding of their root causes (QuIC, 2000). It called for the development of standardized definitions of medical errors and adverse events as well as further efforts to collect data, measure medical errors, and understand why medical errors occur. In particular, QuIC recommended that AHRQ establish joint research solicitations on errors with other government agencies, and that federal agencies assist health care providers in developing the skills necessary to analyze adverse events and near misses through root cause analysis, trending, and search tools. The September 2000 QuIC National Summit on Medical Errors and Patient Safety Research identified epidemiology as a research priority and defined goals for knowledge development.

AHRQ Strategy and Actions

AHRQ's CQuIPS has been charged with evaluating methods for identifying medical errors and developing and testing methods for evaluating quality of care and enhancing patient safety (AHRQ, 2003). Many of the patient safety projects funded by AHRQ are making contributions to both methodological development and knowledge of patient safety epidemiology. This work covers types of patient safety issues and health care settings for which little or no previous epidemiological information existed.

MEASURING THE EPIDEMIOLOGY OF PATIENT SAFETY ISSUES

The most immediate challenge for understanding the epidemiology of patient safety issues is to develop a standard definition for medical errors and adverse events. An accompanying challenge is to estimate rates of errors and events using consistent data and methods.

What Is a Medical Error?

The IOM report defined an *error* as "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim." The IOM categorized problems of misuse as a *safety concern*, which it defined as "avoidable complications that prevent patients from receiving full potential benefit of a service." Overuse and underuse of services remain in the domain quality of care. The QuIC report extended the IOM definition of an error to include "… problems in practice, products, procedures, and systems." It also expanded the consideration of errors to include "near misses" or "close calls," incidents that could have resulted in harm but did not because of timely intervention or chance. The definition of medical errors used by AHRQ is "mistakes made in the process of care that result in or have the potential to result in

harm to patients." Mistakes can be the result of an action that is taken (error of commission) or an action that is not taken (error of omission)" (AHRQ, 2003). This is a broader definition of medical errors and may include aspects of overuse and underuse of services.

What Should We Be Measuring?

When examining the epidemiology of patient safety, it is important to define carefully the types of events involved, including medical errors, near misses, and adverse events. For the goal of improving patient safety, the most important events to be tracked are adverse events, which are direct measures of harm to patients. By identifying errors and near misses, and correcting system problems contributing to them, it should be possible to reduce rates of adverse events. As stated in the QuIC report, it is unlikely that we will ever be able to estimate precisely the incidence rate of errors, given the dependency upon humans to recognize that an error has been made, to distinguish this from an adverse outcome from appropriate treatment, and to record the occurrence in the medical record or reporting system (QuIC, 2000). Until there is greater agreement of when an error occurs, the ability to use reporting efforts to generate valid estimates of medical error rates is questionable.

No commonly accepted method of classifying errors, near misses, and adverse events currently exists, and indeed, the QuIC report cautions that a single classification system may not be sufficient for addressing all of the IOM recommendations. Various classifications have been suggested that are based on the type of health care services, severity of the injury, legal definition, type of setting, and type of individual involved. Others focus on medical errors in general (McNutt and Abrams, 2002), adverse drug events (Malpass et al., 1999), nursing care (Woods and Doan-Johnson, 2002; Benner et al., 2002) and primary care (Dovey et al., 2002; Makeham et al., 2002; Elder and Dovey, 2002).

Where Is Epidemiological Data on Patient Safety Obtained?

Epidemiologic data on the incidence of medical errors and adverse events come from a variety of sources, including medical chart reviews, administrative data, medical malpractice claims, state reporting systems, Food and Drug Administration (FDA) adverse-event reports, JCAHO sentinel event reporting system, CDC NNIS System, PSRS in the VA National Center for Patient Safety. Each individual data source underestimates the incidence of medical errors and adverse events (Thomas and Petersen, 2003). In particular, voluntary reporting systems are more likely to yield underestimates than mandatory reporting systems. As discussed in Chapter 4, reporting systems cannot be used alone to generate estimates of the incidence or prevalence of medical errors, but they can provide sufficiently detailed information to identify factors common to errors being reported.

CURRENT KNOWLEDGE OF PATIENT SAFETY EPIDEMIOLOGY

Despite issues of definition and measurement, increased research and reporting activities have generated substantial information on patient safety epidemiology. Table 5.1 summarizes the aspects of patient safety epidemiology that are addressed in each of our information sources, with tabulations of the total number of AHRQ-funded patient safety projects that are developing epidemiological information on each issue.

Epidemiology Synthesized in the IOM Report

The 2000 IOM report, *To Err Is Human*, was the first major summary of the literature on the incidence, severity, costs, and causes of medical errors and adverse events in the United States. This report is the source of the now widely cited and debated estimate that medical errors in hospitals result in 44,000 to 98,000 deaths annually in the United States, making them the eighth leading cause of death (IOM, 2000). Further, these hospital-based events are only a fraction of the total occurring across health care. The report identified many types of patient safety problems, but not much detail was provided on the frequency or severity of these issues. The report focused on two types of studies – patients experiencing non-medication adverse events or those experiencing the more common medication-related adverse events. The studies generally were retrospective in design and used adverse events as the starting point. Because many adverse events do not involve errors and errors not resulting in harm were not included, it is difficult to extrapolate from the results to estimate the incidence and impact of medical errors.

Table 5.1
Patient Safety Epidemiology Information Available from Published Documents and Addressed by AHRQ-Funded Projects

	Addressed in IOM report	Addressed in evidence report	New articles published since 2000	Number of patient safety projects addressing issue
Medication ordering or administration	X	X	41	21
Nosocomial infections	X	X	3	3
Falls, pressure ulcers, restraint related		X	6	3
Nurse staffing		X	3	9
Provider fatigue, working conditions		X	1	12
Surgical or invasive procedure errors	X	X	7	5
Diagnostic or treatment errors	X	X	20	11
General patient safety	X	X	19	34
Other		X	5	5

Epidemiology from the Evidence Report on Patient Safety Practices

The UCSF-Stanford patient safety evidence report (Shojania et al., 2001) provides a more detailed summary for a much broader set of patient safety issues than does the IOM report, including issues related to nursing homes, outpatient care, and adverse events that occur during transport of critically ill patients. However, the epidemiology of each issue is summarized from only a few articles. Therefore, despite its broader content base, the evidence report was not able to present in-depth information for any given issue.

Epidemiology in Recent Published Medical Literature

More than 90 articles were published from 2000 through 2003 that provided information on the rates, types, or causes of medical errors or adverse events.[4] Medication errors were the

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[4] We identified these articles by conducting an electronic search of the MEDLINE database to identify articles published in English through June 2003 using the subject heading *medical errors,* and limiting the search to articles classified with the subheading *statistics & numerical data*. Abstracts were reviewed to identify articles related to the rates of or risk factors for medical errors or adverse events, and to catalog articles into patient safety issue categories. Articles were obtained when content could not be discerned from the abstract.

most frequently studied patient safety issue (43 percent of articles), with over 60 percent of these studies focused on hospitalized patients. Other patient safety issues that were commonly the subjects of epidemiological studies were general patient safety (48 percent) and diagnostic errors (45 percent). Three studies used the AHRQ patient safety indicators to develop information on the national incidence rates for these indicators in hospitals.

In recent years, reviews of patient safety epidemiology have started to appear in the literature. Areas reviewed include medication errors in general and in special populations, emergency medicine, laboratory medicine, and missed diagnoses detected on autopsy. None of the reviews we examined offered information usable for national estimates of medical errors or adverse events.

Specific Gaps in Epidemiology Information on Errors and Patient Safety

More than 75 percent of medical procedures and 60 percent of surgeries are performed in outpatient settings (Hall and Lawrence, 1998; NCHS, 1999), where inadequate infrastructure and numerous handoffs of the patient from one service to another can increase opportunities for error (Hammons et al., 2001). In addition, safety risks may be higher for outpatient care than for inpatient care because outpatient settings have extensive care transitions but also have less regulation, less peer interaction, and less developed policies and procedures specifying requirements to perform specific procedures. As of 2000, little research had been conducted specifically examining patient safety in ambulatory care.

Although it is recognized that underserved and minority populations receive lower quantities and quality of health care than the general population, little is known about whether the care provided to underserved and minority populations is less safe than that provided to the general population. Populations identified as high risk for medication errors include children requiring weight-based dosing of drugs, and the elderly or very ill, who are likely to be on numerous medications that may interact, or for which the patient may have contraindications (IOM, 2000).

CONTRIBUTIONS OF AHRQ-FUNDED RESEARCH PROJECTS

To better understand the potential contributions of the AHRQ-funded research to our knowledge of patient safety epidemiology, we determined the number of projects studying the epidemiology of patient safety (i.e., identifying, tracking, or analyzing the types or frequencies of medical errors or adverse events in any health care setting or examining effects of working conditions, staffing patterns, or worker fatigue) or the underlying causes of medical errors or adverse events (i.e., in a particular institution, health care system, outpatient clinic, or other setting). To be classified as generating knowledge in this area, analysis of epidemiology or contributing causes did not need to be the primary focus of the study. Each project was counted only once within any one category, but may contribute to and be counted in multiple categories.

The patient safety projects funded in FY2000 and FY2001 should add significantly to what is known about the epidemiology and causes of medical errors and adverse events. As shown in Table 5.2, an estimated 38 projects (44 percent) are examining the epidemiology of patient safety issues as part of their research, and 43 projects (50 percent) are performing analyses of contributing causes. A list of these projects is provided in Appendix B. Collectively, these projects will be generating 75 sets of results on various epidemiological issues and 84 sets of results on contributing causes. Additional analysis shows that projects in all of the RFA groups

are contributing to these efforts, with the Reporting Demonstrations (12 projects), Working Conditions (10 projects), Developmental Centers of Excellence in Patient Safety (DCERPS) (10 projects) leading the way. However, as Table 5.3 illustrates, the number of studies targeting epidemiologic issues for specific target populations (e.g., the elderly, minorities, low-income individuals, and those who are vulnerable due to poor health status) is relatively small.

Table 5.2
Patient Safety Issues Addressed by AHRQ-Funded Projects for
Epidemiology or Root Cause Analysis

Patient Safety Issue	Epidemiology		Analysis of Causes	
	Number	Percentage	Number	Percentage
Medication ordering / administration	18	24.0	14	16.7
Nosocomial infections	2	2.7	2	2.4
Falls, pressure ulcers, restraint related	3	4.0	2	2.4
Nurse staffing	6	8.0	7	8.3
Provider fatigue / working conditions	7	9.3	8	9.5
Surgical / invasive procedure errors	4	5.3	4	4.7
Diagnostic or treatment errors	8	10.7	8	9.5
Equipment / device failure	2	2.7	5	6.0
General patient safety	21	28.0	29	34.5
Other	4	5.3	5	6.0
Total number of issues studied	75	100.0	84	100.0
Number of projects studying issues	38		43	

Table 5.3
Special Population Groups for which AHRQ-Funded Projects Address
Patient Safety Epidemiology

Type of Patient Safety Issue	Special Population Group				
	Elderly	Minorities	Low Income	Vulnerable Health Status	Other
Medication ordering, administration	5	6	6	5	2
Nosocomial infections	1				
Falls, pressure ulcers	2	1	1		
Nurse staffing	2			1	
Provider fatigue, working conditions	2	1	1	2	
Surgical, invasive procedure errors					
Diagnostic or treatment errors	1	3	3	4	1
Equipment / device failure	1		1	1	1
General patient safety	5	6	6	3	1

Projects are addressing patient safety epidemiology in a variety of patient care areas and health care settings (data not shown). Patient care areas receiving the greatest focus are pharmaceutical administration, nursing care, and critical care, including pediatric and neonatal intensive care units. Projects are also addressing epidemiological issues in health care settings

other than hospitals, including settings for which little is yet known about patient safety epidemiology.

ISSUES AND ACTION OPPORTUNITIES

Our scan of the available data on the epidemiology of patient safety issues confirms that systematic or consistent estimates of the current incidence and severity of medical errors or adverse events do not yet exist. Numerous published papers report this information for specific issues, health care settings, and geographic locations, but the information has not been synthesized in a way that enables conclusions to be drawn about the country's current patient safety status or the priority issues that merit attention.

The FY2000 and FY2001 patient safety projects are generating important new information on the epidemiology and causes of patient safety risks and hazards for a broad range of issues across a variety of patient care areas and settings. This new information has the potential to contribute substantially to the current state of knowledge of patient safety epidemiology.

Issues to Consider

The epidemiological information generated from the patient safety projects will need to be synthesized and interpreted to enable users to incorporate the information in their patient safety activities. Such a synthesis will enhance AHRQ's ability to "raise the awareness that patients are at risk for iatrogenic injury and harm," and should provide useful information to guide future actions to improve patient safety practices. However, the synthesis is not expected to produce national-level estimates of the epidemiology of patient safety issues. The absence of standards for defining medical errors, near misses, and adverse events, and for measurement of these events, will preclude quantitative synthesis for many of the study results.

The fragmentation of data sources for epidemiological studies is apparent from the work we reviewed. A relatively small fraction of the published work drew upon national or state-level databases, such as HCUP, statewide reporting systems, Medicare, or Medicaid, which would be among the most feasible data sources for a national database. This fragmentation further challenges efforts to aggregate results from multiple studies. The use of the AHRQ patient safety indicators with the HCUP data by three recent studies is an encouraging sign of movement in this direction (Thomas and Petersen, 2003; Bates et al., 1995; Zhan and Miller, 2003). However, the ability of administrative data to identify patient safety problems is also limited.

As discussed in Chapter 4, the successful establishment of a national patient safety data repository would begin to provide the data needed to perform analyses and develop robust estimates of the incidence and severity of patient safety events. Even as such a data capability evolved, however, it would be necessary to manage issues of incomplete data reporting as well as standards for measurement, to achieve valid epidemiological estimates.

Suggestions for AHRQ Action

- **AHRQ should ensure that the results of epidemiological studies by the patient safety projects are summarized in usable forms for a variety of stakeholders and for future decisions on patient safety priorities.**

Summaries and reviews of the projects' results could take multiple forms, focusing on the epidemiology of a particular patient safety issue (e.g., medication errors), a patient population

(e.g., pediatrics), or a health care setting (e.g., nursing homes). Limitations of the estimates should be identified clearly to assist users in interpreting the information correctly.

- **Definitions and standards for measurement methods should be established by AHRQ as the basis for valid and consistent epidemiological estimates for patient safety issues.**

As a federal agency, AHRQ is in a good position to provide the leadership for the development of national standards for measuring patient safety epidemiology by engaging partners in the private and public sector. This work should be an extension of the consensus process for development of national patient safety measures and standards for a national database, which would build upon the existing PSIs and related analyses.

- **AHRQ should fund the development of a review report that summarizes the current state of knowledge on patient safety epidemiology and presents the best available estimates of the incidence and severity of errors and adverse events.**

In addition to a summary of the findings of the patient safety projects, the various organizations working on patient safety issues need an epidemiological resource analogous to the evidence report on patient safety practices. The report should draw upon available data in the published literature, existing reporting systems, Census data, and other national or state data sources, and it should be updated regularly as new science and data become available.

- **Future AHRQ funding for research on patient safety epidemiology should focus on topics that have been addressed least frequently thus far, placing a priority on areas that are high risk for patient harm.**

From our review of the epidemiology research published since 2000 and the work of the patient safety projects, there are a number of issues for which the epidemiology and risk to vulnerable populations have not yet been well addressed (e.g., falls, pressure ulcers, surgical or invasive procedures). Several types of care (e.g., oncology, pediatric, psychiatric, and palliative) and health care settings (e.g., hospital ancillary services, long-term care, and home care) also merit more attention.

CHAPTER 6. PROCESS EVALUATION:
ESTABLISHING EFFECTIVE PATIENT SAFETY PRACTICES

> *Development of new patient safety practices and field testing of these practices, to assess their effectiveness under real world health care conditions and to enhance their effectiveness for broader adoption.*

The development of scientific evidence for patient safety practices has involved two methodological challenges. The first is that the "landscape" of practices that might reduce error rates and patient harm is not clearly bounded. The second is that, for many of these interventions, it is not possible to evaluate performance using traditional scientific methods (e.g., randomized clinical trials), which makes it difficult to establish evidence for their effectiveness.

This chapter describes the state of knowledge regarding which practices have been documented to be effective in reducing medical errors and preventing adverse events in our health care system and, specifically, how the FY2000 and FY2001 patient safety projects are contributing to that knowledge base. We use as the starting point for this analysis the evidence report on patient safety (Shojania et al., 2001) as well as the patient safety practices recommended in the NQF report (2001), which together provide the most comprehensive synthesis of currently available scientific evidence on the effectiveness of patient safety practices. We examine the extent to which the patient safety projects are contributing to expansion of the evidence base on effective practices by mapping the practices they are testing against those covered in the evidence report and NQF report. Using this information, we begin to identify practices for which we still have insufficient evidence to assess effectiveness.

The following key questions are examined this year and will be revisited in subsequent years of the evaluation:

- What do we know from evidence reports and other sources about which practices are or have the potential to be effective in improving patient safety?

- For which patient safety practices do field tests by AHRQ grantees or others offer information to support effective adoption of the practices by the broader health care system?

- What are the field tests documenting regarding effects on patient safety outcomes and the costs, cost effectiveness, and return on investment of the practices being tested?

- What are the field tests learning about barriers or unintended outcomes that need to be managed to introduce tested new practices effectively?

- To what extent are implementation methods and tools being developed and applied to support expanded use of tested practices across provider organizations?

- What additional information from field tests is needed to support the efforts of health care organizations to effectively implement improved patient safety practices?

As the longitudinal evaluation proceeds, this chapter will document what is being learned directly from the projects about the effectiveness of new practices. As results emerge, this new information will contribute to expanding the scientific evidence base regarding these practices.

POLICY CONTEXT

The IOM Report

The 2000 IOM report, *To Err Is Human*, drew attention to the need for additional work to develop and apply knowledge that will make care safer for patients. The IOM report states that AHRQ should evaluate methods for identifying and preventing errors, and fund dissemination and communication activities to improve patient safety (IOM, 2000). The report specifically notes the need to establish a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety.

QuIC Response

In response to the IOM report, the QuIC committed to the following specific actions:

- Under the leadership of the CQuIPS, promote the development and dissemination of evidence-based, best patient-safety practices to provider organizations.

- Test the application of human factors knowledge to the design of health care products, processes and systems; identify best practices in reducing errors; fund patient safety Centers of Research Excellence; and support research and demonstrations on-site, as well as level-of-care and cross-cutting research, such as in diagnostic accuracy, informatics applications, and systems re-engineering.

- Develop tools for the public and private sector to support efforts to enhance patient safety, including identifying tools and approaches from other industries that could be applied to the health care sector and develop community-based settings that can serve as laboratories for error reduction through medical specialty societies, primary care networks, and integrated service delivery networks.

AHRQ Strategy and Actions

In the initial stage of its strategy for expanding knowledge on effective patient safety practices, AHRQ funded the Systems-Related Best Practices projects that started in FY2000 and the six RFA groups of patient safety projects that started in FY2001. It also funded the development of the evidence report on safety practices and the NQF report on patient safety practices. A later focus of AHRQ's efforts was on funding research for field testing and implementing of evidence-based practices and processes that eliminate hazards and reduce the risk of harm. AHRQ is continuing to build evidence on effective patient safety practices by funding additional research on practices for health care issues and settings for which current evidence remains weak.

THE EVIDENCE BASE FOR PRACTICES TO IMPROVE PATIENT SAFETY

Evidence Report on Patient Safety

AHRQ commissioned the evidence-based practice center (EPC) at UCSF–Stanford University 2001 to prepare an evidence report on patient safety practices (called hereafter the "evidence report"). The EPC sought to apply the standard evidence-based medicine

methodology to establish causation, but they recognized this would be difficult for many patient safety practices. For example, research methods such as a double-blind randomized controlled trial are not available or possible for many patient safety practices. In addition, their search for evidence needed to include studies on safety practices employed in non-health care settings, such as aviation (Shojania et al., 2001).

A total of 79 patient safety practices are evaluated in the report, and they are categorized into five groups: greatest, high, medium, low, and lowest strength of evidence regarding impact and effectiveness (Shojania et al., 2001: Table 57). The report also organizes the practices into two research groups: "research likely to be highly beneficial" and "research likely to be beneficial" (Shojania et al., 2001: Table 58). Some practices may not appear in these tables due to a lack of available evidence. Because most available scientific evidence was clinical in nature, practices shown to offer a clear opportunity for patient safety improvement tended to be clinical rather than organizational. In addition, lack of evidence hampered the promotion of certain practices, particularly those outside standard health care, as candidates for further research. Given limited funding that constrained the number of practices that could be studied, the authors chose to begin with those that have shown the greatest promise.

The report was criticized by some researchers for focusing on practices that are medical technology advances rather than systems-related practices, ignoring the IOM Report conclusion that systems approaches are the very practices that will most improve patient safety. Examples of practices omitted from the report are sponge counts in surgery, intraoperative monitoring of anesthesia, checklists, and multi-faceted systems changes. The commentary also contrasted the rigorous evidence requirements applied in the evidence report (though the requirements were relaxed for some practices) and the evidence required for changes made in the areas of anesthesia and aviation, in which practices that made common sense were introduced (Leape et al., 2002). In response to criticism on the evidence standards used, Shojania et al. (2002) emphasized the need for evaluating safety practices, even those that seem to satisfy common sense, citing the example of removing intravenous potassium from wards. Though this practice was well intentioned, the result was the hoarding of the drug on wards, resulting in uncontrolled dispensation.

Although the evidence report has attracted some criticism, it has made a major contribution by clearly delineating those practices for which evidence of effectiveness and efficacy meet the standard of evidence-based medicine decision-making. It has been well received in the health care provider community as supplying a needed resource for identifying patient safety best practices.

Other Sources of Evidence on Effective Practices

We identified three other potential sources of scientific information on the effectiveness of patient safety practices. These are the NQF, the VA, and the SBIR projects on clinical informatics funded by AHRQ. Of these, published systematic information on effective practices was available only from the NQF, although information should become available from the SBIR projects. At least some of the evidence developed by the VA research may be in published papers that are included in the materials used by the EPC to develop the evidence report.

INFORMATION FROM PROJECTS FOR ADOPTION OF NEW PRACTICES

Although it is too early to assess which of the projects funded by AHRQ offer new information to support the effective adoption of practices by the broader health care community, we are able to characterize the types of practices being developed and tested by the projects and how they relate to the practices addressed in the evidence report and the NQF report. We evaluated the 86 projects in the eight RFA groups designated as part of the patient safety project initiative (seven groups of AHRQ-funded projects and one group of HRSA-funded projects). Of these projects, 47 (55 percent) had interventions focusing on developing or testing new practices to improve safety. Projects that are studying more than one type of practice were counted more than once.

Issues, Practices, and Settings Examined by the Patient Safety Projects

As shown in Table 6.1, AHRQ has succeeded in addressing a broad mix of patient safety issues, with many projects working on more than one practice. The issues addressed by the largest number of projects are general patient safety (44 projects) and medications (29 projects). Substantial numbers of projects are addressing most of the other issues identified. Quite a few of the patient safety projects consider patient safety issues for special populations in their work.

Table 6.1
Issues and Special Populations Addressed by Patient Safety Projects

	Number of Issues Addressed	Percentage of Totals
Patient Safety Issues		Of All Issues
Medication ordering, administration	29	18.8
Nosocomial infections	5	3.2
Falls, pressure ulcers, restraint related	7	4.5
Nurse staffing	12	7.8
Provider fatigue, working conditions	16	10.4
Surgical / invasive procedure errors	12	7.8
Diagnostic or treatment errors	18	11.7
Equipment / device failure	5	3.2
General patient safety	44	28.7
Other issues	6	3.9
Total number of issues studied	154	100.0
Average number per project	1.8	
Issues for Special Populations		Of the 86 Projects:
Elderly	18	20.9
Minority populations	19	22.1
Low income	16	18.6
Vulnerable health status	11	12.8
Other vulnerable populations	7	8.1

The types of patient safety actions and health care settings tested by the projects are summarized in Table 6.2. In general, the projects are fairly evenly distributed across the practice categories. The actions addressed by the fewest projects are patient/consumer awareness of patient safety, administrative actions to prevent error, and use of technology to prevent

diagnostic errors. The projects also study practices across a variety of health care settings, although there is some clustering in a few settings. Settings not addressed in much depth by the projects include hospital ancillary services, community-based diagnosis or treatment services, and home care.

Table 6.2
Patient Safety Actions and Settings Addressed by Patient Safety Projects

	Number of Actions or Settings Addressed	Percentage of Total Actions or Settings
Patient Safety Action		
Administrative actions to prevent error	3	0.9
Altering physical environment/infrastructure	12	3.8
Altering staffing/work conditions/scheduling	14	4.4
Causes of errors (root cause analysis)	43	13.6
Effecting change in patient safety culture	17	5.4
Epidemiology of medical errors	38	12.0
Health professional education/awareness	37	11.7
Monitoring/reporting adverse drug events	27	8.5
Monitoring/reporting adverse events	24	7.6
Patient/consumer awareness of patient safety	4	1.2
Patient/family communication of errors	11	3.5
Protocols to prevent non-medication errors	13	4.1
Protocols to prevent medication errors	15	4.7
Provider proficiency/training to prevent errors	27	8.5
Use of technology to prevent diagnostic errors	4	1.2
Use of technology to prevent medication errors	17	5.4
Use of technology to prevent other errors	6	1.9
Other	5	1.6
Total number of actions	317	100.0
Average number per project	3.7	
Health Care Setting		
Outpatient clinic, provider's office	28	21.7
Inpatient acute care	28	21.7
Hospital ancillary	3	2.3
Hospital outpatient diagnosis or treatment	9	7.0
Entire hospital	16	12.4
Community-based diagnosis or treatment	2	1.6
Nursing home or inpatient rehab care	10	7.8
Home care	3	2.3
Health system	15	11.6
Health profession educational setting	14	10.8
Other	1	0.8
Total number of settings	129	100.0

Patient Safety Projects in the Evidence Report and NQF Report

The evidence report and NQF report address a portion of the total range, or landscape, of patient safety practices that exist and might be used to reduce errors and adverse events. To make sound decisions about future funding, AHRQ must identify which of the practices addressed in these reports require further evidence to better document their effectiveness, and which new practices should be explored to begin to establish evidence for them. To accomplish this, AHRQ first must have a clear picture of how the practices being assessed by its current patient safety projects "map" to the patient safety practices described in both reports. Therefore, we analyzed the content of the projects to determine how many were studying practices related to a particular evidence report chapter or NQF practice. We present an overview of our findings here. Additional results are presented in detail in Appendix C.

A total of 50 patient safety projects are testing, studying, or implementing a practice covered in both reports. As shown in Table 6.3, 38 patient safety projects (28 research projects and 10 intervention projects) are expected to contribute to building new knowledge about practices for which additional research is likely to be highly beneficial or beneficial. Projects also are exploring many practices not covered in the evidence report that may prove effective in improving patient safety, which has the potential to fill gaps in the current evidence on patient safety practices, such as incident reporting and root cause analysis. Numerous projects are conducting research in areas where the only evidence that a particular practice reduces the occurrence of errors is in industries outside of medicine, such as promoting a culture of patient safety.

Of the 13 NQF safe practices that do not appear in the evidence report, seven are addressed by at least one patient safety project. The practices that are being studied by the greatest number of projects are related to patient safety culture and nursing staffing.

A total of 42 projects are examining issues and practices that are not addressed at all in the patient safety evidence report, so the knowledge generated by these projects should expand the evidence base yet further. (These projects are not shown in Table 6.3 because the practices they address are not addressed in either the evidence report or the NQF safe practices.) Four of these are focusing entirely on epidemiology or analyses of the causes of patient safety issues; the remaining 38 are working across a variety of practices involving education/training, monitoring or reporting errors, infrastructure, protocols to prevent errors, etc.

These positive findings show that the AHRQ-funded patient safety projects have the potential to expand the evidence base on patient safety practices. These results are notable when considered in the context of the chronology of activities early in the patient safety initiative. Decisions on funding these projects were made in the same time period that AHRQ funded the development of the evidence report. Therefore, AHRQ and its reviewers did not have the evidence report information to help guide funding decisions. The choices on mix of projects were guided primarily by the recommendations in the QuIC report. The fact that the funded projects indeed are covering practices for which the evidence report determined more evidence was needed suggests there was some shared understanding on research needs, even in the absence of the formal assessment provided by the evidence report.

Table 6.3
Number of AHRQ Projects Covering Evidence Report Chapters and NQF Safe Practices

Name of Detailed Table	# of research projects testing or studying the practices	#of intervention projects implementing the practices
Evidence Report: Impact and Effectiveness		
Greatest strength of evidence	0	0
High strength of evidence	14 [1]	1
Medium strength of evidence	5	5
Lower impact or strength of evidence	11	4
Lowest impact or strength of evidence	0	0
Evidence Report: Further Research		
Likely to be highly beneficial	17 [2]	6
Likely to be beneficial	11	4
Evidence Report: Not Rated, But Covered in Projects	63 [3]	45 [5]
NQF-Endorsed Safe Practices		
In the evidence report	34 [4]	16 [6]
Not in the evidence report	5	2

[1] Eleven of the research projects and one of the intervention projects in this set are related to evidence report Chapter 39: Changes in Nursing Staffing.

[2] Eleven of the research projects and three of the intervention projects in this set of projects are related to evidence report Chapter 39: Changes in Nursing Staffing.

[3] Sixteen of the research projects in this set of projects are related to evidence report Chapter 40: Promoting a Culture of Safety; nine relate to Chapter 4: Incident Reporting; and seven relate to Chapter 42: Information Transfer.

[4] Sixteen of the research projects in this set of projects are related to NQF Safe Practice #1/ evidence report Chapter 40: Create a Healthcare Culture of Safety; and 11 relate to NQF Safe Practice #3/ evidence report Chapter 39: Specify an Explicit Protocol Be Used to Ensure an Adequate Level of Nursing.

[5] Sixteen of the intervention projects in this set of projects are related to evidence report Chapter 4: Incident Reporting; and seven relate to Chapter 40: Promoting a Culture of Safety.

[6] Seven of the intervention projects in this set of projects are related to NQF Safe Practice #1/ evidence report Chapter 40: Create a Healthcare Culture of Safety; and one relates to NQF Safe Practice #3/ evidence report Chapter 39: Specify an Explicit Protocol Be Used to Ensure an Adequate Level of Nursing.

COST, COST EFFECTIVENESS, AND RETURN ON INVESTMENT

In addition to determining the effects on patient safety outcomes, information about whether and how to adopt a new practice in a particular setting is vital to end-users. Once a practice has been determined to be effective, decision makers then need answers to the following key questions: (1) what is the cost of implementing the practice, (2) is the practice cost effective relative to other practice options, and (3) what is the short-term gain and ultimate return on investment (ROI) for the provider from implementing the practice? Included in any cost effectiveness assessment should be consideration of the risk that a new practice might introduce new opportunities for error.

Because the majority of the current patient safety projects are still in process, they could collect this information between now and the end of their research. While some of the RFAs specifically requested that grantees work to supply information on costs and ROI, it is not clear how many of the grantees are capturing this information.

BARRIERS AND UNINTENDED OUTCOMES

By reviewing the barriers or unintended outcomes involved in implementing a specific patient safety practice and developing strategies to overcome them, AHRQ and other facilitating organizations can help health care organizations introduce new practices more effectively. From the interviews that we conducted with project principal investigators, we have information about the barriers they have encountered in carrying out their research.

We asked each of the grantees whether they had made any significant changes, either in tasks or in timeline, to their project work plans from what was originally proposed. Of the 83 grantees who answered this question, 67 (81 percent) reported they made changes to their projects. The most commonly reportedly change in plans was a delay in project timeline. Reasons cited for the delays included (1) technology problems and barriers; (2) recruiting and staffing difficulties; (3) changes in research team membership and PI affiliations; (4) challenges in coordinating across multiple sites; (5) inconsistency in cooperation by outside partner organizations; (6) IRB problems; and (7) legal issues related to HIPAA and/or malpractice. Project delays were also reported in connection with more conventional research problems, such as difficulty in refining survey instruments, or in obtaining and refining outside datasets.

The other difficulty most commonly encountered by the grantees was the challenge of collaborating effectively with outside partner organizations, and coordinating across multiple sites (24 grantees identified this issue). The grantees reported that they addressed these problems by hiring appropriate personnel, building relationships with key contacts, and efforts to communicate effectively while responding to the concerns and needs of their partners.

ADDITIONAL INFORMATION NEEDED FROM FIELD TESTS

At this early stage of the research and intervention projects, it is premature to address questions regarding the content of their results. Therefore, the following two evaluation questions listed at the beginning of this chapter cannot yet be answered:

- To what extent are implementation methods and tools being developed and applied to support expansion of use of tested practices across provider organizations?

- What additional information from field tests is needed to support the efforts of health care organizations to effectively implement improved patient safety practices?

These questions can stimulate preparation for implementation activities as the projects begin to generate their results and products. Effective support tools for a new practice or technology should include practical information about what is required to actually make it function effectively. Beyond information on costs, ROI, and barriers, end-users would benefit greatly from having well-documented steps in the implementation process that serve as a "how to" guide for carrying out the intervention, including technical details that will need to be managed, time required to implement the practice, and the resources that will be required to make the implementation a success. By establishing a mechanism by which technical support and assistance can be made available to health care practitioners and organizations during these early stages of implementation, AHRQ can play a critical role in facilitating the change process.

ISSUES AND ACTION OPPORTUNITIES

Our review of the patient safety projects indicates that they are well positioned to expand the scientific evidence on the effectiveness of practices for improving patient safety, including

issues of importance to vulnerable populations, specific practices that the patient safety evidence report identified as in need of further research, and substantial numbers of practices not rated by the evidence report.

Issues to Consider

Establishing an evidence base for effective patient safety practices and tools is a multiyear research investment that requires contributions from multiple parties. AHRQ provides national leadership and significant financial support in this area, but investment by and partnerships with other organizations are also required. The preliminary information from our assessment is encouraging because it confirms that new ground is being covered, and it identifies several areas where further practice development and testing are needed. However, a full assessment of the contributions of the patient safety projects to the evidence base cannot be made until the projects publish their results. AHRQ and other stakeholders should focus future research on the practices for which the need for more evidence is greatest.

The early feedback from the patient safety projects regarding the barriers or challenges they encountered in their research offers some insights that AHRQ can apply to future work. In particular, there was a recurring theme of delays when working with new technologies, which will be salient for the information technology projects that AHRQ plans to fund in FY2004. The projects also reported operational and technical coordination problems among multiple organizations involved in their work. Such issues can be expected to be commonplace in implementation initiatives to stimulate adoption of improved practices.

Suggestions for AHRQ Action

- **As the AHRQ-funded patient safety projects and other research generate new evidence on the effective practices, AHRQ should update the evidence report on patient safety to incorporate this evidence and should make the evidence information readily available to users through web-based and other communication media.**

The large amount of research funded by AHRQ and other organizations has accelerated the science of patient safety practice. The evidence report should be updated regularly to keep the evidence base as current as possible, including findings from the patient safety portfolio, other AHRQ-funded projects, work of the VA and others, and projects funded by foundations.

- **AHRQ should commit resources to define the standards of evidence that should apply for assessing the effectiveness of patient safety practices, and to determine methods for prioritizing which practices should be implemented.**

The criticisms of the patient safety evidence report raise valid points regarding the inability to apply traditional standards of evidence to many patient safety practices. Where strict standards of evidence can be applied, such as for clinical practices or technological interventions, they should be used. But alternative, scientifically defensible standards are badly needed to guide use of other available methods (e.g., quasi-experimental designs) for assessing many of the non-clinical interventions that are so important for patient safety, especially systems-based interventions involving multiple changes to health care processes.

- **Future AHRQ research funding should focus on testing patient safety practices that are promising, but for which evidence regarding their effects on safety outcomes is lacking or insufficient.**

Even as this report was being prepared in late 2003, AHRQ continued to move forward in expanding the patient safety initiative by awarding additional patient safety grants, and the introduction of the health information technology grants in FY2004 will expand it yet further. We expect that these projects also will contribute to strengthening the base of knowledge on patient safety practices.

As decisions are made on funding future research, projects should be funded that focus on the patient safety issues, types of care, and care settings that are most in need of information on effective practices. Information from the evidence report and the current patient safety projects should be used to pinpoint areas where limited funding can best be invested. Our preliminary assessment suggests that the following practices require additional research:

- o Reporting errors or events to patients and families, and the role and validation of the informed consumer in reducing risk and preventing harm
- o Practices for safe care for vulnerable populations
- o Administrative actions to prevent errors
- o Use of technology to prevent non-medication errors
- o Practices in ambulatory care, long-term care, and home care
- o Other practices for which research is likely to be beneficial, as identified in the evidence report.

- **AHRQ should support work to document the costs, cost effectiveness, and return on investment of promising patient safety practices to make the business case for their adoption in the field.**

Health care organizations want to know not only the effectiveness of a potential new practice or technology but also its financial implications for the organization. Making the business case will be essential to achieving adoption of the new patient safety practices being studied by the AHRQ-funded projects, regardless of how effective they have been documented to be.

- **To support health care organizations in adopting evidence-based patient safety practices, AHRQ should collaborate with users to establish implementation guides and tools with practical "how to" information that reduce barriers to implementation progress.**

To ensure successful adoption of patient safety practices beyond the "field test" environment, end-users need to know what works in practice and what issues they need to manage. Working in partnership with users in the health care community, AHRQ should arrange for the development of "how to" materials containing practical information for end-users by drawing upon products and lessons from the projects it has funded, as well as the 30 safe practices identified by the NQF. Various applications of the practices also could be field-tested by AHRQ's existing research networks to generate additional information.

CHAPTER 7. PROCESS EVALUATION:
BUILDING INFRASTRUCTURE FOR EFFECTIVE PRACTICES

Establishment of the health care structural and environmental elements needed for successful implementation of effective patient safety practices, including an organization's commitment and readiness to improve patient safety (e.g., culture, information systems), hazards to safety created by the organization's structure (e.g., physical configurations, procedural requirements), and effects of the macro-environment on the organization's ability to act (e.g., legal and payment issues).

Patient safety infrastructure is a broad concept that includes capabilities at both the national level (e.g., research capacity to generate new knowledge on effective practices, a national reporting and monitoring system) and within local health care delivery organizations (e.g., information systems, a patient safety–oriented culture). Another part of infrastructure, which we refer to as the "macro-environment," encompasses external regulatory and market forces that influence patient safety activities. The existence of a basic infrastructure is essential for efforts to improve patient safety.

During the first two years of the patient safety program, AHRQ has focused resources on supporting projects that build the capacity to conduct research on patient safety and that expand our knowledge base on patient safety issues and practices. As the program has matured, AHRQ has been turning its attention to expanding the infrastructure through the health system, using the knowledge gained from this work.

In this chapter, we review the policy context and what is known about elements of effective patient safety infrastructure. We then discuss AHRQ's strategy for building infrastructure and assess how its current and planned projects and activities are contributing to these goals. Our assessment draws upon information from a variety of data sources, including published documents, interviews and focus groups with AHRQ staff and grantees, and interviews with other key informants in the public and private sector.

Key questions we examine this year and will revisit over the four-year evaluation are:

- What is known about the following structural and environmental elements that need to be in place to support effective patient safety practices in a health care organization?
  - Patient safety culture
  - Information systems
  - Adverse-event reporting systems
  - Interdisciplinary teams
  - Multi-institutional collaborations
  - Quality improvement systems and measures through which improved patient safety practices would be implemented

- How are AHRQ and its funded patient safety projects contributing to establishment of infrastructure to support patient safety in health care organizations across the country?

- What have we learned from existing research and practice networks funded by AHRQ about how to establish infrastructures that stimulate and support effective practices?

- What additional research or development work is needed to strengthen effective infrastructures for patient safety practices in the health care system?

Because most projects are still underway and results are pending, our assessment of performance during this year focuses on establishing baseline information on early activities to which future developments and activities will be compared.

POLICY CONTEXT

IOM Report

The 2000 IOM report, *To Err Is Human*, provided a sobering assessment of the lack of basic infrastructure necessary to reduce medical errors and ensure patient safety. The report cited a wide diversity of factors that likely contribute to medical errors and suggested a variety of changes in existing structures and practices within the health care system necessary to improve patient safety. Many of these suggestions related to infrastructure and were targeted to a variety of stakeholders. The relatively few recommendations pertaining to infrastructure that were directed at AHRQ included the following:

- Establish an effective nationwide reporting system with both mandatory and voluntary components, and convene states to share information and expertise

- Encourage the development of voluntary reporting efforts, and fund and evaluate pilot projects for reporting systems both within individual health care organizations and collaborative efforts among health care organizations

- Work with professional societies to develop community-based, collaborative initiatives for error reporting and analyses and implementation of patient safety improvements.

Implicit in the role envisioned for AHRQ was an expectation that it would help coordinate diverse efforts across a variety of public and private sector stakeholders. In this respect, many of the other IOM recommendations directed at other organizations were also meant to inform AHRQ's approach to patient safety. Examples are recommendations to health care organizations and professionals to "implement non-punitive systems for reporting and analyzing error within their organizations" or to "establish interdisciplinary team training programs for providers that incorporate proven methods of training" (IOM, 2000).

QuIC Response

In its response to the IOM report, the QuIC noted that the majority of the IOM's recommendations would require joint efforts involving a broad array of public, state, and private partners. Among the more than 100 specific action items in the QuIC report, many related directly or indirectly to improving patient safety infrastructure.

The QuIC called for AHRQ to convene national conferences and expert meetings within one year to set a coordinated research agenda and develop adequate reporting mechanisms (QuIC Report, 2000). With respect to learning from errors, AHRQ was to investigate, develop, and test strategies to provide feedback to clinicians and institutions on methods for improving patient

safety (QuIC Report, 2000). Similarly, AHRQ was to work with other federal agencies to expand research aimed at developing or evaluating informatics systems to identify, track, and address patient safety concerns and to evaluate the effectiveness of physician order entry systems.

AHRQ Strategy and Actions

AHRQ's patient safety strategy includes actions to help strengthen the infrastructure needed for improving patient safety performance in the health care community. One component is the funding of infrastructure-building as part of the patient safety research grants it funded. Another component is the support of networks organized by health care organizations that integrate research capabilities into delivery systems. AHRQ funding for these networks has included support for research and development work on patient safety issues. AHRQ intends to expand the role of these networks for testing patient safety implementation initiatives as part of its activities to disseminate products generated by the patient safety grants.

KNOWLEDGE ABOUT INFRASTRUCTURE FOR PATIENT SAFETY PRACTICES

At the time that the IOM report, *To Err Is Human*, was released in 2000, there already was a significant body of knowledge about the key elements of an effective patient safety infrastructure. In many instances, this knowledge was still largely anecdotal or descriptive. In others there was compelling evidence for these structures or practices based on solid data, particularly from examples outside the health industry (Leape et al., 2002). This literature has expanded in the four years since the IOM report, in part due to AHRQ's efforts, but many questions remain unanswered. We highlight below some of these key elements.

Patient Safety Culture

Beginning in the mid-1990s, there has been a fairly rapid paradigm shift in patient safety, from an emphasis on the role of individual failure to a focus on systems failures as the more important cause of patient harm (Leape, 1994). A positive safety culture can greatly increase reporting of errors and efforts to reduce them by affording some protections from litigation or penalties within an organization (IOM, 2000). There also has been growing recognition of the negative effects that a culture focusing on blame and punishment can have on efforts to improve patient safety. Although there is consensus about the importance of a positive safety culture, there is far less agreement about how best to foster meaningful cultural change. There also is little information about the extent of progress that health care organizations have made toward creating effective patient safety cultures.

Information Systems

Well-designed information systems can greatly reduce many types of medical errors. Information systems can present providers with timely reminders of key aspects of care that have not been performed or warnings about potential problems (e.g., drug interaction or critical lab value). Although some health care systems or organizations, such as the VA, have already implemented relatively advanced information systems (Corrigan et al., 2002), most providers lack this infrastructure. Implementation of information systems has proven to be quite challenging and expensive, in part due to human factors associated with their use as well as lack of usable off-the-shelf systems. For example, computerized order entry systems have proven to be a reliable way to reduce medication errors in some settings, but poorly designed or implemented systems may introduce new errors. Further study is needed to identify the most

effective ways to achieve the full potential value of information technology while managing its potential risks.

Adverse-Event Reporting Systems

Event reporting systems are useful for identifying errors and understanding factors underlying them, both within health care organizations and for external oversight (Leape, 2002). Adverse-event reporting mechanisms can be designed for two purposes: (1) as part of a (usually mandatory) public system for reporting serious events that threaten or cause patient harm; and (2) as a voluntary, confidential system, typically within an institutional program for improving patient safety. For either purpose, the goal is to analyze the information collected to identify ways to prevent future errors (IOM, 2000). Although there is general consensus that reporting systems are essential to patient safety improvement efforts, the optimal features and implementation of such systems remain less clear.

Interdisciplinary Teamwork

Training of teams of clinical staff to enhance teamwork in key health care procedures (e.g., labor and delivery, surgery) is effective in reducing errors and safety problems in a variety of complex settings. For example, a crew resource management approach in the aviation industry has been highly effective in reducing safety problems (IOM, 2000). Such approaches have been uncommon in the health care sector, where unspoken hierarchies may undermine effective teamwork that can prevent errors. Many patient safety experts, including those who wrote the IOM report, recommend establishing interdisciplinary training programs that incorporate a mix of management styles and skills.

Multi-Institutional Collaborations

Collaborations among health care institutions allow opportunities for synergy in patient safety efforts, and particularly in the development of adverse-event reporting systems. Multi-institutional collaborations allow participants to leverage their own technical capabilities with those of their partners, while creating a larger volume of collective adverse-event data for analysis and use in quality improvement processes. By aggregating patient safety data for analysis across multiple organizations or settings of care, patterns in adverse events can be detected that would not be observable with a smaller database. Aggregated data also can facilitate comparisons of adverse events across different organizations within a single care domain. As discussed in Chapter 4, however, valid and complete data, as well as consistent data standards, are needed to achieve data aggregation across organizations.

Quality Improvement Systems and Measures

Patient safety problems represent one facet of the quality of health care, and many of the issues surrounding quality improvement described in the *Quality Chasm* report (IOM, 2002) are directly applicable to improving patient safety practices. Continuous quality improvement processes consist of regular, incremental changes made to improve practices, guided by measurement, monitoring, and feedback on performance (Imai, 1986). In particular, success in making improvements depends strongly on effective monitoring and reporting of performance by establishing transparency of information and accountability. Use of quality improvement methods in health care grew substantially in the 1990s. Thus far, however, health care organizations have had limited success in achieving measurable improvements in health care

processes or outcomes, often due to inadequate follow-through in implementing practice changes (Solberg et al., 1998; Kilgore et al., 1999; Gallet et al., 2000; Laurila et al., 2001).

INFRASTRUCTURE BEING BUILT BY THE PATIENT SAFETY PROJECTS

The FY2000 and FY2001 patient safety projects are addressing several aspects of infrastructure, and they offer strong potential to contribute to enhancement of the infrastructure in the health care system. Table 7.1 summarizes the infrastructure components being targeted by each RFA project group. Because most of the projects are still in progress and their empirical results not yet known, it is premature to draw firm conclusions about the contributions of individual projects. Nevertheless, the aims and preliminary activities from a number of projects are revealing.

Table 7.1
Patient Safety Infrastructure Components Addressed by
the FY2000 and FY2001 Patient Safety Projects

Type of Project	Number of Grantees	Patient safety culture	Information systems	Adverse-event reporting systems	Interdisciplinary teams	Multi-institutional collaborations	Quality improvement systems
Patient safety grantees:							
Centers of excellence	3	X	X	X	X	X	X
Developmental centers (DCERPS)	18	X	X	X	X	X	X
Reporting demonstrations	16		X	X			X
Clinical informatics	11		X				X
Working conditions	21				X		
Dissemination and education	6	X			X		X
HRSA clinical training	5	X			X		
Survey instruments:							
Culture survey	1	X					
Adverse-event reporting system survey	1			X			
Patient safety network for reporting	1		X	X		X	

Reporting Demonstrations

The Reporting Demonstrations are evaluating large demonstrations of patient safety reporting systems in states, health care systems, and networks of providers, to evaluate adverse-event reporting strategies and related patient safety interventions. Many Reporting Demonstrations contribute directly to refinement of public health reporting infrastructures. Several of these projects are also noteworthy for the partnerships undertaken between AHRQ and state-sponsored reporting systems, which will help ensure the continuation of reporting system refinements beyond the period of the AHRQ funding. Lessons from the Reporting Demonstrations about barriers and issues they encounter during the course of their work could become the topics of future research on patient safety infrastructure.

Centers of Excellence and Developmental Centers in Patient Safety Research

The two patient safety RFA groups with a primary focus on infrastructure development are the three Centers of Excellence (CoEs) and 18 DCERPS. These projects respond to a core recommendation of the 2000 IOM report calling for establishment of research centers to ensure multidisciplinary research capacity dedicated to patient safety problems and interventions. The CoEs are designed to enhance patient safety through the development of new assessment tools and technologies, conduct of demonstration projects, formulation of new educational programs, and dissemination of fundamental and applied research results. AHRQ is using the DCERPS mechanism to foster the growth of new multidisciplinary patient safety research centers, with the goal of their attaining the level of capability of the CoEs. All the DCERPS are engaged in building their infrastructure and pursuing patient safety pilot studies. Their sustainability is likely to depend, in significant measure, on continued funding to support their maturation and ongoing research.

The work of the CoEs and DCERPS was still underway as of September 2003, so they had not yet generated products that could be assessed for substantive contributions to patient safety improvements. The very establishment and operation of the interdisciplinary centers, however, are key infrastructure products. They also potentially offer a secondary infrastructure contribution through their long-term commitment to encouraging implementation and dissemination of patient safety knowledge and techniques in the health care community.

Clinical Informatics to Promote Patient Safety (CLIPS)

The CLIPS group of grants was funded to examine the role of computerized decision support systems and clinical informatics applications in promoting patient safety and reducing error. Many of the CLIPS projects are relevant to infrastructure because they involve the development and evaluation of new technologies that support clinical practice, which could become integrated into the health care infrastructure over time. Their ultimate contribution to infrastructure development depends on how successfully they are disseminated and adopted across broader organizations and settings. Costs and ROI will be important drivers of adoption decisions by providers and insurers.

Working Conditions

AHRQ funded the Working Conditions grants to strengthen the scientific evidence on the nature and severity of effects that health care workplace conditions have on quality of care and patient safety, and to identify improvements in working conditions that health care organizations can be encouraged to adopt. Improving health care working conditions will require both effective dissemination of research findings on the evidence for change and making a business case for adoption of improved workplace standards or practices by health care organizations. Many of the projects recognize this, and have been examining both effects and costs for the issues they are studying.

HRSA Interdisciplinary Clinical Training

The five patient safety projects funded by HRSA contribute to building the clinical resources aspect of infrastructure through interdisciplinary training on patient safety for medical and nursing students. Each project is experimenting with a different training model, including joint activities between medical and nursing schools as well as community-based approaches. Many of them report difficulties in getting separate educational institutions, each with its own

tradition and educational approach, to compromise on the design and schedules for shared educational programs. Such barriers are likely to persist as efforts to integrate patient safety into clinical education are expanded.

INFRASTRUCTURE BUILDING BY AHRQ SYSTEMS PROJECTS AND ACTIVITIES

Integrated Research and Delivery Networks

AHRQ has established four different types of networks of organizations to serve as interdisciplinary mechanisms for focused research and development work in health services delivery and quality improvement. AHRQ's other systems projects and collaborative partnerships also offer possibilities for synergy and leveraging of resources. As described below, these mechanisms offer established infrastructures with experience in bringing effective new practices into the field, and have substantial potential to serve as active partners in the implementation of effective new patient safety practices that emerge from the current research.

 (1) The Integrated Delivery System Research Network (IDSRN). The IDSRNs are networks based on integrated delivery systems that link the nation's top researchers with some of the largest health care systems to conduct research on cutting-edge issues in health care on an accelerated timetable. AHRQ awarded five-year master contracts to nine IDSRNs in 2000, through which specific projects are funded under a task order mechanism. Collectively, the IDSRNs provide health services in a wide variety of settings to over 55 million Americans. For purposes of research, they capitalize on the rich databases and abundant opportunities for applied investigation that integrated delivery systems offer. The IDSRNs are an important resource for studying patient safety risks and hazards, and task orders have been awarded for 16 IDSRN projects that address aspects of patient safety.

AHRQ has begun to take steps to integrate IDSRN activities more closely with those of other centers within the Agency, and the IDSRNs offer yet further potential. To date, most patient safety projects funded for IDSRNs have been for research, with only a few funded to field test patient safety practices. As AHRQ increasingly pursues applied research and field testing of patient safety practices, products, and tools, the IDSRNs are well positioned to contribute substantially more capability to this initiative.

 (2) Practice-Based Research Network (PBRN). As a research resource, AHRQ's PBRNs offer an impressive network of community-based providers in ambulatory care settings. As of 2000, AHRQ supported 19 PBRNs, comprising more than 5,000 primary care clinicians across 49 states and serving almost 7 million patients. Several of the patient safety Reporting Demonstration projects involve PBRNs as participants in reporting systems being tested. The PBRNs are potentially strong resources for field applications of patient safety practices.

 (3) HIV Research Network (HRN). The HRNs presently include 18 medical institutions that treat more than 16,000 patients with HIV disease across the United States. These institutions are gathering and analyzing data on a number of patient safety variables for this vulnerable population, including drug adherence and side effects, adverse drug reactions, aspects of physician-patient communication, and incidence rates for Pneumocystis carinii pneumonia and Mycobacterium avium complex (complications associated with advanced HIV disease). The HRNs also have developed a network intranet site, where members can exchange information on best practices to minimize the risk of errors.

(4) Centers for Education and Research on Therapeutics (CERTs). These centers constitute a national demonstration program to conduct research and provide education to advance the optimal use of therapeutics (e.g., drugs, medical devices, and biological products). The program consists of seven centers and a coordinating center that are funded under AHRQ cooperative agreements. AHRQ administers the program in consultation with the FDA. Each of the CERTs is actively engaged in patient safety research through supplements to its core grant. Two CERTs have also received patient safety grants from AHRQ; one is a CoE grantee and the other is a Reporting Demonstration grantee.

Training Grants for Developing Researchers

One aspect of building patient safety infrastructure through research capacity involves supporting the development of new patient safety researchers. Through a series of established training grant mechanisms, AHRQ has dedicated funds specifically to support this effort. For example, AHRQ has granted dissertation support awards to young researchers working toward their graduate degrees, and career development awards for junior researchers who show potential for conducting patient safety research. AHRQ also supported established researchers seeking to refocus themselves on patient safety, having funded nine training grants in patient safety.

Patient Safety Improvement Corps (PSIC)

PSIC is an AHRQ and VA partnership that began in FY2003 to improve patient safety through professional education. Program content for the PSIC focuses on the practical application of patient safety science, human factors, measurement, evaluation, organizational theory, safety culture, change implementation and management, medical errors reporting and analysis, medical legal issues, and tools. By focusing training on professionals who can apply and disseminate these sorts of patient safety techniques in their home institutions, PSIC aspires to promote broad implementation of established patient safety practices. AHRQ plans to train a team in every state by the end of the initial training program. As of September 2003, 15 states have teams in the training program. Once the initial training program is complete, AHRQ plans to move on to a train the trainer program.

Evaluation of DoD Team Training Activities

Interdisciplinary team training is specifically addressed in the 2000 IOM report. The DoD is currently funding team training activities, applying the principles and practices of aviation crew resource management to patient safety and health care settings. At DoD's request, AHRQ is funding an independent evaluation of the DoD medical team training programs, which are prototypes that have potential for wider application outside the DoD.

Collaborations with Private Organizations

At the relatively early point of the patient safety initiative in late FY2003, most of AHRQ's collaborations with the private sector thus far have been for the conduct of conferences and provision of technical information through conferences and other meeting formats. These include collaboration with the National Patient Safety Foundation for coordinating patient safety conferences. With the exception of the IDSRNs noted above, AHRQ was just beginning to pursue structured partnerships with specific private health care providers for implementing patient safety initiatives. Future AHRQ collaboration with private organizations might focus on developing related infrastructure, at the same time that the agency is helping health care organizations position themselves to implement new interventions. Much could be learned about

infrastructure requirements from such collaborative efforts, including lessons that might be disseminated to other private organizations contemplating similar interventions.

Collaborations with Consumer Groups and Patient Advocates

The IOM report highlights the importance of involving patients and families in initiatives to improve patient safety. Anecdotal evidence also suggests that active involvement by patients and families is important to overcoming organizational inertia and resistance to change. Most patient advocates we interviewed felt that the perspectives of patients and their families were largely absent from current efforts to improve patient safety at both local and national levels. AHRQ has sponsored patient safety conferences that included patient advocates and consumers, but consumer involvement in other activities has been limited to date, as has research on the effects of patient and family involvement on patient safety. Consumer groups could be productive partners for AHRQ in implementing initiatives to test market new practices from the patient's perspective and to change attitudes and culture with respect to patient safety issues.

THE EXTERNAL ENVIRONMENT AS PART OF INFRASTRUCTURE

The creation and maintenance of an infrastructure that supports effective patient safety practices is inevitably affected by an array of external forces, many of which are beyond the control of the participants involved. We refer to these collective forces as the "macro-environment." As AHRQ, other federal agencies, and the private sector address infrastructure needs, their strategies must take into account both the reinforcement and the limitations placed upon them by this macro-environment (QuIC, 2000). Some examples of macro-environmental factors that can affect efforts to improve patient safety include legal and regulatory factors affecting health care providers; financial incentives created by payment systems and taxation design; competitive pressures of the health care market place; requirements of purchasers and insurers; and regulatory rules affecting AHRQ as a federal agency. Future efforts to bring about needed changes in patient safety practices will require identifying specific macro-environmental factors that affect progress, leveraging those that can be supportive of that work, and pursuing legislative or legal changes to those that are barriers to achieving patient safety improvements.

For example, the macro-environmental factor of legal issues in adverse-event reporting is especially relevant to establishing a national patient safety data repository. In its simplest form, adverse-event reporting involves investigation of, and reporting upon, a range of negative events that occur in the health care system, typically in situations where iatrogenic injury is suspected, or where other public health concerns are implicated.

At this time, the federal government does not have a general legal framework for adverse-event reporting in health care, but this would change if Congress enacts the proposed Patient Safety and Quality Improvement Act (H.R. 663 and S. 720, respectively [see Chapter 2]). These bills would create new protections for adverse-event reporting systems in health care, and would help foster a national reporting scheme in which hospitals, nursing homes, and physicians could report medical errors to new private patient safety organizations (which would then analyze such reports and provide feedback). Event reporting under either of these bills would be voluntary, and would be entitled to protection from discovery in civil litigation.

ISSUES AND ACTION OPPORTUNITIES

AHRQ has made tangible progress in developing infrastructure to support patient safety implementation activities. Virtually all of the groups of patient safety projects are addressing

infrastructure issues, and two groups have infrastructure development as a primary goal. Development of several components leading to a national data repository is underway in an incremental process, with more work planned in the near future.

Issues to Consider

Infrastructure is a multidimensional concept that includes everything from establishing research capacity in institutions to embedding clinical protocols and technologies in standard health care procedures. Thus, conclusions about AHRQ's success in promoting patient safety infrastructure depend on the how broadly that term is interpreted and what judgments are made about the relative importance of different aspects of infrastructure in the larger patient safety policy landscape. At the national level, strategic partnerships among AHRQ, researchers, federal and state agencies, private sector entities, and professional organizations will serve as an infrastructure to support the transformation of patient safety research findings into safer practices. It is both noteworthy and laudable that a number of the projects currently in AHRQ's patient safety research portfolio already involve these types of partnerships.

As a federal agency, AHRQ is not in a position to "build" a patient safety infrastructure alone. A better metaphor might be that AHRQ is "seeding" patient safety infrastructures (i.e., facilitating and funding targeted demonstrations and collaborations that ultimately become self-perpetuating). AHRQ's research network programs (IDSRNs, PBRNs, HRNs, and CERTs) are impressive examples of "seeding" infrastructures through creative partnerships among entities in the private sectors. Given finite resources, however, these networks should be applied strategically to leverage partnership and network formation on a larger scale among organizations in the health care system.

Suggestions for AHRQ Action

- **AHRQ should undertake a variety of partnerships with public and private sector organizations to explore creative ways for putting tested new patient safety products and knowledge into practice in the health care system.**

The Patient Safety Improvement Corps (PSIC) is an excellent example of a creative partnership that takes full advantage of the respective capabilities of AHRQ and a partner, in this case the VA. As the Corps works to strengthen the capabilities of states and health care organizations, its operating experiences will provide lessons on partnering strategies for other patient safety collaborative initiatives. AHRQ partnerships with national professional organizations also offer a strategy for building patient safety standards and protocols in specific professional settings and contexts.

- **AHRQ should pursue a focused strategy to integrate the patient perspective into activities to improve patient safety performance, including relevant research, consumer reporting on their experiences with care, and consumer involvement in activities by health care organizations.**

The patients experiencing the consequences of medical errors are a critical part of the system, but they tend to be marginalized in activities to improve patient safety performance. AHRQ can provide leadership in this area by pursuing a threefold strategy for consumer contributions:

- Patient reports on their experiences with care to document patient safety events and their concerns, for example, addition of patient safety questions to the CAHPS survey to provide a vehicle for routinely gathering patient-reported data
- Involvement of patients in dynamic partnerships with hospitals and other health care organizations to identify and correct events, including seeking their guidance on how best to communicate events that occur to patients and families
- Ensuring that patient safety measures capture the points of greatest risk on the trajectory of the patient through the health care system.

- **AHRQ should explore mechanisms for establishing contingency financing of dissemination and implementation activities to provide flexibility to respond to needs or opportunities identified in the field.**

  The practice improvement process can be very unpredictable. As health care organizations explore various approaches to adopting new practices, they will have learning curves that involve many failed efforts and shifts in strategy. AHRQ could serve as a resource to support the implementation process as new needs for infrastructure or technical support arise from these activities if it established a mechanism to finance experimental strategies. For example, AHRQ might allocate a portion of its budget and fund special grants for temporary financial support for a special need within an already existing implementation activity. Funding could be given to support development of a training program or specific tools needed to help providers implement a new practice, the need for which had not foreseen at the start of the implementation activity. This mechanism can be viewed as an implementation equivalent of investigator-initiated research proposals.

- **Continued funding support should be provided for DCERPS and other projects that are beginning to build patient safety research infrastructure in order to enable them to become self-sustaining.**

  The DCERPS show promise in building capacity and contributing to infrastructure, but this potential and the government's investment in these networks may be lost if FY2004 funds are not available to support their continued development after the start-up projects are completed. We note that AHRQ has advised the DCERPS projects since the inception of their grants that a critical part of their development process was to create other avenues of support after this funding ended. However, little funding is available from the private sector, and some of the DCERPS projects may be vulnerable because they are not yet self-sustaining. A cost-sharing approach might be used to continue to support those centers committed to the work.

- **AHRQ should expand its efforts to take full advantage of its already established network infrastructures to serve as testing grounds for new patient safety interventions.**

  AHRQ had a great deal of foresight in establishing the IDSRNs, PBRNs, CERTs, and HRNs, recognizing the importance of partnerships with the field in achieving quality of care improvements. These networks have the service delivery and evaluation capabilities needed for field testing new patient safety practices, which have yet to be fully tapped. AHRQ also might undertake larger collaborative activities among multiple networks (e.g., an IDSRN and a PBRN) to test methods for rapid diffusion of best safety practices across care delivery sites.

CHAPTER 8. PROCESS EVALUATION:
ACHIEVING BROADER ADOPTION OF EFFECTIVE PRACTICES

> *The adoption, implementation, and institutionalization of improved patient safety practices to achieve sustainable improvement in patient safety performance across the health care system.*

Although it is too early in the evaluation process to determine whether and to what extent the safety practices emerging from the AHRQ-funded work are being adopted, it is an optimal time to consider the capabilities that will be needed for broad and successful adoption of effective patient safety practices. We focus on issues regarding the facilitation of information exchange, the transfer of knowledge and practices to the broader health care community, and the dissemination of products from the patient safety portfolio of projects.

The following key questions are assessed here and will be tracked over the four-year evaluation:

- To what extent has there been active exchange of information among the AHRQ-funded projects to enrich their knowledge base and products?

- To what extent is new evidence on effective practices and implementation methods being disseminated to the broader health care system?

- Are tangible "success stories" emerging from the research and development work that have achieved measurable effects on patient safety outcomes?

- What systematic programs are in place or under development by AHRQ or other organizations to provide technical support to health care providers for implementing tested patient safety practices?

- Are patient safety outcomes improving, as measured by established measures, as a result of the cumulative efforts of generating knowledge, testing new practices, building an infrastructure, disseminating knowledge, and providing technical support for implementation?

This first evaluation report draws upon information from published documents, individual interviews and focus groups conducted with the AHRQ and HRSA funded projects, interviews with staff within AHRQ and other government agencies, interviews with staff from non-profit organizations, and interviews with other key informants.

POLICY CONTEXT

IOM Report

The 2000 IOM report sets forth two recommendations that specifically pertain to achieving broader adoption of tested practices (IOM, 2000). The first states that "AHRQ should … fund dissemination and communication activities to improve patient safety"; the second states that "Health care organizations should implement proven medication safety practices."

QuIC Response

In its response to the IOM report, the QuIC stated that federal agencies would engage in the following specific actions (QuIC, 2000):

- Under the leadership of the CQuIPS, the QuIC will promote, at the executive level, the development and dissemination of evidence-based, best patient safety practices to provider organizations.
- The QuIC agencies will work collaboratively with professional societies to promote awareness of medical errors problems and to identify ways to improve the education, credentialing, and accreditation processes to rigorously examine safety knowledge and practices. AHRQ will work with private-sector groups to educate providers and purchasers about improving patient safety.

AHRQ Strategy and Actions

Since the FY2000 and FY2001 patient safety grants were funded, AHRQ has pursued three components of a dissemination and adoption strategy. First, it has worked to stimulate interaction and exchange of information among the funded grantees to achieve synergies across their research projects. Second, as the grantees' research progressed, AHRQ began preparing for the dissemination of the knowledge and products being generated by the research. Third, AHRQ has initiated activities to stimulate and support the adoption of improved patient safety practices in the field, with the intent to expand this part of its strategy in upcoming years.

INTERACTION AND EXCHANGE OF INFORMATION AMONG GRANTEES

A unique feature of the patient safety project portfolio is AHRQ's effort to stimulate and facilitate the exchange of information among the patient safety grantees. Grantee interactions are intended to support more rapid development of the professional capacity for patient safety research and the creation of synergy that will accelerate progress toward better patient safety outcomes. This approach diverges from the traditional way that AHRQ and others (e.g., the National Institutes of Health) have worked with research grantees. The status of specific activities to encourage interactions among the patient safety projects is described briefly below.

Annual Grantee Meetings

Each year, AHRQ sponsors a meeting of all grantees for the purposes of cross-fertilization among the projects, with the larger objective of achieving synergy to generate overall results from the patient safety initiative that are larger than the sum of the individual parts. The annual meetings have been viewed very favorably by the grantees, as have the workshops before and after the conference. Researchers found it fruitful to interact with each other, and they appreciated the opportunity to discuss challenges to conducting patient safety research and potential solutions. They voiced a strong preference for sessions that focus on problem solving and what it takes to make a project successful. They also requested more networking opportunities during the meetings, both with each other and with the invited speakers.

Information Exchange Mechanisms

We found substantial evidence in our interviews and review of materials that, in general, the grantees value interacting with each other. Many have found it useful to share expertise, confer about research approaches, exchange experiences with new patient safety–related technologies, and discuss problems and potential solutions. There appears to be a positive

atmosphere for sharing information and lessons learned within the RFA groups, although there has been less exchange across RFA groups. However, grantees stressed that their project budgets could not support significant networking activity.

The interviews with the RFA groups funded by AHRQ, as well as the five HRSA-funded grantees, revealed differing perspectives among the researchers about the need for and desired amount of interaction. The more experienced researchers tended to indicate that they already were networked with colleagues, while newer researchers actively sought opportunities for interaction. Therefore, a single approach to facilitating interaction will not satisfy all of them. Some of the RFA groups (e.g., the Reporting Demonstration projects) have had quarterly conference calls for information exchange since the start of funding.

Some grantees in groups that have not had regular calls expressed a desire to have them in the future. Grantees suggested having some calls with issue-oriented agendas set by the grantees, opening calls to all interested patient safety grantees, and adding a visual/web component to the calls when appropriate (e.g., when discussing taxonomies). In addition to the regularly scheduled RFA group interactions, the Coordinating Center has arranged interactions based on AHRQ and grantee identified needs (e.g., special technical assistance calls).

Opportunities for AHRQ to support future efforts and facilitate discussion beyond the end of the grant cycle could continue to stimulate synergy among the grantees. For example, updates on the AHRQ patient safety portfolio could be built into other conferences typically attended by the grantees, or a national network of patient safety researchers and policy makers could be created. AHRQ might pursue ongoing information exchange in partnership with a national foundation that is willing to help continue the dialogue and dissemination of information to a wider audience.

DISSEMINATION OF NEW KNOWLEDGE AND PRACTICES

To establish a baseline for our subsequent evaluation of dissemination and implementation activities, we provide some early indicators of how AHRQ has disseminated information on effective safety practices in the early years of the initiative. *Dissemination* is defined as the broad communication and distribution of information on new knowledge and practices (i.e., generating awareness); *implementation* is defined as the act of introducing new, tested patient safety practices into use in health care organizations (i.e., broader adoption). We identify factors to consider in preparation for translating research to facilitate adoption of effective practices in the field.

Early Indicators of Dissemination to the Health Care System

We developed four early indicators for dissemination of patient safety information to the broader health care system. These indicators serve as early markers for understanding whether the information (e.g., epidemiology and evidence on safety practices) is reaching AHRQ's ultimate intended audience: practitioners and the institutions within which they work.

(1) Amount and Type of Products from FY2000-01 Grantees. In August 2003, we conducted a Coordinating Center web site and library search to identify products from the portfolio of 86 AHRQ and HRSA-funded patient safety projects. We identified a total of 1,155 published documents authored by the 86 PIs, of which 751 documents were for patient safety studies. Counts of these 751 documents by year are presented in Table 8.1. Only 40 (5.3 percent) of the patient safety documents were related to the PI's AHRQ project. Of the 40

patient safety products identified as funded by AHRQ, 36 were journal articles, one was a bibliography, two were conference presentations, and one was a published tool.

Table 8.1
Number of Patient Safety Products Produced by AHRQ and HRSA-Funded
Patient Safety Grantees, 1997-2003

Year	Patient Safety, Project Related	Patient Safety, Not Project Related	Patient Safety, Not Clear If Related	Total
Year unknown	1	0	8	9
1997	0	53	0	53
1998	0	68	2	70
1999	0	79	1	80
2000	0	107	5	112
2001	3	120	8	131
2002	19	101	53	173
2003 (half year)	17	74	32	123
Total	40	602	109	751

Table 8.1 highlights changes in patient safety productivity among the principal investigators on the AHRQ and HRSA-funded projects. The number of products emerging from the patient safety grantees increased as the projects matured and drew closer to completion. In addition, there has been a steady increase each year in the total number of patient safety products. It appears from these findings that the products disseminated at this early juncture are still heavily focused on traditional peer review journal articles.

(2) Use of Communication Vehicles by AHRQ and Other Organizations to Push Information. Another early marker of diffusion of patient safety information to the health care system is the degree to which organizations are communicating information to the broader health care community. AHRQ and other organizations have made significant strides in using a variety of communication vehicles (e.g., conferences, websites and newsletters) to raise awareness about patient safety, to communicate findings about best practices, and "push" information about best practices to practitioners.

Our review of the number and type of patient safety conferences being held or scheduled between 2001 and 2004 by select governmental agencies and other state-based alliances shows a steady increase since 2001, from eight in 2001 to 47 scheduled to occur in 2004. To date, AHRQ and the NPSF have been the primary supporters of patient safety–related conferences, but there is a growing private sector presence.

The AHRQ *Research Activities* newsletter provides a helpful synopsis of work done by AHRQ-funded grantees. Our review of issues between 1999 and 2003 found eight articles on patient safety epidemiology and eight articles on patient safety knowledge and practice, some of which reflect work funded through the AHRQ patient safety initiative. This newsletter is targeted to and read by primarily the research community; it is not designed to reach health care practitioners and decision makers.

Our review of the AHRQ web site found it to be visited by many people with differing interests, so it offers potential for reaching a wide audience, including end-users. With further development, the AHRQ web site offers a rich opportunity for disseminating patient safety information tailored to different audiences. By creating a consolidated web site that organizes

available patient safety information, AHRQ could create a national "go to" resource for a variety of users, to assist those who want to adopt safe practices.

       (3) Dissemination and Influence of AHRQ EPC Report on Safe Practices. The 2001 AHRQ evidence report has been made available largely through the AHRQ web site. As of August 2003, AHRQ's publications clearinghouse had sent out 567 copies of the full report and 4001 copies of the summary report (AHRQ personal communication, 2003). Numerous other copies of the report were downloaded from the AHRQ website. The evidence report has had a major influence on the work of the NQF in developing its *Safe Practices for Better Healthcare* consensus statement, which in turn represents an important step toward implementation of the practices.

       (4) Adoption of Patient Safety Practices in Standards and Policies. We conducted a search of the practices of leading organizations that develop consensus standards, accreditation standards, and policy statements to determine whether, as of 2003, any of the organizations had adopted standards or policies promoting safe practices in the delivery of health care. We found information for patient safety policies or standards being used currently by the JCAHO, NCQA, URAC, and Medicare. The only other item found was an AAP policy statement issued in 2001, called "Principles of Patient Safety in Pediatrics," which is a list of recommendations for keeping pediatric patients safe.

Current Impressions of Dissemination Among Patient Safety Grantees

       Overall, the patient safety grantees understood that dissemination is an important part of the patient safety initiative and that academic publications are not enough to fully disseminate their findings to a broader health care audience. Many grantees reported trying to share their work in unconventional ways, including partnering with industry, making taxonomies and survey instruments available, and giving presentations during the course of the project.

       Despite these positive dissemination activities by grantees, challenges remain. AHRQ and the grantees are working to ensure that work products of grantees are communicated to AHRQ in a systematic or timely way. Some suggestions made by grantees to improve the timely sharing of information include more stringent reporting requirements for grantees, improved product tracking methods by the Coordinating Center, and improved communication among the project officers and the AHRQ centers where the patient safety projects are managed.

       Grantees felt it was important to balance the need to show results quickly with the need to give the research process adequate time to ensure valid conclusions. Many grantees were not comfortable disseminating preliminary data, and especially for long-term projects, they believed it was unlikely that grantees could generate results early in the project life. Grantees also felt that intellectual property issues could be overlooked in efforts to get products out the door quickly In addition, they expressed concerns that publishing results in AHRQ reports could preclude their ability to publish in peer-reviewed journals.

       Grantees would like to work with AHRQ to determine which dissemination strategies the grantees could lead and which would be led more effectively by AHRQ and other partner organizations. Grantees also noted that it would be helpful to have dedicated budgets for dissemination activities (e.g., travel to present their findings and products to others, package products). Funding and staff support for marketing efforts also is a concern within AHRQ. To truly reach end-users, AHRQ will need to serve as a change agent—a role quite different from its

traditional role as a research agency. Inadequate resources to support this effort are a significant barrier.

Translating Evidence into Practice—Defining a Dissemination Strategy

Our assessment highlights the importance of having a clear strategic plan for disseminating the information emerging from the patient safety project portfolio, to maximize the impact of this work. The plan should specify the tasks to be performed and the roles and responsibilities of the AHRQ offices and centers, and of the Coordinating Center, for each task. Lines of communication among the participants are established up front in the RFAs along with terms for grants or cooperative agreements, including provisions for AHRQ officers to have access to the grantees for information about their work. It then takes work to ensure that these procedures are followed. Having a collaborative dissemination plan in place will help to reduce the frequency of misinterpretation and procedural missteps, thereby minimizing confusion or tension that might slow down the process.

To assist AHRQ in formulating an effective dissemination strategy, we have identified key steps in the process, which are listed in a suggested AHRQ action at the end of this chapter. These steps flow from thoughts shared during the interviews conducted with grantees, opinion leaders, AHRQ staff (former and present), and staff within other federal agencies as well as from discussions among the evaluation team. In particular, we note the importance of sharing the grantees' products and lessons learned with a broad audience. To do so, AHRQ will need to develop an array of channels through which to funnel information to a diverse set of end-users beyond the peer-reviewed health care journals. Larger syntheses will need to be published to help practitioners and policy makers digest the aggregate findings. Another issue is publication of process information (the "how to" and challenges of implementation), which will be of practical use to end-users who are committing resources to implementing the new practices (e.g., hospital administrators, risk managers). AHRQ will need to capture sufficient budget to support these marketing activities as part of a viable dissemination strategy.

Tangible Patient Safety Success Stories

At this stage of the initiative, it was too early to glean the full essence of what the projects had accomplished. However, in our initial interviews at least five of the projects reported successes in having a real-time effect on patient safety in the institutions within which they are working, as providers are acting on their findings by changing practices and procedures. In addition, some of the projects have established interactive processes through which regular feedback occurs between the systems of care delivery and the researchers' tracking and analyses. A related success reported by many projects is the establishment of long-term relationships with participating providers, many of which are leading to additional collaborations. These achievements can serve as informative case reports for other health care organizations seeking to improve patient safety.

TECHNICAL SUPPORT FOR IMPLEMENTATION OF TESTED PRACTICES

For end-users (e.g., hospitals, physicians, nurses) to move research into practice, relevant findings must be made available to them via the communications channels they typically use. End-users need practical information that will enable them to decide whether to adopt a practice and how to put it to work effectively, as well as technical support for implementing the new practices. As described below, AHRQ funds a number of programs that field test research

findings and provide technical support to end-users in the health care system. As the evaluation moves forward, we will continue to monitor AHRQ's use of these existing programs for disseminating the research emerging from the patient safety portfolio.

AHRQ WebM&M

The AHRQ WebM&M, launched in February 2003, is the nation's first web-based patient safety resource and journal that provides a national forum to simulate the review of cases and discussion that occurs in hospital morbidity and mortality conferences, with an emphasis on patient safety issues. This product is reaching directly to clinicians to communicate information about new patient safety practices as part of a dissemination and adoption strategy.

Patient Safety Improvement Corps

The PSIC, which commenced in FY2003 with continuation funding through FY2005, is a partnership program between the VA and AHRQ that serves as a key component of a strategy for dissemination and adoption of improved patient safety practices. The initiative is designed to increase the number of individuals nationally who are capable of supporting the implementation and operation of patient safety programs by states and health care organizations.

Secretarial Initiative on Patient Safety Hospital Information Technology

Of the $84 million requested by AHRQ for patient safety activities in FY2004, the agency committed $50 million to help hospitals invest in information technology designed to improve patient safety. AHRQ also plans to use $10 million of the proposed patient safety funding to accelerate the adoption of information technology standards in health care.

User Liaison Program (ULP) with States

The ULP, established in 1978, contributes to AHRQ's broader mission by synthesizing and disseminating research findings to local, state, and federal health decision makers. The ULP has prior experience in reaching a broader audience, including provider groups, hospital managers, health plan managers, business groups, and consumers. ULP has conducted patient safety workshops regularly since 2001, including impacts of medical errors, patient safety in rural hospitals, and methods for states to improve patient safety. ULP has also partnered with numerous states to inform health care policy makers about the most relevant patient safety research and best practices.

Translating Research Into Practice (TRIP)

In fiscal year 1999, AHRQ published its first TRIP initiative. The purpose of TRIP-I was to generate new knowledge about approaches that promote the utilization of rigorously derived evidence to improve patient care. TRIP-II is designed to extend practices proven in one setting to diverse applied settings by testing their effectiveness under different field conditions. An important aspect of TRIP-II is the presence of partnerships among researchers and health care organizations, such as integrated service delivery systems, practice-based networks, academic health centers and managed care organizations. Two areas of focus for TRIP-II are improving the health care of minority populations and using information technology (e.g., computer-based clinical decision-support systems) to translate research findings into health care improvements and health policy.

Research and Practice Networks

AHRQ had the foresight to fund several types of formal networks that bring together researchers, clinicians, and health care systems for interdisciplinary research under applied settings (i.e., IDSRNs, PBRNs, HRNs, and CERTs). As discussed in Chapter 7, these networks have existing interorganization infrastructures and are positioned to serve as active partners in implementing effective patient safety practices that emerge from the current research.

ISSUES AND ACTION OPPORTUNITIES

The process of bringing new patient safety knowledge and products into widespread practice in the health care system requires both creativity and persistence. The primary players in adoption of new patient safety practices are health care providers and other stakeholders with influence over them, including purchasers, insurers, accreditation and credentialing organizations, and consumers. By serving as a facilitator and providing technical support for their activities, AHRQ has the opportunity to build synergy that will hasten the adoption of new practices for patient safety improvements.

Issues to Consider

AHRQ will need to choose its initiatives strategically to leverage its finite resources for the greatest possible ROI. Early accomplishments in both information dissemination and technical support for patient safety practice improvements serve as useful first steps for moving the implementation process forward.

We have identified four principles that AHRQ can apply to crafting its full implementation strategy. First, match the right people to the right task, with researchers doing what they do best and health care providers carrying out the implementation activities. Second, engage private organizations to lead partnerships with health care organizations for initiatives on best practices with AHRQ's involvement and support. Third, apply market-based interventions that stimulate desired changes by creating incentives for providers to improve patient safety performance. Fourth, draw upon already existing infrastructure to support practice improvements, including the AHRQ-sponsored networks and others that can lead in turn to further infrastructure development.

The dissemination of findings and products from the patient safety projects represents an intersection of two challenges for AHRQ. The first is a structural challenge – the large number of projects that will be generating results, which the current system of health care publications does not have ready capacity to absorb. The second is a process challenge – the need for a creative and comprehensive dissemination strategy that will enable AHRQ and its grantees to effectively move the project output into the hands of a diverse mix of users and stakeholders. As AHRQ continues to develop and adjust its strategy, learning from its experience with the dissemination process, it can draw upon the expertise and resources of private sector partners, taking the lead on some dissemination activities and supporting others.

Despite the emphasis placed on dissemination and practice change for the patient safety grants awarded in 2000 and 2001, including explicit direction in the RFA that project dissemination strategies should extend beyond peer-reviewed journal publications to include other proactive outreach, the grantees reported that project budgets did not include support for dissemination activities by the grantees. Thus, AHRQ may bear most of the administrative workload and cost for these activities. Alternatively, it could charge the Coordinating Center

with substantial responsibility for the dissemination activities, or it could award a separate contract to perform this function.

Suggestions for AHRQ Action

- **AHRQ should design and carry out a cohesive strategy to disseminate the new knowledge and products of the patient safety projects to the broad spectrum of stakeholders that will put them into practice in the delivery of safer health care.**

The end users for dissemination activities are health care providers and others involved in ensuring the safety and quality of health care (e.g., policy makers, purchasers, consumers). A well-designed and executed dissemination strategy will be required to make them aware of new knowledge and/or practices. We suggest an eight-step strategy to achieve this end:

1. *Collect and track the necessary information* from the patient safety projects so accurate and complete information is disseminated to the users. Information collected should include a summary of products from each project, a description of findings and lessons learned, applicability of study findings in clinical settings, effects of any interventions on patient care processes or outcomes, and return on investment.

2. *Synthesize findings* that are emerging from the patient safety projects, highlighting broad lessons learned and key issues to be addressed. The process of translating evidence into practice requires effective communication of how tested methods can be implemented in everyday practice across a variety of settings.

3. *Identify strategic partners* that can serve as communication channels to end-users, and explore options for collaborative initiatives. Examples of potential partners include Academy Health, AHA, IHI, IOM, Leapfrog, NQF and JCAHO.

4. *Use existing AHRQ technical support and communication functions* that offer strong capabilities in many aspects of a comprehensive dissemination and implementation strategy. Examples include the AHRQ web site, the Office of Communications and Knowledge Transfer, and the Coordinating Center.

5. *Commit reasonable funding for AHRQ's marketing and communication functions*, either through new funding or by reallocations from other activities. This is an area where synergy might be achieved across the marketing and communications functions of other AHRQ programs.

6. *Set priorities for dissemination and practice change*, taking into consideration factors such as the severity of the patient safety issue, the availability of interested partners, the potential for successful intervention, and opportunity for large effects or returns on investment.

7. *Identify specific audiences* and tailor messages to them, including Congress, state governments and coalitions, health care organizations, physicians and other practitioners, educational institutions, and others.

8. *Secure some "early wins"* to communicate as visible success stories that garner attention and serve as a catalyst for more activity.

- **AHRQ should identify and test alternative strategies for AHRQ to serve as a catalyst that motivates and supports initiatives by health care organizations to implement new patient safety practices.**

    The technical support function that AHRQ can provide for end-users needs to build upon the agency's technical strengths and conform to its budget constraints. A variety of strategies to provide support and catalyze change should be tested to learn which of them work best. AHRQ should seek out a menu of ideas to explore with potential partners for implementing patient safety initiatives. In addition, users could be consulted or involved early in future research processes as research questions are being defined, to ensure the research is addressing issues of importance to them. AHRQ's status as a federal agency defines boundaries for its capabilities and limitations that help to determine its most effective roles for implementation initiatives. The roles of its partnering organizations should complement AHRQ's capabilities, drawing upon their operational flexibility and other relevant strengths. Such divisions of labor should be developed collaboratively with potential private sector partners.

- **AHRQ should develop a monitoring process to measure the effects of individual implementation initiatives on patient safety practices and outcomes, as well as the cumulative effects of all the patient safety activities on key outcome measures.**

    Although the development of a monitoring process would be costly, such a process will be required to assess the extent to which patient safety improvements are achieved as a result of the AHRQ patient safety initiative. The cost might be managed by focusing on specific aspects of practices or through collaborative data collection with other organizations. Ideally, this process could be supported in part by the eventual development of a national patient safety data repository, which has the potential to ameliorate the current absence of clearly accepted measures for patient safety outcomes and baseline data for such measures. The short-term need to establish baseline data on key measures may have to rely on existing patient safety projects as the primary sources of measures and data.

CHAPTER 9. CONCLUSION

In this first evaluation cycle, we have observed, documented, and assessed the start-up and initial operations through September 2003 of the AHRQ patient safety initiative, learning from participants and other stakeholders about the activities and interactions involved in the process. These individuals also have shared with us their concerns and ideas for future work.

In general, both external leaders and the AHRQ staff believe the agency has done an impressive job in starting the patient safety initiative and has taken a productive approach for spending the patient safety funding on research to generate new knowledge. The patient safety initiative serves as a model for building multiyear budgets based on a trajectory of research and for explicitly linking investments in knowledge development in early years to dissemination and practice improvement activities in later years. Evaluation research also is an integral part of the initiative.

FUTURE DIRECTIONS AND PRIORITIES

We identify here four priorities that we believe in the aggregate will have the strongest positive impact on the future of the AHRQ patient safety initiative. We drew upon our assessments of the context, inputs, and processes of the initiative to identify these priorities. We conclude with a brief description of the next steps planned for our longitudinal evaluation, including preparation for the product component of this assessment.

Accountability and Patient Safety Goals

The high expectations initially set forth for achieving a 50 percent reduction in errors in five years have been replaced by recognition among participants and observers that the goal was both incorrect and unrealistic, especially given the relatively limited funding appropriated for the patient safety initiative. While setting a goal of low tolerance for patient risk is useful for establishing performance accountability, interim objectives also should be designed to pull the health care system toward that goal incrementally. As AHRQ and its partners in the patient safety community move ahead in implementing safer health care practices, they also should work to frame interim objectives that establish appropriate performance expectations for the health care system. In particular, there should be a realistic match between the objectives defined and the financial resources allocated for programming to achieve them.

A National Patient Safety Data Repository

The ability to measure patient safety issues and monitor progress in practice improvements nationally is one of the key components of a strategy for achieving safer health care in this country. An effective monitoring and measurement capability based on consistent national standards is essential to (1) provide the feedback and accountability to stimulate practice improvements by health care organizations; and (2) enable AHRQ to fulfill its accountability to Congress for achieving patient safety improvements. We encourage AHRQ to continue to move actively on this aspect of the initiative, adjusting strategy as opportunities arise, and dedicating resources to the work.

Given the basic challenge involved in creating national standards that are useful for multiple users, we suggest that this be an initial focus of AHRQ's data building activities. In particular, AHRQ can use its position as a federal agency to facilitate a consensus process with the goal of enhancing participation from multiple stakeholders across the country.

The Role of AHRQ in Making Practice Changes Happen

As a federal agency, AHRQ operates in a unique external environment of legislative oversight and regulatory requirements. The conditions imposed by this environment create both advantages and constraints that influence AHRQ's ability to stimulate and support improved patient safety practices in the nation's health care system.

Both congressional and administrative factors influence the AHRQ patient safety work. For example, when Congress appropriated the AHRQ FY2001 funds for patient safety research, it provided little additional funding to support AHRQ's internal operations for managing the patient safety program. With this financial constraint, existing AHRQ staff have had to absorb the increased demands created by the large new program. In addition, federal agencies must follow a number of regulatory requirements when carrying out program activities (e.g., procedural rules for funding projects, OMB approval requirements for survey data collection). These requirements provide important protections for the people of this country, but they can involve time-consuming procedures that slow progress toward patient safety goals or discourage private sector organizations from participating.

The aspect of the AHRQ patient safety initiative that may be most vulnerable to the federal bureaucracy is the translation of new knowledge into improvements in patient safety practices in the field. This mission involves AHRQ's participation in active public-private partnerships, supporting health care organizations in their implementation activities. Strategic use should be made of the respective assets of the government and the private sector. Where the government role brings a unique capability to the table, it should be used. Where AHRQ or other federal agencies face barriers that limit their ability to act, appropriate action should be taken to remove the barriers or strategies should be used that draw upon the strengths of the private sector.

Balancing Research and Adoption Activities

During FY2004, the patient safety initiative will enter a period of transition, as the existing projects conclude their research, the Patient Safety Improvement Corps enters the field, new Challenge Grants proceed with their work, and other activities move ahead to bring new knowledge and practices to end-users. During this process, AHRQ will be balancing internal staff activities and workload surrounding the new implementation activities, which involve substantially more uncertainty than the funding and oversight of research projects. AHRQ will also be deciding how best to use the new funding in the FY2004 budget—both those funds earmarked for information technology and the remaining funds available for other patient safety research and implementation.

One could argue for applying more resources to implementation activities in order to achieve greater progress in the advancement of safer health care practices. However, AHRQ is unique as a funder of research, and reduction of AHRQ funding for priority research topics might well lead to some of them going unfunded. Relatively more of the resources of other federal or state agencies and the private sector might be used to undertake or support implementation initiatives, leveraging the funding available from AHRQ for this work. While there are no "correct" answers to this question, we encourage AHRQ to deliberate carefully to seek the optimal use of its finite resources, both human and financial.

NEXT STEPS

In this evaluation report, we have used the CIPP evaluation framework to present current findings with respect to the context, inputs, and processes of the AHRQ patient safety initiative. With the initiative concluding its second year of activity as of September 2003, the work to support the broader adoption of effective practice in the larger patient safety system was just beginning. Therefore, it is premature to comment on the extent to which new evidence on effective practices and implementation methods are being disseminated to the health care system. Results from the FY2000 set of grants and contracts are just starting to emerge, and the majority of projects that were funded in FY2001 and FY2002 will not complete their work until fall 2004. The products and knowledge being generated by those projects will provide content for implementation activities to support broader adoption of effective new practices.

In subsequent reports, we will continue to track AHRQ's activities with respect to each component of our framework for an effective patient safety system: monitoring progress and maintaining vigilance; knowledge of epidemiology of patient safety risks and hazards; development of effective practices and tools; building infrastructure for effective practices; and achieving broader adoption of effective practices. As the four-year evaluation proceeds, these process chapters of the report will be expanded to assess:

- What new epidemiological knowledge is being generated by the AHRQ-funded patient safety projects currently underway?
- What is being learned directly from the projects about the effectiveness of new practices?
- How is this new information contributing to expanding the scientific evidence base regarding these practices?
- What progress is being made in building a national patient safety infrastructure?
- What success stories are emerging from the work?

Preparation for evaluation of the products and outcomes of the patient safety initiative will commence in FY2004 with a focus on patient safety measures and data collection capabilities. Future developments and activities will be compared to the baseline information presented in this first report. As new, effective patient safety practices become more broadly adopted in the general health care system, associated reductions in patient harm can be expected. The ability to observe such outcomes, however, depends on having in place a valid set of measures as well as the reporting, measurement, and data systems for collecting valid and reliable data on those measures. Although a national data repository does not exist at this time, AHRQ has defined an incremental strategy for its development. As progress is made on national patient safety data availability, and our evaluation team begins to collect available outcome information from the patient safety projects, improvements in patient safety outcomes will be assessed.

APPENDIX A.
ORGANIZATIONS AND PROJECT GROUPS INVOLVED IN
THE PATIENT SAFETY INITIATIVE

Federal Organizations Involved in the Patient Safety Initiative

Agency for Healthcare Research and Quality (AHRQ) – the agency within the Department of Health and Human Services that has been designated the lead agency for the federal patient safety initiative, to which Congress appropriated funding for patient safety research and development activities.

AHRQ National Advisory Council – an external advisory body, consisting of national-level policy experts, which provides AHRQ with policy guidance for design and execution of its program of work.

Center for Quality Improvement and Patient Safety (CQuIPS) – the AHRQ center that was designated to provide leadership for the patient safety initiative. It is one of five centers within the AHRQ organizational structure.

Patient Safety Evaluation Center – a center under contract with AHRQ to perform a longitudinal, formative evaluation of the patient safety initiative. AHRQ contracted with RAND in 2002 to serve a four-year term in this capacity.

Patient Safety Research Coordinating Center – a component of AHRQ's patient safety initiative that serves as a stimulus and facilitator of interactions among the patient safety grantees. AHRQ contracted with Westat in 2001 to serve a three-year term in this capacity. To obtain grantee guidance and feedback from the grantees, the Coordinating Center established a Grantee Steering Committee with a representative from each of the RFA groups.

Patient Safety Task Force – established within DHHS in April 2001, the task force has membership from AHRQ, the Centers for Medicare and Medicaid Services, Federal Drug Administration, and Centers for Disease Control. Its mission is to coordinate patient safety activities of these agencies, including integration of data collection on medical errors and adverse events, coordination of research and analysis efforts, and collaboration on reducing the occurrence of injuries that result from medical errors.

Quality Interagency Coordination Task Force (QuIC) – a collaborative effort among Federal agencies to ensure that all federal agencies involved in purchasing, providing, studying, or regulating health care services are working in a coordinated way toward improving quality of care The QuIC membership has representatives from the Departments of Health and Human Services, Labor, Defense, Veterans Affairs, and Commerce; Office of Management and Budget; Office of Personnel Management; U.S. Coast Guard; Federal Bureau of Prisons; National Highway Transportation and Safety Administration; and the Federal Trade Commission.

The Patient Safety Projects Funded by AHRQ

A total of 81 projects have been awarded AHRQ funding as part of its patient safety portfolio. These include six projects under the Systems-Related Best Practices RFA issued in

2000 as well as 75 projects funded under the six RFAs issued in 2001. Summary information on these groups of projects is provided below.

Systems-Related Best Practices to Improve Patient Safety

RFA No. HS-00-007 (6 projects)   Release Date: December 16, 1999

Focus of projects: improve the safety of health care through the identification and prevention of avoidable system errors. Projects were to use rigorous research methods and designs to test the effectiveness of the transfer and application of best practices to reduce serious preventable systems-related medical errors to achieve sustainable improvements in patient safety. Project results should be generalizable to other sites and settings.

Health Systems Reporting, Analysis, and Safety Improvement Research Demonstrations

RFA No. HS-01-003 (16 projects)   Release Date: February 2, 2001

Focus of projects: support large demonstrations in states, health care systems, and/or networks of providers to test reporting strategies, patient safety interventions, or methods of analyzing data to identify factors that put patients at risk in a wide variety of medical settings. These projects were to use technology, staff training, and other methods to reduce errors; develop replicable models; develop mechanisms that encourage reporting and corrective action; and develop methods to minimize paperwork burden on health care professionals.

Clinical Informatics to Promote Patient Safety

RFA No.HS-01-006 (11 projects)   Release Date: February 22, 2001

Focus of projects: develop and test the use of innovative technologies applied in various health care settings, to assess their contribution to measurable and sustainable improvements in patient safety and quality of care. Examples are hand-held electronic medication and specimen management systems, training simulators for medical education, computerized bar-coding, patient bracelets, smart cards, and automated medication dispensing systems in clinical settings.

The Effect of Health Care Working Conditions on Quality of Care

RFA No. HS-01-005 (5 & 16 projects)   Release Date: March 26, 2001

(Five from the $50 million and 16 from the $7 million working conditions appropriations)

Focus of projects: identify, characterize, and directly measure the effect of the health care work environment on the safety and quality of care provided by health care workers. These projects were to examine how staffing, fatigue, stress, sleep deprivation, and other factors can lead to errors, how the environment of care affects the ability of providers to improve safety, and how interactions with the built environment affect the provision of safe care.

Centers of Excellence for Patient Safety Research and Practice

RFA No. HS-01-002 (3 projects)   Release Date: October 24, 2000

Focus of projects: support established cross-cutting teams of researchers and health care facilities and organizations in geographically diverse locations (including rural and urban areas) which will determine the causes of medical errors and develop new knowledge to support the work of the demonstrations.

Developmental Centers for Evaluation and Research in Patient Safety

RFA No. HS-01-007 (18 projects)   Release date: November 8, 2000

Focus of projects: develop new multidisciplinary research teams to improve the nation's capacity in patient safety research, expand the patient safety knowledge base, and establish mechanisms to incorporate new knowledge into actual practice. These grants included planning for activities to enhance the capacity to conduct quality research and translate research findings into practice, as well as performance of a pilot study in subsequent years of funding.

Patient Safety Research Dissemination and Education

RFA No. HS-01-008 (6 projects)   Release Date: April 23, 2001

Focus of projects: fund researchers and organizations to develop, demonstrate, and evaluate new approaches to improving provider education in order to reduce errors, such as teaching new knowledge on patient safety and developing curricula, continuing education, simulation models, and other provider training strategies.

The Patient Safety Projects Funded by HRSA

The five patient safety projects funded by HRSA are developing and testing methods for interdisciplinary training on patient safety for medical and nursing students. Each project is experimenting with a different training model, including joint activities among medical and nursing schools as well as community-based approaches. The HRSA projects have been included in the activities of the patient safety portfolio, including attendance at annual grantee conferences, representation on the grantee steering committee, and support by the PSRCC for inter-grantee collaboration.

APPENDIX B.
PATIENT SAFETY PROJECTS WITH POTENTIAL TO GENERATE PATIENT SAFETY EPIDEMIOLOGY INFORMATION

Grant Title	PI Name	PI Institution
Improving Medication Safety Across Clinical Settings	Bates, David W.	Brigham and Women's Hospital
Addressing Preventable Medication Use Variance in Mississippi	Brown, Andrew C.	University of Mississippi Medical Center
Quality Care and Error Reduction in Rural Hospitals	Cook, Ann F.	University of Montana
Effects of Extended Work Hours on ICU Patient Safety	Czeisler, Charles A.	Brigham and Women's Hospital
The Center for Improving Patient Safety	Dittus, Robert S.	Vanderbilt University
Impacts of Unit-Level Nurse Workload on Patient Safety	Donaldson, Nancy E.	University of California, San Francisco
Working Conditions & Adverse Events in Home Health Care	Feldman, Penny Hollander	Visiting Nurse Service of New York
Surveillance, Analysis, and Interventions to Improve Patient Safety	Fraser, Victoria J.	Washington University
Impact of Personal Digital Assistant Devices on Medication Errors	Galt, Kimberly A.	Creighton University
Oregon Patient Safety Evaluation Center	Hickam, David Howard	Oregon Health & Science University
The American Academy of Family Physicians DCERPS-PC	Hickner, John M.	The American Academy of Family Physicians
Strategic Alliance for Error Reduction: California Healthcare	Hilborne, Lee H.	University of California, Los Angeles
Center for Patient Safety in Neonatal Intensive Care	Horbar, Jeffrey D.	University of Vermont
Impact of Electronic Prescribing on Medication Errors	Johnson, Kevin Brian	Johns Hopkins University
Work Conditions of Surgery Residents and Quality of Care	Jonasson, Olga	American College of Surgeons
Reporting System to Improve Patient Safety in Surgery	Khuri, Shukri F.	American College of Surgeons
Patient Safety in Home Care	Kovner, Christine T.	New York University
Improving Patient Safety: Health Systems Reporting	Layde, Peter M.	Medical College of Wisconsin
Minimizing Error, Maximizing Outcome: The Physic	Linzer, Mark	University of Wisconsin Department of Medicine
HIV Error Reduction Using a Genotype Database	Novak, Richard M.	University of Illinois at Chicago
Patient-Based Strategy to Reduce Errors in Diabetes Care	O'Connor, Patrick J.	Health Partners Research Foundation
Applied Strategies for Interventions for Patient Safety	Pace, Wilson D.	University of Colorado Health Center
Nurses' Working Conditions: Effects on Medication Safety	Pepper, Ginette Alyce	University of Colorado, Health Sciences Center
The CERTs Prescribing Safety Program	Platt, Richard	Harvard Pilgrim Healthcare
Intensive Care Unit Safety Reporting System	Pronovost, Peter J.	Johns Hopkins University
Staff Nurse Fatigue and Patient Safety	Rogers, Ann E.	University of Pennsylvania School of Nursing
CCH/RUSH Diagnostic Error	Schiff, Gordon	Hektoen Institute

Evaluation and Research Center		
Systems Approach for Improving Region-Wide Patient Safety	Sirio, Carl A.	University of Pittsburgh
Malpractice Insurers' Medical Error Prevention Study	Studdert, David M.	Harvard University
Center for Evaluation and Research in Pediatric Safety	Taylor, James Alexander	University of Washington
Using Prospective MDS Data to Enhance Resident Safety	Teigland, Christie	Foundation for Long Term Care
Translating Safety Practices from Aviation to Healthcare	Thomas, Eric James	University of Texas Health Science Center Houston
Accountability and Health Safety: A Statewide Approach	Thorpe, Kenneth E.	Georgia Hospital Association
Do Organizational Factors Influence Both Patient and Worker?	Trinkoff, Alison M.	University of Maryland School of Nursing
Center for Safety in Emergency Care	Wears, Robert L.	University of Florida
The Relation of Hospital Workload to Patient Safety	Weissman, Joel Steven	Massachusetts General Hospital
Patient Safety Improvement Using Reporting Systems	Williams, Scott D.	Utah Department of Health
Suncoast Developmental Center for Patient Safety Evaluation & Research	Wolfson, Jay	University of South Florida

APPENDIX C.
ANALYSIS OF AHRQ PATIENT SAFETY PROJECTS IN THE CONTEXT OF THE EVIDENCE REPORT AND NQF SAFE PRACTICES

Table C.1
Percentage of Evidence Report Chapters and NQF Safe Practices
Covered by AHRQ Projects

Name of Detailed Table	Percent of Evidence Report Chapters or NQF Safe Practices covered by AHRQ research projects	Percent of Evidence Report Chapters or NQF Safe Practices covered by AHRQ intervention projects
Evidence Report: Impact and Effectiveness		
Greatest strength of evidence	0% (0/11)	0% (0/11)
High strength of evidence	21% (3/14)	7% (1/14)
Medium strength of evidence	14% (3/22)	9% (2/22)
Lower impact and/or strength of evidence	27% (4/15)	13% (2/15)
Lowest impact and/or strength of evidence	0% (0/11)	0% (0/11)
Evidence Report: Further Research		
Likely to be highly beneficial	17% (5/30)	10% (3/30)
Likely to be beneficial	14% (4/29)	7% (2/29)
Evidence Report: Not Rated, But Covered in AHRQ Projects	88% (14/16)	69% (11/16)
NQF-Endorsed Safe Practices		
In the evidence report	47% (8/17)	35% (6/17)
Not in the evidence report	38% (5/13)	15% (2/13)

As shown by these findings, the patient safety projects have the potential to expand the evidence base on patient safety practices. Decisions on funding these projects were made in the same time period that AHRQ funded the development of the evidence report. Therefore, AHRQ and its reviewers did not have the evidence report information to help guide funding decisions. The choices on mix of projects were guided primarily by the recommendations in the QuIC report. The fact that the funded projects indeed are covering practices for which the evidence report determined more evidence was needed suggests there was some shared understanding on research needs, even in the absence of the formal assessment provided by the evidence report.

Table C.2
Topics or Practices Not Rated in the Evidence Report But Covered in AHRQ Projects

Chapter	Patient Safety Practice	Number of research projects testing/ studying this practice or topic	Number of intervention projects implementing this practice or topic
4	Incident Reporting	9	16
5	Root Cause Analysis	4	6
8	Computer Adverse Drug Event (ADE) Detection and Alerts	1	1
9	Protocols for High-Risk drugs: Adverse Events Related to Anticoagulants	3	0
15	Prevention of Nosocomial Urinary Tract Infections	0	1
16	Prevention of Intravascular Catheter-Associated Infections	1	2
26	Prevention of Falls in Hospitalized and Institutionalized Older People	2 (one is in ambulatory setting)	2
28	Prevention of Delirium in Older Hospitalized Patients	1 (long-term care facility)	0
40	Promoting a Culture of Safety	16	7
41.1	Use of Human Factors Principles in Evaluation of Medical Devices	2	0
42	Information Transfer	7	0
46	Fatigue, Sleepiness, and Medical Errors	5	0
50	Other Practices Related to Patient Participation	6	1
51	Practice Guidelines	0	1
53	Clinical Decision Support Systems	4	2
54	Educational Techniques Used in Changing Provider Behavior	2	6

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