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TECHNICAL REPORT

Assessment of the AHRQ Patient Safety Initiative

Moving from Research to Practice
Evaluation Report II (2003–2004)

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PREFACE

The Agency for Healthcare Research and Quality (AHRQ) 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 covers the period from October 2003 through September 2004. It is the second of what will be four annual reports prepared by RAND during the evaluation. Building on the previous evaluation report, *Context and Baseline* (Report I) (Farley et al., 2005), which covers the period October 2002 through September 2003, this report updates the policy context that frames the AHRQ patient safety initiative, documents the evolution and current status of the priorities and activities being undertaken in the initiative, and lays out a framework and possible measures for evaluating the effects of the initiative on patient outcomes and stakeholders other than patients. Implications of the evaluation findings are discussed with respect to future AHRQ policy, programming, and research, and suggestions are presented for strengthening AHRQ activities as the initiative moves forward. The content and format of each report are designed to provide a stable structure for the longitudinal evaluation; the results of each year's assessment contribute to a cumulative record of the initiative's evolution.

The contents of this report will be of interest to national and state policymakers, 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.

This work was sponsored by the Agency for Healthcare Research and Quality, Department of Health and Human Services, for which James B. Battles, Ph.D., serves as project officer.

This work was conducted in RAND Health, a division of the RAND Corporation. A profile of RAND Health, abstracts of its publications, and ordering information can be found at www.rand.org/health.

TABLE OF CONTENTS

PREFACE.....	iii
FIGURES.....	vii
TABLES.....	ix
EXECUTIVE SUMMARY.....	xi
ACKNOWLEDGMENTS.....	xix
ACRONYMS.....	xxi
CHAPTER 1. INTRODUCTION.....	1
Evaluating the Patient Safety Initiative.....	1
Evaluation Approach and Methods.....	5
About This Report.....	6
CHAPTER 2. CONTEXT AND INPUT EVALUATIONS.....	7
The Policy Context.....	7
Strategic and Organizational Context.....	8
Update on AHRQ Patient Safety Activities.....	9
Groups of Patient Safety Projects.....	11
AHRQ Leadership for National Patient Safety Activities.....	13
Financial Resources and Budgets.....	13
Issues to Consider.....	14
CHAPTER 3. PROCESS EVALUATION: MONITORING PROGRESS AND MAINTAINING VIGILANCE.....	17
Building from <i>Evaluation Report I</i>	17
Standards for Patient-Safety-Reporting Systems.....	18
Availability and Use of Patient Safety Measures.....	19
Data Availability on Patient Safety Performance.....	20
Issues and Action Opportunities.....	21
CHAPTER 4. PROCESS EVALUATION: PATIENT SAFETY EPIDEMIOLOGY / EFFECTIVE PRACTICES AND TOOLS.....	25
Building from <i>Evaluation Report I</i>	25
Epidemiology of Patient Safety Risks and Hazards.....	26
Update on the FY 2000 and FY 2001 Patient Safety Projects.....	27
The Challenge Grants.....	27

Standards of Evidence for Patient Safety Practices	31
Issues and Action Opportunities	33
CHAPTER 5. PROCESS EVALUATION: BUILDING INFRASTRUCTURE FOR EFFECTIVE PRACTICES	37
Building from <i>Evaluation Report I</i>	37
Patient Safety Partnerships	38
The Patient Safety Improvement Corps	42
Models for Consumer Involvement.....	44
Issues and Action Opportunities	47
CHAPTER 6. PROCESS EVALUATION: ACHIEVING BROADER ADOPTION OF EFFECTIVE PRACTICES	51
Building from <i>Evaluation Report I</i>	51
Products from Patient Safety Grantees.....	52
Use of Existing AHRQ Program Initiatives to Speed Adoption.....	52
Lessons on Moving Research into Practice.....	55
Preparing for Dissemination of Patient Safety Innovations	55
Issues and Action Opportunities	58
CHAPTER 7. PRODUCT EVALUATION: SELECTION OF OUTCOME MEASURES	61
Building from <i>Evaluation Report I</i>	61
Conceptual Framework for the Product Evaluation	61
Perspectives on Patient Safety Measures	64
Candidate Sets of Measures for Evaluation of Outcomes.....	65
Issues and Action Opportunities	67
CHAPTER 8. CONCLUSION.....	69
Future Directions and Priorities	69
Next Steps for the Evaluation.....	70
Appendix A AHRQ-Funded Patient-Safety-Reporting Demonstrations.....	71
Appendix B Summary of the AHRQ-Funded Challenge Grants.....	73
REFERENCES	75

FIGURES

Figure S.1 The Components of an Effective Patient Safety System.....	xii
Figure 1.1 The Components of an Effective Patient Safety System.....	5
Figure 2.1 Trends in AHRQ Budgets for Patient Safety and Other Expenses, FY 2000–FY 2005.....	14
Figure 5.1 Patient Safety Partnerships by Organization Type.....	41
Figure 5.2 Patient Safety Partnerships by Type of Activity	42
Figure 7.1 Conceptual Model of Potential Effects of the National Patient Safety Initiative.....	62

TABLES

Table 1.1. Time Line for Reporting Results from the Longitudinal Evaluation of the National Patient Safety Initiative	3
Table 2.1. AHRQ Patient-Safety Performance Goals and Targets for Fiscal Years 2002–2005.....	10
Table 2.2. History of AHRQ Funding for Groups of Patient Safety Grants, FY 2000–FY 2005.....	11
Table 4.1. Information on Patient Safety Epidemiology Available from Recently Published Articles and Addressed by AHRQ-Funded Challenge Projects	26
Table 4.2. Patient Safety Issues and Special Populations Addressed by the Patient Safety Challenge Projects	28
Table 4.3. Number of AHRQ Projects Covering Evidence Report Chapters.....	29
Table 4.4. Components of a Patient Safety Infrastructure Addressed by AHRQ Patient Safety Projects	30
Table 5.1. Types of Organizations Interviewed for the Analysis of Patient Safety Partnerships.....	39
Table 5.2. Patient Safety Activities of Organizations in the Partnership Analysis.....	39
Table 5.3. Types of Organizations Reported in the Interviews as Involved in Patient Safety Partnerships.....	40
Table 5.4. Types of Patient Safety Activities Reported for the Partnerships	40
Table 5.5. Desirability and Feasibility of Various Approaches to Involving Consumers in Patient Safety Activities.....	46
Table 6.1. Number of Patient Safety Products Produced by Patient Safety Grantees, 1997–2004.....	52
Table 6.2. Key Components for Successful Patient Safety Interventions, Identified by AHRQ-Funded Project Leaders as “Needed”.....	56
Table 7.1. Potential Product-Evaluation Measures for Infrastructure Development and Use of Patient Safety Practices	66
Table 7.2. Potential Categories of Product-Evaluation Measures for Patient Outcomes	67
Table 7.3. Possible Product-Evaluation Measures of Effects for Nonpatient Stakeholders.....	67

EXECUTIVE SUMMARY

As of October 2004, it has been three years since the U.S. Congress funded the Agency for Healthcare Research and Quality (AHRQ) to establish the national patient safety research and implementation initiative. With these funds, AHRQ has committed to improving patient safety in the U.S. health care system by developing a comprehensive strategy for supporting expansion of knowledge about patient safety epidemiology and effective practices and by identifying and disseminating the most effective practices. AHRQ contracted with the RAND Corporation 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 for providing regular feedback to support the continuing improvement of this initiative.

This report—*Moving from Research to Practice: Evaluation Report II*—is the second of four annual evaluation reports to be prepared by the evaluation center. The first report—*Context and Baseline: Evaluation Report I* (Farley et al., 2005)—covers the period from October 2002 through September 2003, and it focuses on assessing the context and goals that served as the foundation for the patient safety initiative and on developing baseline information for the process evaluation. *Evaluation Report II* covers October 2003 through September 2004, during which the evaluation continued to document activities, progress, and issues involved in (1) conducting the AHRQ-funded patient safety projects; (2) building the infrastructure to support implementation of improved patient safety practices; and (3) disseminating research results and products. In addition, we present a framework and possible measures for evaluating the effects of the patient safety initiative on outcomes for patients and stakeholders other than patients.

EVALUATION FRAMEWORK

The Policy Context

In early 2000, the Institute of Medicine (IOM) published the report *To Err Is Human: Building a Safer Health System*, which mobilized national efforts to improve the safety of the U.S. health care system (Kohn, Corrigan, and Donaldson, 2000). The IOM called for leadership from the Department of Health and Human Services (DHHS) in reducing medical errors, identifying AHRQ as the national focal point for patient safety research and practice improvements. In response to the IOM report, the Quality Interagency Coordination Task Force (QuIC) identified more than 100 actions designed to create a national focus on reducing errors, strengthening the patient-safety knowledge base, ensuring accountability for safe health care delivery, and implementing patient safety practices (QuIC, 2000).

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 public and private organizations, the agency can leverage finite resources and achieve synergy through collaboration.

The Evaluation Model

The overall evaluation design is based on the Context-Input-Process-Product (CIPP) 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, Madaus, and Kellaghan, 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 the choice of a strategy or assessing an existing strategy against the alternatives.
- ***Process evaluation*** assesses progress in implementing plans relative to the stated goals for future activities and outcomes.
- ***Product evaluation*** identifies consequences of the program for various stakeholders, intended or otherwise, to determine the effectiveness of and provide information for future program modifications.

A Framework for the Process Evaluation

The process evaluation is the largest and most complex component of the evaluation because many aspects of the health system are affected by AHRQ’s work and that of numerous other organizations involved in patient safety. We adopted a national perspective, the goal of which was to assess the progress of the AHRQ initiative and the activities of other federal agencies in the context of the larger U.S. patient safety system.

We identified five system components that are essential to bringing about improved practices and a safer health care system for patients. Together, these components provide a cohesive framework for the process evaluation. They work together to bring about improved practices and a safer health care system for patients, as shown in Figure S.1. The components are (1) monitoring progress and maintaining vigilance; (2) establishing knowledge of the epidemiology of patient-safety risks and hazards; (3) developing effective practices and tools; (4) building infrastructure for effective practices; and (5) achieving broader adoption of effective practices. Our process evaluation examined progress in strengthening each of these components.

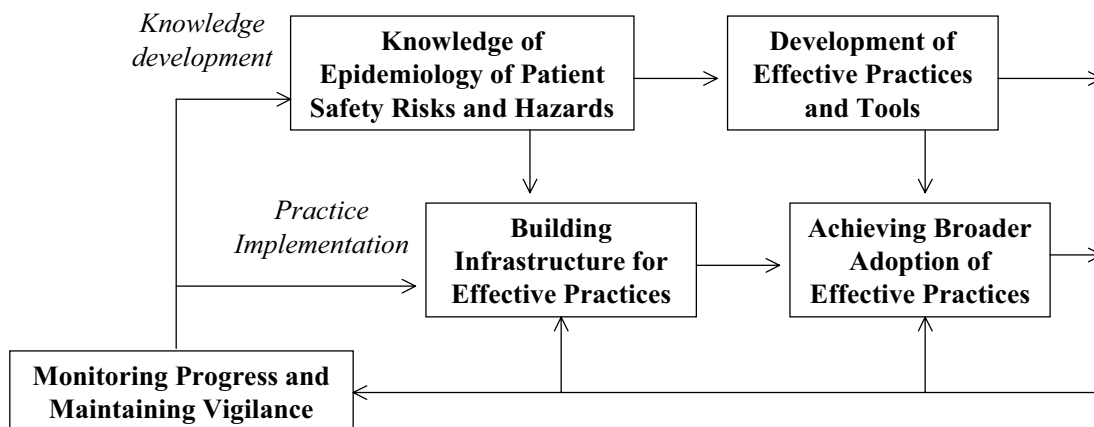


Figure S.1 The Components of an Effective Patient Safety System

The component for monitoring progress and maintaining vigilance is identified first and placed on the bottom left side of the figure, reflecting the need for early data on patient safety issues to help guide intervention choices, as well as ongoing 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, which contribute to practice implementation—building infrastructure and adopting effective practices (in the second row of the figure).

FINDINGS FROM THE CONTEXT AND INPUT EVALUATIONS

Context Evaluation

External events continue to influence the patient-safety strategy and activities of AHRQ and other federal agencies. In *Evaluation Report I*, we identified the following consequences for AHRQ: a clear mandate by Congress for AHRQ leadership; a need to balance research and implementation; resource constraints; accountability for results; and coordination of multiple activities. Two subsequent major events have altered the scope of the patient safety initiative or were expected to do so. The first is the shift in focus of patient safety appropriations toward grants that advance the implementation of health information technology (health IT). The second is the impending passage of legislation that would create protections for adverse-event reporting systems and establish patient safety organizations (PSOs).

Input Evaluation

During FY 2004, AHRQ made several changes to its overall management and focus that have implications for the agency's approach to implementing patient safety improvements:

- Adoption of a new mission and strategic plan designed to improve quality and safety in health care through a combination of scientific research and actions.
- Establishment of ten portfolios of work that are intended to achieve greater synergy among related activities undertaken across the five AHRQ centers and to provide clearer information to external audiences about what the agency does.
- Establishment of the Research Empowering America's Changing Healthcare System (REACH) program to design and support performance-improvement implementation activities.

Cumulative funding for patient safety projects has generated a substantial body of work since FY 2000. The six systems-related best-practice grants funded in FY 2000 were followed by 75 projects in six groups, funded in FY 2001. The 13 patient safety challenge grants were funded in FY 2003, and the first health-IT grants and contracts were funded in FY 2004 (108 projects).

Collectively, these policy, organizational, and project-funding changes have several implications for AHRQ's future activities, including the need to create an interdisciplinary culture for action, balance its expanded implementation function with its traditional research role, and prepare for pending PSO legislation.

FINDINGS AND ACTION OPPORTUNITIES FROM THE PROCESS EVALUATION

Monitoring Progress and Maintaining Vigilance (Chapter 3)

AHRQ-sponsored activities for the development of a national-level data network capability proceeded on several fronts in 2003–2004. Several AHRQ-funded projects have generated important contributions to building a patient-safety reporting and data infrastructure, including

the IOM data standards project, the federal data system project, and activities of the 16 reporting demonstrations that were part of the FY 2001 group of patient safety grants. Other AHRQ-supported activities also show promise in this area, including the Patient Safety Improvement Corps (PSIC), work on a common taxonomy for patient-safety-reporting systems, and funding of state-level health-IT demonstrations. AHRQ faces both an opportunity and a challenge to play a key role in bringing about a national-level patient safety data network with the capability to monitor patient safety performance data and enable sharing of information across organizations. AHRQ's leadership will be required to stimulate dissemination and adoption of data and system standards, including working closely with end users to ensure that the system designs are serving their needs. More work also is needed on developing a comprehensive set of patient safety measures that address care across health care settings and on encouraging adoption of these measures by accreditation and credentialing organizations.

Suggestions for AHRQ Action

- As the state and regional health information systems projects progress, AHRQ should leverage this work to encourage broad use of the data standards recommended in the 2004 IOM report (Aspden et al., 2004).
- AHRQ should build upon the technical products of the federal data system project by pursuing expanded use of the newly developed reporting and data-warehouse capability, with the goal of moving toward a national data repository with multiple public and private users.
- AHRQ should place a priority on establishing a broader set of national patient safety measures that represent the most important safety aspects of the patient's health care experience in a variety of settings. To do so, it should use a structured consensus process involving multiple stakeholders and build upon the existing Patient Safety Indicators.
- 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 adopting the measures as standards in their accreditation processes.

Establishing Knowledge of the Epidemiology of Patient Safety Risks and Developing Effective Practices and Tools (Chapter 4)

The contribution of AHRQ-funded projects to the knowledge base on patient safety epidemiology and practices continues to grow. Although only a relatively small share of the total knowledge that these projects are likely to generate has surfaced thus far, much more will become available with the publication of the AHRQ compendium of patient safety papers and subsequent journal articles. Recent additions to this body of work are the 13 challenge grants funded in FY 2003, which focus on implementation strategies to address a broad range of patient safety issues.

As results emerge from the patient safety projects, it will be critical to synthesize them in ways that make the information accessible to various end users. These include the scientific community, which will use the results for updating the body of evidence on patient safety practices, and the health care community, which will adopt the new practices that have been shown to be effective. Health care providers also need to know the business case for practices, which is not being addressed well by the funded projects. AHRQ has been preparing to perform these syntheses.

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.
- AHRQ should establish definitions and standards for measurement methods as the basis for valid and consistent epidemiological 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.
- AHRQ should commit resources to define the standards of evidence that should apply for assessing the effectiveness of patient safety practices. To this end, AHRQ should support a panel process to produce recommendations for standards of evidence for patient safety.
- As the patient safety projects generate new evidence on practices and as standards of evidence have been adjusted to apply more effectively to patient safety practices, AHRQ should update the evidence report on patient safety to incorporate new evidence for widespread availability to users.
- AHRQ should pursue a twofold strategy to generate information on the business case for promising patient safety practices: (1) Require all of its funded patient-safety projects that are conducting practice interventions to collect and report data on implementation costs as part of their research; and (2) identify some of the projects that have successful interventions and separately fund analyses of the cost-effectiveness and return on investment for those interventions.
- For subsequent patient-safety-implementation grants, AHRQ should focus on funding efforts by nonacademic medical centers, to improve the generalizability of findings on patient safety practices.
- AHRQ should consider the development of a noncompetitive renewal mechanism for especially promising patient safety projects.

Building Infrastructure for Effective Practices (Chapter 5)

Analyses of three disparate infrastructure-development activities—partnership activities, the PSIC, and consumer involvement in patient safety—reveal an active infrastructure-building process for supporting patient safety improvements. From interviews with 35 organizations, we identified 135 partnerships among 98 participating organizations. As AHRQ expands its outreach for implementation, we should find increased AHRQ involvement in partnerships when this analysis is repeated in 2005–2006. The PSIC participants are bringing their new skills home to train others and put the techniques to work. In addition, active consumer involvement in the patient safety activities of local health care organizations is gaining momentum.

As AHRQ considers future options for extending its role in the development of partnerships and the PSIC, it will need to choose strategically where to invest its limited resources. Consumers should continue to be the spearhead of future consumer-involvement actions, but there are ways in which AHRQ might help them accomplish their goals.

Suggestions for AHRQ Action

- AHRQ should seek out new strategic partnerships, especially in areas where little collaboration currently exists, while strengthening existing partnerships.
- Wherever possible, AHRQ should eliminate real and perceived barriers to partnering with other organizations (private or public).
- AHRQ should seek ways to maintain and build on the network of trainees who have gone through the Patient Safety Improvement Corps training.
- AHRQ should expand the Patient Safety Improvement Corps model to include stakeholders in addition to state governments and hospitals.
- AHRQ should fund Centers of Excellence for Consumer Engagement to study the effect of involving patients and families in patient safety activities.
- AHRQ should partner with consumer organizations and organizations with expertise involving patients and families to disseminate best practices for consumer engagement in patient safety improvement.
- AHRQ should encourage the use and evaluation of information technology to increase consumer awareness of patient safety issues and provide a means for consumers to report errors at the time they occur.

Achieving Broader Adoption of Effective Practices (Chapter 6)

It is a significant challenge to translate research findings into practice by end users so that changes toward a patient-safety culture and improved practices can be achieved in the U.S. health care system. End users view AHRQ as a leader in patient safety research and knowledge. Its contribution to knowledge is being seen in early evaluation results. AHRQ-funded projects were found to have generated 70 new products between July 2003 and July 2004, 61 of which were journal articles, suggesting that project leaders continue to focus on traditional peer-reviewed publications for communicating research results.

Because AHRQ is not an organization on the “front line” of health care delivery—where changes in practices need to occur to improve safety—it is essential for AHRQ to identify and develop strategic partnerships with those who can provide the translation bridge to end users and the systems in which they work. AHRQ should continue to explore how to best use its existing programs and funding mechanisms to engage end users in adopting safe practices. Although this step can be taken in the absence of new funding, these programs would benefit from additional resources that would allow AHRQ to make significant inroads in changing the American health care system. At the current level of staff and budget, the agency’s influence as a change agent in transforming health care may be seriously constrained.

Suggestions for AHRQ Action

- AHRQ should develop and implement a strategic plan that specifies how the agency will disseminate new patient-safety knowledge and products to the broad spectrum of stakeholders, as well as actions it will take to facilitate adoption of new and safer practices.
- AHRQ should expand its internal infrastructure and budget to support future knowledge-transfer and dissemination work, so that its work is funded appropriately, has effective leadership and appropriate expertise to conduct the work, and has the support of the agency director.

- AHRQ should expand investment in AHRQ’s existing programs that support practice adoption, using those programs strategically to promote translation of patient safety research into practice, with specific guidance on which patient safety applications should be pursued.
- AHRQ should develop “mentoring grants” that extend the successful work of implementation grantees more broadly across the health care system by enabling them to provide implementation support to other organizations.
- AHRQ should seek to build partnerships with health-care providers and other end users to secure their input at the front end of the research process (so that research products are end-user-driven) and by extending the resources and reach of the agency for translation and diffusion of practices.

THE PRODUCT EVALUATION AND SELECTION OF MEASURES

To assess the effects of the patient safety initiative, this evaluation will establish a foundation of data sources and defined measures that can serve as a starting point for ongoing monitoring of progress in improvements in patient safety practices and outcomes. In identifying candidate measures of effects of the patient safety initiative, we include effects on both patient outcomes and stakeholders other than patients, as well as effects on infrastructure development and the introduction of proven patient safety practices. For example, measures are being explored for patient outcomes (e.g., hospital readmission rates, adverse medication events, patient-reported events), effects on other stakeholders (i.e., providers, state governments), and effects on infrastructure development (e.g., National Quality Forum patient safety events in state reporting systems).

As AHRQ updates its patient safety strategy, this evaluation resource can be built into its scope of work to enable assessments of effects to continue after this evaluation is completed. This work also may help increase data availability by encouraging data collection by other organizations, which would contribute to content development for a national patient safety data network.

Suggestions for AHRQ Action

- AHRQ should develop Consumer Assessment of Healthcare Providers and Systems (CAHPS®) surveys or survey modules for patients to report on patient safety issues in ambulatory care, hospital services, and long-term care settings.
- AHRQ should work with organizations in the field to initiate measurement capabilities for tracking effects for which data sources do not yet exist.

NEXT STEPS FOR THE EVALUATION

In 2004, nearly five years since the publication of the IOM report *To Err Is Human*, the national patient safety initiative has gained full momentum, and AHRQ is expanding its activities from knowledge development to implementation. From our observations of AHRQ’s patient safety strategy and the current activities of its grantees and field organizations, we have identified several priorities that we encourage AHRQ to pursue in the near future:

- Facilitate movement toward a *national patient safety data repository* by encouraging use of consistent data standards, as recommended by the IOM, and establish a set of national patient-safety measures for assessing performance.

- Disseminate *patient-safety knowledge and products* from the FY 2000–FY 2001 projects, including development of “off-the-shelf” products that can be used readily by health care organizations.
- Modify the *standards of evidence* used to assess the effectiveness of patient safety practices, to enable rigorous assessment of practices that cannot be tested using randomized control study designs.
- Assess the role of *health information technology* in achieving safer health care practices and its interface with the human aspects of care delivery, using results of the newly funded health-IT grants as well as knowledge generated by other patient safety projects that have addressed the use of technology for patient safety practices.
- Provide mechanisms to support consumer-led organizations in their pursuit of active *patient involvement* with health care organizations for actions to achieve safer care, including dissemination of the models they are using to a broader health care audience.
- Expand *partnerships with other organizations* involved in patient safety to achieve synergy in patient safety improvements by leveraging the combined expertise of these organizations and AHRQ’s finite resources.

In 2004–2005, as the patient safety evaluation center embarks on the third year of its work, the RAND project team will continue gathering information on the evolution of the patient safety initiative through our process-evaluation activities. At the same time, we will begin to collect and analyze data for the product evaluation, assessing the effects of the initiative on patient outcomes and stakeholders other than patients.

ACKNOWLEDGMENTS

We gratefully acknowledge the participation of numerous individuals in the evaluation process. At the national level, AHRQ staff and staff of other federal agencies and private-sector organizations involved in patient safety activities have provided useful perspectives and information on the initiative's approach and activities.

The principal investigators of the AHRQ-funded patient safety and other related projects or initiatives have also contributed valuable information through their participation in interviews and focus groups, and by providing written materials about activities relevant to the patient safety initiative. Grantees have shared their experiences in the execution of their research activities, as well as in the cross-grantee collaborative activities supported by AHRQ and its contractors. Individuals in other organizations involved in patient safety activities have also been generous with their time and information, enabling us to gain a comprehensive understanding of the growing volume of patient safety activities occurring in the field and of AHRQ's contribution to them.

Our AHRQ project officer, James Battles, has been instrumental in guiding the conceptual formation and execution of the evaluation. His support derives from a commitment to objective, formative evaluation, and to creating opportunities for learning over time, both of which provide a strong foundation for this evaluation. We also thank our RAND colleagues Chau Pham, Liisa Hiatt, Scott Ashwood, and Stacy Fitzsimmons for their indispensable contributions to our data collection and analysis processes. Finally, we thank Elizabeth Sloss and Patricia Stone for their comments on an earlier draft of this report. Any errors of fact or interpretation are, of course, the responsibility of the authors.

ACRONYMS

AHA	American Hospital Association
AHRQ	Agency for Healthcare Research and Quality
AMA	American Medical Association
AMGA	American Medical Group Association
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CDC	Centers for Disease Control and Prevention
CDOM	Center for Delivery, Organization, and Markets
CEO	chief executive officer
CERT	Center for Education and Research on Therapeutics
CIPP	Context-Input-Process-Product
CMS	Centers for Medicare and Medicaid Services
CP3	Center for Primary Care, Prevention, and Clinical Partnerships
CPOE	computerized physician order entry
CQuIPS	Center for Quality Management and Patient Safety
DHHS	Department of Health and Human Services
DoD	Department of Defense
EHR	electronic health record
EPC	Evidence-based Practice Center
FDA	Food and Drug Administration
FMEA	failure mode and effects analysis
HCUP	Healthcare Cost and Utilization Project
HIPAA	Health Insurance Portability and Accountability Act
health IT	health information technology
HRSA	Health Resources and Services Administration
ICU	intensive care unit
IDSRN	Integrated Delivery System Research Networks
IOM	Institute of Medicine
JCAHO	Joint Commission on Accreditation of Health Care Organizations
JHU	Johns Hopkins University
MHA	Michigan Hospital Association
MPSMS	Medicare Patient Safety Monitoring System
NCPS	National Center for Patient Safety
NORC	National Opinion Research Center
NPSF	National Patient Safety Foundation
NQF	National Quality Forum
OCKT	Office of Communications and Knowledge Transfer
PBRN	Practice-Based Research Network
PFQ	Partnerships for Quality
PI	principal investigator

PO	project officer
PRA	probabilistic risk assessment
PSI	Patient Safety Indicator
PSIC	Patient Safety Improvement Corps
PSO	patient safety organization
PSTF	Patient Safety Task Force
QIO	Quality Improvement Organization
QIPMO	Quality Improvement Program for Missouri
QuIC	Quality Interagency Coordination Task Force
RCA	root cause analysis
RCT	randomized control trial
REACH	Research Empowering America's Changing Healthcare System
RFA	Request for Application
ROI	return on investment
TRIP	Translating Research into Practice
UCSF	University of California, San Francisco
ULP	User Liaison Program
USP	United States Pharmacopeia
VA	Department of Veterans' Affairs

CHAPTER 1. INTRODUCTION

As of October 2004, it had been three years since the U.S. Congress funded the Agency for Healthcare Research and Quality (AHRQ) to establish the national patient safety research and implementation initiative. With these funds, AHRQ has committed to improving patient safety in the U.S. health care system by developing a comprehensive strategy for supporting expansion of knowledge about patient safety epidemiology and effective practices and by identifying and disseminating the most effective 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 for providing regular feedback to support the continuing improvement of this initiative. AHRQ specified that the evaluation 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 on meeting the objectives of the initiative, and make recommendations for improvement. The evaluation also is to assess overall initiative effects, outcomes, and adoption diffusion, using both qualitative and quantitative assessment approaches.

This report—*Evaluation Report II*—is the second of four annual evaluation reports to be prepared by the evaluation center. The information and analyses presented in *Evaluation Report I* cover the period October 2002 through September 2003 and focus on assessing the context and goals that served as the foundation for the patient safety initiative and on developing baseline information for the process evaluation. *Evaluation Report II* covers October 2003 through September 2004, during which the evaluation continued to document activities, progress, and issues involved in (1) conducting the AHRQ-funded patient safety projects; (2) building the infrastructure to support implementation of improved patient safety practices; and (3) disseminating research results and products. In addition, we present a framework and possible measures for evaluating the effects of the patient safety initiative on outcomes for patients and other stakeholders.

EVALUATING THE PATIENT SAFETY INITIATIVE

The Policy Context

In early 2000, the Institute of Medicine (IOM) published the report *To Err Is Human: Building a Safer Health System*, calling for leadership from the Department of Health and Human Services (DHHS) in reducing medical errors, and identifying AHRQ as the national focal point for patient safety research and practice improvements (Kohn, Corrigan, and Donaldson, 2000). In response to this report, the Quality Interagency Coordination Task Force (QuIC)¹ identified more than 100 actions designed to create a national focus on reducing errors,

¹ 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.

strengthening the patient safety knowledge base, ensuring accountability for safe health care delivery, and implementing patient safety practices (QuIC, 2000).

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 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 public and private organizations, the agency can leverage finite resources and achieve synergy through collaboration.

The Evaluation Model Used

Through this longitudinal evaluation, 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 Context-Input-Process-Product (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, Madaus, and Kellaghan, 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 the initiative's 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.

Table 1.1 illustrates the sequence of the four stages of the CIPP model as applied to this program evaluation. The activities covered in this second evaluation report are shown in the shaded column. They include updates on context changes and changes in goals or strategy, key components of the process evaluation, and initial identification of potential outcome measures and data sources. The third year of the evaluation will cover these same activities, as well as additional components of the product evaluation. The fourth evaluation year will focus on the product evaluation to assess the effects of the patient safety initiative on various stakeholders.

Table 1.1.
Time Line for Reporting Results from the Longitudinal Evaluation
of the National 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 of patient safety activities related to the initiative	X			
Assessment of contributions by AHRQ-funded patient safety projects to <i>patient safety knowledge</i> and <i>patient safety practices</i>	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 effects			X	X

Major Stakeholder Groups Addressed

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

- *Patients* – those individuals receiving health care services, bearing the effect of adverse health care events, and having a direct stake in the occurrence of those events

- *Providers*—individuals, including physicians, nurses, and the organizations that employ them, who 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*—entities that license health care providers and (in many instances) operate adverse-event-reporting systems, and that have a stake in tracking adverse events and in promoting remediation efforts by providers
- *Patient safety organizations*—entities that are working to promote best practices, education, and technology adoption in patient safety, and that have a stake in building collaborations to achieve these ends
- *Federal government*—agencies in the federal government involved in patient safety activities, in particular AHRQ and other Department of Health and Human Services (DHHS) agencies.

A Framework for the Process Evaluation

For AHRQ’s patient safety initiative, the process evaluation is the largest and most complex component of the evaluation because many aspects of the health system are affected by AHRQ’s work and that of numerous other organizations involved in patient safety. We identified five system components that are essential to bringing about improved practices and a safer health care system for patients; together, these components provide a cohesive framework for the process evaluation, as shown in Figure 1.1. Our process evaluation examined progress in strengthening each of these five system components. For each component, it addressed the three questions identified above: (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?

This system framework 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. The system components are 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.

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,

hazards to safety created by the organization’s structure, and effects of the macro-environment on the organization’s ability to act.

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.

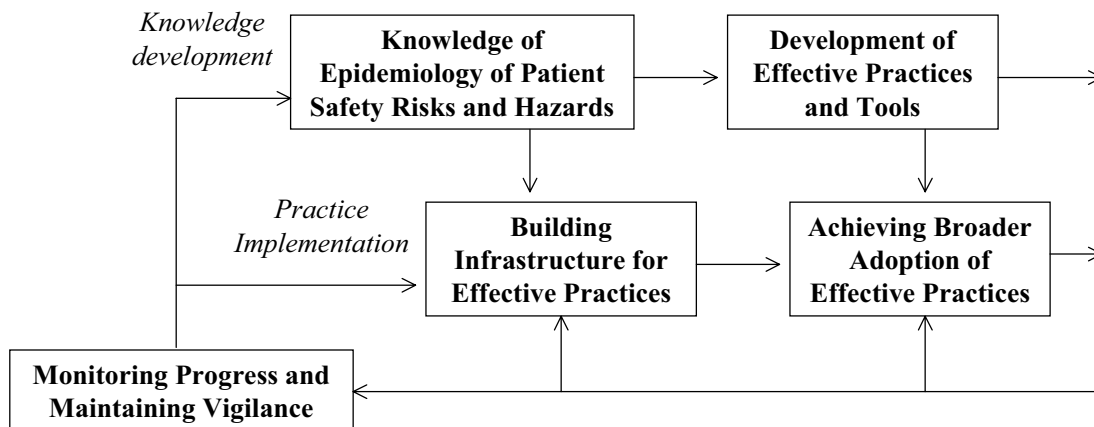


Figure 1.1 The Components of an Effective Patient Safety System

The component for monitoring progress and maintaining vigilance is identified first and placed on the bottom 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 adopting effective practices (in the second row of the figure).

EVALUATION APPROACH AND METHODS

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, and working with public and private organizations to put the knowledge and practices to work in the health care system.

At the local level, AHRQ projects are 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. The Patient Safety Research Coordinating Center (hereafter called the Coordinating Center) is funded by AHRQ to serve as an administrative extension of the agency staff to help achieve the synergy to make “the whole initiative greater than the sum of its parts.”

To obtain information specific to the individual funded projects, we used four data sources: (1) the AHRQ database containing basic information on the patient safety projects that are part of the initiative; (2) proposals prepared by the research teams operating the patient safety projects; (3) focus groups conducted with each project group; and (4) individual interviews conducted with the principal investigator of each patient safety project. Data from the AHRQ database were used to identify which projects were funded under each Request for Application (RFA), the type of funding provided, and identification and contact information for the project principal investigators. These data were supplemented with data that RAND extracted and coded from the proposals submitted for the projects; with these data, we characterized the projects regarding the patient safety issues they addressed, the practices being tested, settings of care, special populations, contribution to building new evidence for patient safety practices, and other information. RAND conducted the focus groups and individual interviews using written interview protocols, to document grantees' experiences in carrying out their projects and obtain their feedback on the larger patient safety initiative.

ABOUT THIS REPORT

This evaluation report updates information on the status of the AHRQ patient safety initiative and examines progress in carrying out the component activities that were identified in *Evaluation Report I*. The recommendations we offer focus on actions that AHRQ is in a position to take and are intended as suggestions to help guide the agency's future strategy and activities. In some cases, we reiterate recommendations offered in *Evaluation Report I*; in other cases, we offer new recommendations or extensions of previous ones, based on what we have learned in the most recent evaluation analyses conducted in 2003–2004.

The remaining seven chapters of the report are organized according to the context, input, process, and product components of the CIPP evaluation model. Chapter 2 focuses on the context and input components, summarizing the history leading up to funding of the patient safety initiative and presenting updated information on AHRQ's patient safety strategy, activities, and budget. Chapters 3 through 6 present assessments from our process evaluation on the progress and current status of the AHRQ patient safety initiative, organized according to the five-component patient safety system structure presented in Figure 1.1 and defined above. Chapter 3 addresses monitoring and vigilance, Chapter 4 addresses the two components of developing knowledge on patient safety epidemiology and practices, Chapter 5 addresses infrastructure, and Chapter 6 addresses activities for adoption of effective practices.

Chapter 7 introduces the product-evaluation component of the CIPP model. Here, we present the conceptual framework we plan to use for evaluating the effects of the patient safety initiative on patient outcomes and other stakeholders in years 3 and 4 of the evaluation, and we identify categories of measures that will be pursued for use in assessing initiative effects. Chapter 8 concludes with a summary of the current status of the AHRQ patient safety initiative and describes the next steps in our longitudinal evaluation.

Readers should note that, unless otherwise stated, the information presented in this report is current as of September 2004. Assessment of the additional activities related to AHRQ's national patient safety initiative that have been undertaken since that time will be included in *Evaluation Report III*.

CHAPTER 2. CONTEXT AND INPUT EVALUATIONS

This chapter updates the information presented in *Evaluation Report I* regarding the policy context that frames the AHRQ patient safety initiative (context evaluation), as well as the priorities and activities being pursued by AHRQ as it implements the initiative (input evaluation).

THE POLICY CONTEXT

The events that led to formation and funding of the national patient safety initiative may be summarized as follows:

- The science of patient safety was relatively immature as this initiative began in 2000. Knowledge of the epidemiology of safety in health care was limited, the body of published research was inadequate for establishing evidence regarding the effectiveness of practices to improve patient safety, and recognition or acceptance within the health care system that there was a “patient safety problem” was lacking.
- Strong public sentiment and support for reducing health care harm to patients was stimulated by the IOM report *To Error Is Human: Building a Safer Health System*, first released on November 30, 1999. As a result, Congress took action to make patient safety a national policy priority.
- Following a difficult period in which AHRQ had received criticism and had been at risk of being discontinued, the agency, under new leadership, received reauthorization in 1999 with a new mandate from Congress, including a leadership role in patient safety.
- Congress enacted the initial appropriation of \$50 million for FY 2001 and designated AHRQ to lead the federal patient safety initiative and fund needed research. The funding was viewed by many as small relative to the resources needed to develop better patient-safety knowledge and apply practice improvements.
- In response to this new national priority, starting in 2000, patient safety activities were undertaken by numerous organizations, including federal agencies, state governments, state coalitions, health care providers, professional associations, and other private organizations.

Challenges for the AHRQ Patient Safety Initiative at Baseline

In *Evaluation Report I*, we found that this context has created the following consequences for AHRQ as it implements 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 reducing 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 those activities and to encourage consistent standards of practice.

Recent Events

Two major events during 2003–2004 either have altered the scope of the patient safety initiative or were expected to do so. One of these was the shift in focus of patient safety appropriations toward health information technology (health IT) grants, starting in FY 2004. The other was the pending passage of legislation that would create protections for adverse-event-reporting systems and establish patient safety organizations (PSOs).

In FY 2004, as the patient safety projects funded in FY 2001 were nearing completion, Congress appropriated \$50 million to support health-IT projects that improve patient safety and quality in health care and another \$10 million to support health-IT standards development. In our interviews, patient safety grantees and other stakeholders expressed mixed reactions to this shift in focus. Few disputed the importance of building this capability in the health care system. However, many felt that research and development efforts need to address human and technological considerations, and interactions among them, in a balanced way. They were concerned that loss of funding for the human side of patient safety improvement may weaken the momentum and effectiveness of interventions.

In August 2004, the Senate passed the “Patient Safety and Quality Improvement Act” (S. 720), which would create new protections for adverse-event-reporting systems in health care and would help foster a national reporting mechanism through which hospitals, nursing homes, and physicians could report medical errors to new, private PSOs. The House already passed a similar bill (H.R. 663) in March 2003. Under either of these bills, event reporting would be voluntary and entitled to protection from discovery in civil litigation. As of September 2004, these bills were going into conference, with final legislation expected to be enacted in early 2005. If AHRQ assumes responsibility for this function, it will be in a position to identify additional potential partners for patient safety activities. Without final legislation, it still is not clear what the components of the PSO program will be, what the timing will be for carrying it out, and whether Congress will appropriate funding for AHRQ to carry out the work.

STRATEGIC AND ORGANIZATIONAL CONTEXT

AHRQ Mission, Strategy, and Goals

The evolution of the AHRQ patient safety initiative is best examined in the context of the agency’s overall strategy and goals. During FY 2004, AHRQ defined a new mission that moves the agency away from its previous focus on research and toward an explicit commitment to quality and safety in health care through a combination of scientific research and promotion of improvement (AHRQ, 2004a). The strategic plan that guides its activities has four goals: safety/quality, efficiency, effectiveness, and organization excellence.

Standard Portfolios for AHRQ Work

Toward the end of FY 2004, AHRQ management introduced a matrix organization structure designed to achieve greater synergy among related activities and to provide clearer information to external audiences about what the agency does. Ten portfolios of work were

established, each with a designated leader responsible for managing and coordinating the mix of activities included within its scope. The ten portfolios are:

- System capacity and bioterrorism
- Data development
- Care management
- Cost, organization, and socio-economics
- Health information technology
- Quality/safety of patient care
- Long-term care
- Pharmaceutical outcomes
- Training
- Prevention

Because the portfolios are relatively new and still under development, it is not always clear which projects should be in which portfolio. Some issues, such as the patient safety initiative, cut across portfolios, requiring additional coordination. The central activities of the patient safety initiative reside within the quality/safety of patient care portfolio, but the health-IT grants are in the health information technology portfolio, and the Patient Safety Indicators (PSIs) are in the data development portfolio. Other new programs, such as the Research Empowering America's Changing Healthcare System (REACH), are being designed to support AHRQ's performance improvement implementation activities. According to AHRQ staff, REACH will identify mechanisms that can mobilize coordinated actions, thereby yielding greater effects on safety improvement. The FY 2005 budget includes \$6 million to fund new grants and contracts under this program.

AHRQ Patient Safety Strategy and Goals

In 2003, AHRQ established a new patient safety plan, which replaced its initial ten-year plan. In accordance with this strategy, AHRQ is using a four-element framework to structure its long-range work and performance assessment: (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 performance goals and fiscal-year targets for implementing the first three elements of this plan are listed in Table 2.1.

UPDATE ON AHRQ PATIENT SAFETY ACTIVITIES

This analysis considers factors contributing to program changes that occurred in 2003–2004 and implications for future patient safety activities. It is based on information obtained from documents and Web sites, as well as from interviews conducted with key AHRQ leaders and staff.

AHRQ Organization

AHRQ's overall programming is managed by five centers, all of which are involved in the patient safety initiative to varying degrees. Three of the centers—the Center for Quality Improvement and Patient Safety (CQuIPS), the Center for Primary Care, Prevention, and Clinical Partnerships (CP3), and the Center for Delivery, Organization, and Markets (CDOM)—are the most actively involved in patient safety activities. CQuIPS, which managed the patient safety grants awarded in FY 2000 and FY 2002, has primary responsibility for overall management of the patient safety initiative. CP3 has the lead responsibility for awarding and managing the health-IT grants that were funded in FY 2004.

The New Quality and Safety of Patient Care Portfolio

The quality and safety of patient care portfolio is the most mature of the ten new portfolios; its scope generally matches that of CQuIPS. It contains all of the grants bundled with the FY 2000/FY 2001 patient safety funding, as well as the challenge grants funded in FY 2003, the Patient Safety Improvement Corps (PSIC), and other patient safety partnering initiatives. The separation of health-IT projects and the PSIs into other portfolios may fragment efforts to achieve a unified patient safety strategy.

Table 2.1.

AHRQ Patient-Safety Performance Goals and Targets for Fiscal Years 2002–2005

Identify the Threat

Performance Goal: By 2010, patient safety events reporting will be standard practice in 90 percent of hospitals nationwide.

FY 2005	Continue reporting on patient safety events and begin to analyze the number and types
FY 2004	Pilot the system at 50 hospitals and begin reporting on patient safety adverse events
FY 2003	Develop reporting mechanism and data structure through the National Patient Safety Network

Identify and Evaluate Effective Practices

Performance Goal: By 2010, double the number of patient safety practices that have sufficient evidence available and are ready for implementation. (Use the Evidence-based Practice Center [EPC] report for baseline data.)

FY 2005	Have five health care organizations/units of state/local governments evaluate the effect of their patient safety best practices interventions
FY 2004	Have in place six health facilities or regional initiatives to implement interventions and service models on patient safety improvements
FY 2003	Make awards to at least six facilities or initiatives

Educate, Disseminate, and Implement to Enhance Patient Safety

Performance Goal: By 2010, successfully deploy hospital practices so that medical errors are reduced nationwide.

FY 2005	Have on-site experts in patient safety in 15 additional states or major health care systems
FY 2004	Train ten states or major health care systems through the PSIC program; ensure that five health care organizations or units of state/local government implement evidence-based, proven safe practices
FY 2003	Establish a PSIC training program; award up to five grants to health care organizations or units of state/local government for implementing evidence-based proven safety practices
FY 2002	Conduct a planning study

SOURCE: AHRQ justification for FY 2005 budget (AHRQ, 2004a).

Support by Coordinating and Resource Centers

At the start of the patient safety initiative, AHRQ established the Patient Safety Research Coordinating Center (Coordinating Center) to serve as a stimulus and facilitator of interactions among the projects funded in FY 2000 and FY 2001. The first contract was awarded to Westat, effective October 2001, with a three-year term that ended in September 2004. As described in

Evaluation Report I, difficulties in accomplishing the intended functions were encountered early in the contract period, limiting the Coordinating Center’s ability to provide the proactive coordination role that had been originally envisioned.

In 2004, AHRQ awarded a new three-year, \$3.75-million Coordinating Center contract (with provision for two one-year options at \$1.5 million per year) to the National Opinion Research Center (NORC). This contract places much greater emphasis on dissemination and implementation activities, as well as on development of tools and products for the health care community. In addition, the new Coordinating Center will support broader patient safety activities within the agency, including managing the quality and patient safety portfolio, and will interface with the AHRQ health-IT program.

Accompanying the funding of the health-IT grants, AHRQ awarded NORC a separate five-year, \$18.5-million contract to serve as the AHRQ National Resource Center for Health Information Technology (Resource Center). The Resource Center provides technical services and support for the health-IT grantees and assists AHRQ with managing the health-IT program. Its specific functions are to provide technical assistance to grantees; serve as a repository for best practices; help develop, maintain, and export knowledge for clinicians and patients; offer expert support for providers and communities; perform and sponsor educational activities; and develop and disseminate tools to help providers and organizations utilize health IT.

GROUPS OF PATIENT SAFETY PROJECTS

Chronology of Patient Safety Grants Funded by AHRQ

Early congressional expectations for patient safety mirrored those for AHRQ in general; specifically, the agency was to support good research that will lead to improvements in practice. In subsequent years, Congress has continued to appropriate funds to support patient safety grants and activities. The history of funding for patient safety grants is summarized in Table 2.2. AHRQ also has continued to fund investigator-initiated projects on patient safety issues. These additional projects contribute to expansion of the patient safety knowledge base, and their products should be included in the information applied in the field to improve patient safety practices and outcomes.

Table 2.2.
History of AHRQ Funding for Groups of Patient Safety Grants, FY 2000–FY 2005

Fiscal Year	Type of Grant	Annual Funding Amount
FY 2000	Systems-related best practices	\$2 million
FY 2001	Six groups of patient safety grants	\$50 million
FY 2001	Working conditions	\$7 million
FY 2003	Challenge grants	\$4 million
FY 2004	Health-IT grants and contracts	\$50 million
FY 2005	Patient safety partnerships	\$3 million

Patient Safety Projects Funded by AHRQ in FY 2000 and FY 2001

A total of 81 projects were awarded AHRQ funding as part of the FY 2000–FY 2001 quality and safety of patient care portfolio, with CQuIPS responsible for their overall management. AHRQ obligated a total of \$142 million over the life of the multiyear grants; the

reporting demonstrations represent half of the spending. The following groups of projects were funded:

- Systems-related best practices to improve patient safety (six projects)
- Research demonstrations of health systems reporting, analysis, and safety improvement (16 projects)
- Clinical informatics to promote patient safety (11 projects)
- Effect of health care working conditions on quality of care (five from the \$50-million and 16 from the \$7-million working-conditions appropriations)
- Centers of Excellence for patient safety research and practice (three projects)
- Developmental centers for evaluation and research in patient safety (18 projects)
- Patient safety research dissemination and education (six projects).

Patient Safety Projects Funded by HRSA in FY 2001

AHRQ and the Health Resources and Services Administration (HRSA) have also collaborated to include five HRSA-funded projects in the activities of the patient safety project group, with the intention of enhancing opportunities for exchanging information and increasing synergy among the researchers. The HRSA projects began in September 2001, and they were funded for a total of \$2.4 million. Their focus is on developing and testing methods for interdisciplinary training on patient safety for medical and nursing students. Two principal investigators for the HRSA projects also have AHRQ-funded projects in the safety of patient care portfolio.

Challenge Grants for Patient Safety Practices Funded in FY 2003

In FY 2003, AHRQ awarded nearly \$4 million for 13 challenge grants, including seven grants for implementation of proven patient safety practices and six grants to test the use of risk-assessment techniques for identifying and reducing patient safety issues in health care organizations. The challenge grants are unique in that they employ a shared-cost financing structure, whereby AHRQ provides up to 50 percent of the total cost of each project and the awardees provide a minimum of 50 percent of the total costs. The risk-assessment projects have one-year grants, intended to produce plans for implementing interventions that address patient safety issues identified through the risk assessments. The implementation projects have grants of up to two years, intended to put proven practices into place and assess resulting effects on patient safety hazards. As of fall 2004, the risk-assessment grants were drawing to a close and the implementation grants were beginning their second year of funding.

Health Information Technology Grants Funded in FY 2004

In September 2004, AHRQ awarded \$50 million in new funding for projects to implement and evaluate the use of health IT for improving patient safety and quality of care, with half the funds to be spent in rural areas. Part of this appropriation was awarded to projects funded through three separate RFAs (i.e., planning grants, implementation grants, and grants to demonstrate the value of health IT). All funded projects are required to submit a dissemination plan including agreement to work with the Office of Communications and Knowledge Transfer (OCKT).

The CP3 has overall responsibility for the health-IT projects. A lead project officer (PO) from CP3 has been designated for each of the three project groups, and POs in CP3, CQuIPS,

and the CDOM are overseeing the individual projects. Each participating PO is required to maintain at least five grants, ensuring his/her commitment to the work. AHRQ management personnel appear to be well aware of the important interface between the health-IT projects and other aspects of the safety of patient care portfolio.

State and Regional Demonstrations in Health IT Funded in FY 2004

Part of the \$50 million appropriated for health IT was set aside for funding state and regional projects that are expected to achieve measurable improvements in the quality, safety, efficiency, or effectiveness of care as a result of data-sharing and interoperability measures. Approximately \$5 million was awarded to five state-level projects in FY 2004 (Colorado, Indiana, Rhode Island, Tennessee, and Utah), with plans to fund additional projects in the future. The awards are in the form of contracts with a five-year period of performance.

Grants for Partnerships for Implementing Patient Safety Funded in FY 2005

AHRQ released an RFA in September 2004 for a new set of patient safety grants that will implement safe practice interventions designed to eliminate or reduce medical errors, risks, hazards, and harms associated with the process of care. Up to \$3 million will be awarded under the cooperative-agreement mechanism, to fund ten to 15 grants for up to 24 months in duration. Applicants must have already completed a risk assessment for the proposed interventions and be able to assess the effect of the intervention on the processes of care and the patient population. Dissemination activities are also explicitly written into this RFA. AHRQ encourages applicant institutions to make a substantial commitment of support by providing resources to the projects, but it is not requiring a specified matching-funds ratio.

AHRQ LEADERSHIP FOR NATIONAL PATIENT SAFETY ACTIVITIES

AHRQ was the only federal agency that received substantial increases in funding specifically for patient safety work. As emphasis has shifted to initiatives for improving patient safety practices, other agencies, such as the Centers for Medicare and Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and HRSA, have also become more involved in implementing patient safety improvements in the field.

AHRQ has been directing the integrated database project on behalf of the Patient Safety Task Force (PSTF), and funding for the work is contained in AHRQ's budget. The PSTF was established in 2001 with the charge of developing an integrated data system for patient safety data reported to the DHHS agencies.

In its broader role within this national patient safety structure, AHRQ has continued to provide leadership and support for the QuIC. The QuIC has built momentum in recent years, and it has several projects under way for developing quality indicators and voluntary hospital reporting. In addition, the QuIC sponsored the Second National Patient Safety Research Summit held in November 2003.

FINANCIAL RESOURCES AND BUDGETS

As shown in Figure 2.1, AHRQ's patient safety budget has been increasing or stable since the start of the initiative. It increased from 18.4 percent of the AHRQ budget in FY 2001 to 26.3 percent in FY 2004. If Congress approves AHRQ's proposed FY 2005 budget, patient safety will become 27.6 percent of the total AHRQ budget, with \$60 million of the \$84 million in

appropriations allocated for health-IT products (\$50 million for health-IT projects and \$10 million to support health-IT standards development).

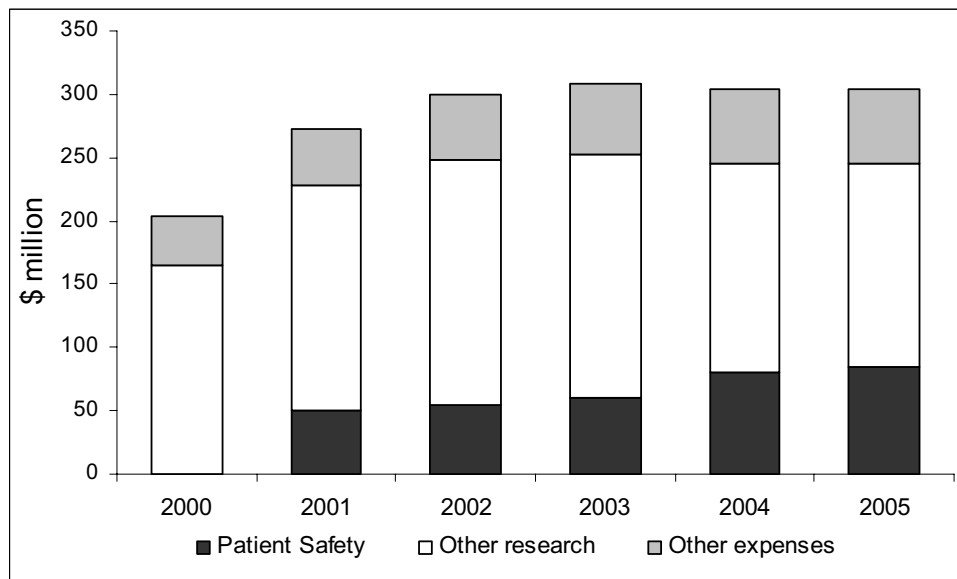


Figure 2.1 Trends in AHRQ Budgets for Patient Safety and Other Expenses, FY 2000–FY 2005

SOURCE: DHHS Budget in Brief, fiscal years 2002, 2003, 2004, and 2005.

NOTE: Other research areas include Translating Research into Practice (TRIP), Consumer Assessment of Healthcare Providers and Systems (CAHPS), Healthcare Cost and Utilization Project (HCUP), and other quality, cost-effectiveness, and intramural research. Other expenses include Medical Expenditures Panel Surveys, Current Population Survey, and program support.

ISSUES TO CONSIDER

The patient safety initiative is one of the most structured programs that AHRQ has undertaken. From the beginning, the initiative was a model for building multiyear budgets based on a trajectory of research and for explicitly linking investments in knowledge development in early years to subsequent practice-improvement activities. As the initiative moved forward in FY 2004, AHRQ continued to test new techniques, learning from previous experience and applying those lessons to improve subsequent approaches.

Creating a Culture for Action

The agency's strategic and organizational changes during FY 2004 were established to provide a foundation for creating an interactive culture within the agency for carrying out defined portfolios of work. The goal of these changes is to make a difference in implementing performance improvements in the health care system. This larger agency mission should provide a foundation that both reinforces and learns from the specific activities undertaken in the patient safety initiative. At the same time, AHRQ further developed the core patient safety work that is housed in CQuIPS while adjusting to encompass the new health-IT projects based in CP3.

Through these changes AHRQ is moving toward an interdisciplinary patient safety culture within the agency, which should enhance its ability to stimulate effective patient safety improvements in the field.

Balancing the Patient Safety Initiative

As a result of the congressional mandate that expanded AHRQ's role to encompass both traditional support of health care research and stimulation of changes in health care delivery practices, AHRQ has experienced ongoing tension between its research and implementation functions. This tension continues with the most recent FY 2005 budget. In this environment, AHRQ funding for research to develop new knowledge on patient safety practices has declined. We encourage the agency to earmark a portion of its funding for continued research in areas for which patient safety knowledge is still lacking.

There is also a need to balance the roles of CQuIPS and CP3 in managing their respective portions of the overall patient safety initiative. From a positive perspective, this division of leadership offers a rich opportunity to achieve effective cross-center collaboration. Both centers have heavy workloads, and they need the involvement of each other, as well as other center staff, to effectively manage the work.

Pending Patient Safety Organization Legislation

If Congress enacts the proposed "Patient Safety and Quality Improvement Act" (H.R. 663 and S. 720) and AHRQ is designated as the implementing organization, this new responsibility will substantially increase both its scope of responsibility and workload. Anticipating this increase, agency staff have begun preparing to implement the program as they await news on the final legislation. From an evaluation perspective, this legislation is a classic example of an external event that could have enormous consequences for the rest of the patient safety initiative, both positive and negative. We will track its progress to assess its implications for achieving the overall goal of improving the safety of the U.S. health care system.

CHAPTER 3. PROCESS EVALUATION: MONITORING PROGRESS AND MAINTAINING VIGILANCE

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.

This chapter focuses on the first of five system components of an effective patient safety system, as depicted in Figure 1.1 of this report. This component is monitoring progress and maintaining vigilance, as defined in the box above.

BUILDING FROM EVALUATION REPORT I

The ability to assess performance on established patient safety measures is essential for any system to be effective in minimizing risk of harm to patients. Therefore, it is vital for the health care community to have performance information that can be used to set priorities for reducing patient risk and consequences, and to monitor the community's progress in achieving planned practice improvements. This information also is important for AHRQ's ability to report to Congress what has occurred as a result of federal investments in patient safety research and to adjust investments in its safety of patient care portfolio.

Evaluation Report I examined the key components needed for success in developing a national-level repository for patient safety data, including standard patient safety measures and consistent data standards for reporting systems. It also assessed the current status of data availability and use of patient safety standards in the field. We concluded that establishing a national information resource may be one of the most important steps for the national patient safety initiative, as well as one of the most difficult. A national data repository must be able to receive data from multiple, diverse reporting sources, which requires establishment of an agreed-upon set of patient safety measures, as well as consistent data standards and user interfaces.

Activities have proceeded on several fronts during 2003–2004, bringing the system somewhat closer to achieving a national data repository. Several AHRQ-funded projects that were in process or being initiated when *Evaluation Report I* was published have generated important contributions to building an infrastructure for patient safety reporting and data. They include the IOM data standards project, the federal data system project, and activities of the 16 reporting demonstrations that were part of the FY 2001 group of patient safety grants. Other activities supported by AHRQ also show promise in this area, including the PSIC, work on a common taxonomy for patient-safety-reporting systems, and the newly funded state-level health-IT demonstrations.

In this chapter, we document these recent activities and offer suggestions to AHRQ for building upon these developments. Our evaluation addresses the following research questions related to monitoring activities:

- What progress has been made in establishing and using national standards and measures for achieving consistency in patient-safety-reporting systems?

- To what extent are national-level data available on the performance of the U.S. health care system on patient safety measures, and how has this extent changed since last year?
- How has the status changed since last year in the use of generally accepted patient safety measures for assessing performance as part of accreditation or other credentialing processes?
- What steps need to be taken to enhance the capability for effective monitoring of patient safety performance?

Our assessments draw upon information provided by a variety of data sources, including relevant written materials and documents, interviews with AHRQ staff, other federal agency staff, representatives of state reporting systems, and principal investigators (PIs) for the patient safety demonstrations.

STANDARDS FOR PATIENT-SAFETY-REPORTING SYSTEMS

AHRQ has established the goal of developing a reporting capability through a national data repository. Its strategy has been to move incrementally toward this goal by supporting work on patient safety data standards and by integrating access to patient safety data across federal agency systems. AHRQ funded two projects to begin this process. The first project, performed by the IOM, was to establish standards for consistent collection, coding, and reporting of patient safety data. The scope of the project was expanded in May 2003, when the DHHS requested that the IOM also provide guidance on the key capabilities of an electronic health record system. The second project was the Federal Data System Project, which was to develop software for a reporting interface that integrates reporting of patient safety data for two existing federal reporting systems. Both projects generated products during 2003 and 2004.

IOM Project on Patient Safety Data Standards

The IOM released a report on November 20, 2003, *Patient Safety: Achieving a New Standard of Care*, that presented the results of this work (Aspden et al., 2004). The report recommends that all health care organizations establish comprehensive patient safety systems that provide immediate access to complete patient information and decision support tools for clinicians and their patients. The systems should capture patient safety information as a by-product of care and use that information to design even safer delivery systems (Aspden et al., 2004). The report notes further that a national health information infrastructure is required to enable data exchange and communication across the data systems created by these local systems.

The ability to transfer data easily from one computer to another will be achieved by establishing data standards that are used consistently by health care data systems across the country. According to the 2004 IOM report, the following elements need to be standardized for health care data: definition of data elements; data interchange formats; terminologies; and knowledge representation. Although a myriad of technical standards currently exists in the health field, there is growing standardization through the work of national standard-setting organizations, such as the Office of Management and Budget's Consolidated Health Initiative and the patient safety interest group within Health Level Seven, a non-profit standards-development organization that sets standards for clinical and administrative health care data.

Federal Data System Project

With oversight by the DHHS PSTF, AHRQ contracted to create an adverse-event-reporting interface system that integrates reporting for the adverse-event-reporting systems of the

CDC National Healthcare Safety Network and the FDA. In October 2002, AHRQ awarded a two-year, \$5.9-million contract to the KEVRIC Company, Inc., to create a common user interface as the first phase of system development. The system consists of two components: a Web-based event-reporting screen, which is the interface with the user, and a data warehouse, a place in the agencies' data files in which the data reside. The plan was to extend this common system to include all safety-related reporting systems operated by the CDC, the FDA, and CMS, as well as other non-DHHS systems. As of September 2004, an estimated 85 percent of the developmental work on the Web-based reporting system had been completed.

In summer 2004, AHRQ entered into a memorandum of understanding with the CDC and FDA that focuses on the software needs of users attempting to address a specific patient-safety problem (e.g., obtaining rates of adverse drug events, ease of submitting data). By repeating this exercise for a number of patient safety problems, they expect to identify the common core elements of a system. This approach was intended to ensure that the staff of the two agencies are actively engaged in the design of the integrated system.

An advisory panel made up of end users, health-professional and health-care organizations, and other stakeholders and leaders from the field has encouraged AHRQ to modify the system so that it would also be of value to health care organizations and other users. Ultimately, this reporting interface and data warehouse could serve as a foundation for a national patient-safety data repository. A potential confounding factor, however, is that other organizations are pushing their own taxonomies, which differ from those of this system.

Other Efforts to Support Patient Safety Reporting

The 16 reporting demonstrations funded by AHRQ in FY 2001 have been testing a diversity of reporting systems. (See Appendix A for a list of these projects.) The grantees encouraged AHRQ to lead a process to establish taxonomy standards. In response, AHRQ funded a National Quality Forum (NQF) project to establish standards for taxonomies for adverse-event-reporting systems and is working with a technical advisory committee of clinicians and other stakeholders who are providing input on users' needs. As of October 2004, this project was still under way.

As efforts have progressed at the federal level for a national data repository, AHRQ also has pursued other interventions that are stimulating increased patient safety reporting at the state level (see Chapter 5). Two activities offer particular potential for expanding reporting activities over time—the PSIC and the newly awarded health-IT grants for state and regional demonstrations, which are specifically designed to test issues of interoperability.

AVAILABILITY AND USE OF PATIENT SAFETY MEASURES

The absence of a set of national patient safety measures that are generally accepted in the health care community has hindered the ability to track patient safety outcomes. Several agencies and private organizations, including AHRQ, have developed various sets of measures that apply to some health care sectors, as described in *Evaluation Report I*. One of the measure sets is the Patient Safety Indicators, which were developed for AHRQ by the University of California, San Francisco (UCSF)–Stanford University EPC (McDonald et al., 2002). As demonstrated by the PSIs, the publication of measures by AHRQ, as the lead agency in the patient safety initiative, tends to stimulate movement toward consistent use of those measures. In 2003–2004, the evaluation team investigated a variety of data systems that could be sources

for measures of patient-safety performance (see Chapter 7). This information also can be used in furthering efforts to establish a national set of patient safety measures that will serve as a foundation for monitoring trends in performance of the U.S. health care system.

Accreditation and credentialing organizations 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 those measures and standards for their accreditation or credentialing processes. In *Evaluation Report I*, we summarized the patient safety–related activities of several national accreditation or credentialing entities. The patient safety policies and actions of two of these entities—the Joint Commission on Accreditation of Health Care Organizations (JCAHO) and the Medicare program—developed further in 2003–2004.

JCAHO established its first national patient safety goals for application in its accreditation process in January 2003. Standards for patient safety practices include recommendations to improve accuracy in patient-identification processes, effectiveness of communications among caregivers, safety of using high-alert medications, procedural safeguards against wrong surgery, safety in using infusion pumps, and effectiveness in clinical alarm systems. Data from annual JCAHO surveys of hospitals provide information on trends for compliance with these (and other) JCAHO standards (data are available on a commercial basis through JCAHO’s DataMart at <https://dsa.trihost.com/store>).

As one of the largest health insurance programs in the U.S., Medicare also can influence patient safety practices. Effective March 2003, a new condition of Medicare participation was established that requires hospitals participating in Medicare to develop and implement a quality-assessment and performance-improvement program for identifying patient safety issues and reducing medical errors (CMS, 2003). CMS does not plan to establish standardized patient safety measures for Medicare until a national core set of hospital performance measures, including patient safety measures, is developed through collaborative activities currently under way. CMS has also been actively engaged in other initiatives for improving patient safety, including patient safety learning pilots, in which local institutions are pursuing patient safety initiatives, and the Medicare Patient Safety Monitoring System (MPSMS), which uses data for hospital inpatient stays, abstracted from medical charts, to generate national estimates of incidence rates for several patient safety events. MPSMS data can be used for benchmarking by local health care organizations. In addition, the algorithms have been packaged so that they can be used by other organizations.

DATA AVAILABILITY ON PATIENT SAFETY PERFORMANCE

According to the National Academy of State Health Policy, more than 20 states now have mandatory patient-safety-reporting systems in place, which require hospitals and other health care facilities to monitor and report on the occurrence of specific types of adverse events (Flowers and Riley, 2001; Rosenthal, Booth, Flowers, and Riley, 2001; Rosenthal and Booth, 2003). In addition, the 16 AHRQ-funded reporting demonstration projects were developing and testing reporting systems. To gather information on the current status of patient-safety-data-reporting systems and issues involved in obtaining valid and reliable data, we conducted semi-structured interviews with all of the PIs of the reporting demonstrations, three of which were

projects by state reporting systems, and we also interviewed officials from four other states that had government mandates for patient safety reporting (for a total of seven state systems).

As reported by both the PIs of the AHRQ-funded reporting demonstration grants and the other state officials, most forms of patient safety monitoring can be classified as either active or passive. State mandatory reporting schemes fall in the active category and are currently characterized by significant heterogeneity in the types of reporting measures that are included, thus limiting their utility for monitoring efforts that cross state boundaries. The AHRQ grantees sought to monitor a broad range of patient safety measures in their reporting systems, with some focusing on adverse events and others focusing on medical errors. Given this wide diversity, some of the reporting systems may be better suited for local quality-improvement efforts, and others might more readily apply to regional or national patient safety monitoring.

Passive patient safety monitoring schemes present an alternative for examining trends on a national basis. For example, AHRQ's PSIs take advantage of a readily available data source that could potentially be examined nationally. AHRQ grantees and others are working to develop more-comprehensive patient-safety-coding schemes for hospital discharge data, which could enhance patient safety monitoring capabilities in the future. Investigators also are working on more-sophisticated passive surveillance mechanisms in a number of specialized clinical domains. These mechanisms are mostly at an early stage of development, however, and their dependence on localized information-technology resources (e.g., facility-based electronic health records [EHRs]) is likely to limit their near-term scalability and usefulness for national patient safety monitoring.

ISSUES AND ACTION OPPORTUNITIES

AHRQ faces both an opportunity and a challenge to play a key role in bringing about a national patient safety data repository. The work generated in 2003–2004 by key AHRQ-funded projects is helping build the elements of this network. Similarly, the federal data system project adds a key technical component in the form of a Web-based patient-safety-reporting interface and data warehouse. Additional projects by AHRQ and other organizations also contribute to building momentum for a national information capability.

The IOM report on patient safety data standards (Aspden et al., 2004) offers recommendations for a consistent information infrastructure and data standards upon which health care organizations can build. There is no guarantee, however, that users will choose to adopt the recommended standards. AHRQ's leaders can be called on to stimulate dissemination and adoption of these standards, including working closely with end users to ensure that the system designs are in fact serving their needs. More work also is needed on developing a comprehensive set of patient safety measures that address care across health care settings.

Issues to Consider

Interviews we conducted with the state reporting systems and the patient-safety-reporting demonstrations highlight how much work still lies ahead. The existing state reporting systems present an eclectic mix of measures and reporting requirements. The taxonomies used in the reporting demonstrations are similarly diverse. Indeed, the grantees have been concerned about the absence of a standard taxonomy and have been working with AHRQ and the NQF to establish one.

The IOM report on patient safety data standards (Aspden et al., 2004) is well positioned to serve as a key reference for data standards and other specifications for a national information system. Most of the standards it recommends have been adopted by official federal standard-setting bodies, and their official status should help move them into practice. Examples include messaging standards established by Health Level 7 for clinical data and by the Institute for Electrical and Electronics Engineering for medical device data (Standard 1073). But much work still remains to build buy-in for a system design from the broader health care community.

The same issues exist for the new patient-safety-reporting interface and data warehouse. The strategy AHRQ is pursuing—testing this product with end users—strengthens the product while building buy-in from users with whom it is being tested. These users then can help in future dissemination efforts as early adopters of the system.

With respect to the content of the data to be reported, the work that the patient safety evaluation center is doing to assess the effects of the initiative will build sets of measures that can be considered as candidates for the selection process. With these considerations in mind, we offer the following suggestions for AHRQ action with respect to monitoring progress and maintaining vigilance.

Suggestions for AHRQ Action

- **As the state and regional health information systems projects progress, AHRQ should leverage this work to encourage broad use of the data standards recommended in the 2004 IOM report (Aspden et al., 2004).**

With the IOM recommendations on record, organizations across the country now have standards available to apply in their individual systems. The health care community needs to be informed of these standards and, when necessary, provided with technical support—e.g., consultation on data elements and software modifications and support in working with end users—to help them implement reporting systems that use those standards. As a greater number of local, regional, and state systems use the same standards, interoperability will increase, evolving toward a national network for data reporting and monitoring.

- **AHRQ should build upon the technical products of the federal data system project by pursuing expanded use of the newly developed reporting and data-warehouse capability, with the goal of moving toward a national data repository with multiple public and private users.**

The technical success of the federal data system project during FY 2004, as reported by AHRQ staff, provides a software product that also can serve as the basis for the national network. Through the active participation of health care organizations and federal and state agencies to field-test multiple applications in a variety of health care settings, this new reporting capability can be refined to be useful to increasing numbers of potential users. AHRQ already has embarked on this testing with some organizations, which is an important step toward establishing the desired system with consistent data standards and comparable data across organizations.

- **AHRQ should place a priority on establishing a broader set of national patient safety measures that represent the most important safety aspects of the patient's health care experience in a variety of settings. To do so, it should use a structured consensus**

process involving multiple stakeholders and build upon the existing Patient Safety Indicators.

In *Evaluation Report I*, we offered three recommendations addressing the need to establish national patient safety measures. To facilitate this process, we suggested adaptation of the consensus process used by UCSF and Stanford University to select the HCUP patient safety indicators. This suggestion consolidates and reiterates the earlier recommendations. Establishing a national set of patient safety measures is another priority for achieving a safer health care system, which goes hand in hand with a national data repository. Additional measures are needed not only for inpatient-care safety issues not covered by the PSIs but also for safety issues in ambulatory care, long-term care, and other settings. Monitoring of these measures will increase accountability in the system and help stimulate actions for improving performance.

- **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 adopting the measures as standards in their accreditation processes.**

This suggested action is repeated as it was presented in *Evaluation Report I*. AHRQ should continuously seek opportunities to engage accreditation and credentialing organizations, including the JCAHO, Medicare, National Committee for Quality Assurance, American Accreditation HealthCare Commission, and others, in development processes to help ensure that the systems and measures being designed are useful to them. These organizations have an important influence on patient-safety practice improvements by holding accredited health care providers—physicians and other practitioners, hospitals, long-term care facilities, and a variety of other health care organizations—accountable for effective practices.

CHAPTER 4. PROCESS EVALUATION: PATIENT SAFETY EPIDEMIOLOGY / EFFECTIVE PRACTICES AND TOOLS

***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.*

This chapter focuses on the second and third of the five system components of an effective patient safety system, as depicted in Figure 1.1. These two components contribute to development of knowledge regarding patient safety epidemiology and effective practices and tools, as defined in the box above.

BUILDING FROM EVALUATION REPORT I

This chapter combines two components of the evaluation framework: establishing knowledge of epidemiology of patient safety risks and hazards; and developing effective patient safety practices and tools. In the epidemiology chapter of *Evaluation Report I*, we examined what was known at that time about the epidemiology of patient safety risks and hazards, and the extent to which the AHRQ-funded projects were developing epidemiological information and filling in identified gaps in knowledge. In the effective practices and tools chapter, our strategy was similar. We discussed what was known about the effectiveness of different patient safety practices and how AHRQ-funded projects fit into building needed evidence.

Here, we examine new contributions that AHRQ grantees have made to the published literature on patient safety epidemiology; we then assess how those contributions have added to the evidence for safety practices and tools. This year, we focus on the challenge grants funded in FY 2003. We conclude with a discussion of the standards of evidence for patient safety.

In this second evaluation year, we examined the following key questions related to patient safety epidemiology and effective practices and tools:

- What additional information has been published about patient safety epidemiology in the past year, and how have the AHRQ-funded research projects contributed to this new information?
- What additional research and field tests on new patient-safety practices and tools are being conducted by AHRQ-funded projects, and how are they contributing new knowledge regarding practices for which further scientific evidence is needed?

- What progress has been made by the AHRQ-funded projects in documenting the effects of new patient safety practices and tools on patient safety outcomes and the costs, cost-effectiveness, and return on investment?
- What issues need to be addressed regarding establishing standards of scientific evidence to assess the effectiveness of new patient safety practices?

EPIDEMIOLOGY OF PATIENT SAFETY RISKS AND HAZARDS

Based on a MEDLINE database search of articles published in English between July 2003 and June 2004, Table 4.1 presents counts of articles and projects addressing epidemiology for each of a number of patient safety issues. During this period, 66 articles were published that provided information on the rates, types, or causes of medical errors or adverse events. These articles addressed a total of 70 patient safety issues, with medication errors having the largest share of publications (27 articles). Over half the articles addressed hospital-based issues, reflecting the well-known emphasis on this health care setting over ambulatory care or other settings. Issues strongly related to inpatient care include nosocomial infections, falls, nurse staffing, provider fatigue, and surgical procedures; others (e.g., medication ordering) involve research in a mix of settings. The currently funded patient safety grantees contributed only four papers to the literature on patient safety epidemiology in the period. We anticipate that this number will increase substantially between now and 2006, as the grants reach completion and manuscripts are written and published.

Table 4.1.
Information on Patient Safety Epidemiology Available from Recently Published Articles and Addressed by AHRQ-Funded Challenge Projects

Patient Safety Issue	New articles published in July 2003–June 2004		Number of AHRQ Challenge Grants Addressing Issue
	Total Number Published	By AHRQ Patient Safety Grantees	
Medication ordering or administration	27	1	6
Nosocomial infections	0	0	1
Falls, pressure ulcers, restraint-related	0	0	0
Nurse staffing	3	0	1
Provider fatigue, working conditions	3	0	1
Surgical or invasive-procedure errors	1	0	3
Diagnostic or treatment errors	17	1	2
General patient safety	19	2	2
Other issues	0	0	4
Total number of issues addressed	70	4	20
Average number per article/project	1.1	1.0	1.5

Also shown in the table, the 13 newly funded challenge grantees have the potential to contribute to increasing the understanding of patient safety epidemiology through future publications. Nine of the projects are performing retrospective risk assessments, root-cause analyses, or research that may generate information on the incidence of errors or adverse events for 20 patient safety issues. Six projects are examining issues related to errors in medication ordering or administration.

UPDATE ON THE FY 2000 AND FY 2001 PATIENT SAFETY PROJECTS

The patient safety projects funded in FY 2000 and FY 2001 now are either completed or close to completion, and most of the grantees are turning their attention to publishing findings and disseminating products and results for use by the health care community. As reported in the interviews conducted in Year I, the grantees believe that the current patient safety initiative is generating new knowledge for which further testing is needed to better assess validity and generalizability. New research questions also are emerging from their work. Grantees perceived a lack of future AHRQ funding opportunities in the form of supplements and continuations, and they voiced a desire for additional funding through follow-up R01 research grants, because many institutions are not able to meet the matching-funds requirement of the challenge grants.

An additional concern expressed by grantees was that the loss of the research infrastructure created by the shift of funding to health IT could slow the momentum in patient safety research and the synergies derived from it. Finally, many of the grantees believe that the narrow focus of the FY 2003 challenge grants and the FY 2004 health-IT grants will limit AHRQ's flexibility in supporting additional valuable research identified by the current projects.

The grantees offered a variety of recommendations for future patient safety funding during the interviews. Some suggested that AHRQ focus on funding those grantees who successfully implemented their initial projects. Others felt that AHRQ should spread the funding as much as possible, recognizing that it is "feeding a field." Many grantees felt that the next phase of projects should be based on products and findings from the first round of work. Grantees also voiced the need for AHRQ to fund projects in areas in which less is known, such as ambulatory care.

Finally, we note that a number of the earlier grantees are leveraging their initial patient safety funding through the challenge grant funding. Of the 13 challenge grants funded, seven of the PIs were either a PI or a named co-investigator on a grant in the FY 2000–FY 2002 patient safety project group.

THE CHALLENGE GRANTS

As noted in Chapter 2, in fall 2003, AHRQ awarded nearly \$4 million to support 13 safe-practices challenge grants (six risk-assessment grants and seven implementation grants). These projects are intended to make care safer for patients and to provide AHRQ and the health care field with information about patient safety risks and what can be done to intervene successfully in a variety of health care settings. Appendix B summarizes the 13 challenge grants.

The six risk-assessment projects involve the use of established assessment and analytic approaches, such as root cause analysis (RCA), process mapping, failure mode and effects analysis (FMEA), and probabilistic risk assessment, to address a wide range of potential risks for patients in areas of health care delivery. These projects have been conducted across the United States, with two in the Northeast, two in the West, and one each in the Southwest and Midwest.

The seven implementation projects allow grantees to put proven practices and tools in place and evaluate whether they reduce or eliminate patient safety hazards in their institutions. The grants are focused on a wide variety of health care settings, including operating rooms, intensive care units (ICUs), and other units within hospitals, as well as ambulatory care clinics, pharmacies, and nursing homes. Four of the projects involve more than one medical institution. Additionally, four projects are implementing new technologies such as "smart" intravenous

pumps and bar-code systems. Five of the implementation grants are clustered in the Midwest, and two of them are in the West.

Contributions to Building Patient Safety Practices

Table 4.2 presents tabulations showing how the challenge grants are contributing to patient safety issues and practices. Both the implementation and risk-assessment grants are addressing a variety of patient safety issues, and at least one challenge grant is addressing each of the listed patient safety issues. Both sets of grants are also addressing issues for special populations.

Table 4.2.
Patient Safety Issues and Special Populations Addressed
by the Patient Safety Challenge Projects

Patient Safety Issue	Number of Issues by Type of AHRQ Patient Safety Challenge Project	
	Risk Assessment	Implementation
Medication ordering/administration	3	4
Nosocomial infections	—	2
Nurse staffing	2	—
Provider fatigue, working conditions	2	—
Surgical / invasive-procedure errors	1	1
Equipment / device failure	—	1
Ordering / administering blood	—	1
Administrative events	2	—
Wrong patient / procedure / test	1	—
General patient safety	1	2
Other issues	2	—
Total number of issues studied	14	11
Average number per project	2.3	1.6
Special Populations		
Elderly	1	2
Minority populations	1	—
Low income	1	—
Health vulnerable	3	1
Other vulnerable ^a		1

^a Vulnerable due to socioeconomic factors, access, or other issues.

New Contributions to Evidence on Practices. In July 2001, the UCSF–Stanford University EPC published the evidence report on practices to improve patient safety (Shojania et al., 2001). The report evaluates 79 patient safety practices based on ratings of the strength of evidence and potential effect for each practice. It also organizes the practices into two research groups: “research likely to be highly beneficial” and “research likely to be beneficial.” The evidence report lists 30 practices for which research is likely to be highly beneficial, including, for example, perioperative glucose control to reduce surgical site infections, changes in nursing staffing, computerized physician order entry (CPOE), use of analgesics for patients with abdominal pain, and use of bar coding for patient identification. It lists 29 additional practices for which research is likely to be beneficial, including, for example, use of hip protectors for falls

and injuries, use of crew resource management (teamwork), antibiotic-impregnated catheters, and geriatric consultation services for hospital-acquired complications.

Table 4.3 presents the findings of our assessment of the challenge grants’ potential to contribute new science regarding the effectiveness of patient safety practices. Collectively, these 13 projects are addressing practices for which additional scientific evidence is needed. For example, the projects are addressing 11 practices for which there is only medium or lower strength of evidence. In addition, the projects are addressing 17 practices for which the evidence report indicated that further research would be beneficial or highly beneficial, as well as eight practices that were not rated or addressed in the evidence report.

Table 4.3.
Number of AHRQ Projects Covering Evidence Report Chapters

Name of Evidence Report Detailed Table	Number of Challenge Grant Projects Addressing the Practices
Number of grantees	13
Evidence Report: Impact and Effectiveness	
Greatest strength of evidence	4
High strength of evidence	2
Medium strength of evidence	5
Lower impact or strength of evidence	5
Lowest impact or strength of evidence	1
Evidence Report: Further Research	
Likely to be highly beneficial	11
Likely to be beneficial	6
Evidence Report: Not Rated, But Covered in Projects	5
Practice not addressed in evidence report	3

Addressing Infrastructure Issues. Using the key aspects of patient safety infrastructure identified in *Evaluation Report I*, we summarize in Table 4.4 AHRQ’s FY 2003 patient safety grantees’ potential to contribute to enhancement of the infrastructure by project group, based on the projects’ aims. The new grants address all of the six infrastructure components.

Lessons from the Challenge Grants

Many grantees attributed their success in strengthening patient safety practices to distinct institutional resources and characteristics that made them uniquely ready to take action. In our interviews, many expressed doubt that the challenge-grant requirements could be met by health care institutions that do not have the cutting-edge capabilities possessed by the current group of grantees.

The collaboration between Johns Hopkins University (JHU) and the Michigan Hospital Association (MHA) provides a possible model for effecting large-scale change. This project employs the MHA as an implementation arm for facilitating the dissemination of prepackaged interventions developed by patient safety specialists at JHU across more than 100 hospital ICUs. About 30 states have coalitions like the MHA that could act as networks to facilitate dissemination of patient safety practices among stakeholders.

Table 4.4.
Components of a Patient Safety Infrastructure
Addressed by AHRQ Patient Safety Projects

	Risk Assessment	Safe-Practices Implementation
Number of grantees	6	7
Infrastructure component:		
Patient safety culture		X
Information systems	X	X
Adverse-event-reporting systems	X	X
Interdisciplinary teams	X	X
Multi-institutional collaborations		X
Quality-improvement systems	X	X

Grantees stressed the importance of AHRQ’s role in funding patient safety research. The implementation grantees praised AHRQ for its focus on implementation, which they believe will push the field of patient safety forward by providing information on barriers to and facilitators of implementation in real-world clinical settings. Similarly, the risk-assessment grantees praised AHRQ’s willingness to push the methodological frontier by awarding grants to test new applications of risk-assessment methods in the health care field. Both sets of grantees would like to see AHRQ participate in more collaborative research funding across federal agencies, which might help leverage other federal funds for patient safety research.

Regarding the value of the 50-50 match requirement for funding, essentially all grantees stated that their participating institutions were supporting far more than 50 percent of project costs, especially if information technology was involved. Most of the risk-assessment grantees felt that the matching requirement did not help them gain the commitment of their institutional leadership, which, by and large, they already had; rather, the requirement added a time-consuming burden to the grant-preparation process. The implementation grantees, on the other hand, felt that the 50-50 match requirement was advantageous because the proven organizational commitment helped with recruiting clinicians, nurses, and patients for the studies. Other negative implications of the 50-50 match requirement noted by grantees included conflicts created by shared funding across “soft” and “hard” money departments, and the need for sophisticated accounting support.

Grantees mentioned several concerns related to challenge-grant time lines. First, the short time between notification of award and actual receipt of the first award payment forced many teams to ramp up immediately. This issue appeared to be more of a problem for the implementation grants than for the risk-assessment grants because of the multiple departments and institutions involved in their projects. In addition, several of the implementation grantees felt that two years was too short to implement a complex project, especially one involving the purchase and implementation of new technology.

Challenge grantees also offered comments on the role of health IT in patient safety. Some of the grantees cautioned that, although information technology may go a long way toward addressing patient safety issues, significant work on human factors and process management is also required to implement these technologies effectively. Other grantees expressed concern that

many hospitals, especially those in rural areas, will not be able to afford the kinds of technologies (e.g., computerized physician order entry and electronic medical records) that are rapidly becoming the backbone of patient safety interventions. Even for those hospitals and communities that can afford the technology, the unique challenges of implementing the technology in different settings must be taken into account.

Several areas for future AHRQ funding were suggested by the challenge grantees:

- More in-depth studies of how health care providers interact with information systems
- Theoretical research in human factors and engineering
- Studies that address the cost-effectiveness of patient safety
- Building a pipeline of patient safety interventions, either through a separate funding stream or by providing current grantees a longer time line in which to develop, package, and carry out an intervention
- Projects that focus on improvement in specialty areas
- Providing leadership on the use of incident reporting systems within institutions
- Creating synergy between AHRQ's patient safety and quality agendas by helping to advance the science of quality improvement through analysis of measures used by CMS and JCAHO
- Helping health care organizations in smaller communities, and especially in rural areas, to be competitive for the challenge grants.

STANDARDS OF EVIDENCE FOR PATIENT SAFETY PRACTICES

The Healthcare Research and Quality Act of 1999 directed AHRQ to identify “methods or systems to rate the strength of the scientific evidence underlying health care practice, recommendations in the research literature, and technology assessments” (West et al., 2002). *Evaluation Report I* reviewed the evidence report on patient safety practices produced by the UCSF-Stanford EPC (Shojania et al., 2001) and the issues about standards of evidence raised in reaction to it (Leape, Berwick, and Bates, 2002).

At the Second National Summit on Patient Safety Research in November 2003, the panel on effective practices and tools was charged with addressing research needs regarding development and field-testing of effective patient safety practices, taking into account the level of evidence needed to assess patient safety practices (QuIC, 2003). The panel noted that, for many patient safety practices, it is impractical or impossible to evaluate performance using randomized controlled trials (RCTs), which traditionally have been used to assess interventions in clinical medicine. The panel concluded that other types of evidence should be considered and that standards need to be developed that define what is an acceptable body of evidence for alternative research designs and analytic methods.

Judgment of the Evidence

AHRQ contracted with the Research Triangle Institute–University of North Carolina EPC to produce an evidence report that describes systems to rate the strength of evidence, including methods to evaluate both the quality of individual studies and the body of evidence relating to a particular health care question. The evidence report and accompanying article provide a useful basis upon which to build efforts for revising standards of evidence for patient safety practices,

including an evaluation of assessment schemes for rating the strength of a body of evidence (West et al., 2002; Lohr, 2004).

The report assesses studies outside the RCT domain, including discussion of their relative strengths and weaknesses. However, the greatest contribution of this research to patient safety may well be its evaluation of assessment schemes to rate the strength of a body of evidence. The ability to incorporate results from a variety of study designs into a determination of the overall body of evidence is particularly important for patient safety, which involves a diversity of practices that require different methodological approaches for evaluating their effects.

Assessing Patient Safety Practices

The establishment of more appropriate standards of evidence for patient safety practices can be expected to have two closely related effects. First, the standards will broaden the scope of patient safety practices that can be assessed for effectiveness according to scientific evidence. Second, the availability of the standards will strengthen research studies that are assessing those practices.

As the patient safety projects funded by AHRQ illustrate, a large number of diverse interventions are involved in achieving safer health care practices, including specific clinical techniques, specific administrative processes, and system processes. Many patient safety practices, such as implementation of multiple changes in a system process for a clinic or an entire institution, cannot be tested in RCTs. An early step in setting standards of evidence for these practices should be to establish criteria for determining when RCTs should be used and when other designs are appropriate. Decisions must also be made regarding which types of other designs are most suited for testing different types of practices, the required components of each design, and rules for execution of each design to ensure the validity of its results.

Developing Consensus on Standards of Evidence

The Second National Summit on Patient Safety Research recommended that AHRQ establish a panel of experts to address the issue of refining standards of evidence for patient safety practices. We endorse this recommendation as an important next step in the process of defining acceptable study designs and conditions for their use. Panel members should include leaders from the medical scientific community, other sectors (e.g., aviation) that have improved safety or identified areas of need, health care and medical leaders involved in making resource decisions, and methodologists. Basic steps that should be undertaken by the panel are as follows:

- Identify the research designs that will be accepted as sources of evidence for different types of patient safety practices.
- Establish guidance regarding required elements for each design, such as sample size, use of controls, unit of observation, when applied to various types of patient safety practices.
- Establish guidance for judging the effectiveness of the implementation of each research design as a study is carried out.
- Develop methodologies for aggregating the results of studies of diverse research designs to establish a body of evidence for a practice.

Many of the FY 2000 and FY 2001 patient safety projects and all of the implementation challenge grants have included practice interventions with evaluation components. The

experiences of these projects in assessing effects is a solid starting point for exploring future research design options that are appropriate to the study of various patient safety practices.

ISSUES AND ACTION OPPORTUNITIES

The contribution of AHRQ-funded projects to the knowledge base on patient safety epidemiology and practices should continue to grow, especially with the publication of the AHRQ compendium of patient safety papers and subsequent journal articles. Recent additions to this body of work are the 13 challenge grants funded in FY 2003, all of which are testing the practical implementation of risk-assessment techniques or proven patient safety practices.

Issues to Consider

As results emerge from the patient safety projects, it will be critical to synthesize them in ways that make the information accessible to various end users, including the scientific community, which will update the body of evidence on patient safety practices, and the health care community, which will adopt the new practices that have been shown to be effective. AHRQ currently is preparing to perform these syntheses, which will require thorough review of the study designs and methods to judge the soundness of their results. Health care providers also need to know the business case for practices, which guides their decisions on which practices to adopt.

Suggestions for AHRQ Action

We offer below several suggestions for actions that address these issues, encompassing both patient safety epidemiology and effective patient safety practices.

Patient Safety Epidemiology. The following three suggestions, which were offered previously in *Evaluation Report I*, anticipate needs for action as the patient safety projects generate findings on patient safety epidemiology. The volume of published results should increase rapidly during FY 2005. Anticipating the coming availability of results, we offer the suggestions again in this report.

- **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 care area (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. Future epidemiological measurement should be designed to reduce or eliminate these limitations as data quality and consistency permits.

- **AHRQ should establish definitions and standards for measurement methods 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 leadership for the development of national standards for measuring patient safety epidemiology. This work should be an extension of the consensus process for development of national patient safety indicators and standards for a national database. A first step would be to prepare a review of the definitions and methods currently being used by state reporting systems, the AHRQ reporting demonstrations, and individual studies.

- **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 as recommended above, the various organizations working on patient safety issues need an epidemiological resource analogous to the evidence report on patient safety practices. Such a report should draw upon available data in the published literature, existing reporting systems, Census data, and other national or state data sources. Benchmarks should be created to provide baseline information on the epidemiology of patient safety issues. Ultimately, the national patient safety data repository could be a primary source of data.

Effective Patient Safety Practices. The following suggestions for AHRQ action emerged from our review of the original patient safety projects and the challenge grants, as well as from anticipation of the health-IT grants funded in FY 2004. They address the issue of standards of evidence and other areas in which action could help strengthen the information generated on effective practices.

- **AHRQ should commit resources to define the standards of evidence that should apply for assessing the effectiveness of patient safety practices. To this end, AHRQ should support a panel process to produce recommendations for standards of evidence for patient safety.**

Patient safety practices can be assessed appropriately only if standards of evidence are defined that are relevant to the unique nature of patient safety interventions while still ensuring that the research meets standards for objectivity, validity, and replicability. A panel consisting of experts on patient safety and evidence-based decisionmaking would provide a mechanism for reaching consensus on acceptable standards of evidence, including possible use of specific scenarios for study methods that provide concrete examples to help focus consensus formation and panel discussions.

- **As the patient safety projects generate new evidence on practices and as standards of evidence have been adjusted to apply more effectively to patient safety practices, AHRQ should update the evidence report on patient safety to incorporate new evidence for widespread availability to users.**

The large amount of research that AHRQ and other organizations have funded is beginning to produce a wealth of new scientific evidence on patient safety practices that needs to be incorporated into assessments of best practices. Before this step can be taken, the standards of evidence for practice effectiveness need to be refined and made more relevant to patient safety practices. The evidence report, then, should be updated regularly to keep the evidence base as current as possible, including findings from both the AHRQ-funded patient safety projects and other research.

- **AHRQ should pursue a twofold strategy to generate information on the business case for promising patient safety practices: (1) Require all of its funded patient-safety projects that are conducting practice interventions to collect and report data on implementation costs as part of their research; and (2) identify some of the projects that have successful interventions and separately fund analyses of the cost-effectiveness and return on investment for those interventions.**

Making the business case will be essential to achieving adoption of the new patient safety practices in the field, regardless of how effective they are documented to be. Health care organizations want information on both the effectiveness of a new practice or technology and its financial implications for the organization. We suggest that the projects be asked only to collect the cost data, not to analyze it, because past experience has shown that most health care researchers do not have the expertise to perform credible cost-effectiveness or ROI analyses. With the cost information available, other analysts could be funded to perform these analyses on the most promising interventions.

- **For subsequent patient-safety implementation grants, AHRQ should focus on funding efforts by nonacademic medical centers to improve the generalizability of findings on patient safety practices.**

A large proportion of AHRQ's patient safety research dollars has gone to academic medical centers. Those centers are often in the best position to compete for funding because they already have information-technology infrastructure, resources, a cadre of sophisticated investigators, and a culture supportive of change. This approach is likely to improve the validity of AHRQ-funded research; however, it is not where most of the medical care in the United States is delivered. AHRQ needs to develop an appropriate funding mechanism for nonacademic medical centers, such as small and medium-sized integrated health systems, community hospitals, rural hospitals, and primary care practices.

- **AHRQ should consider the development of a noncompetitive renewal mechanism for especially promising patient safety projects.**

It is clear that the challenge grants were not designed to provide sustained funding for patient safety initiatives within institutions, nor is it appropriate to expect that federal funding will be provided to individual institutions or communities in perpetuity. However, there may be special situations in which particular projects hold the most promise for advancing aspects of the national patient safety agenda and for which AHRQ might decide that they would be effective for capitalizing on its initial investment. For this reason, AHRQ should consider creating a noncompetitive renewal mechanism to enable the most successful projects, for example, to take their project to "the next level" or to replicate their project within another institution or health care system.

CHAPTER 5.

PROCESS EVALUATION:

BUILDING INFRASTRUCTURE FOR EFFECTIVE PRACTICES

***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, hazards to safety created by the organization's structure, and effects of the macro-environment on the organization's ability to act.*

This chapter focuses on the fourth of five system components of an effective patient safety system, as depicted in Figure 1.1. This component is building infrastructure for effective practices, as defined in the box above.

BUILDING FROM EVALUATION REPORT I

In *Evaluation Report I*, we delineated a number of infrastructure elements that are critical for the successful adoption of improved patient safety practices throughout the United States, including patient safety culture, information systems, adverse-event-reporting systems, interdisciplinary teams, multi-institutional collaborations, and quality-improvement systems and measures. We also highlighted how the FY 2000–FY 2001 patient safety projects are addressing infrastructure issues, and we explored the contributions of other AHRQ-funded vehicles to patient safety infrastructure development. In this report, we detail three aspects of infrastructure development that were highlighted briefly in *Evaluation Report I* as areas of opportunity for AHRQ—establishing partnerships with other organizations, training in patient safety skills through the Patient Safety Improvement Corps, and involving consumers in patient safety.

Our evaluation addresses the following research questions related to infrastructure:

- To what extent is there an infrastructure of interorganization partnerships that is pursuing collaborative approaches to improving patient safety practices?
- How are AHRQ activities and funded projects contributing to establishment of an infrastructure that supports implementation of effective patient safety practices across the country?
- What models are being used to enable the active participation of consumers in partnerships for achieving improved patient safety practices?
- What additional research or development work is needed to strengthen the establishment of effective infrastructures for patient safety practices in the health care system?

Our assessments draw upon information from a variety of data sources, including interviews with members of state teams that attended the first round of training for the PSIC, interviews with consumer groups, interviews with leaders of public- and private-sector organizations on collaborative activities in patient safety, and written materials relevant to these programs or activities. Details on the conducted interviews are provided below for each topic area addressed. Data from the interviews with organization leaders were used to perform a descriptive analysis and a formal network analysis of patient safety partnerships (Scott, 2000;

Wasserman and Faust, 1994). RAND intends to repeat the network analysis in 2005–2006 to assess the extent to which the partnerships evolve from this 2004 baseline period.

PATIENT SAFETY PARTNERSHIPS

In interviews conducted during 2002–2003 with key stakeholders, we repeatedly heard that AHRQ must build strategic partnerships if it is to be a successful force in improving the safety of the U.S. health care system. We examined this issue by conducting interviews with a broad range of organizations to identify recent or current partnership activities in patient safety. To provide a consistent structure for the analysis, we defined a *partnership* as “a formal relationship, either ongoing or limited in time, between individuals or groups that is characterized by mutual cooperation and responsibility for the achievement of a specified goal.” We specifically excluded from the definition activities such as membership on another organization’s board and grants or other contractual relationships (e.g., between AHRQ or a foundation and its grantees).

Organizations Represented in the Interviews

A total of 38 organizations that were national in scope were identified for interviews. The organizations were known or expected to be involved in patient safety activities and reflected a wide array of possible end users who could effect change in patient safety practice. The organizations were identified through earlier interviews with national patient safety stakeholders, as well as through the evaluation team’s knowledge based on an environmental scan of the patient safety field in the first year of the evaluation.

Semi-structured interviews were conducted with representatives of 35 of the organizations that agreed to participate. The interviews collected general information on the types of patient safety initiatives the organizations were doing, the sources of tools they were using in that work, and relationships with AHRQ. Then, interviewees were asked to identify each patient safety partnership in which they were involved and, for each partnership, to identify the nature of the partnership, length of time it has existed, roles of participating organizations, resources supporting the partnership, and how successful they thought it has been.

Representatives of the organizations interviewed were grouped into seven major categories, as shown in Table 5.1. About one-third of the interviewees identified their organizations as having an extremely diverse constituent base, sometimes so broad as to include all Americans (e.g., patients and consumers). The other two-thirds of the respondents described their organizations as having a much more narrowly targeted constituency. Examples include member organizations for hospital-based pharmacists, internists, medical groups, or health insurance plans.

Patient Safety Activities of the Organizations Represented in the Interviews

Patient safety was a primary or major focus for nearly all respondents, regardless of organizational category, although the extent of interest in patient safety by the organizations’ constituents varied from broad to specific. The constituents’ needs identified most commonly by respondents included best practices, tools, educational materials, and specific information on areas of patient safety relevant to organizational expertise. We also learned that the respondents’ organizations engage in multiple and varied patient safety activities, as shown in Table 5.2. These activities were funded through a variety of mechanisms, such as grants from AHRQ and other organizations, federal contracts, member dues, and general operating funds.

Table 5.1.
Types of Organizations Interviewed for the Analysis of Patient Safety Partnerships

Type of Organization	Number of Organizations
Accreditation or standards-setting entity	4
Foundation	3
Government department or agency	9
Health care delivery system or membership organization for health plans or providers (e.g., AHA, AMA, AMGA)	12
Health policymaking entity	3
Health care purchasers or groups of purchasers	2
Consumer organization	1
Academic or research organization	1
Total	35

Table 5.2.
Patient Safety Activities of Organizations in the Partnership Analysis

Type of Patient Safety Activity	Number (Total=35)	Percentage (%)
Education activities on patient safety	32	92
Sponsor or participate in patient safety conferences	31	89
Develop or provide tools for better patient safety practices	29	83
Participate in patient safety research	21	61
Perform patient safety training	22	64
Provide technical assistance for practice improvement	22	64
Set patient safety standards	22	64
Collect or analyze patient safety data	20	58

Network Analysis Results

Based on our network analysis using the interview data, we identified 135 partnerships among 98 different organized entities. Fifty-eight (43 percent) of the partnerships were between two organizations (i.e., dyads), representing 52 organizations. The remaining 77 partnerships were between three or more organizations (i.e., group partnerships) and represented 49 unique group partnerships. Of the 50 unique dyads for which both organizations were interviewed, only seven of the partnerships were mentioned by both organizations (14 percent). This is likely due to the difficulty a single respondent may have in being aware of all patient safety activities occurring across departments within a large, complex organization, such as many of those in our sample. Our analysis assumes that a partnership existed between two organizations if one was reported by a respondent in either organization.

Characteristics of Partnership Relationships. The 98 organized entities included in our network data fell into eight organization types, based on their primary missions and the stakeholder groups they represent, as shown in Table 5.3. The group partnerships correspond to bundles of relationships through which multiple organizations are connected, even if each organization is not denoted separately in our analysis.

Table 5.3.
**Types of Organizations Reported in the Interviews as
Involved in Patient Safety Partnerships**

Type of Organization	Number	Percentage (%)
Accreditation or standard-setting	4	4.1
Consumer or purchaser	4	4.1
Foundation	3	3.1
Health industry or professional	16	16.3
Health policy	4	4.1
Government	13	13.3
Academic or research	5	5.1
Group partnership	49	50.0
Total	98	100.0%

Nearly all of the partnerships mentioned by respondents were ongoing as of the interviews (90 percent), and many (61 percent) had been in existence for more than a year. Some respondents (40 percent) reported that the partnerships were too new to determine success. Of the 21 respondents who were able to judge the success of a partnership, they deemed over 79 percent of the partnerships to be successful and described only five partnerships as not successful.

As shown in Table 5.4, the partnerships engage in a wide range of activities related to patient safety. Approximately 30 percent of these activities involve disseminating patient safety information (including organizing conferences and providing information to constituency groups) or developing standards and guidelines, and over a quarter involve intellectual exchange, representing discussions between organizations that may or may not result in products. A smaller proportion of partnerships focuses on research-related activities (funding or conducting research), education and training (including technical assistance for constituency groups or other individuals), development of patient-safety tools (e.g., to improve medication safety), or policy change and advocacy (e.g., changing or making suggestions about patient safety regulations).

Table 5.4.
Types of Patient Safety Activities Reported for the Partnerships

Type of Patient Safety Activity ^a	Number	Percentage (%)
Research-related	19	14.7
Dissemination	34	26.4
Intellectual exchange	32	24.8
Standards & guidelines development	36	27.9
Tools development	18	14.0
Education & training	21	16.3
Policy change & advocacy	12	9.3
Other	11	8.5

^a Categories are not mutually exclusive.

Partnership Structures Identified. Most of the organizations are linked in an overall infrastructure around patient safety. AHRQ is highly central within the overall network of partnerships, having more patient safety partnerships than any other organization included in the

lower-right quadrant of Figure 5.1, the group partnerships reflect the complex connectedness between many of the organizations.

Figure 5.2 displays networks around four types of partnership activities: disseminating patient safety information, developing patient safety standards or guidelines, providing education or training, and developing tools to improve patient safety. Again, a star represents AHRQ, circles represent other organizations, and diamonds are group partnerships. We note that no partnerships were reported between AHRQ and consumer and purchaser organizations or health policy organizations. Only one foundation identified a current partnership with AHRQ. These types of organizations represent opportunities for AHRQ to diversify its partnership activities in patient safety.

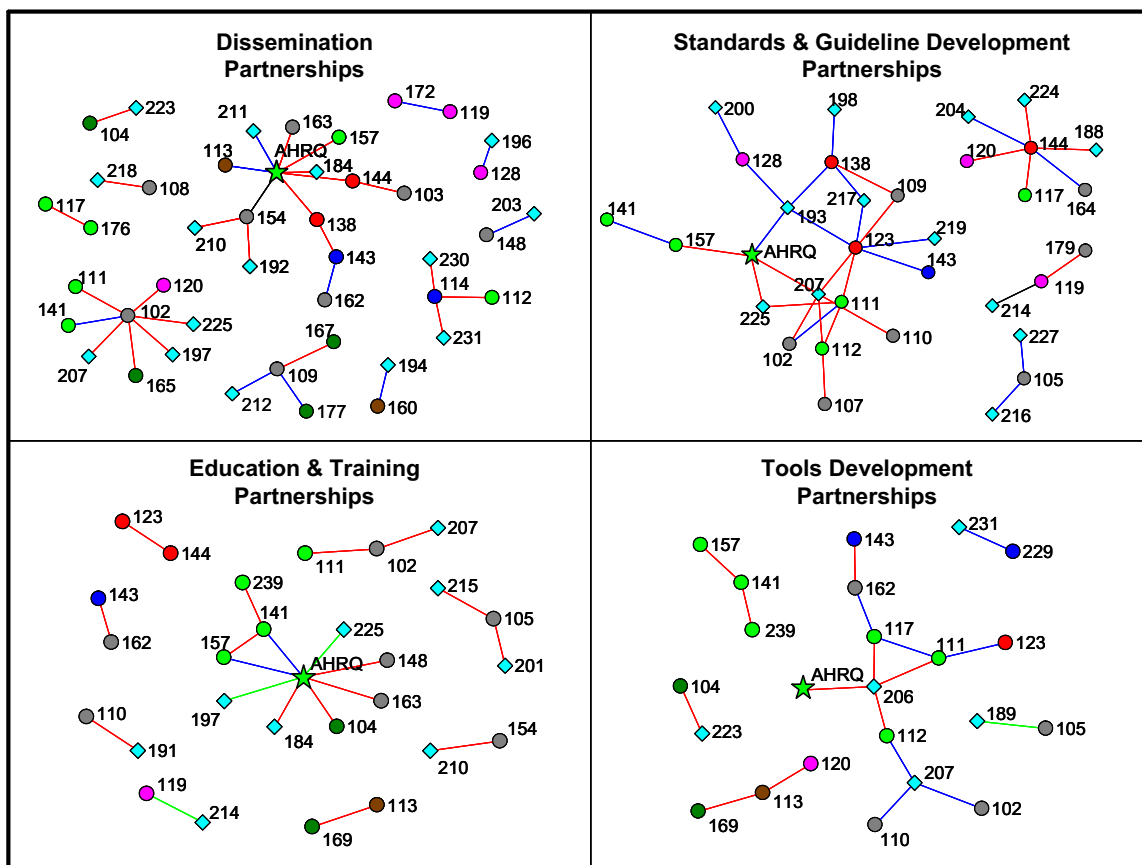


Figure 5.2 Patient Safety Partnerships by Type of Activity

THE PATIENT SAFETY IMPROVEMENT CORPS

The Patient Safety Improvement Corps, led and funded by AHRQ, is a joint training initiative of AHRQ and the Department of Veterans' Affairs (VA) National Center for Patient Safety (NCPS) and Employee Education System. AHRQ is providing \$7 million of funding over four years to train two- to four-member teams of state health agency representatives and staff from agencies' partner hospitals from every state in the country. The primary goal of the PSIC is

to improve patient safety across the nation by creating a corps of health care professionals with the ability to

- conduct effective investigations of reports of medical errors
- prepare meaningful reports on the findings
- develop and implement sustainable system interventions based on report findings
- measure and evaluate the effect of the safety intervention
- ensure the sustainability of effective safety interventions by transforming them into standard clinical practice (AHRQ, 2004b).

The training is composed of didactic sessions led by NCPS and other experts, homework to complete between sessions, and a patient-safety-improvement project. Participants are expected to return to their organizations to apply the skills they learned. They attend three one-week sessions held in September, January, and May. Participants progress from learning basic patient-safety principles and concepts to training in more-sophisticated skills, such as statistical techniques for assessing patient risks. Each participant receives a set of books and other resources to create patient safety libraries in their organization. A Web site and listserv also were established for trainees and instructors.

More than 50 trainees from 15 states completed the program in the first year (September 2003 through May 2004). The second year of training, which began in September 2004, included teams from 21 states, with Maryland and Massachusetts having a second team trained. It is anticipated that the remaining 16 states will have teams trained during FY 2005. Once AHRQ has trained teams from all 50 states, it plans to move on to the next stage: creating a train-the-trainer model to broaden the reach of the PSIC to more individuals and organizations.

RAND researchers conducted group interviews with 11 of the state teams during the final week of the first PSIC training to assess their experiences with the training, how they were using the training within their organizations, and thoughts for improving the program. A written interview protocol was used to ensure that the same information was collected from all groups in the unstructured interview process. Time constraints and group availability prevented us from interviewing the remaining groups, but the consistency of results among those interviewed indicates that these results are representative of the participants' experiences.

Response to the 2003–2004 PSIC Program

The first-year teams were enthusiastic about the training they received through PSIC. Participants reported that the best aspects of the training were the opportunities for networking, excellent library of patient safety resources, access to experts in the field, increased ability to teach best practices, and enhanced understanding and relationships between states and hospitals.

Many PSIC participants reported that they were using the skills they learned and the materials provided in their training. Some of them were sharing their materials with individuals within and outside their organizations, and others had started training others or were using the materials on safety culture. Some state team members were using their training to inform the state reporting systems and legislature, as well as training state surveyors. Many participants were eager to take their skills to the next level, but they reported needing guidance on becoming effective trainers and on other ways to utilize their training. They expressed a desire to continue education opportunities through PSIC and to have continued contact with AHRQ and NCPS.

Feedback from the First Trainees for Future PSIC Training

Participants' suggestions for improving future training included

- more hands-on time and practice with tools
- more time to interact with the other teams
- more discussion of projects during the first week of training
- inclusion of a session on use of statistical process-control charts to track trends over time
- guidance on how to change the clinical work environment and create consensus around patient safety in an organization
- baseline information on patient safety activities in the participating states (e.g., status of reporting systems).

Participants asserted that a wide variety of other individuals would benefit from PSIC or similar training, including hospital CEOs, boards of directors, the media, members of the state legislature, consumers, hospital associations (which could then train individual hospitals), Quality Improvement Organizations (QIOs), state clinical boards, risk managers, quality-improvement managers, and physicians. In response to participants' feedback, AHRQ created a listserv for the current class, invited teams to the Annual Patient Safety Research Meeting, and included a second team from two states in the 2004–2005 PSIC training.

MODELS FOR CONSUMER INVOLVEMENT

Many leading organizations in quality and patient safety have encouraged increased collaboration among providers, patients, and families as a means for improving the quality and safety of care (Institute for Family Centered Care, 2002). The IOM, for example, has repeatedly noted the importance of patient and family involvement as part of the health care team (Kohn, Corrigan, and Donaldson, 2000; IOM, 2002; Aspden et al., 2004).

In response, several years ago, AHRQ, along with the American Hospital Association (AHA) and the American Medical Association (AMA), developed and began distributing a set of tips and steps that consumers can take to help make their care safer (AHRQ, 2000). Similarly, in 2002, the JCAHO and CMS launched *Speak Up*, a national initiative using brochures, posters, and buttons to urge patients to take a role in preventing health-care errors by becoming active and informed participants on the health care team. The National Patient Safety Foundation (NPSF) offers similar tips (NPSF, 2004). Despite these efforts, in interviews during the first year of this evaluation, we heard frequent critiques that public- and private-sector patient safety activities were underutilizing or ignoring the potential roles of patients, families, and consumer-advocacy organizations.

In this phase of the evaluation, we sought to examine how consumers are being involved in patient safety efforts collaboratively with other key stakeholders and to identify factors that either facilitate or act as barriers to their involvement. We conducted in-depth interviews with ten leaders of consumer organizations focused on patient safety and quality, asking about their organization's activities, with whom they collaborated, and what innovative or promising models they could identify for involvement of patients and their families in patient safety efforts. We then interviewed key informants with the health care organizations mentioned most frequently in the consumer interviews. We also acquired selected documents and articles from searches of the literature and Web and from the interviewees.

Evidence Regarding Consumer Involvement in Patient Safety Activities

Much of the momentum for involving patients and families in patient safety activities comes from the patient-centered care literature. Studies have shown, for example, that patient-centered care can improve patient satisfaction, adherence to treatments, and clinical outcomes (e.g., Cleary and Edgman-Levitan, 1997; Fremont et al., 2001). Research has also established that patients and their families can reliably report whether or not certain processes of care occurred, including key aspects of care not well captured by clinician reports or medical records (Cleary et al., 1991; Davies and Ware, 1998). Literature on consumers and their potential roles in patient safety is still quite limited, but more evidence is beginning to emerge, including results from several AHRQ grantees.

Most of this evidence relates to consumer reporting of medical errors and adverse events (NPSF, 2003; “How Safe Is Your Hospital?” 2002; Weingart et al., 2005; Suresh et al., 2004). Epidemiological studies of medication-related errors in primary care suggest that these reports are generally accurate (Gandhi et al., 2003). In addition, patients report events not identified by other sources, including events that clinician reviewers would not classify as an adverse event (Culpepper, Hickner, and Pace, 2004). Two small studies have examined interventions to activate patients in ways that could reduce medical errors (Weingart et al., 2005; McGuckin, 2001). Patient power issues were also raised in an ethnographic study of parents of premature babies in neonatal intensive care units (Hurst, 2001). We expect that additional light will be shed on these and related issues as evidence emerges from several AHRQ grantee projects that are addressing patient-involvement issues.

Existing and Emerging Infrastructure for Consumer Involvement

The consumer patient safety movement generally comprises numerous small organizations with disparate goals and relatively little interaction among them or other key stakeholders. Although this movement is still in its infancy, there are signs of maturation. Some key, national-level consumer organizations are working to foster collaborative partnerships among patients, families, and providers in order to make health care safer. They include Consumers Advancing Patient Safety, Patient and Family Advisory Committee of the NPSF, and the Institute for Family Centered Care. Numerous other consumer-oriented organizations are operating at the local or regional level, some focusing on improving safety for a single condition and others focusing on specific issues. Examples of two such organizations are Medically Induced Trauma Support Services and Persons United Limiting Substandards and Errors.

Hospitals and other health care organizations have made only limited progress on involving patients and families in patient safety efforts. Hospitals serving children were more likely than others to have done so (e.g., establishing family advisory committees). Major reasons mentioned by hospitals for lack of progress include being overwhelmed with other patient-safety-improvement activities, liability issues, Health Insurance Portability and Accountability Act (HIPAA) issues, lack of evidence that involving patients and families is beneficial or cost-effective, or not knowing how to go about making necessary changes.

Models for Involving Patients and Families

Preliminary research into consumer-involvement strategies suggests a number of approaches for involving patients and families in patient safety activities. We asked respondents to comment on each identified approach, as well as to suggest other approaches they believe have value. Respondents’ opinions on nine identified approaches are summarized in Table 5.5.

Table 5.5.
Desirability and Feasibility of Various Approaches to Involving Consumers in Patient Safety Activities

Approach	Comments
Educate and activate consumers to be vigilant for errors	Pros: Could help prevent some errors from happening. Patients and families often are already vigilant for problems; more effectively empowering them could decrease anxiety and make them more effective in that role. Cons: Would scare already anxious or unnecessarily tax overwhelmed patients or families. Awkward and may put patient at risk of perceived or actual retribution by caregivers.
Routinely obtain reports about errors from patients and families	Pros: Could help identify errors not reported by providers or documented in the medical record. Could be used to target initiatives and monitor improvements. Accelerate development of patient safety culture. Cons: Patient-safety teams already overloaded trying to address (e.g., through RCAs) reports from providers. Difficulty separating the real safety issues from “noise.”
Include consumers on patient safety committees (e.g., within hospitals)	Pros: Help ensure that patient perspective incorporated into discussions and planning. Increases accountability and transparency. Can help stimulate positive changes in organizational culture. Cons: Liability and confidentiality issues. Highly dependent on consumer chosen; specific roles of consumer need to be better defined. Can slow pace of meetings.
Include consumers on research selection or oversight committees	Pros: Could help ensure that patient perspective included in research design. Successful examples are including patients on internal review boards and including cancer survivors on relevant review or site-visit teams. Cons: Needs to be right kind of person, preferably with sophistication in the topic. Specific role needs to be defined.
Include consumers on regional and national initiatives	Pros: Could help ensure that consumer perspective included in policy. Successful examples available. Cons: Needs to be right kind of person. Specific role needs to be defined.
Include consumers on teams making hospital rounds ^a	Pros: Help ensure patient perspective taken into account during rounds. Could help facilitate rounds. Cons: Privacy and liability issues; could disrupt work flow. Have to develop clinical teams that can work in multidisciplinary fashion before including patients.
Increase family access to ICU patients ^a	Pros: Increase satisfaction and emotional support of patients and families. Family members can be of assistance to busy nurses, and may help prevent adverse events. Cons: Interfere with work flow; could distract nurse and lead to more errors. Could be stressful for families viewing certain procedures.
Use consumers as peer support when errors do occur ^a	Pros: Badly needed (for both patient and provider). Can be more effective than counseling by provider or hospital representative. Cons: Liability and confidentiality issues.
Employ emerging information technologies to inform and involve patients and families	Pros: Interactive; allows patients and families to access and absorb information at their own pace. Can encourage patients to be more active participants. “Real-time” identification of errors or close calls. Relatively easy to track errors. Cons: Expensive; unclear extent to which patients or families would use. May not be as useful for severely ill patients or for patients with low socioeconomic status who have less familiarity with Web.

SOURCE: Interviews with representatives from ten patient-safety consumer organizations and hospitals with which they have worked, in which respondents were asked to comment on approaches for involving consumers in patient safety activities.

^a Not part of original interview protocol or asked of all respondents.

In general, the representatives of consumer organizations were enthusiastic about most of the approaches we identified and believed that each was feasible, expressing only a few caveats. By contrast, responses from representatives of hospitals and other health care organizations were more mixed and tended to include many more caveats and concerns about feasibility.

The central theme that emerged throughout our assessment is the need for a shift to a health care model in which partnership among consumers, clinicians, and health care organizations is the norm. Of particular interest, a number of respondents discounted the feasibility of some approaches because of perceived or real barriers in their organization, which already have been overcome or proven to be unfounded in other organizations (Berwick and Kotagal, 2004). This gap in knowledge suggests the need for more dissemination of research results and experience in this area.

ISSUES AND ACTION OPPORTUNITIES

The above analyses reveal that an active process is under way for developing infrastructure to support patient safety improvements. The network analysis shows patterns of multiple partnerships for various patient safety activities in which AHRQ is an active partner. In addition, the PSIC has become a constructive force in training people in the field on patient safety techniques, and active consumer involvement in the patient safety activities of local health care organizations is picking up momentum.

Issues to Consider

AHRQ has had direct roles in both the development of partnerships and the PSIC, whereas it has not been as actively involved in implementation efforts for consumer-involvement strategies. As AHRQ considers future options for extending these activities, it will need to choose strategically where to invest its limited resources, which types of partnerships to lead, and which partnerships would be better led by other organizations. For example, consumers should continue to be the spearhead of future consumer-involvement actions, but there are ways in which AHRQ might help them accomplish their goals.

Suggestions for AHRQ Action

- **AHRQ should seek out new strategic partnerships, especially in areas where little collaboration currently exists, while strengthening existing partnerships.**

Finite resources dictate that AHRQ choose its partnering activities strategically, but each additional partnership offers the opportunity to accelerate development of patient safety infrastructure. By continuously reassessing partnerships, AHRQ will be well positioned to reconfigure them in ways that enhance its influence without straining its available resources. For instance, AHRQ could shift away from a hub-and-spoke network model, in which it incurs the costs for producing and disseminating all the information, toward a configuration with numerous cross-links between partners and multidirectional information flow. Multidirectional flow of information also would afford AHRQ the opportunity to gain knowledge and insights from partners.

- **Wherever possible, AHRQ should eliminate real and perceived barriers to partnering with other organizations (private or public).**

AHRQ can further enhance its status as an attractive and effective partner by being flexible in working with other organizations and by demonstrating awareness of their perspectives and

realities. For example, explicitly acknowledging that businesses need to take ROI into account can help foster AHRQ's credibility with end users and increase the perceived value of partnering with it. Similarly, less-cumbersome application procedures and more-creative arrangements for funding would afford small, nonacademic organizations more opportunities to work with AHRQ.

- **AHRQ should seek ways to maintain and build on the network of trainees who have gone through the Patient Safety Improvement Corps training.**

To ensure that the PSIC reaches its full potential, AHRQ should rapidly expand mechanisms to maintain interactions and collaborations among PSIC participants who have completed the training. AHRQ already has taken important steps in this direction, but further steps can help promote an esprit de corps among the graduates and enhance successful application of their patient safety skills. AHRQ might adapt approaches used by CDC's Epidemic Intelligence Service or the Robert Wood Johnson Health Policy Scholars for those who complete their programs.

- **AHRQ should expand the Patient Safety Improvement Corps model to include stakeholders in addition to state governments and hospitals.**

As the initial phase of PSIC training is completed, AHRQ can expand PSIC's reach by including other kinds of stakeholders in the training. The inclusion of two QIOs in the second year of PSIC training is a move in this direction. We encourage inclusion of other types of stakeholders, such as representatives of ambulatory care facilities or large integrated delivery systems, to broaden and accelerate the effect of the training on the patient safety infrastructure.

- **AHRQ should fund Centers of Excellence for Consumer Engagement to study the effect of involving patients and families in patient safety activities.**

As more health care organizations take steps toward involving patients and families in patient safety efforts, lessons about how to overcome common barriers to patient and family involvement may be generalizable to other organizations. These lessons and best practices should be documented and disseminated to other providers and settings. In addition, these consumer-led organizations are uniquely positioned to assess the effects of the involvement of patients and families in different aspects of patient safety and care.

- **AHRQ should partner with consumer organizations and organizations with expertise involving patients and families to disseminate best practices for consumer engagement in patient safety improvement.**

To accelerate the implementation of effective approaches to consumer involvement, AHRQ should promote programs and publications that provide guidance to providers and consumers on constructive ways to work collaboratively on improving patient safety. For example, such a program could take the form of a PSIC in which AHRQ partners with a consumer-led organization; the faculty conducting the training would be providers and consumers.

- **AHRQ should encourage the use and evaluation of information technology to increase consumer awareness of patient safety issues and provide a means for consumers to report errors at the time they occur.**

New and emerging information technology, such as interactive television in hospital rooms, creates the capacity to educate patients about their conditions and the roles they and their families can play in preventing medical errors. Such technologies can allow for the

administration of brief periodic inpatient surveys about whether any medical errors or problems occurred during the last day. They can also provide personal Web portals that patients or their families can use to report medical errors to appropriate staff.

CHAPTER 6.

PROCESS EVALUATION:

ACHIEVING BROADER ADOPTION OF EFFECTIVE PRACTICES

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.

This chapter focuses on the last of five system components of an effective patient safety system, as depicted in Figure 1.1. This component is achieving broader adoption of effective practices, as defined in the box above.

BUILDING FROM EVALUATION REPORT I

The large number of products and significant knowledge generated by the FY 2000–FY 2001 AHRQ patient safety projects provide content for implementation activities to support broader adoption of effective new practices. The challenge is to ensure that the results get into the hands of end users and that the tools and assistance are useful for facilitating integration of the new findings into practice.

In *Evaluation Report I*, we provided a preliminary assessment of the efforts that AHRQ and other key organizations had undertaken to support and promote the adoption and institutionalization of improved patient safety practices. In this report, we continue to monitor output from the patient safety grantees, and we examine existing AHRQ funding vehicles and activities that could be used to support the dissemination and adoption of safety practices. We also synthesize lessons from grantees on moving research into practice and examine AHRQ's efforts to define a strategy for knowledge transfer and adoption of patient safety practices. The key questions addressed in this report are as follows:

- To what extent is new evidence on effective practices and implementation methods being disseminated to the broader health care system?
- How are existing AHRQ programmatic vehicles for translating research into practice (i.e., Integrated Delivery System Research Networks [IDSRNs], TRIP, Partnerships for Quality [PFQ], User Liaison Programs [ULPs], Centers for Education and Research on Therapeutics [CERTs], and Practice-Based Research Networks [PBRNs]) being used to test field applications of new patient safety practices, and what role might they play in the future to facilitate knowledge transfer and application of new patient safety tools into practice?
- What are the experiences of and lessons learned from the patient safety grantees that have implications for moving research findings into practice?
- What actions has AHRQ undertaken to prepare for disseminating the information and tools from the FY 2000–FY 2002 grants and contracts in patient safety?

To address these questions, the RAND evaluation team drew upon information from published documents, interviews with patient safety grantees, interviews conducted with AHRQ

project officers and principal investigators of funded projects, and discussions with individuals from AHRQ, the Coordinating Center, and the Patient Safety Grantee Steering Committee.

PRODUCTS FROM PATIENT SAFETY GRANTEES

In July 2004, we updated our previous searches of the Coordinating Center Web site and library databases to identify products from the portfolio of 86 AHRQ- and HRSA-funded patient safety projects. We merged new products found with the existing database of products produced between 1997 and June 2003. Among the 99 projects, eight PIs had two funded projects each. Thus, the 99 projects correspond to 91 unique PIs. We also conducted a complete search of this full time period (1997 through July 2004) for the 13 challenge grant projects funded in 2003.

We found a total of 1,231 documents related to patient safety authored by the 91 PIs (Table 6.1). Only 109 (8.9 percent) of the patient safety documents were related to the PI's AHRQ project, all produced from 2001 to 2004. Of these 109 products, 96 were journal articles, five were conference presentations, two were editorials, and one each was a bibliography, newspaper article, reporting system, software product, survey, and taxonomy. We also identified 41 patient safety-related products that were authored by the challenge-grant PIs, which is not surprising: Approximately half of the challenge-grant PIs between 2003 and 2004 were AHRQ patient safety grantees from the FY 2000–FY 2002 funding.

In *Evaluation Report I*, 39 products produced through June 2003 were identified as funded by AHRQ, so 70 additional products have been produced between July 2003 and July 2004. Of the 70 new products, 61 were journal articles, suggesting a continued heavy focus on traditional peer-reviewed publications as the means for communicating research results.

Table 6.1.
Number of Patient Safety Products Produced by Patient Safety Grantees, 1997–2004

Year	Patient Safety, Project Related	Patient Safety, Not Project Related	Patient Safety, Not Clear If Related	Total
Year unknown	2	0	4	6
1997	0	67	0	67
1998	0	84	3	87
1999	0	95	1	96
2000	0	129	8	137
2001	4	143	15	162
2002	29	124	67	220
2003	51	210	96	357
2004 (January–June)	23	51	25	99
Total	109	903	219	1,231

USE OF EXISTING AHRQ PROGRAM INITIATIVES TO SPEED ADOPTION

AHRQ currently funds a number of program initiatives that serve as vehicles for transferring knowledge, conducting applied research, and engaging end users in the health care system in adopting proven safety practices. These programs are IDSRNs, CERTs, PBRNs, ULP, TRIP, and PFQ. Most of these initiatives have limited budgets and small numbers of staff. Several of these programs are not operated exclusively out of a single center within AHRQ; they involve staff coordination across the agency.

Using information from interviews with AHRQ project officers and leaders of funded projects in all six programs, we assessed whether and how these existing program vehicles are being used to move patient-safety research and tools into practice and to identify future patient-safety knowledge-transfer opportunities that build on these efforts. We first interviewed the lead AHRQ project officer for each program. We used an interview protocol designed to obtain information on the history, structure, and purpose of each program; solicit their views on how these vehicles could be used to move new patient-safety research and tools into practice; identify challenges encountered in doing translation work; and elicit recommendations for enhancing the programs' effectiveness in disseminating improved practices to the field. We then sampled and interviewed a total of 14 funded projects across the six programs: two IDSRNs; two TRIPs; two PFQs; three ULPs; three PBRNs; and two CERTs. We sought their perspectives on how these programs had been used to implement translation work (in particular, for patient safety), and how they might be used in the future to move patient safety research into practice.

Assessment of Success in Translating Research into Practice

There was general agreement among those interviewed that the projects completed to date in the network programs have been quite successful in moving research or tools into practice by end users. However, evidence to support this conclusion is scant. The strength of these vehicles was in establishing partnerships with real-world players; when those partnerships were strong, the likelihood for successfully translating research into practice was high. This success could have been enhanced with additional funding. Several factors were identified by the respondents as important for successfully changing practices in the field:

- Providing implementation tools that have high utility in the practical world
- Actively involving end users in driving the agenda
- Having conduits to encourage engagement and use (e.g., Web applications) and linking agents (i.e., champions) to spread the information and increase the likelihood of success.

ULPs for disseminating information about patient safety were extremely useful to end users, primarily because their focus was on creating a dialogue with participants and building networks, tailoring programs to participants' needs, and providing readily available, digestible material that enabled states to get the lay of the land quickly. The importance of collaboration—getting all stakeholders to talk at the same table—was seen as a critical feature of the ULP meetings. It was noted that hosting a successful meeting requires recruiting the right presenters, setting an end-user-driven agenda, and aggressively facilitating the meeting—all challenging tasks. Several participants noted that general awareness about the issue of patient safety has increased, and more stakeholders from across the system are focused on and discussing patient safety.

End Users Reached by the Work of These Programs

The AHRQ knowledge transfer and adoption program initiatives are intended to reach various audiences, including state health policymakers, practitioners, health systems, and business leaders and purchasers. End users that have been reached through the network programs include the following: pharmacists, senior administrators, quality-improvement personnel, home health agencies, state health departments and policymakers, CMS, purchasers, clinicians, QIOs, hospital labs, malpractice carriers, benefits-design staff, IT staff, acute care hospitals, and other health care providers (e.g., nurses, physical therapists, nursing home staff). We note that consumers are conspicuously absent from this list.

Sustainability and Expansion of Projects

Sustainability of the work undertaken by these implementation programs is a key issue that will affect AHRQ's ability to drive safety improvements more broadly in the U.S. health care system. A practice improvement that is *sustainable* is one that can be continued indefinitely with minimal effort because it has become a part of normal practice. Among those interviewed, few thought that sustainability had been achieved within their own projects. Barriers to sustainability include resource limitations, absence of legal protections, the complexity and cost of interventions, technical-assistance needs, and lack of cooperation across states.

Readiness for Replication

Some project leaders believed that the work and tools produced by these program initiatives were ready for replication elsewhere; others thought it was too early to tell or that the work was still “developmental” and could not be readily replicated in other settings. Additional elements required to make these products ready for widespread adoption include leadership support, training, money, and technical assistance.

Role of Knowledge Transfer and Adoption Programs Moving Forward

Interviewees agreed that the AHRQ programs possessed important strengths that should be leveraged for moving patient safety work into the field—primarily, the involvement of large health care systems and practices with end users that implement the work quickly (e.g., IDSRNs, PBRNs). Several of those interviewed commented that AHRQ could be more proscriptive about the work it wants accomplished, by moving program findings directly to the PBRNs, IDSRNs, or the PFQs and providing specific guidance to its grantees and contractors regarding patient safety applications that should be pursued. However, limitations of these knowledge-transfer programs were noted, including limited budgets and lack of leadership in the field of research translation.

Improving AHRQ Programs to Support Patient Safety Dissemination and Adoption

Interviewees agreed that the existing AHRQ programs could be used more effectively to achieve the goals of AHRQ's patient safety agenda, particularly with respect to dissemination and adoption. They recommended that AHRQ undertake the following actions:

- Require funded projects to identify their dissemination plans in their proposals, making explicit that dissemination is part of the research and not an afterthought.
- Include funds for dissemination work in RFAs.
- Provide technical assistance and training to funded projects for broadly disseminating their findings beyond traditional academic audiences.
- Find ways to shorten the lag time between announcement of a project mission and the funding cycle so that projects can respond more quickly to the needs of end users.
- Set clear agendas that provide grantees and contractors with explicit priorities for a rapid-cycle mechanism and a clear time frame.
- For the PBRNs, consider funding centers rather than specific projects for creating the necessary permanent infrastructure for ongoing project work.
- Continue to build capacity among researchers to focus on translating research into practice, through project funding and technical assistance.

- Provide existing findings and tools from its funded research to the knowledge-translation programs (e.g., IDSRNs, PBRNs) and support the implementation of these findings and tools, rather than asking the researchers/contractors to identify their own priorities.
- As the health-IT project work proceeds, work with the health-IT industry to identify technology features needed to address patient safety issues effectively.
- Assist funded researchers to learn more about the barriers to implementation and identify ways to maximize the experience of others.
- Compile evidence on the effectiveness of alternative strategies for moving research into practice effectively.
- Involve more end users in the development of future patient-safety-research plans so that their needs can be met more effectively.
- Engage in ongoing dialogue with nonresearch decisionmakers to help them understand how to use research findings, thus strengthening the real-world application of those findings.

A universal message was that AHRQ requires increased funding to accomplish its dissemination and adoption work more effectively. Although the translational programs have been popular, they are still limited in scope and budget, and the work is occurring in isolated and incremental ways that do not permit rapid, wide-scale adoption of new practices. AHRQ resources also are important for filling the gaps in patient safety education at the state level.

LESSONS ON MOVING RESEARCH INTO PRACTICE

In the interviews with leaders of the AHRQ FY 2000–FY 2001 projects, challenge grants, and networks for research and practice, we heard similar messages regarding enabling conditions that are necessary for improving patient safety practices. In Table 6.2, we present a synthesis of the key components for a successful intervention that the leaders of these AHRQ-funded projects identified. The factors are organized into three categories: structural components that ideally should be in place as an intervention is introduced, components of the intervention-implementation process, and components of results from the intervention needed for sustainability. The table indicates which components were identified by grantees in each of the three groups, highlighting common experiences across projects. We will use this framework in future grantee interviews to further refine these findings.

PREPARING FOR DISSEMINATION OF PATIENT SAFETY INNOVATIONS

As of the end of FY 2004, AHRQ's preparation for dissemination of the patient safety findings and products has focused on methods to develop a comprehensive inventory of the FY 2000–FY 2001 project work and to synthesize the findings. In addition, AHRQ has prepared an internal document that addresses a range of issues for moving the dissemination process forward, including development of a methodology for classifying and ranking the importance of emerging products so that the agency can assign resources accordingly.

A strategic plan and organizational structure for disseminating these products and information to the health care community need to be in place within AHRQ. As of September 2004, AHRQ has established a limited structure for dissemination, and it does not yet have a written strategic plan. Ultimately, AHRQ will need to work in a technical-assistance mode with end users in order to become more familiar with the types of information sources the users rely on and to learn how best to package the information so that it is responsive to the end users'

needs and interests. This approach to dissemination differs substantially from AHRQ’s traditional public-relations activities.

Table 6.2.
Key Components for Successful Patient Safety Interventions,
Identified by AHRQ-Funded Project Leaders as “Needed”

Key Components Needed	FY 2000– FY 2001 Projects	Challenge- Grant Projects	Projects in Research Networks
<i>Structural Components:</i>			
Existing relationships among involved organizations	X	X	
Prior experience with relevant technologies		X	
Institutional commitment and leadership	X	X	X
Prior experience in performance improvement		X	
Integrated data systems	X	X	
Supportive organizational culture	X	X	X
Existing trust among participating stakeholders	X	X	
<i>Components of Implementation Process:</i>			
Choice of feasible and simple intervention			X
Champions designated to drive the process		X	
Interdisciplinary and skilled staff team	X	X	X
Team commitment and perseverance	X	X	X
Financial support for the change process		X	X
Participative planning process for the intervention			X
Expected return on investment from change		X	
Buy-in from all disciplines involved or affected	X		X
Effective transition to new practices		X	
Management of interorganization activities	X	X	
Management of evolving technologies	X	X	
Management of proprietary-information issues			X
Technical assistance and training	X		X
Change in organizational culture		X	
Open communication with stakeholders	X	X	X
Effective use of data for transparency	X	X	
Benefits that accrue to all involved		X	
Plan for HIPAA privacy requirements	X		
<i>Components of Results:</i>			
Evidence of effects on costs and outcomes		X	
Infrastructure to sustain new practices			X
Evaluation integrated into regular business process		X	
Dissemination of results to other organizations	X		X

Synthesis of Project Results

As of 2004, AHRQ staff plan to synthesize the results of the patient safety projects themselves, with help from the Coordinating Center and other knowledge-transfer contractors. Given the complexity of the information, it will be important for those with clinical and technical expertise, as well as contextual knowledge (e.g., some of the grantees), to be involved in the

synthesis process. There will also be a need to address the issue of intellectual property rights, which may limit how AHRQ or its partners can disseminate some of the patient safety products.

AHRQ and the Coordinating Center have pilot-tested a methodology for ranking projects and synthesizing results from published articles for application to actual products. Through this process, they have learned that classification works better when groups of related papers are reviewed together. To help the agency understand the broader context of which the emerging patient safety products will be a part, AHRQ has dedicated two full-time staff to conducting an inventory of all non-AHRQ-funded educational programs that relate to patient safety.

Development of an Inventory of Products

Over the course of 2003–2004, AHRQ and the Coordinating Center have worked to secure and inventory products from patient safety grantees and contractors. In fall 2003, the Coordinating Center initiated a product-updating process with all the patient safety grantees and contractors. AHRQ also has used the RFA-group grantee calls during 2004 to remind and encourage researchers to send in products. The Coordinating Center indicates that most grantees and contractors have submitted project updates with summary information about products. However, in most cases, AHRQ and the Coordinating Center do not have the actual products from these projects. In part, this may be because a large number of projects did not complete their work by the original funding deadline and have requested no-cost extensions. Another reason is the proprietary nature of some of the products. A final reason may be the inherent tension between AHRQ’s interest in publicizing results from work it has funded and researchers’ more narrow focus on making sure their work gets published.

Early Dissemination Activities

Drawing on existing resources, the AHRQ Office of Communications and Knowledge Transfer is organizing and operating all patient safety dissemination activities. One challenge for the OCKT staff is that they do not have the content expertise—either substantive or contextual—that will be required to synthesize the project findings. AHRQ has also initiated a series of technical-assistance calls with researchers that focus on dissemination and are designed to engage grantees as agents of dissemination. The AHRQ “Dissemination Planning Tool,” developed by the Patient Safety Steering Committee and the Coordinating Center, is currently being used by some AHRQ grantees and contractors.

AHRQ is pursuing two other major dissemination activities. The first is a collaborative project with the Department of Defense (DoD) on preparing “Advances in Patient Safety,” a four-volume compendium of patient safety work that will be disseminated to DoD health care providers and facilities. The second is an emerging partnership to engage Premier Hospitals, AHA, and VA in using the patient safety culture survey with their members. The culture survey has been ready for dissemination since January 2004, but thus far it has been distributed to only a small number of facilities nationally.

AHRQ’s Role as a Change Agent

To become a successful change agent, AHRQ needs to work on changing its current dissemination practices. Recent work from Bradley et al. (2004) identified five factors associated with the successful diffusion of innovation into practice that may offer lessons for AHRQ as it attempts to transform itself into a translation organization: (1) strong support of senior management; (2) effective leadership; (3) a supportive organizational culture; (4) planning

for sustainability from the start; and (5) creating an infrastructure with resources and expertise devoted to diffusion of practices.

Specifically, AHRQ will need to take a systems approach and establish an organizational culture that embraces implementation collaboration with end users from the bottom up as opposed to its current culture of dealing with researchers from the top down. As discussed in Chapter 2, AHRQ already has embarked on organizational changes that emphasize performance-improvement implementation in the field and include patient safety as a component. These changes are improving its position to disseminate information from the patient safety initiative, but mobilizing necessary resources in the face of fixed budgets remains a challenge.

Finite budget, staffing, and infrastructure constraints will limit AHRQ's ability to mount a successful and sustained dissemination effort. Therefore, it will be important for AHRQ to build both internal infrastructures and external partnerships to move forward with a clearly focused dissemination strategy and support the dissemination activities. Such progress will require leadership at the agency director level, coupled with hands-on management authority and responsibility by someone positioned high within the agency.

ISSUES AND ACTION OPPORTUNITIES

Issues to Consider

It is a significant challenge to translate research findings into practice by end users so that changes to a patient safety culture and in practices in the U.S. health care system can be achieved. End users view AHRQ as the leader in patient safety research and knowledge; however, the agency is not seen, nor does it operate, as an organization on the front line of health care delivery—which is where changes in practices need to occur to improve safety. Therefore, it will be essential for AHRQ to develop strategic partnerships with those who can provide the translation bridge to actual end users and the systems in which they work. Moreover, the agency should continue to explore how to better use its existing programs and funding mechanisms to engage end users in adopting and implementing safe health care practices. These actions should be factored into a comprehensive strategic plan for disseminating new knowledge and practices into the health care community.

Suggestions for AHRQ Action

- **AHRQ should develop and implement a strategic plan that specifies how the agency will disseminate new patient-safety knowledge and products to the broad spectrum of stakeholders, as well as actions it will take to facilitate adoption of new and safer practices.**

In *Evaluation Report I*, we recommended that AHRQ develop a cohesive strategy to disseminate the new knowledge and products from the patient safety projects, and this recommendation continues to stand. The strategy should provide for transferring patient safety knowledge to end users and should define the agency's role in supporting the adoption of new practices, including strategies for leveraging the agency's limited resources, along with resources of public and private partners to maximize the effect on safety improvements.

- **AHRQ should expand its internal infrastructure and budget to support future knowledge-transfer and dissemination work, so that its work is funded appropriately,**

has effective leadership and appropriate expertise to conduct the work, and has the support of the agency director.

AHRQ needs to have an organizational structure that can effectively carry out the strategic dissemination plan for patient safety. This effort is more likely to succeed if there is a centralized team with dedicated agency director–level support as well as sufficient staff with the appropriate skills and experience. AHRQ should consider engaging firms that have expertise in working with government agencies on communications issues in health care to extend its internal-staff resources dedicated to knowledge-transfer work, help with the development of a strategic plan for dissemination, and provide technical assistance to grantees. Broad-scale success in carrying out a dissemination strategy is contingent on the agency’s securing additional resources—both human and financial. At the current level of staff and budget, the agency’s influence as a change agent in transforming the American health care system will be seriously constrained.

- **AHRQ should expand investment in AHRQ’s existing programs that support practice adoption, using those programs strategically to promote translation of patient safety research into practice, with specific guidance on which patient safety applications should be pursued.**

Through its existing programs, AHRQ has developed considerable knowledge and expertise to support its broader mission of knowledge transfer and adoption of new practices into the American health care system. The lessons learned from these programs are a significant resource for AHRQ to draw upon in defining its strategic dissemination plan for patient safety and in helping grantees understand the factors that have proven most successful in adoption of new health care practices. Additionally, AHRQ has an opportunity to strategically use these programs as one of the drivers for knowledge transfer and adoption of patient safety practices. AHRQ can strengthen the effects of these programs by providing grantees and contractors more-specific guidance on work that should be done (i.e., requiring projects to focus on particular patient safety issues) and tying funding to projects that meet the agency’s goals of improving patient safety. While this step can be taken in the absence of new funding, existing programs currently are small in scope and therefore would benefit from additional resources so that AHRQ can make significant inroads in changing the American health care system.

- **AHRQ should develop “mentoring grants” that extend the successful work of implementation grantees more broadly across the health care system by enabling them to provide implementation support to other organizations.**

A number of patient safety grantees, in particular those with challenge grants, are successfully engaged in translating research into practice and promoting the adoption of new technologies. However, these projects are largely being conducted within the confines of academic medical centers that have unique characteristics (i.e., sophistication with grant writing and use of research in practice) and do not represent mainstream health care delivery. AHRQ has an opportunity to extend the reach of successful grantees by having them serve as mentors to other organizations that require technical assistance in many of these areas, by developing “mentoring grants” to provide continuation funding to existing grantees who seek partners to extend their work to a larger number of nonacademic sites. The challenge grantees, in particular, are uniquely poised to provide technical assistance because of their focus on implementation activities.

- **AHRQ should seek to build partnerships with health-care providers and other end users to secure their input at the front end of the research process (so that research products are end-user-driven) and by extending the resources and reach of the agency for translation and diffusion practices.**

Our interviews repeatedly revealed that end users and organizations that represent them tend to find AHRQ products difficult to use “off the shelf” and that the product designs are not driven by end-user demands or needs. To change safety practices across the country, it will be essential for AHRQ to build partnerships with end-user organizations to serve as translation bridges. In addition, AHRQ should seek ways to enhance end-user input and involvement in the development of new products—for example, including end users in the development of grant and contract solicitations and reviews of proposals, as well as requiring that grants and contracts include meaningful roles for end users in their projects. Such partnerships will allow AHRQ to deal more directly with end users while providing opportunities to leverage limited dissemination and communication resources.

CHAPTER 7. PRODUCT EVALUATION: SELECTION OF OUTCOME MEASURES

BUILDING FROM *EVALUATION REPORT I*

The selection and tracking of patient-safety outcome measures is a key component of this evaluation. It is still too early in the initiative to be able to detect many changes in patient outcomes because the patient safety implementation activities are just beginning to build momentum. Growth in these activities should be observable, however, and should ultimately yield measurable improvements in patient outcomes.

Efforts to document improvements in national patient safety performance will depend on having standardized patient safety measures that can be tracked over time on a regional or national basis. Such measures are currently at an early stage of development, as are the monitoring systems they support (see Chapter 3). Nevertheless, some measures are available that can be used to assess national trends in patient safety performance. Further, by identifying the range of patient safety dimensions that warrant monitoring, future measurement efforts by AHRQ and others can be focused on those dimensions for which monitoring is needed.

As documented in *Evaluation Report I* and updated in this report, a wide range of activities has been undertaken through the patient safety initiative to generate new knowledge, build infrastructure, and support implementation efforts across the country. We identify outcome measures for key steps in this process, first to assess the extent to which improved practices are being implemented, and then to assess how these changes are contributing to improved patient outcomes and effects on other stakeholders.

In preparation for identifying candidate measures, we conducted interviews with leaders of all 16 AHRQ-funded reporting demonstrations, as well as with representatives from four additional state reporting systems, to gather information on their use of patient safety measures and related practical issues (see Chapter 3 for additional details on the interviews). We then identified data resources and sets of measures that are most likely to be useful for analysis of national patient-safety trends, drawing from information provided in these discussions and from published information from various organizations. Finally, we developed an inventory of patient safety measures that are currently used by AHRQ grantees and several state reporting systems.

In this chapter, we begin by defining a conceptual framework for the dimensions of patient safety activities and effects that should be monitored. Then, we discuss the key issues identified thus far in our measure-development process, and we describe the approach we plan to take for performing the outcome evaluation and for using the candidate indicator sets we have identified.

CONCEPTUAL FRAMEWORK FOR THE PRODUCT EVALUATION

As discussed in Chapter 1, the structure of this evaluation is based on the CIPP model. The fourth component of that model is “product evaluation,” in which the consequences and effectiveness of the patient safety initiative are assessed for various stakeholder groups.

For the process evaluation, we defined five components of a system for achieving a safer health care system: monitoring progress and maintaining vigilance; establishing knowledge of epidemiology of patient safety risks and hazards; developing effective practices and tools; building infrastructure for effective practices; and achieving broader adoption of effective

practices. For the product evaluation, we are focusing on the last two components—infrastructure development and adoption of effective practices. Both components involve actions taken to change what is happening in patient safety practices, the outcomes of which should be improved practices, fewer adverse events, and reduced harm to patients.

We use the model presented in Figure 7.1 to guide our strategy for identification and analysis of measures to assess the progress of the national patient safety initiative in achieving these outcomes. According to this model, actions taken in the health care system for development of infrastructure lead to adoption of effective patient safety practices by providers, as depicted in the box “Achieving Broader Adoption of Effective Practices.” Practice adoption, in turn, should achieve improved outcomes for patients. Both infrastructure development and practice adoption also affect the other stakeholders involved in the initiative to improve national patient safety.

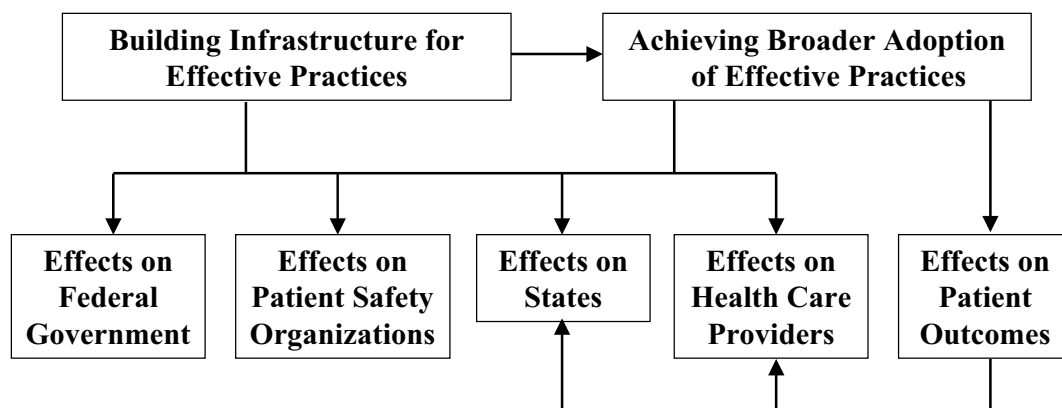


Figure 7.1 Conceptual Model of Potential Effects of the National Patient Safety Initiative

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

- *Patients*—who receive health care services, bear the negative effects of adverse health care events, and have a direct stake in the occurrence of those events.
- *Providers*—including physicians, nurses, and the organizations that employ them, that 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*—that license health care providers and (in many instances) operate adverse-event-reporting systems and have a stake in tracking adverse events and in promoting remediation efforts by providers
- *Patient safety organizations*—that are working to promote best practices, education, and technology adoption in patient safety and that have a stake in building collaborations to achieve these ends.
- *Federal government*—agencies involved in patient safety activities—in particular, AHRQ and other DHHS agencies.

When data on patient outcomes and effects on other stakeholders are available, we will attempt to measure changes in those outcomes over time. However, since the availability of national-level data for most patient outcome measures is still limited, we will also examine other steps in the implementation process to assess the potential for effects on patients. Data on infrastructure, practices, and effects of the initiative will need to be tracked for each of the key health care settings. We will focus on three settings: ambulatory care (with primary care as the central component), hospital-based care, and long-term care. Because so much of the patient safety work to date has focused on hospital-based issues, data will be more readily available for this setting than for ambulatory care or long-term care settings. We will continue to pursue measurement opportunities in the other settings as the evaluation proceeds.

Dimensions of Infrastructure and Effective Practices

The measures we define for infrastructure development and adoption of effective practices will use the organization as the unit of observation. Through this evaluation work, we plan to focus on the following specific dimensions of infrastructure and practice adoption, which we have identified as the key elements in each system component:

- | <u>Infrastructure Development</u> | <u>Adoption of Effective Practices</u> |
|--|---|
| <ul style="list-style-type: none">• Reporting and data systems• Information and tools for action• Partnerships for action• Patient safety culture• Legal protections for reporting• Curricula for patient safety training• Technical support system for action | <ul style="list-style-type: none">• Reporting of near misses and events• Use of risk-assessment techniques• Adoption of patient safety practices• Strengthening of teamwork in care• Clinician training in patient safety |

Given the decentralized nature of the U.S. health care system, patient safety activities are under way at a multitude of levels, including activities at the federal and state levels and actions taken by individual health care systems and practitioners to improve patient care processes. Health care providers are the key implementers for adoption of effective practices, through which they improve the safety of care for patients. For infrastructure development, actions at all levels are important.

Dimensions of Effects on Patients

RAND researchers will use the patient or event as the unit of analysis for the patient-outcome measures whenever possible. Depending on the data source, some of this information may only be available as aggregated by organizations. In these cases, we plan to use the aggregated data as long as we can verify the validity of the counts and rates.

We have identified three general sources of measures of patient outcomes that have the potential to be used together to “triangulate” information on the effects of patient safety practices: (1) data from patients’ self-reports in response to surveys; (2) events reported by providers in their own reporting systems or to state-level reporting systems; and (3) data from health care claims, encounter records, and other administrative sources.

Self-reported survey data would provide potentially powerful information on patients’ perceptions of their experiences with patient safety issues, many of which are quite visible to the patients. To be useful for assessing effects of the national patient safety initiative, however,

surveys across the country would need to use a consistent set of questions that are technically valid. The CAHPS® surveys would have the best potential for meeting these requirements, given their national status and widespread use. However, CAHPS does not include patient safety questions at this time.

Patient safety events reported by providers capture events that are not observable to patients, especially if the reporting includes not only harmful events but also near misses and events without harm. Reported events have two disadvantages, however, that we address in the outcomes evaluation. First, underreporting is known to be an issue, especially for voluntary reporting systems. To the extent that underreporting rates remain consistent over time, these data can yield useful trend information, although the estimates of absolute levels would be biased. Second, reported events often cannot be measured as rates because it is difficult to establish valid denominators for them.

Health care claims and encounter records contain a great deal of useful information in the diagnostic codes that are reported. These data already have been used in a variety of ways to identify patient-safety issues and measures. In addition, several of the AHRQ-funded patient safety projects have used administrative data to identify rates for patient safety issues. An important limitation of these data is that they do not offer information on the clinical-care processes associated with the encounters. Therefore, they cannot identify many patient safety issues that require more detail on clinical content or processes, especially for events that occur during transitions in care.

Dimensions of Effects on Other Stakeholders

In assessing effects of the patient safety initiative on nonpatient stakeholders, the primary groups of interest are the health care providers who are working to identify patient safety problems and to address those problems in effective and sustainable ways. In addition to providers, many other stakeholder organizations are involved; they are setting policy and performance expectations, funding research and development efforts, developing products and tools to support improved practices, and otherwise stimulating changes in the health care system. This diversity of players with an equal diversity of roles poses a challenge for evaluation of the effects on these groups.

PERSPECTIVES ON PATIENT SAFETY MEASURES

Among the FY 2000–FY 2001 patient safety projects, the reporting demonstrations are the most likely to yield specific results that can be generalized nationally. A goal of these demonstrations has been to achieve consistency in reporting taxonomies and data standards to enable aggregation of data over larger areas. Thus, we began our investigation of patient safety measures and monitoring through a series of discussions with officials in state reporting systems and with AHRQ grantees in the reporting demonstrations group.

Several points emerged that guide our search for candidate outcome measures. First, because patient safety issues occur throughout the health care system in myriad clinical settings and procedures, a large variety of potential patient safety measures might be of interest in different contexts. Second, the measures vary in their level of clinical specificity. Third, some forms of patient safety measurement are subject to significant technical and practical limitations, which may constrain efforts to use them more broadly (e.g., problems in defining the denominator). Fourth, measures with similar content and data sources may be qualitatively

distinct in important ways. Finally, some standardized patient-safety measures appear to be emerging incrementally as new measure sets are developed and adopted by organizations across the country.

Our challenge is to select measures that meet the needs of the evaluation or have potential to do so in the near future. As a practical matter, problems with data availability will limit the measures that are usable for regional or national trending. In year 3 of the evaluation, we will begin to work with available measures and will document limitations imposed by the data. As the ongoing refinement of patient-safety measures and monitoring capabilities yields over time a broader pool of data resources, we can add new measures to the evaluation.

CANDIDATE SETS OF MEASURES FOR EVALUATION OF OUTCOMES

Our goal for this second evaluation year was to identify candidate sets of measures that can be tested as sources of outcome measures in future evaluation analyses. Candidate measures ultimately identified should meet the following criteria to be useful for the evaluation:

- Contribute to covering key patient-safety issues across the scope of health care practices and settings
- Contribute to covering a range of effects on stakeholders, as well as the practices in the field that yield those effects
- Provide information that represents the entire country on either a regional or national basis
- Can be evaluated with data from existing and available sources
- Allow tracking of trends longitudinally, ideally including several years of baseline data preceding the start of the patient safety initiative.

Table 7.1 provides several sources of measures for addressing progress in infrastructure development and use of patient safety practices. We have identified three measure sets that will be pursued for infrastructure development. Two sets are based on data collected by RAND as part of this evaluation (i.e., RAND Network Analysis and data from the Survey on Hospital-Based Adverse Event Reporting conducted by RAND); the other will be based on information from statewide reporting systems. Three activities currently under way by national-level organizations are potentially strong sources of data for measures of the adoption of patient safety practices. These are the Leapfrog Group survey on patient safety practices, the JCAHO measures on patient safety practices, and the Institute for Safe Medicine Practice Surveys.

We identify in Table 7.2 several possible sources of data that can be used to define measures for patient outcomes, some of which already have been used by others for this purpose. We plan to use measures that already have been developed and tested, such as the AHRQ PSIs based on national hospital-discharge data. We also plan to seek other measures from existing datasets, with the goal of covering a range of patient safety issues and health care settings.

Table 7.1.
**Potential Product-Evaluation Measures for Infrastructure Development
and Use of Patient Safety Practices**

Types of Measure	Potential Data Source	Availability
<i>Development of Infrastructure</i>		
Organizational collaboration on patient-safety issues and strategies	RAND network analysis	Yes
Adoption of state-based reporting systems using IOM standards	State-based patient-safety-reporting systems	Unclear
Use of NQF patient safety events in state reporting systems	State-based patient-safety-reporting systems	Unclear
Adoption of adverse-event-reporting systems by hospitals	RAND survey on Hospital-Based Adverse Event Reporting	Yes
Effective practices for which tools are developed for implementation	TBD	
Improved patient safety culture in hospitals	TBD	
Legal protections for reporting	Review of state laws; PSO legislation	Partial
<i>Use of Effective Patient Safety Practices</i>		
Adoption of NQF safe practices by hospitals	Leapfrog surveys of patient safety practices	Partial/unclear
Adoption of JCAHO-defined patient safety practices by hospitals.	JCAHO surveys of patient safety practices	Yes
Survey data on a variety of safe medication-practice issues	Institute for Safe Medicine Practice surveys	Partial/unclear
Use of risk-assessment methods	TBD: hospitals, ambulatory care, long-term care sources	
Completed teamwork training	TBD: hospitals	
Patient safety taught in residencies	TBD: hospitals, residencies	

TBD = to be determined as measurement capability develops.

Effects for Nonpatient Stakeholders

Table 7.3 illustrates several possible types of effects that could be evaluated for health care providers, state governments, and organizations serving as facilitators or initiators in patient safety. For providers and state governments, improved patient outcomes aggregated at the organization level are effects that merit documentation. In addition, there are direct effects at the organization level, such as establishment of a culture that is nonpunitive and focused on achieving safe health care environments. Financial aspects of their operations are also important to document, to help assess the costs and returns on investment of patient safety progress. The effects for patient safety organizations may be less apparent but should focus on the amounts and types of activities such organizations have stimulated and their effects on the providers with which they have worked.

Table 7.2.
Potential Categories of Product-Evaluation Measures for Patient Outcomes

Type of Outcome	Potential Data Source	Availability
<i>Ambulatory Care Setting</i>		
Hospital readmission rates	TBD: HCUP database; other claims	
Avoidable hospitalization rates	TBD: HCUP database; other claims	
Adverse medication events	FDA adverse-event-reporting database	Yes
Adverse medication events	USP MEDMARX® data	Partial
Events in the diagnostic testing processes	TBD: Primary care providers	
Events in other transitions in care	TBD: Primary care providers	
<i>Hospital Care Setting</i>		
Hospital inpatient safety outcomes	HCUP database and AHRQ Patient Safety Indicators	Yes
Hospital inpatient safety outcomes	JCAHO sentinel events database	Uncertain
Adverse medication events	FDA adverse-event-reporting database	Yes
Adverse medication events	USP MEDMARX® data	Partial
Hospital nosocomial infections	CDC National Nosocomial Infection Surveillance System	Partial
Outcomes in inpatient care, Medicare population	CMS Medicare Patient Safety Monitoring System; CMS claims records	Yes
Adverse events reported to states	State-based patient-safety-reporting systems	Uncertain
<i>Long-Term Care Setting</i>		
Outcomes in nursing homes	Minimum Data Set from CMS	Request from CMS
Adverse events reported to states	State-based patient-safety-reporting systems	Uncertain

TBD = to be determined as measurement capability develops; USP = United States Pharmacopeia.

Table 7.3.
Possible Product-Evaluation Measures of Effects for Nonpatient Stakeholders

Providers	State Governments	Patient Safety Organizations
<ul style="list-style-type: none"> • Patient outcomes • Patient safety culture • Organization redesign • Financial performance 	<ul style="list-style-type: none"> • Patient outcomes • Use of reporting data • Patient safety culture • Level of expenditures for patient safety work 	<ul style="list-style-type: none"> • Partnership growth • Scope of activities • Effects on providers

ISSUES AND ACTION OPPORTUNITIES

In assessing the effects of the patient safety initiative, this evaluation will establish a foundation of data sources and defined measures that can serve as a starting point for ongoing monitoring of progress in improvements in patient safety practices and outcomes. As AHRQ updates its strategy for the initiative, this resource can be built into its scope of work to enable the assessment of effects to continue after the official evaluation is completed. In addition, this component of the evaluation could serve to increase data availability by encouraging actions by other organizations to collect data for the settings or services relevant to their missions.

Issues to Consider

Limits to data availability reveal themselves at various levels of measurement. In some cases, data may exist but be proprietary, restricted, or otherwise not publicly available. In other cases, data may be readily available but limited to only selected aspects of patient safety outcomes, such as administrative data on hospital inpatient services. A striking example of needed data is the virtual absence of national or regional data on ambulatory care services. In our analyses of available data, we will assess the limits of the underlying data sources to ensure that our assessments are consistent with data constraints.

Given the emerging nature of patient safety data at the national level and the efforts of the evaluation to make the fullest possible use of what data are available, we view the development and standardization of the proposed evaluation measures as likely to become a major product of the national patient safety initiative. This framework can inform AHRQ's efforts to establish greater measurement capability at the national level. The work also has further potential to contribute to content development for the national data repository, which is needed to ensure continued monitoring of patient safety performance in the future.

Suggestions for AHRQ Action

- **AHRQ should develop Consumer Assessment of Healthcare Providers and Systems (CAHPS®) surveys or survey modules for patients to report on patient safety issues in ambulatory care, hospital services, and long-term care settings.**

As discussed above, self-reports from consumers are important sources of information on patient safety, and changes in reported problems can provide insights into the effects of activities for improving the safety of the health care system. In particular, patients and families can identify errors or events that may never be detected by providers as underlying causes of adverse events or that are inherently important but may not lead to severe outcomes. To obtain usable consumer-reported data at the national level, it will be necessary to establish a valid and consistent set of survey questions on patient safety that can be included in surveys administered across the country. The CAHPS surveys developed by AHRQ are becoming the national standards used by organizations and provide a useful model for such an undertaking. Well-designed questions on patient safety issues could be incorporated into the CAHPS products to provide data that can be synthesized across organizations.

- **AHRQ should work with organizations in the field to initiate measurement capabilities for tracking effects for which data sources do not yet exist.**

A growing number of national-level organizations are assuming leadership roles in stimulating patient-safety improvements in the areas for which they are responsible (e.g., the AHA, medical specialty societies, JCAHO). These organizations are also in positions to stimulate measurement of progress in these areas of jurisdiction, and many of them already are doing so. By collaborating with such organizations in the development of measurement processes, AHRQ can leverage its finite resources while also building the infrastructure necessary for maintaining measurement and monitoring on a regular basis.

CHAPTER 8. CONCLUSION

The 2003–2004 evaluation has focused on updating information related to the activities of the patient safety initiative and preparing to perform the product evaluation that will assess the effects of the initiative (i.e., the fourth component of the CIPP evaluation model). We have made extensive use of written materials, information on Web sites, and interviews with individuals involved in various aspects of patient safety work to gather information and assess progress and issues.

In 2004, nearly five years since the publication of the IOM report *To Err Is Human*, the national patient safety initiative is in full swing, and AHRQ is expanding its activities from knowledge development to implementation. The agency has modified its own organization to better position itself for assuming greater responsibility for improving health care, and patient safety is a core component of that work. The FY 2000–FY 2001 projects are beginning to generate results that are building a patient safety knowledge base and providing products and tools for end users to apply in the field. At the same time, new projects have been funded that focus on implementing patient safety practices and health information technology; and other AHRQ activities—such as the PSIC—involve partnerships designed to bring effective patient-safety assessment methods and practices to health care organizations.

Given the size of the U.S. health care system and the patient safety problems it has been documented to have, the task of making the system safer is a daunting one. Although Congress has provided substantial funding to support AHRQ in carrying out this charge, there is consensus among stakeholders and health policy experts that this funding is small relative to the size of the problem. AHRQ is using a variety of approaches to leverage its limited funding, such as cost sharing on the implementation projects it funds and working through partners in the field. Realistically, the achievement of the goal of a safer health care system will depend on the commitment of thousands of organizations around the country, with leadership and technical support from such agencies as AHRQ and other federal and state agencies. As AHRQ has developed and modified its patient safety strategy, it has continued to seek creative approaches to guiding and helping this process, even as it moves ahead with implementing its current activities.

FUTURE DIRECTIONS AND PRIORITIES

From our observations of AHRQ’s patient safety strategy, as well as the current activities of its grantees and field organizations, we have identified several priorities that we encourage AHRQ to pursue in the near future:

- Facilitate movement toward a *national patient safety data repository* by encouraging use of consistent data standards, as recommended by the IOM, and establish a set of national patient safety measures for assessing performance.
- Disseminate *patient safety knowledge and products* from the FY 2000–FY 2001 projects, including development of “off-the-shelf” products that can be used readily by health care organizations.
- Modify the *standards of evidence* used to assess the effectiveness of patient safety practices in order to enable rigorous assessment of practices that cannot be tested using randomized control study designs.

- Assess the role of *health information technology* in achieving safer health care practices and its interface with the human aspects of care delivery, using results of the newly funded health-IT grants as well as knowledge generated by other patient safety projects that have addressed the use of technology for patient safety practices.
- Provide mechanisms to support consumer-led organizations in their pursuit of active *patient involvement* with health care organizations for actions to achieve safer care, including dissemination of the models they are using to a broader health care audience.
- Expand *partnerships with other organizations* involved in patient safety to achieve synergy in patient safety improvements by leveraging the combined expertise of these organizations and AHRQ's finite resources.

NEXT STEPS FOR THE EVALUATION

In 2004–2005, as the patient safety evaluation center embarks on the third year of its work, we will continue gathering information on the evolution of the patient safety initiative through our process-evaluation activities. At the same time, we will begin to collect and analyze data for the product evaluation, assessing the effects of the initiative on patient outcomes and other stakeholders. The focus of the effects analysis will be to establish baseline (historical) data on key outcome measures for several years through 2003, which will then be followed prospectively through the end of the evaluation by adding data for subsequent years as they become available.

For the process evaluation, we will track progress with respect to each component of our framework for an effective patient safety system (Figure 1.1). The focus of our assessments will shift in accordance with AHRQ's patient safety strategy. Specifically, we will assess early activities of the health-IT grants and the use of health IT in patient safety; AHRQ's strategy and activities in disseminating results from the FY 2000–FY 2001 projects; activities of the PSIC and follow-up actions by its trainees; and developments from the challenge grants and the new partnership grants.

Evaluation questions we will address encompass both the process and product phases of the patient safety evaluation:

- What new knowledge regarding patient safety epidemiology and practices is being generated by the patient safety projects most recently funded by AHRQ, and how is this knowledge expanding the scientific evidence base?
- What progress is being made in building a national patient safety infrastructure?
- What actions is AHRQ taking with other organizations to disseminate knowledge, develop products for improving patient safety practices, and provide training for users to encourage broad adoption of proven patient safety practices?
- What effects are the collective activities of AHRQ, other federal and state agencies, and health care organizations across the country having on stakeholders, including but not limited to harm to patients?

APPENDIX A
AHRQ-FUNDED PATIENT-SAFETY-REPORTING DEMONSTRATIONS

Project Number	Project Title	Principal Investigator	Institution	Location
HS11843-01	The CERTs Prescribing Safety Program	Platt, Richard	Harvard Pilgrim Healthcare	Brookline, MA
HS11878-01	Applied Strategies for Interventions for Patient Safety	Pace, Wilson D.	University of Colorado Health Center	Denver, CO
HS11880-01	New York State Safety Improvement Demonstration Project	Osten, Wayne M.	Health Research Inc./New York State Department of Health	Albany, NY
HS11885-01	Patient Safety Improvement Using Reporting Systems	Williams, Scott D.	Utah Department of Health	Salt Lake City, UT
HS11886-01	Malpractice Insurers' Medical Error Prevention Study	Studdert, David M.	Harvard University	Boston, MA
HS11889-01	Improved Patient Safety with Information Technology	Overhage, J. M.	Indiana University	Indianapolis, IN
HS11893-01	Improving Patient Safety: Health Systems Reporting	Layde, Peter M.	Medical College of Wisconsin	Milwaukee, WI
HS11898-01	Surveillance, Analysis, and Interventions to Improve Patient Safety	Fraser, Victoria J.	Washington University	St. Louis, MO
HS11902-01	Intensive Care Unit Safety Reporting System	Pronovost, Peter J.	Johns Hopkins University	Baltimore, MD
HS11905-01	Reporting Systems and Learning: Best Practices	Kaplan, Harold S.	Columbia University	New York, NY
HS11913-01	Reporting System to Improve Patient Safety in Surgery	Khuri, Shukri F.	American College of Surgeons	Chicago, IL
HS11918-01	Accountability and Health Safety: A Statewide Approach	Thorpe, Kenneth	Georgia Hospital Association	Marietta, GA
HS11919-01	Patient-Based Strategy to Reduce Errors in Diabetes Care	O'Connor, Patrick J.	Health Partners Research Foundation	Minneapolis, MN
HS11923-01	Addressing Preventable Medication Use Variance in Mississippi	Brown, Andrew C.	University of Mississippi Medical Center	Jackson, MS
HS11926-01	Systems Approach for Improving Region-Wide Patient Safety	Sirio, Carl	University of Pittsburgh	Pittsburgh, PA
HS11928-01	Evaluate the Effects of Massachusetts Reporting System	Ridley, Nancy	Massachusetts Department of Public Health	Boston, MA

APPENDIX B

SUMMARY OF THE AHRQ-FUNDED CHALLENGE GRANTS

Project Title	Summary of Project
Risk Assessment Projects	
Probabilistic Risk Assessment (PRA) Chicago Transplant Insight Study; University of Chicago	Use PRA techniques and extensive observation to explore risks associated with organ donor and recipient mismatches and assess use of this tool for other patient-safety issues.
Real-Time Assessment of Risk Factors— Medication Errors; Veterans Medical Research Foundation (San Diego)	Use handheld electronic devices to assess real-time medication risk factors and develop institution-specific intervention plans for different hospital settings.
Risk & Recovery in Complex Environments: Labor and Delivery; Beth Israel Deaconess Medical Center (Boston)	Use field observations and hospital staff interviews to map labor and delivery processes and identify system factors affecting care variations and risk of injury. Use findings to develop treatment guidelines.
Risk Models to Improve Long-Term Care Medication Safety; Oregon Department of Human Services (Portland)	In collaboration with a network of long-term care facilities, assess risks of errors in the medication process, and test potential effects of alternative interventions to reduce risk.
Re-Engineering the Hospital Discharge Process; Boston University Medical Center (Boston)	Analyze components of the hospital-discharge process, estimating risk related to each component, and use this information to re-engineer the discharge process to reduce risk of rehospitalization.
Risk Analysis of the Pediatric Chemotherapy Process; St. Jude Children's Research Hospital (Memphis)	Identify risks associated with each step of the pediatric chemotherapy medication process, and use findings to guide use of computerized physician order entry (CPOE) in clinical oncology for testing strategies to reduce medication errors.
Implementation Projects	
Medication Error Reduction: Technologies & Human Factors; University of Wisconsin, Madison	Use “smart” IV pumps and integrated bar-code technology to prevent IV medication errors.
Blood Product Transfusions & Safe Practices Implementation; University of Iowa Hospitals & Clinics	Use wireless scanner and bar-code technologies to improve the tracking of blood samples (for lab testing) and blood-bank products administered to patients.
Improving Drug Safety: Linking Lab and Pharmacy Data; Kaiser Permanente, Colorado Region	Use an electronic alert system designed to detect prescription-drug errors at the point of distribution (i.e., after the prescription is written, but before it is dispensed).
Statewide Effort to Improve Care in ICUs; Johns Hopkins University & Michigan Hospital Association Health Foundation	Implement a comprehensive unit-base safety program to reduce patient mortality in ICUs in Michigan hospitals, including four specific interventions for preventable errors.
Toward a Safety Culture: Reducing Nosocomial Infections; Cincinnati Veterans Administration	Use continual treatment monitoring, analyses, improved education, and greater infection awareness to create safer environment in ICUs and operating rooms in Cincinnati hospitals.
Technology to Improve Medication Safety in Nursing Homes; University of Missouri Nursing School (Columbia)	Use an emerging bedside technology (One Touch eMAR system) in conjunction with the Quality Improvement Program for Missouri (QIPMO) to reduce errors in nursing homes in Missouri.
The Peace Health Community-Wide Electronic Shared Medication List; Sacred Heart Medical Center/PeaceHealth Oregon Region (Eugene)	Use a Web-based, communitywide electronic shared medication list to allow physicians and patients to have access to current, updated medical and medical-history information.

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