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Assessment of the AHRQ
Patient Safety Initiative
Final Report—Evaluation Report IV

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PREFACE

In 2000, the U.S. Congress mandated the Agency for Healthcare Research and Quality (AHRQ) to take a leadership role in helping health care providers reduce medical errors and improve patient safety. AHRQ is fulfilling that mandate through its patient safety research and development initiative. In September 2002, AHRQ contracted with RAND to serve as the patient safety evaluation center for this initiative. The evaluation center was responsible for performing a longitudinal, formative evaluation of the full scope of AHRQ's patient safety activities and providing regular feedback to support the continuing improvement of the initiative over the four-year evaluation period.

This is the fourth and final evaluation report prepared by RAND (see also *Evaluation Reports I, II, and III*—Farley et al., 2005; Farley et al., 2007a, and Farley et al., 2007b). The report presents new results for the period from October 2005 through September 2006, and it synthesizes full evaluation findings over the four-year evaluation period. The annual reports have a consistent structure and format, with each year's assessment contributing to a cumulative record of the initiative's evolution.

This report describes how AHRQ's strategy and activities developed over time, the new knowledge generated by funded projects, and the contributions of various components of the initiative to building a stronger national system for patient safety improvement. It also presents updated baseline data on selected measures for evaluating the effects of the initiative on patient outcomes and other stakeholders. 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 continues to move forward.

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.

We note that following completion of the four-year evaluation, the evaluation center has been assessing the extent to which safe practices are being adopted in the health care community. This work is separate from the original evaluation, with a focus on the field instead of the AHRQ patient safety initiative.

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CONTENTS

Preface.....	iii
Contents	v
Figures.....	ix
Tables.....	xi
Executive Summary	xiii
Acknowledgments.....	xxi
Acronyms.....	xxiii
Chapter 1. Introduction	1
The CIPP Evaluation Model	1
Major Stakeholder Groups Addressed	2
A Framework for the Process Evaluation	3
Overall Approach and Methods	5
About This Report.....	5
Chapter 2. Context and Input Evaluations	7
The Policy Context	7
AHRQ Patient Safety Strategy and Goals	9
AHRQ Organization for the Patient Safety Initiative	12
AHRQ Patient Safety Projects	12
AHRQ Leadership for National Patient Safety Activities	14
Financial Resources and Budgets	14
Strategic Considerations for the Future	15
Chapter 3. Process: Monitoring Progress and Maintaining Vigilance.....	17
Overview.....	17
AHRQ-Supported Work on Patient Safety Monitoring Systems	19
Other Federal and Private Sector Data System Initiatives.....	20
Availability of Patient Safety Measures	21
Use of Measures in Accreditation or Credentialing.....	22
Issues and Action Opportunities	23
Chapter 4. Process: Epidemiology and Effective Practices	27
Overview.....	27
Epidemiology of Patient Safety	27

Updates on the Groups of Patient Safety Projects	30
Contributions of AHRQ-Funded Grants to Safety Practices	31
Health Information Technology Grants	35
Lessons from Interviews for Projects Addressing Practices.....	37
Evidence for Effective Practices.....	41
Issues and Action Opportunities	42
Chapter 5. Process: Building Infrastructure for Effective Practices.....	45
Overview.....	45
National-Level Patient Safety Partnerships	45
High Reliability Organizations	52
Use of the Hospital Survey on Patient Safety Culture.....	53
Patient Safety Improvement Corps	54
Update on AHRQ Networks	58
Mechanisms for Consumer Involvement.....	59
Payment for Patient Safety Performance	60
Issues and Action Opportunities	61
Chapter 6. Process: Achieving Broader Adoption of Effective Practices	65
Overview.....	65
Framework for Achieving Adoption of Effective Practices	65
Products Generated from Patient Safety Grantees.....	69
Dissemination Activities for Grantee Products.....	70
Intervention Effects for Initial Patient Safety Projects	72
Factors for Successful Implementation of New Practices	73
Other Initiatives for Patient Safety Improvements	76
Issues and Action Opportunities	77
Chapter 7. Product Evaluation of Effects	81
Overview.....	81
Framework for the Product Evaluation.....	82
Exploring Effects on Stakeholders and Practices	83
Outcome Measures from State Reporting Systems	84
Baseline Outcome Trends From Existing Reporting Sources	86
Baseline Trends in Encounter-Based Outcome Measures	90
Feasibility of Estimating Patient Safety Initiative Effects.....	92

Lessons from the Baseline Trend Data	94
Issues and Action Opportunities	95
Chapter 8. Summary Assessment	97
Views of National Stakeholders on Safety Progress.....	97
Summary Findings	99
Future Directions and Priorities	100
Next Steps for the Evaluation	101
References.....	103

FIGURES

Figure S.1 The Components of an Effective Patient Safety System.....	xiii
Figure 1.1 The Components of an Effective Patient Safety System.....	4
Figure 2.1 Trends in AHRQ Budgets for Patient Safety and Other Functions, FY 2000–2007..	15
Figure 4.1 Conceptual Framework for Health IT	35
Figure 5.1 AHRQ’s Direct Partners Network, 2004 and 2006	49
Figure 5.2a Dissemination Partnerships, 2004 and 2006.....	50
Figure 5.2b Standards and Guidelines Partnerships, 2004 and 2006.....	51
Figure 5.2c Education and Training Partnerships, 2004 and 2006.....	51
Figure 5.2d Tools Development Partnerships, 2004 and 2006.....	52
Figure 6.1 A Two-Step Model for Dissemination of Innovation.....	67
Figure 7.1 Conceptual Model of Potential Effects of the National Patient Safety Initiative.....	82
Figure 7.2 History of the Establishment of Existing State Reporting Systems	86
Figure 7.3 National Rates of Falls and Pressure Ulcers Among Nursing Home Residents, MDS Data, 2000-2005	87
Figure 7.4 Number of Sentinel Events Reported to the Joint Commission, for Top Four Types of Events, 1995-2005	88
Figure 7.5 Frequency of Medication Events Reported to MedMARx by Type of Event.....	89
Figure 7.6 Trends for Selected PSI Measures, 1994–2003 (1).....	91
Figure 7.7 Trends for Selected PSI Measures, 1994–2003 (2).....	91
Figure 7.8 Trends for Selected UT-MO Measures, 1994–2003 (1).....	92
Figure 7.9 Trends for Selected UT-MO Measures, 1994–2003 (2).....	92
Figure 8.1 Theoretical Diffusion Curve for Adoption of Innovations (Rogers, 2003).....	101

TABLES

Table 1.1 Timeline for Reporting Results from the Longitudinal Evaluation of the National Patient Safety Initiative.....	3
Table 2.1 Current Status of AHRQ on its Patient Safety Performance Goals and Fiscal Year Targets.....	10
Table 2.2 History of AHRQ Funding for the Patient Safety Projects, FY 2000–FY 2006	13
Table 3.1 Evaluation Questions and Assessments for Monitoring and Vigilance.....	18
Table 4.1 Evaluation Questions and Assessments for Patient Safety Epidemiology and Practices	28
Table 4.2 Patient Safety Epidemiology Information Available from Recently Published Articles and Addressed by AHRQ-Funded Patient Safety Projects, Through June 2006	29
Table 4.3 Patient Safety Issues and Special Populations Addressed by the AHRQ-Funded Patient Safety Projects	32
Table 4.4 Patient Safety Actions Addressed by the AHRQ-Funded Patient Safety Projects	33
Table 4.5 Health Care Settings Addressed by the AHRQ-Funded Patient Safety Projects.....	34
Table 4.6 AHRQ-Funded Projects Covering Evidence Report Chapters	34
Table 4.7 Profile of the Health IT Projects Funded by AHRQ, by Group	36
Table 4.8 Number and Types of Partner Organizations for the AHRQ-Funded Health IT Projects.....	37
Table 4.9 Technologies Being Addressed by the Health IT Projects and Other Patient Safety Projects.....	38
Table 5.1 Evaluation Questions and Assessments for Infrastructure for Effective Practices.....	46
Table 5.2 Organizations Interviewed for the Patient Safety Partnership Analysis, by Type of Organization.....	47
Table 5.3 All Organizations Reported as Members of Patient Safety Partnerships, by Type of Organization.....	48
Table 5.4 Increases in Patient Safety Partnership Activities, 2004 to 2006	49
Table 5.5 Percentage of Skills or Tools Used by PSIC Trainees at One Year and Two Years Post-Training, for the First and Second Year Trainees.....	56
Table 5.6 How the PSIC Training Influenced Patient Safety Actions by States, Reported in One-Year Follow-Up Interviews with the Year 1 and Year 2 Trainees, 2005 and 2006	57
Table 5.7 How the PSIC Training Influenced Patient Safety Actions by Hospitals, Reported in One-Year Follow-Up Interviews with Year 1 and Year 2 Trainees, 2005 and 2006	57
Table 6.1 Evaluation Questions and Assessments for Broader Adoption of Effective Practices	66

Table 6.2 Change Agency Actions Taken by AHRQ to Support Diffusion of Patient Safety Practices and Products	68
Table 6.3 Number of Patient Safety Products Produced by AHRQ and HRSA-Funded Grantees, 1997–2006	70
Table 6.4 Number of Health IT Products Produced by AHRQ-Funded Grantees, 2002–2006...	70
Table 6.5 Key Factors for Successful Implementation of Safety Improvements Identified from the Literature Review	74
Table 6.6 Grantees’ Reports on Evidence-Informed Implementation Success Factors.....	75
Table 7.1 Potential Measures of Infrastructure Development and Use of Patient Safety Practices for the Product Evaluation.....	83
Table 7.2 Percentage of Grantees that Reported Their Intervention Affected Various Stakeholder Groups.....	84
Table 7.3 Strength of Effects on Stakeholder Groups for Patient Safety Intervention Projects..	84
Table 7.4 Selected Patient Safety Outcome Measures Used in the Baseline Analysis.....	90
Table 8.1 Assessment of Progress for the Five Patient Safety Components	98

EXECUTIVE SUMMARY

As of September 2006, it has been five years since the U.S. Congress funded the Agency for Healthcare Research and Quality (AHRQ), in the Department of Health and Human Services (DHHS), to establish the national patient safety research and implementation initiative. AHRQ contracted with RAND in September 2002 to serve as the evaluation center for this initiative. This report—*Evaluation Report IV*—is the last of four annual evaluation reports to be prepared by the evaluation center. It presents results for the period from October 2005 through September 2006 and synthesizes findings over the full four-year evaluation period.

EVALUATION FRAMEWORK

Through this longitudinal evaluation, lessons from the current experiences of AHRQ and its funded projects can be used to strengthen subsequent program activities. The overall study 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 study design allows for an overall assessment of the initiative’s activities and how they fit into the larger scope of national patient safety activities, including synergies achieved through collaborative activities with other organizations. Effects of the patient safety initiative are assessed for six major stakeholder groups: patients, providers, states, organizations engaged in patient safety activities, the federal government, and insurers.

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

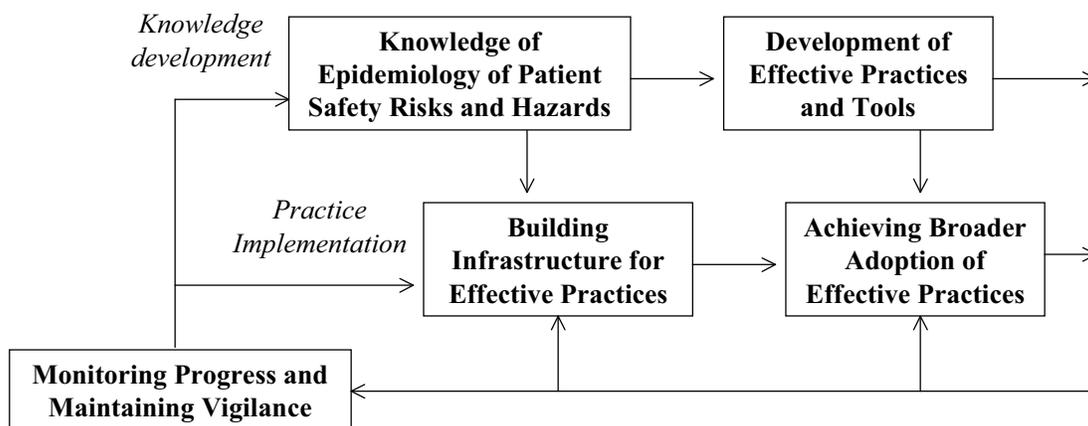


Figure S.1 The Components of an Effective Patient Safety System

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 (in the second row of the figure), which contribute to practice implementation—building infrastructure, (such as strengthening patient safety culture or training a workforce skilled in safety) and adopting effective practices.

THE CHANGING CONTEXT DURING THE INITIATIVE

The formation and funding of the AHRQ patient safety initiative occurred in an historical context most notably influenced by the Institute of Medicine (IOM) report published in 2000 entitled *To Err Is Human: Building a Safer Health System*. The initiative was designed within a policy context that created high expectations for achieving patient safety improvements. In Evaluation Report I, we identified the following implications for AHRQ, which continue to be relevant in 2006:

- *AHRQ leadership*—a clear mandate by Congress for AHRQ to provide leadership in effecting change in patient safety practices.
- *Balance between research and implementation*—the need for AHRQ to maintain a balance in the resources it applies to its traditional role of funding health services research and its new mandate to catalyze implementation of patient safety improvements in health care.
- *Resource constraints*—modest appropriation of funding relative to the work at hand, including research to strengthen knowledge and actions to bring that knowledge to the health care community and increase adoption of safer practices.
- *Accountability for results*—high expectations by Congress that AHRQ demonstrate progress in improving patient safety practice and reduction of harm to patients.
- *Coordination of multiple activities*—a diversity of patient safety activities being undertaken by multiple public and private organizations, which requires a coordination role for AHRQ to achieve synergy among them and to encourage consistent standards of practice.

Since the start of the initiative, several major external developments have had actual or potential effects on its strategy and activities. These developments include: the shift in focus of patient safety appropriations toward health information technology (health IT) grants, starting in FY 2004 and continuing through FY 2007, with a new emphasis on ambulatory care settings; the passage of the Patient Safety and Quality Improvement Act (PSQIA) of 2005 (Public Law 109-41), which the Secretary of the DHHS tasked AHRQ to implement; several new private-sector initiatives to improve patient safety that started in 2005 and have gained momentum in the past year; and the *Executive Order: Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs* (White House, 2006).

AHRQ'S APPROACH TO THE PATIENT SAFETY INITIATIVE

During FY 2004, AHRQ defined a new mission and strategic plan to guide its activities, which reflects a dual emphasis on research and implementation. Cumulative funding for patient safety projects has generated a substantial body of work since FY 2000. The five systems-related best practice (SRBP) grants were funded in FY 2000, followed by 81 patient safety projects funded in FY 2001. The 13 patient safety challenge grants were funded in FY 2003, and 109

health IT grants were funded in FY 2004. In FY 2005, 17 grants for Partnerships in Implementing Patient Safety (PIPS) were awarded, as were 14 new health IT implementation grants. In September 2006, AHRQ funded a new set of projects to research and evaluate the use of simulation techniques to improve patient safety. Between 2001 and 2006, AHRQ gradually placed greater emphasis on support of implementation-oriented projects and activities, and in FY 2007, it began to address safety issues in ambulatory care while continuing the dissemination and implementation of results based on its earlier work.

AHRQ established the Patient Safety Research Coordinating Center (hereafter, Coordinating Center) at the start of the patient safety initiative, which serves as a stimulus and facilitator of interactions among the projects funded under the initiative. AHRQ also established a National Resource Center for Health Information Technology (hereafter, Resource Center) in FY 2004, which provides technical assistance and support for the health IT grantees and assists AHRQ with managing the health IT program.

In our assessment of the scope of activities for the patient safety initiative, we have identified several overarching issues and recommendations for AHRQ to consider as it moves forward with the initiative.

- *Building a national data repository and reporting capability*—Expand the participants in the development process to include a small number of leading health systems that are particularly interested in a national data network, and strengthen their commitment to using it. Their contribution can help ensure that the national data network offers value to users.
- *Collaborative strategies for diffusion of effective safety practices*—Collaborate with partner organizations to respond in a timely way to user demand, making careful choices about which practices to emphasize, which support tools to develop, and how to expand their use.
- *Active engagement of providers and consumers*—Explore various mechanisms to engage providers and consumers in the decisionmaking and design processes for patient safety practices and tools to ensure their usefulness to end users.
- *Balancing future patient safety funding*—Continue to support research projects in areas where better knowledge is needed, while at the same time funding health IT and implementation projects.

PROGRESS IN BUILDING PATIENT SAFETY CAPABILITY AND ACTIONS

Monitoring Progress and Maintaining Vigilance (Chapter 3)

With the passage of the PSQIA, AHRQ is well positioned to achieve a national patient safety data capability based on the PSQIA data network provisions. However, consensus must still be reached among diverse stakeholders on system design, contents, and standards that are consistent with those used for the larger national health information network being developed by the DHHS Office of the National Coordinator of Health Information Technology (ONC) and collaborating organizations. To this end, a modified Delphi consensus process was conducted in 2006 as part of this evaluation, in which national patient safety experts identified a limited set of priority patient-safety outcome measures for monitoring safety performance and some initial measures for ambulatory and long-term care settings. The participating experts concluded that

almost all the measures require further development before they can be used for national monitoring.

Suggestions for AHRO Action

- Continue to pursue the current strategy and actions to establish a national patient-safety data capability through implementation of the PSQIA provisions for a network of databases, including use of a public-private collaborative approach for establishing definitions and specifications for the measures and data to be contained in the system.
- Based on the results of the national Delphi consensus process conducted in 2006, support the follow-up work needed to ensure that the measures identified are well validated and used appropriately for national monitoring and assessing progress in improving patient safety in the country.
- In partnership with the office of the National Coordinator of Health IT (ONC) and other relevant federal agencies, develop clear federal guidance on standards and other requirements for interoperability of health IT, including provisions that make the investment in health IT more compelling and easier for low-resource organizations.
- Promote the adoption of consistent data and measurement standards among state-level reporting systems and submittal of these data to the national network of databases when the network is operational, including tracking the characteristics of state-level reporting systems over time.

Knowledge of Epidemiology of Patient Safety Risks and Development of Effective Practices and Tools (Chapter 4)

The numerous patient safety projects funded by AHRQ since FY 2000 have the potential to contribute substantial new knowledge on patient safety epidemiology and scientific evidence for a range of safe practices. Because many of these projects involve viable partnerships across communities, AHRQ's support has enabled creation of models that will help others implement patient safety practices and health IT to support those practices. To make change happen, multiple factors need to be in place, and the implementation teams need to persevere in carrying out the work. Important opportunities exist for AHRQ to build knowledge of patient safety epidemiology and practices. A current priority for AHRQ should be to get the knowledge generated by funded projects into the hands of providers and policymakers.

Suggestions for AHRO Action

- Maintain an ongoing monitoring process that uses data from the national network of patient safety databases and published research, to examine shifts in trends for patient safety epidemiology in specific aspects of health care, and to identify emerging safety issues that need to be addressed to ensure the safety of health care practices.
- Together with the Coordinating and Resource Centers, establish structured start-up support and training for first-time grantees to help them understand their responsibilities and respond to AHRQ's expectations.
- Build upon its early success in supporting health IT development in rural areas through further development of flexible, inexpensive IT solutions, accompanied by funding support that is responsive to the needs of organizations in rural areas and other low-resource organizations.

- Continue to explore mechanisms to strengthen the evaluation component of the health IT implementation projects, including both training and technical assistance on evaluation methods, as well as alternative approaches to ensure that the impacts of these projects are effectively documented and analyzed.
- Using the growing volume of published results from the patient safety projects, as well as information on commonly used evaluation designs for these studies, facilitate establishment of standards of evidence for the commonly used evaluation designs, and support use of these standards to update the evidence report on patient safety practices.

Building Infrastructure for Effective Practices (Chapter 5)

AHRQ's efforts over the past four years have contributed to building a national patient-safety infrastructure, which is vital to stimulate and support the implementation of patient safety practices across the country. In particular, there was a substantial increase between 2004 and 2006 in the number of patient safety partnerships among AHRQ and other national-level organizations, which will support future dissemination activities, and likely will be reinforced by the products of other AHRQ work. The Patient Safety Improvement Corps (PSIC) also has been successful in training participants in patient safety issues and skills, who actively have applied what they learned in their work. The PSIC "graduates" trained thus far, however, represent a small fraction of health care personnel in the country, and further training capability is needed to reach much larger audiences. Engaging in partnerships has proven to be a useful strategy for leveraging scarce resources and strategically expanding the players engaged on safety issues. Partnerships could also be used to fund the production and dissemination of tools. In considering future options for building infrastructure, AHRQ will need to choose strategically where its finite investments can achieve the maximum effect.

Suggestions for AHRQ Action

- Sustain and build upon the success of the PSIC program by dedicating a portion of each annual patient safety budget to continued expansion of patient safety skills and knowledge through refresher courses for PSIC graduates, new training for additional individuals, and reinforcement of training for senior health care leaders.
- Ensure that a clear definition and explicit performance criteria for high-reliability health care organizations are established and that health care organizations nationwide are provided guidance and tools to become high reliability organizations.
- Together with other public and private entities, substantially increase education and outreach efforts to heighten consumer and provider awareness about patient safety issues and the value of collaboration among patients, families, and providers for improving the safety of care.
- Working collaboratively with other public and private funders, create more opportunities for consumer organizations to obtain support for their patient safety efforts and to achieve working partnerships with provider organizations for safety and quality of care.
- Develop guidance for the field regarding which design options and patient safety measures are most appropriate for use in incentive payment systems, such as pay-for-performance.

Achieving Broader Adoption of Effective Practices (Chapter 6)

During 2005 and 2006, AHRQ's dissemination activities accelerated in step with the results emerging from the patient safety projects funded between FY 2000 and FY 2004. Based on the results of the FY 2000–2001 projects, the Coordinating Center has identified numerous practices for which product packaging and dissemination work can bring meaningful resources to health care providers. AHRQ itself has generated toolkits to help health care organizations improve their patient safety cultures and teamwork effectiveness. As the activities of other national, field-based initiatives for implementing safe practices continue to expand and providers increasingly recognize their value, AHRQ will likely experience increased pressure from the field for additional evidence on safe practices and the tools to help implement them.

Suggestions for AHRO Action

- Set priorities for specific patient safety practices to be addressed in practice dissemination activities, and collaborate with partnering organizations to ensure that end users obtain information and tools in a timely manner to support their adoption of safe practices.
- Engage health care providers actively in every phase of its processes for synthesizing research findings on practice effectiveness and subsequent product and tool development in order to ensure their value and usability.
- Conduct a focused communication strategy to encourage hospitals to implement the 30 safe practices established by the National Quality Foundation.
- Establish an integrated clearinghouse on patient safety, including linkages to information provided by other organizations, that is the “go to” place for users nationwide.
- Develop mechanisms to support health care providers as they continue to adopt newly proven patient safety practices to ensure their sustainability.

MEASURING EFFECTS OF THE INITIATIVE ON PATIENT SAFETY

Analysis of baseline trends is a necessary initial step in exploring the impact of AHRQ's own patient safety activities. In addition, our efforts to track outcomes using measures based on encounter data highlight the importance of having a reliable data infrastructure and reliable definitions of measures for accurately estimating outcome rates over time. Validity issues associated with reported adverse events preclude their use for estimating rates of changes in patient safety outcomes, but they remain important contributors to the vigilance aspect of monitoring because changes in the events reported could signal emerging patient safety problems.

Future actions by AHRQ are needed to help develop the capability for monitoring trends in both patient safety outcomes and adoption of safe practices by health care providers. Ambulatory and long-term care settings continue to be a priority for development of measures, and state-level reporting systems may have the potential to aggregate data on a regional or national basis. Issues that continue to hinder progress in developing an acceptable monitoring system and measurement methods are limited data availability and lack of consensus regarding measures to be used for monitoring.

Suggestions for AHRO Action

- Validate the integrity of the Patient Safety Indicators (PSIs) against results for measures based on data abstraction from medical records, and clearly document the methodology

and coding for calculating the PSIs, while striving to minimize coding shifts that could lead to inappropriate interpretation of outcome trends.

- Place a priority on developing a set of patient safety measures for ambulatory care settings, and foster establishment of a data infrastructure that can support measurement for ambulatory care patient-safety issues.
- Work collaboratively with other organizations to establish an infrastructure and procedures for regular collection of data on the use of effective patient safety tools and practices by health care organizations, along with reports from the organizations about the effects of those tools and practices on care processes and clinical outcomes.

FUTURE DIRECTIONS

Over the course of this initiative, the patient safety evaluation center has examined actions undertaken directly by AHRQ to improve patient safety as well as related developments nationwide. In the process evaluation, we have documented the potential contributions of AHRQ-funded patient safety projects to expansion of knowledge for patient safety epidemiology and practices. We have also tracked AHRQ-related activities regarding the development of needed system components and dissemination of knowledge and products to health care providers across the country. In the product evaluation, we have analyzed baseline trends for selected patient outcome measures for which national-level data were available, and we established the groundwork for future assessment of the initiative's effects on practices and stakeholders.

Views of National Stakeholders on Safety Progress

To assess more broadly the initiative's progress to date, the patient safety evaluation center conducted interviews with 18 representatives from a diverse set of national stakeholder organizations. There was general agreement among the individuals interviewed that much work remains to be done to advance patient safety in the United States. Although awareness of patient safety issues and the need to improve has increased, progress in achieving actual safety improvements has been limited.

The stakeholders gave moderately weak ratings for progress being made nationally with respect to the five components of a safer health care system and slightly stronger ratings for AHRQ's effectiveness in providing leadership for these efforts. Virtually all the stakeholders interviewed expressed solid appreciation for the patient safety work that AHRQ has conducted to date, particularly in light of its limited resources. The stakeholders recommended that AHRQ work more aggressively on partnering with other organizations to ensure that evidence-based practices are adopted by front-line health care workers, and on disseminating results from the patient safety projects.

Summary Findings

Using a triangulation approach to assess the progress of the patient safety initiative, we considered the combined results from three separate analyses, all of which are presented in this report. The first was an assessment of how well the initiative was performing relative to the goals that AHRQ had established for itself which is reported in Table 2.1 (Chapter 2). The second was an independent assessment by the evaluation center of the progress made on the broader set of key activities that AHRQ had undertaken. This component used the collective results presented in the process evaluation chapters (Chapters 3 through 6), which addressed each

of the five system components defined in the evaluation framework. The third was elicitation of the perspectives of national stakeholders regarding how much progress was being made in patient safety improvement across the country and how AHRQ was contributing to that progress (Chapter 8).

Aggregating the results from these three assessments, the following summary findings were determined for the five system components:

Monitoring and Vigilance: Limited progress.

Knowledge of Patient Safety Epidemiology: Strong progress.

Development of Patient Safety Practices: Strong progress.

Infrastructure for Effective Practices: Moderate progress.

Adoption of Effective Practices: Limited progress.

Future Actions and Priorities

According to Rogers' S-shaped model for diffusion of innovations (Rogers, 2003), the adoption rate for any one particular innovation will be slow as long as only the early adopters are involved. The adoption rate will increase as the innovation proves to be successful and more users become engaged. As the innovation matures, adoption then levels off. After five years of the patient safety initiative, the United States stands at the threshold of the upward moving portion of the curve (Figure 8.1), with more and more health care providers beginning to put proven safety practices to work.

To advance beyond this threshold, AHRQ will need to continuously reinforce adoption activities through dissemination of information and tools to support practices, and through active partnerships with organizations that are leading related initiatives in the field. A list of specific priorities that we suggest for actions by AHRQ is presented in Chapter 8. At the same time, more research is needed on patient safety issues that have not yet been carefully examined, such as advancing patient safety in ambulatory and long-term care settings.

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 during our interviews with them. Their participation has enabled us to gain a comprehensive understanding of the growing volume of patient safety activities occurring in the field, partnerships that have been formed to stimulate safety improvements, and 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, Susan Lovejoy, Scott Ashwood, and Stacy Fitzsimmons for their indispensable contributions to our data-collection and analysis processes. Finally, we thank Lee Hilborne, Gordon Schiff, and Lucian Leape for their comments on an earlier draft of this report. Any errors of fact or interpretation in this report remain the responsibility of the authors.

ACRONYMS

AHA	American Hospital Association
AHIC	American Health Information Community
AHIMA	American Health Information Management Association
AHRQ	Agency for Healthcare Research and Quality
AHRQ PSNet	AHRQ Patient Safety Net
AMA	American Medical Association
CAPS	Consumers Advancing Patient Safety
CDC	Centers for Disease Control and Prevention
CIPP	Context-Input-Process-Product
CMS	Center for Medicare and Medicaid Services
CP3	Center for Primary Care, Prevention, and Clinical Partnerships
CQuIPS	Center for Quality Management and Patient Safety
DHHS	Department of Health and Human Services
DoD	Department of Defense
DRG	diagnosis-related group
DOQ-IT	Doctors' Office Quality Information Technology
EHR	electronic health record
FDA	Food and Drug Administration
HCUP	Healthcare Cost and Utilization Project
HIMSS	Healthcare Information and Management Systems and Society
HQA	Hospital Quality Alliance
HRO	high reliability organization
HRSA	Health Resources and Services Administration
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
IT	information technology
IHI	Institute for Healthcare Improvement
IOM	Institute of Medicine
MDS	minimum data set
MPSMS	Medicare Patient Safety Monitoring System
MSA	metropolitan statistical area
NHII	national health information infrastructure
NHIN	Nnational Health Information Network
NHQR	National Health Quality Report
NIS	National Inpatient Sample
NORC	National Opinion Research Center
NQF	National Quality Forum
NVHRI	National Voluntary Hospital Reporting Initiative
OCKT	Office of Communications and Knowledge Transfer

ONC	Office of the National Coordinator of Health Information Technology
PBRN	practice-based research network
PI	principal investigator
PIPS	Partnerships in Implementing Patient Safety
PSIC	Patient Safety Improvement Corps
PSI	Patient Safety Indicator
PSOs	patient safety organizations
PSQI	patient safety and quality improvement
PSQIA	Patient Safety and Quality Improvement Act
PSTF	Patient Safety Task Force
QAPI	quality assessment and performance improvement
QIO	quality improvement organization
QuIC	Quality Interagency Coordination Task Force
RFA	request for application
RHIO	Regional Health Information Organization
SCIP	Surgical Care Improvement Project
SID	state inpatient databases
SRBP	systems-related best practice
UT-MO	Utah-Missouri
USP	United States Pharmacopeia
VA	Department of Veterans' Affairs

CHAPTER 1. INTRODUCTION

In early 2000, the Institute of Medicine (IOM) published the report entitled *To Err is Human: Building a Safer Health System*, calling for leadership from the U.S. Department of Health and Human Services (DHHS) in reducing medical errors, and recommending the Agency for Healthcare Research and Quality (AHRQ) as the lead agency for patient safety research and practice improvement (IOM, 2000). 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, strengthen the patient safety knowledge base, ensure accountability for safe health care delivery, and implement patient safety practices (QuIC, 2000).

As of September 2006, it has been five years since the U.S. Congress funded AHRQ, in the Department of Health and Human Services (DHHS), to establish the national patient safety initiative. This initiative represents one of numerous, important patient safety efforts being undertaken by organizations across the country. AHRQ's leadership can provide motivation and guidance for the activities of others and, by integrating its work with that of other public and private organizations, can leverage finite resources and achieve synergy through collaboration. 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 identifying and disseminating the most effective practices.

AHRQ contracted with RAND in September 2002 to serve as the evaluation center for this initiative. The evaluation center is responsible for performing a longitudinal evaluation of the full scope of AHRQ's patient safety activities, and providing regular feedback to support the continuing improvement of this initiative. This report—*Evaluation Report IV*—is the last of four annual evaluation reports to be prepared by the evaluation center. It presents results for the period from October 2005 through September 2006 and synthesizes findings over the full four-year evaluation period.

THE CIPP EVALUATION MODEL

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' perspectives are also assessed.
- ***Process evaluation*** assesses progress in implementation of plans relative to the stated goals for future activities and outcomes. Activities undertaken to implement the patient

safety initiative are documented, including any changes made that might alter its effects, positively or negatively.

- ***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 types of evaluations included in the CIPP model as applied to this program evaluation. The activities covered in this final report are shown in the shaded column. These include updates on the context and input evaluations, and continued assessment of patient safety initiative activities through the process evaluation. The product evaluation is composed of updates of baseline trends for selected measures, preliminary assessments of the patient safety initiative on selected measures, and identification of approaches and issues for continued monitoring of impacts on various stakeholders.

MAJOR STAKEHOLDER GROUPS ADDRESSED

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

- *Patients*, who receive health care services and bear the impact of adverse health care events, have a direct stake in the prevention of those events.
- *Providers*, including physicians, nurses, other health care professionals, and the organizations that employ them, also have a stake in the occurrence of adverse events, as well as in the adoption of clinical and organizational practices designed to promote safety.
- *States* that license health care providers and (in many instances) operate adverse-event reporting systems have a stake in tracking adverse events and in promoting remediation efforts by providers.
- *Organizations working in patient safety* to promote best practices, education, and technology adoption in patient safety have a stake in building collaborations to achieve those ends.
- *Federal government agencies* involved in patient safety activities—in particular, AHRQ and other DHHS agencies—have responsibilities for various aspects of patient safety.
- *Insurers and health plans* that contract with providers for health care services for their insured populations are concerned about how adverse events and actions to improve patient safety affect their costs and their members' outcomes.

Table 1.1
Timeline 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 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 impacts			X	X

A FRAMEWORK FOR THE PROCESS EVALUATION

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

Monitoring Progress and Maintaining Vigilance. Establishment and monitoring of measures to assess performance improvement progress for key patient safety processes or

outcomes, while maintaining continued vigilance to ensure timely detection and response to issues that represent patient safety risks and hazards.

Knowledge of Epidemiology of Patient Safety Risks and Hazards. Identification of medical errors and causes of patient injury in health care delivery, with a focus on vulnerable populations.

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 (e.g., culture, information systems), hazards to safety created by the organization’s structure (e.g., physical configurations, procedural requirements), and effects of the macro-environment on the organization’s ability to act (e.g., legal and payment issues).

Achieving Broader Adoption of Effective Practices. The adoption, implementation, and institutionalization of improved patient safety practices to achieve sustainable improvement in patient safety performance across the health care system.

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

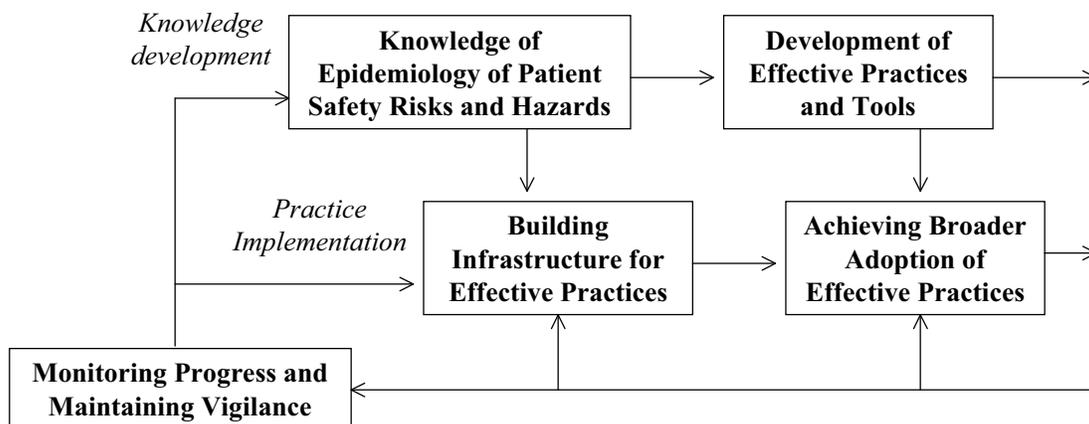


Figure 1.1 The Components of an Effective Patient Safety System

OVERALL APPROACH AND METHODS

The study 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. At the local level, AHRQ-funded 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, or are fully implementing new practices or infrastructures to support those practices. AHRQ funded the Patient Safety Research Coordinating Center (hereafter, Coordinating Center) to serve as a facilitator of interactions among the patient safety grantees, and to provide technical support to the grantees and AHRQ.

Numerous data-collection methods were employed in this evaluation, tailored to specific aspects of the initiative. (See separate Technical Appendix (Farley et al., forthcoming).) We made use of already existing information from written reports and documents, Web sites, and proposals written for the patient safety projects that were awarded AHRQ funding. We also conducted open-ended interviews with numerous individuals, including AHRQ personnel, grantees, and external stakeholders, to gather information on the dynamics and issues relevant to the patient safety initiative.

ABOUT THIS REPORT

This evaluation report updates information on the current status of the AHRQ patient safety initiative and examines progress in carrying out the component activities that were identified in previous evaluation reports. 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 from earlier evaluation reports; in others, we offer new recommendations or expansions of previous ones, based on our most recent findings. Unless stated otherwise, the information presented in this report is current as of September 2006.

The remaining seven chapters of this 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 evaluation 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. They are 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 development of knowledge on patient safety epidemiology and practice; Chapter 5 addresses infrastructure; and Chapter 6 addresses activities for adoption of effective practices. Chapter 7 presents the results of the product evaluation, including our assessment of effects of the patient safety initiative on patient outcomes and other stakeholders. Chapter 8 summarizes the current status of the AHRQ patient safety initiative, including assessments by key stakeholders on patient safety improvement progress, and identifies key issues and priorities for AHRQ to consider as it moves forward with the initiative.

CHAPTER 2. CONTEXT AND INPUT EVALUATIONS

This chapter updates the information presented in *Evaluation Reports I* through *III* 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 continues to carry out the initiative (input evaluation).

THE POLICY CONTEXT

The historical context that led to formation and funding of the AHRQ patient safety initiative may be summarized as follows:

- The science of patient safety was relatively immature as this initiative began, including limited knowledge of the epidemiology of safety in health care, an inadequate body of published research to establish evidence regarding the effectiveness of practices to improve patient safety, and lack of recognition or acceptance within the health care system that there was a “patient safety problem.”
- Strong public sentiment and support for reducing health care harm to patients was stimulated by the Institute of Medicine (IOM) report, *To Err Is Human: Building a Safer Health System* (IOM, 2000). The Quality Interagency Coordination Task Force (QuIC) then identified more than 100 actions designed to create a national focus to reduce errors, strengthen the patient safety knowledge base, ensure accountability for safe health care delivery, and implement patient safety practices (QuIC, 2000), resulting in action by Congress to make patient safety a national policy priority.
- Following a difficult period in which the agency had received criticism and had been at risk of discontinuation, under new leadership, AHRQ 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. In response to this new national priority, patient safety activities were undertaken by numerous organizations, including federal agencies, state governments, state coalitions, health care providers, academic institutions, professional associations, and other organizations.

Implications for the AHRQ Patient Safety Initiative at Baseline

The initiative was designed within a policy context that created high expectations for achieving patient safety improvements. In *Evaluation Report I*, we identified the following implications for AHRQ, which continue to be relevant in 2006:

- *AHRQ leadership*—a clear mandate by Congress for AHRQ to provide leadership in effecting change in patient safety practices.
- *Balance between research and implementation*—the need for AHRQ to balance its traditional role of funding health services research with its new mandate to catalyze implementation of patient safety improvements in the health care system.
- *Resource constraints*—modest appropriation of funding relative to the work at hand, including research to strengthen knowledge and actions to bring that knowledge to the health care community and increase adoption of safer practices.

- *Accountability for results*—high expectations by Congress that AHRQ demonstrate progress in improving patient safety practice and reduction of harm to patients.
- *Coordination of multiple activities*—a diversity of patient safety activities being undertaken by multiple public and private organizations, which requires a coordination role for AHRQ to achieve synergy among them and to encourage consistent standards of practice.

External Developments Affecting the Patient Safety Initiative

Since the start of the initiative, several major external developments have had actual or potential effects on its strategy and activities, as described below.

Appropriations for health information technology grants. In FY 2004, Congress first appropriated \$60 million to support health information technology (IT) projects designed to improve patient safety and quality of health care. This funding replaced the previous \$50 million in annual patient safety appropriations that had supported the first group of patient safety projects. Congress has maintained its emphasis on health IT, appropriating \$60 million annually for AHRQ-funded health IT projects through FY 2006. The same level of appropriation was proposed for FY 2007, with a new emphasis on health IT that supports patient safety improvements in ambulatory care settings. AHRQ funding to support research on other aspects of patient safety was limited to \$24 million in FY 2006, and the same level of funding was expected for FY 2007.

Legislation for patient safety organizations. The Patient Safety and Quality Improvement Act of 2005 (PSQIA) (Public Law 109-41) was enacted in July 2005. The purpose of the law is to (1) encourage the voluntary reporting of medical errors and adverse events by health care providers; (2) enable the development of a national network of patient safety databases; and (3) reduce the incidence of events that negatively affect patient safety. The law's protections for reporting medical errors and adverse events, along with its support for systematic collection and sharing of data on these events, should help address liability issues, thereby removing barriers to further momentum to patient safety initiatives in the health care sector.

AHRQ has been assigned the lead role for implementing the provisions of the new law, including certification of the patient safety organizations (PSOs) and the design and operation of a national data network. This work is supported by funds included in the annual \$24 million appropriations for non-health IT patient safety activities. The new law has generated considerable interest, with numerous organizations contacting AHRQ about being certified as PSOs. Since 2005, AHRQ staff have devoted considerable time to developing the necessary regulations for the PSOs. Due to limitations in the specificity of the legislation, it has taken time to resolve a number of issues, including who can be a PSO, how to handle single case being reported to multiple PSOs, and effects of and confidentiality concerns about the ability to share data. Therefore, as of September 2006, it was unclear how the national network of databases would evolve, although previous efforts to establish a national data capability suggest that the process will be complex and time-consuming.

Other public and private sector initiatives to improve patient safety. Several patient safety initiatives outside of the AHRQ initiative were initiated in 2005, and they have gained momentum during the past year. Notable examples are the Surgical Care Improvement Project (SCIP) led by a collaborative partnership of public- and private-sector health care organizations; the 100,000 Lives (now the 5 Million Lives) Campaign led by the Institute for Healthcare

Improvement (IHI) with the support of the American Medical Association (AMA), the Centers for Medicare and Medicaid Services (CMS), and other organizations; and transformation of health care providers led by CMS and a number of quality improvement organizations (QIOs). AHRQ is a partner or collaborator in all of these initiatives, as well as the leader of a new initiative on high reliability organizations (HROs) in partnership with health care systems. In addition, the first two cohorts of Patient Safety Improvement Corps (PSIC) trainees have initiated activities to improve patient safety within their organizations.

Presidential Executive Order on Quality Care. Most recently, on August 22, 2006, the President signed an Executive Order entitled *Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs* (White House, 2006). The executive order directs federal agencies that administer or sponsor federal health insurance programs to increase transparency in pricing and quality, encourage adoption of health IT standards, and provide options that promote quality and efficiency in health care.

AHRQ PATIENT SAFETY STRATEGY AND GOALS

The evolution of AHRQ's patient safety initiative is usefully examined in the context of the agency's overall strategy and goals. During FY 2004, AHRQ defined a new mission, which moved 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 and quality, efficiency, effectiveness, and organizational excellence. The AHRQ patient safety initiative is contributing to the first three overall agency goals (AHRQ, 2004a).

AHRQ adopted the following long-term patient safety goal: "By 2010, increase the number of medical errors identified while decreasing the number of severe errors." It is using a four-element framework to structure its long-range work and performance assessment: identifying threats to patient safety; identifying and evaluating effective patient safety practices; teaching, disseminating, and implementing effective patient safety practices; and maintaining vigilance (AHRQ, 2003b). Specific performance goals and related fiscal year targets were established for three of the framework elements (all except maintaining vigilance). Although AHRQ did not establish targets for the goal of maintaining vigilance, the capability to address this goal is closely related to what is needed to address the first goal of identifying threats.

The goals and targets are listed in Table 2.1, along with summary assessments from our evaluation regarding AHRQ's progress in achieving the goals and targets through its patient safety activities over the past five years. While AHRQ has met its fiscal year targets for the goals to *identify and evaluate effective practices* and *educate, disseminate, and implement to enhance patient safety*, it has faced substantial challenges reaching the goals and targets for *identifying threats*. To date, AHRQ's ability to design and execute a national patient safety data capability for monitoring has been hampered by fragmentation of authority across the health system as well as incompatibilities among the multiple standards used for data elements and IT specifications (See Chapter 3). The passage of the PSQIA offers the potential to change this situation. Based on progress thus far, the initiative has the potential for partial or full achievement of its goals. For reducing medical errors, however, success will depend not only on efforts by AHRQ and its collaborating organizations but also on the extent to which health care providers move proactively to improve safety performance in their organizations.

Table 2.1
Current Status of AHRQ on its Patient Safety Performance Goals and Fiscal Year Targets

Goals and Fiscal Year Targets	Status as of End of FY 2006
<i>Identify the Threat</i>	
Performance goal: By 2010, patient safety events reporting will be standard practice in 90 percent of hospitals nationwide.	As of 2005, an estimated 98 percent of hospitals report they have centralized, internal patient safety event reporting systems, but only 12 percent of them are fully computerized. (See hospital survey results in Chapter 3.) None are reporting full safety information to external reporting systems.
FY 2005 Continue reporting on patient safety events and begin to analyze the number and types.	Cannot proceed with external reporting until regional or national reporting systems are in place.
FY 2004 Pilot the system at 50 hospitals and begin reporting on patient safety adverse events.	Not yet met as of FY 2006; may be achieved when external reporting occurs under the PSO program.
FY 2003 Develop reporting mechanism and data structure through the National Patient Safety Network.	Not yet met as of FY 2006, although the national data network for the PSO program has potential to achieve this.
<i>Identify and Evaluate Effective Practices</i>	
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).	On track to achieve goal. Patient safety grants addressed many new practices for which evidence was lacking. Research findings not yet synthesized to assess and grade the evidence.
FY 2005 Five health care organizations or units of state or local governments will evaluate the impact of their patient safety best practices interventions.	Accomplished in second year of the 7 implementation challenge grants; also started for PIPS grants.
FY 2004 Six health facilities or regional initiatives to implement interventions and service models on patient safety improvements will be in place.	Accomplished with first year of work for the 7 implementation challenge grants.
FY 2003 Awards to be made to at least six facilities or initiatives.	Accomplished on schedule. Awarded 13 challenge grants, of which 7 grants were to implement and evaluate new practices.

Goals and Fiscal Year Targets		Status as of End of FY 2006
<i>Educate, Disseminate, and Implement to Enhance Patient Safety</i>		
Performance Goal: By 2010, successfully deploy hospital practices such that medical errors are reduced nationwide.		Too early to assess this goal because impacts of the patient safety initiative are likely to lag several years from date of initial funding for research and development. (See Chapter 7 for baseline trends for selected outcomes tracked by the evaluation.)
FY 2005	15 additional states or major health care systems will have on-site experts in patient safety.	Accomplished on schedule. Trained staff from another 15 states and hospitals in FY 2005. (See Chapter 5)
FY 2004	10 states or major health care systems will have been trained through the Patient Safety Improvement Corps (PSIC) program; five health care organizations or units of state/local government will implement evidence-based proven safe practices.	Accomplished on schedule and exceeded target. Trained staff from 12 states and 12 health care organizations through FY 2004. (See Chapter 5)
FY 2003	Establish a PSIC training program; award up to five grants to health care organizations or units of state or local governments for implementing evidence-based proven safety practices.	Accomplished on schedule. (see Chapter 5)
FY 2002	Conduct a planning study.	Completed

Source: AHRQ Justification for FY 2005 Budget (AHRQ, 2004b).

Until recently, most of AHRQ's patient safety projects have focused on hospital inpatient care, largely because this is the setting for which both knowledge of issues and measurement capabilities were strongest. Over time, it has become clear that little is known about the prevalence of patient safety issues, or practices to improve safety, in ambulatory care. To address this gap, AHRQ has established ambulatory patient safety as a new priority for the initiative. The ambulatory patient safety program has a five-year goal of "measurably improving the safety and quality of care for patients in ambulatory environments using health IT" (AHRQ, 2006). The program is supported by \$29 million from its FY 2007 health IT budget and an additional \$6 million in general patient safety funds.

AHRQ ORGANIZATION FOR THE PATIENT SAFETY INITIATIVE

AHRQ's overall programming is managed by five centers, all of which are involved in the patient safety initiative to varying degrees. 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 have been most actively involved in the patient safety activities to date, and will continue to have lead roles in FY 2007 and beyond. CQuIPS has primary responsibility for overall management of the patient safety initiative. CP3 has the lead responsibility for awarding and managing the health IT grants. The two centers are also working together on the new ambulatory care patient-safety program.

At the start of the patient safety initiative, AHRQ established the Patient Safety Research Coordinating Center to serve as a stimulus and facilitator of interactions among the projects funded in FY 2000 and FY 2001. Two organizations have served as the Coordinating Center. The first contract was awarded to Westat as of October 2001, with a three-year term that ended in September 2004. The second contract was awarded to the National Opinion Research Center (NORC). Under the terms of the second contract, the Coordinating Center places greater emphasis on dissemination and implementation activities and development of tools and products for the health care community. It also supports broader patient safety activities within the agency, including management support for the patient safety and quality portfolio.

Accompanying the funding of the health IT grants, AHRQ awarded to NORC a five-year contract to establish a National Resource Center for Health Information Technology (hereafter, Resource Center). The Resource Center provides technical assistance and support for the health IT grantees and assists AHRQ with managing the health IT program. AHRQ strives to achieve economies of scale by coordinating the work of the Coordinating Center and the Resource Center, and integrating them whenever possible, including the joint conduct of the annual conferences for the two groups of grantees.

AHRQ PATIENT SAFETY PROJECTS

Since enacting the first patient safety appropriation in FY 2001, Congress has continued to appropriate funds to support patient safety grants and activities, maintaining its interest in this health care priority. The history of funding for patient safety grants is summarized in Table 2.2, followed by brief summaries of the grant programs. More detailed information about the projects is provided in *Evaluation Reports I through III*.

Table 2.2
History of AHRQ Funding for the Patient Safety Projects, FY 2000–FY 2006

Fiscal Year	Type of Grant	Annual Funding Amount
2000	Systems-related best practices	\$2M
2001	Six groups of patient safety grants	\$50M
2001	Working conditions	\$7M
2002	[no new projects funded]	
2003	Challenge grants	\$4M
2004	Health IT grants and contracts	\$50M
2005	Partnerships in patient safety	\$3M
2005	Health IT implementation grants	\$7M
2006	Improving patient safety through simulation research	\$2.4M

FY 2000–2001 Patient Safety Grants. A total of 81 patient safety projects were awarded funding, including six projects under the systems-related best practices (SRBP) request for applications (RFAs) issued in 2000 and 75 projects under the six RFAs issued in 2001. CQuIPS has been responsible for the overall management of these projects. AHRQ obligated a total of \$142 million over the life of these multiyear grants; the reporting demonstrations represented half of the spending.

Patient Safety Projects Funded by the Health Resources and Services Administration (HRSA). In September 2001, AHRQ and HRSA collaborated to include five additional HRSA-funded projects in the patient safety initiative. Funded for a total of \$2.4 million, the projects focused on developing and testing methods for interdisciplinary training on patient safety for medical and nursing students.

Challenge Grants for Patient Safety Practices. 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 use of risk assessment techniques for identifying and reducing patient safety issues in health care organizations. The one-year risk assessment grantees completed their work at the end of FY 2004. The three-year implementation grantees were scheduled to complete their work by the end of FY 2006.

Patient Safety Health IT Grants. In FY 2004, AHRQ awarded 104 multiyear grants to implement and evaluate the use of health IT for improving patient safety and quality of care. The projects were funded through three separate RFAs: one-year planning grants, three-year implementation grants, and demonstration grants for up to three years. In FY 2005, AHRQ awarded an additional \$7 million in implementation grants to 16 of the previous planning grantees.

Regional Health Information Organizations (RHIOs). In FY 2004, AHRQ awarded \$25 million in contracts over five years to five states (Colorado, Indiana, Rhode Island, Tennessee, and Utah) to undertake statewide or regional demonstration projects that utilize health IT to improve data sharing and interoperability among health care providers, purchasers, and public and private payers. A sixth contract was awarded to Delaware in FY 2005.

Grants for Partnerships for Implementing Patient Safety. In June 2005, AHRQ awarded 17 cooperative agreements for up to 24 months in duration. The overall goal is for

institutions to work in collaboration with AHRQ to implement safe practice interventions designed to eliminate or reduce medical errors, risks, hazards, and harms associated with the process of care. The grantees are required to develop tools that can be used for future implementation projects at their institutions, and to work with AHRQ on the dissemination of those tools.

Grants for Improving Patient Safety through Simulation Research. In September 2006, AHRQ awarded \$2.4 million to 19 projects to explore the use of and/or adaptation of simulation tools to improve patient safety in diverse health care settings. The awards are cooperative agreements and vary in duration up to a maximum of 24 months.

Ambulatory Care Grants Planned for FY 2007. In FY 2007, AHRQ released RFAs for four sets of ambulatory care patient safety grants focused on use of evidence-based practices, patient-centered care, health IT for medication management, and integration of prospective risk assessment as a decision support tool. Special attention will be paid to the delivery of high-quality care to providers in rural, small community, safety net, and community health center environments.

AHRQ LEADERSHIP FOR NATIONAL PATIENT SAFETY ACTIVITIES

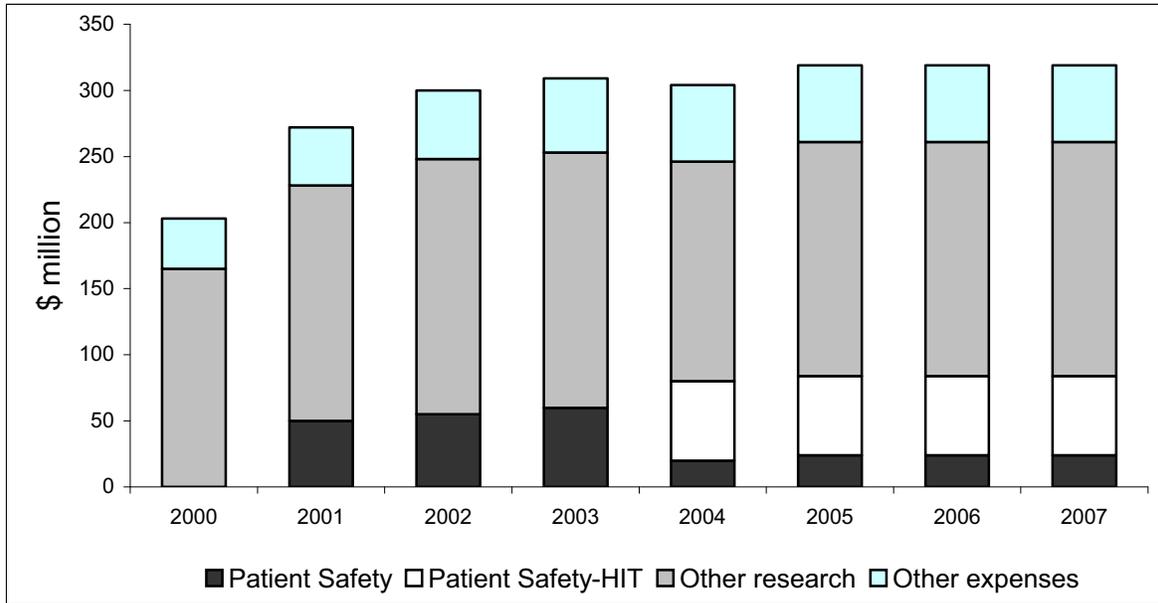
Although AHRQ is the only federal agency that has received substantial funding specifically for patient safety work, other agencies have become increasingly involved in implementing patient safety improvements in the field. These include CMS, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), HRSA, DoD, and the Department of Veterans' Affairs (VA).

Several interagency task forces have also been established to support and inform the nation's patient safety activities. One of these was the Quality Inter-Agency Coordination Task Force (QuIC), in which AHRQ provided leadership and support for its activities. Some of the QuIC's activities addressed patient safety, most notably the two National Summits for Patient Safety Research held in September 2001 and November 2003. The DHHS discontinued the QuIC in 2004 due to changing DHHS priorities.

Another group was the Patient Safety Task Force (PSTF), which was established in 2001 with the charge of developing an integrated data system for patient safety data reported to the DHHS agencies. Soon after this work was discontinued at the end of FY 2004, the PSTF was disbanded because it had not been charged with any additional roles. In its place, AHRQ established a new interagency workgroup, with representation from CMS, FDA, CDC, and HRSA, with the purpose of informing AHRQ's implementation of the PSQIA.

FINANCIAL RESOURCES AND BUDGETS

As Figure 2.1 illustrates, overall patient safety funding increased from 18.4 percent of the AHRQ budget in FY 2001 to 26.3 percent in FY 2004, and has since remained at approximately that level. If Congress approves AHRQ's proposed FY 2007 budget, patient safety will continue to account for 26.3 percent of the total budget. Beginning in FY 2004, support for health IT projects increased substantially, and is expected to remain at the FY 2006 level in FY 2007.



Source: DHHS Budget in Brief, fiscal years 2002, 2003, 2004, 2005, 2006, and 2007.

Note: Other research areas include the Effective Health Care Program, Translating Research Into Practice, Consumer Assessment of Health Plans, 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.

Figure 2.1 Trends in AHRQ Budgets for Patient Safety and Other Functions, FY 2000–2007

STRATEGIC CONSIDERATIONS FOR THE FUTURE

From the outset, the AHRQ patient safety initiative has been a model for building multiyear strategies in which investments in knowledge development research are explicitly linked to subsequent practice improvement activities. As the initiative evolved through 2006, AHRQ gradually shifted toward a heavier emphasis on dissemination activities and support of implementation-oriented projects. Moving into FY 2007, AHRQ shifted focus again to address safety issues in ambulatory care, while continuing the dissemination and implementation of results based on its earlier research. In this context, we return to feedback heard from stakeholders early in the evaluation that AHRQ is seriously underfunded for the huge set of problems requiring attention to achieve patient safety improvements, with which we agree. Absent such expanded funding, AHRQ needs to strategically invest its limited resources in those aspects of the system that can yield that best return in safety. Below, we present four overarching issues and recommendations for AHRQ to consider as it moves forward.

Building a National Data and Reporting Capability. In earlier evaluation reports, we emphasized the importance—and difficulty—of building a national patient safety database and reporting capability. The enactment of the PSQIA provides an important opportunity for achieving both consistent reporting practices and a national data repository. Although the challenges involved in standardizing data elements and achieving system interoperability remain, AHRQ now has a formal mandate and authorization to carry out this work. We endorse the participatory approach that AHRQ is taking to defining data elements and standards, since providers, PSOs, and other organizations will submit their data to a national network only if they

see value in participating and the process is not overly burdensome. In addition to the interagency workgroup that has been organized, we suggest that AHRQ identify a small number of leading health systems that are particularly interested in a national data network to help work through the myriad of technical issues related to data definitions, standards, and system interoperability. As these health systems participate and influence the system design, they will help create a usable national data capability and will become committed to using it. In turn, their use of data from the national system to track their performance relative to aggregate benchmarks should help stimulate participation by others.

Collaborative Strategies for Diffusion of Effective Safety Practices. As health care providers become more aware of patient safety issues and standard-setting organizations push them to improve their safety performance, the pursuit of improved safety practices on the “front lines” of care should accelerate. Since our first evaluation report, we have encouraged AHRQ to work strategically with field-based collaborators to support health care providers in adopting safety practices that are proven to be effective and to disseminate products and tools that support those practices. In doing so, AHRQ should undertake the activities it is best suited to perform as a government agency, while partnering with other organizations that can carry out activities they are best equipped to perform. The strategic issue for AHRQ is finding the most effective, user-friendly ways to make available the wealth of information generated by the patient safety projects. Examples of specific actions that AHRQ can best perform include synthesizing information on project results in full evidence assessments, defining priorities for practices to emphasize that are based on collective results from multiple projects, developing usable products for the practices identified, and communicating information on them.

Active Engagement of Providers and Consumers. To ensure that safety practices and tools are useful to both providers and consumers, it is essential that these end users be directly involved in the development process. In earlier phases of the initiative, AHRQ sought users’ perspectives to guide its decisionmaking, primarily through the two National Summits on Patient Safety Research in 2001 and 2003. Since then, however, there has been limited direct involvement by front-line providers or consumers in assessing implications of research results or development of products or tools. By engaging health care leaders as partners in future practice assessment and product development processes, AHRQ can ensure that its work focuses on priority practices, enhances the viability of the products developed, and accelerates adoption of practices by health care providers. Examples of mechanisms to engage these leaders in the decisionmaking and design processes include a series of regional meetings through which end users can address issues and help rank priorities; user participation in working groups to test products and tools before they are finalized; and pilot tests of the products by a few providers.

Balancing Future Patient Safety Funding. Throughout this evaluation, we have addressed the tension between AHRQ’s research and implementation functions for the patient safety initiative. This tension likely will continue, as knowledge and products emerge from already funded projects and decisions are made regarding future funding priorities. With the new emphasis on ambulatory care issues, AHRQ is now moving into the third phase of its patient safety initiative. As one of the few funding sources for health services research, it remains important for AHRQ to continue to support research that expands patient safety knowledge in needed areas and serves as the critical first step toward building the capability to implement improvements.

CHAPTER 3. PROCESS: MONITORING PROGRESS AND MAINTAINING VIGILANCE

Establishment and monitoring of indicators 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.

OVERVIEW

The ability to assess performance on established patient safety measures is vital to the health care community for reducing the risk of harm to patients and the consequences of such harm. This information will also enable AHRQ to report to Congress on the results of its investments in patient safety research and dissemination so that appropriate adjustments can be made to the patient safety project investments.

A major goal of the AHRQ patient safety initiative is to establish a national data capability that would enable aggregation of patient safety data from local, regional, and state levels, and allow for tracking of changes in patient safety performance across the country. Such a capability would eliminate the proliferation of varying reporting requirements that providers find burdensome and also enhance and support ongoing national efforts to address health care quality, access, and cost issues through strong national health information systems.

AHRQ has been working to develop components of a data capability since 2002, although its progress has been hampered by the absence of formal authorization. With the passage of the PSQIA, AHRQ now has the formal authority to establish PSOs to which health care providers can report data with protection from legal discovery and to develop a national network of databases for aggregation of the reported data. Substantial challenges remain, however, particularly with respect to achieving consensus among varied stakeholders on standards for data content, definitions, and information-system design.

We have reinforced the importance of this goal since the start of this evaluation. We stated in *Evaluation Report I* that a national data repository is a key component of the national patient safety initiative, but it is also one of the most difficult to achieve. Table 3.1 presents the evaluation questions regarding monitoring and vigilance activities addressed by this evaluation, as well as a brief assessment of current status for each question. These assessments draw upon results from all four years of the patient safety evaluation.

In this chapter, we synthesize the evaluation results across the four evaluation years for each of the key components of a monitoring and vigilance system, including a focus on new information from the assessments performed in this final evaluation year. Our findings draw on information provided by relevant written materials and documents and interviews with AHRQ staff, other federal agency staff, representatives of state reporting systems, and principal investigators (PIs) for the AHRQ-funded projects.

Table 3.1
Evaluation Questions and Assessments for Monitoring and Vigilance

Evaluation Question	Summary Assessment
What progress has been made in establishing and using generally accepted sets of measures for patient safety events or outcomes in a range of health care service settings?	A modified Delphi consensus process was run by the evaluation center team in 2006, which identified important outcome measures and assessed validity and measurement issues for them. More work remains to validate many of these measures and address measurement issues and specifications.
What progress has been made in establishing a consistent set of standards for patient-safety reporting systems, for use by both government agencies and health care providers?	AHRQ began work on this with funding to IOM for preparation of its Data Standards report. With passage of the PSQIA, AHRQ started work in 2006 to identify candidate standards for the data content of a national data network and reach consensus on which standards to use. It will be important to achieve agreement on standards, which should complement the information technology standards being developed by DHHS.
What actions have been taken to establish a national-level patient safety data repository?	With passage of the PSQIA, AHRQ has been able to move forward with design of a data capability, under the data network provisions of the act. Plans to begin full implementation of the act in 2007, including progress on the national network of databases, were not met. Delays have hampered progress in both reporting and data.
To what extent are national-level data available regarding the performance of our health care system on patient safety measures, and how has this changed?	Data availability continues to be extremely limited, with heavy reliance on the HCUP data. State reporting systems have grown in number but vary widely in the measures and data they collect. No national-level data are available for ambulatory care, except Medicare data, which has not yet been used for patient safety measurement. More work is needed if effective outcome measurement is to happen.
What is the status of the use of generally accepted patient safety measures for assessing performance as part of accreditation or other credentialing processes?	The primary organization using patient safety measures is the Joint Commission, which has had relevant policies in place for several years, specifically its sentinel events reporting policy. The National Quality Forum (NQF) consensus process has made progress in establishing measure sets, but none of them has been used consistently across the country. Measures for both practice adoption and outcomes should be included.
What steps need to be taken to enhance the capability for effective monitoring of patient safety performance?	Further work is needed on each of the items listed above, to continue progress toward establishing a national data capability. Priority issues to be addressed include standardization of measures and standards, increased data availability at the national level, and measurement issues such as use of rates versus counts.

AHRQ-SUPPORTED WORK ON PATIENT SAFETY MONITORING SYSTEMS

Since 2002, AHRQ has supported four key projects that address the requisite elements of a national data capability, which are summarized below. In addition, recent AHRQ activities related to patient safety monitoring systems are described in greater detail.

- ***IOM project on patient safety data standards*** resulted in recommended standards for patient safety data systems that are under consideration for designing the national data repository (IOM, 2004).
- ***Federal data system project*** yielded a technical product for integrating reporting of patient safety data from two existing federal reporting systems but stopped short of implementation due to financial issues and design constraints (AHRQ staff interviews).
- ***Joint Commission taxonomy for patient safety reporting*** led to the development of the Patient Safety Event Taxonomy, endorsed by the NQF, which provides standards for consistent classification of reported events (Chang, 2005). The taxonomy has subsequently undergone validity testing using data for sentinel events and incident reports; additional work remains for establishing coding specifications and classifying events to ensure consistent application.
- ***RAND study on the contents and standards of state adverse-event reporting systems*** generated a report documenting the data elements collected by state reporting systems and assessing consistency across states in data elements and IT standards (Beckett et al., 2006).

Implementation of the Patient Safety and Quality Improvement Act

More recently, AHRQ's work to develop a national data network has focused on implementing the PSQIA enacted in 2005. In anticipation of the act's passage, AHRQ began compiling information about existing reporting systems. Once the law was passed, AHRQ and other offices within DHHS began preparation for implementing the provisions of the legislation by developing (1) regulations with provisions for PSO designation and the structures and processes for reporting of data to these organizations; and (2) specifications for the national data network, including data definitions and standards and informatics standards. An interagency workgroup was convened with representation from several federal agencies, including the FDA, CDC, CMS, and HRSA, to assist AHRQ with implementation of the law. The development of the regulations has been conducted through a participatory process involving input from throughout DHHS, as well as the Department of Defense (DoD) and the VA. AHRQ also plans to develop the criteria for databases and data formats collaboratively with private-sector organizations.

Survey on Hospital Patient Safety Adverse-Event Reporting Systems

In spring 2006, RAND and the Joint Commission completed data collection for a national survey on adverse-event reporting systems in hospitals, utilizing an AHRQ-funded questionnaire developed and tested by Westat. AHRQ's goal for this survey was to establish a national benchmark of adverse-event reporting systems used in hospitals and to enter the survey data into the national data repository. The survey also provides baseline data for the evaluation of the patient safety initiative. It is planned to conduct the survey a second time in the future, to measure how hospitals' use of adverse-event reporting systems is changing over time. The Joint Commission has used data from the survey as part of its AHRQ-funded research grant to demonstrate and assess the value of health IT for hospitals.

Data were collected from a national random sample of 1,685 hospitals (81 percent response rate) regarding the existence and nature of their reporting systems, reporting of adverse events into the systems, and use of reported data for safety improvements. Overall, 98 percent of the hospitals had comprehensive reporting systems, but there was wide variation in the types of systems used, the nature and completeness of reporting, and their ability to use the data to guide safety improvements in the hospitals. The survey results revealed a need for improvements by hospitals in both their adverse-event reporting and follow-up actions to reduce the likelihood of future events occurring. Hospitals that reported having comprehensive patient safety programs performed better in many areas than did hospitals without safety programs (Farley et al., under review).

OTHER FEDERAL AND PRIVATE SECTOR DATA SYSTEM INITIATIVES

Establishment of consistent standards for health information systems and measures encompasses two general categories of systems: institutional systems adopted by local health care organizations; and reporting systems at regional, state, or national levels through which data from multiple health care organizations can be aggregated. Activities are under way within the DHHS and by private-sector organizations to address consistency in standards and provide support for system infrastructure for both categories of information systems. This work focuses on IT system interoperability for comprehensive health information systems, of which the AHRQ patient safety data network would be one component.

DHHS Work on Interoperable Health Data Systems

The Office of the National Coordinator of Health Information Technology was established by Executive Order 13335 in April 2004. The National Coordinator is charged with coordinating all federal initiatives related to health IT and is guiding the nationwide implementation of interoperable electronic health records (EHR) in both the public and private health care sectors (ONC Web site, 2005). A timeline of key activities related to ONC's work is presented below.

- July 2004—ONC released a strategic plan that lays out four goals for a national health IT agenda and strategies for achieving them.
- March 2005—A health IT Leadership Panel convened by DHHS released a report on the costs and benefits of health IT, and recommended that “widespread adoption of interoperable health IT should be a top priority for the U.S. health care system” (The Lewin Group, 2005).
- June 2005—The Secretary of DHHS formed the American Health Information Community (AHIC), a collaborative of key public- and private-sector experts in health IT, to advise DHHS on strategies for pursuing a common interoperability framework for health IT, and to recommend ways to create a private-sector process for developing health IT standards and for certifying health IT products (ONC Web site, 2007).
- October 2005—DHHS awarded contracts totaling \$17.5 million to three organizations to assist AHIC in pursuing ONC's goals of greater EHR adoption and interoperability of electronic health information (ONC Web site, 2007).
- November 2005—DHHS awarded additional contracts totaling \$18.6 million to four private consortia to create prototypes for a Nationwide Health Information Network (NHIN) architecture.

- May 2006—The Certification Commission for Healthcare Information Technology (the Commission) produced, and the DHHS Secretary approved, a set of certification criteria for EHRs used in ambulatory care settings; interim procedures for ONC to use for assessing organizations that apply to become EHR certification bodies were also established (ONC Web site, 2007).
- July 2006—The Commission announced certification of 22 ambulatory EHR products (Healthcare Information and Management Systems and Society Web site, 2007).

Key industry groups responded to calls by DHHS and ONC for the private sector to take the lead in developing a process and criteria for certifying health IT products. Several private health IT organizations have formed collaboratives for development of EHRs, testing of methodologies and standards, and laying the groundwork for development of a national health information infrastructure (NHII). Taken together, these efforts offer an opportunity for the federal government, including AHRQ, to collaborate with the private sector in achieving the goal of establishing a NHII.

It remains to be seen whether these separate initiatives will complement and build upon each other in a way that substantially reduces the barriers to widespread adoption of health IT. It will be important to assess what effects their efforts have on improving patient safety and quality of care. Assessments also should be made of the extent to which AHRQ and other federal agencies can collaborate with them to establish a NHII and, within that, a national network of patient safety databases.

Electronic Health Records in the Medicare Program

In recent years, CMS has placed increased emphasis on promoting health IT in several of its programs, including its Doctors' Office Quality Information Technology (DOQ-IT) program. DOQ-IT encourages the adoption of EHRs in small- and medium-sized primary care physicians' offices nationwide to improve treatment of Medicare beneficiaries with chronic conditions (CMS, 2007). CMS also is working with QIOs to promote the adoption of other kinds of health IT in a variety of health care settings.

AVAILABILITY OF PATIENT SAFETY MEASURES

The absence of a comprehensive set of national patient safety outcome measures that are generally accepted in the health care community continues to hinder the ability to track patient safety performance. As described in *Evaluation Reports I through III*, various sets of measures have been developed by several agencies and private organizations, including AHRQ. However, virtually all these measures apply to the hospital inpatient care setting. There are no safety measures for ambulatory care and relatively few measures for long-term care. Nor are there measures of processes of care for evidence-based safe practices (e.g., the NQF safe practices), which are as important to track as patient outcomes.

The NQF consensus process for review and endorsement of measures offers the potential to move toward establishment of a generally accepted set of health care measures. However, to date, the NQF has addressed only the 27 serious reportable events that are intended to form the basis for a mandatory state-based reporting system. The Hospital Quality Alliance (HQA) and Ambulatory Quality Alliance also have worked to develop measures, but these measures focus primarily on quality of care based on best practices.

The patient safety evaluation center is assessing baseline trends in patient safety measures. Thus far, we have performed baseline trend analyses on several of the AHRQ patient safety indicators (PSIs), as well as other measures developed by two reporting demonstration projects. The results of this analysis is intended to support efforts to establish a national set of patient safety measures for monitoring health care performance trends (see Chapter 7).

To help identify a set of priority patient safety outcome measures, in 2006 the evaluation team conducted a modified Delphi process to develop consensus among 47 patient-safety clinical and research experts regarding which outcome measures are most important and how ready they are for use in a national monitoring system. The participants, including lead researchers from the AHRQ-funded patient safety projects, were asked to judge the importance of each measure based on the health care origin of the outcome as well as its severity and frequency. Of the 501 candidate outcome measures that were rated, 106 measures were identified as highly or moderately important, including 12 measures for ambulatory care and 23 measures for long-term care. The participants then assessed the validity of the 106 priority measures, and identified additional work required for validity assessment and measurement refinements.

USE OF MEASURES IN ACCREDITATION OR CREDENTIALING

Because accreditation and credentialing organizations set standards and measures for performance of health care providers, they can build synergy toward adoption of national patient safety measures and data standards by providing consistent policy direction to providers. In *Evaluation Reports I through III*, we summarized the patient safety activities of the Joint Commission and Medicare, which are the two national-level accreditation or credentialing entities with the most active patient safety policies and programs.

The Joint Commission

The Joint Commission has been a leader in patient safety, having addressed patient safety in its accreditation process since 1996, with the establishment of its sentinel event policy, followed by a comprehensive patient safety policy. In August 2005, the World Health Organization (WHO) designated the Joint Commission International Center for Patient Safety as the first WHO Collaborating Centre dedicated solely to patient safety (Joint Commission, 2006). The Commission now includes standards for patient safety practices in its accreditation of all health care organizations. To encourage accredited organizations to address patient safety areas of specific concern, it has also established national patient safety goals, which are required to be met to achieve accreditation (Joint Commission, 2005).

The patient safety provisions within the Joint Commission's accreditation process have reached maturity, encompassing a broad range of settings and types of providers, with updates made to its standards and goals as issues change and policy and practices evolve. We examine its sentinel event data in our evaluation of methods for assessing trends in outcomes (see Chapter 7), and they were included in the candidate measures considered in the Delphi process. The Joint Commission also is participating in and supporting numerous efforts to establish additional patient safety measures and measurement capability.

Medicare Program Requirements and Activities

To participate in Medicare, hospitals, other institutional providers, and health plans must meet certain conditions that are intended to protect patient health and safety and assure that high quality care is provided to all patients. The new condition established in 2003 requires hospitals

participating in Medicare to develop and implement a quality assessment and performance improvement (QAPI) program that identifies patient safety issues and reduces medical errors. The QAPI requirement continues to be the foundation of the Medicare patient safety standards.

CMS does not plan to establish standardized patient safety measures for Medicare until a national core set of hospital performance measures is established, including patient safety measures, and it continues to be an active participant in collaborative activities to develop such measures. Through its Medicare Patient Safety Monitoring System (MPSMS), CMS is generating national estimates of incidence rates for a growing number of patient safety measures, which can be used by health care organizations for benchmarking their performance. The first set of MPSMS results was released in 2005, with new measures added each year. The MPSMS measures were included in the candidate measures considered in the Delphi process, and some have been incorporated in the AHRQ National Health Quality Report (NHQR).

ISSUES AND ACTION OPPORTUNITIES

With the passage of the PSQIA, AHRQ is well positioned to achieve a national patient safety data capability based on the PSQI data network provisions. AHRQ has supported the collection and assessment of relevant information through several earlier funded projects, the results of which can be used in the data network development process. However, consensus must still be reached among diverse stakeholders on both the definitions and standards for measures being entered into the data system and the technical interoperability standards for the system itself. In carrying out these tasks, AHRQ can draw upon the information generated by its earlier work in this area. As the larger NHII takes form through the work being overseen by ONC, it also will be important for AHRQ to work with participants in that work to ensure that the standards established for the PSQIA national patient safety network of databases are consistent with those developed for the larger system.

Issues to Consider

Most existing forms of patient safety monitoring can be classified as either spontaneous reporting (i.e., state mandatory reporting systems) or automated data driven (i.e., use of administrative or EHR data). A national patient safety data repository should contain data for measures from both types of monitoring systems. Although most of the developmental attention thus far has been focused on data from spontaneous reporting systems, data standards should encompass measures and data from reporting systems, administrative data sources, and EHRs.

The Delphi consensus process conducted in this evaluation has identified a limited set of patient safety outcome measures for monitoring safety performance and some initial measures to consider for ambulatory and long-term care settings. However, the participating experts also highlighted numerous challenging issues regarding the validity and measurability of many of the measures, concluding that almost all of the measures require further development before they can be used for national monitoring.

Suggestions for AHRQ Action

- **Continue to pursue the current strategy and actions to establish a national patient safety data capability through implementation of the PSQIA provisions for a network of databases, including use of a public-private collaborative approach for establishing definitions and specifications for the measures and data to be contained in the system.**

The establishment of a national patient safety data capability is essential to enable effective tracking of patient safety performance and to eliminate the proliferation of independent (and often conflicting) reporting systems that providers find burdensome. As a federal agency, AHRQ is well positioned to stimulate and facilitate this work. To support the development process most effectively, however, additional funding should be provided to AHRQ. Lacking such funding, it will have to choose among its patient safety priorities, which may weaken its impact. The PSQIA addresses two concerns that have hindered progress: It removed the medical liability barrier through establishment of protected data reporting to the PSOs, and it provided authorization for creating a national network of databases through which data can be aggregated.

The achievement of national consistency in data system structures, variable definitions, and data standards will require consensus among stakeholders, as well as careful consideration of the effects of new standards on other existing systems. Through continued consultation with participating organizations, AHRQ can understand their motivations for reporting data into a national repository, identify concerns that might deter their participation, and develop user-acceptable standards for data and reporting formats.

- **Based on the results of the national Delphi consensus process conducted in 2006, support the follow-up work needed to ensure that the measures identified are well-validated and used appropriately for national monitoring and assessing progress in improving patient safety in the country.**

Despite extensive work by AHRQ and other organizations, a clearly defined set of priority patient safety measures does not yet exist, and measures have been lacking for several health care settings. The establishment of these measures is a necessary element for an effective national data network and should be one of AHRQ's measurement priorities. The Delphi process conducted in 2006 as part of this evaluation has identified a "short list" of important safety measures to consider, but numerous issues need to be addressed before many of the measures will be ready for national use. AHRQ is in a position to fund the research needed to address these issues and to apply the results of that research in the use of safety outcome measures in the data network.

- **In partnership with ONC and other relevant federal agencies, develop clear federal guidance on standards and other requirements for interoperability of health IT, including provisions that make the investment in health IT more compelling and easier for low-resource organizations.**

AHRQ is well positioned to support the recommendations of other federal agencies regarding health IT standards and to influence adoption of these standards through their grant process. Both actions would facilitate the spread of interoperable technology, and be consistent with standards established for a national patient safety data repository. AHRQ also could help states align their local and regional efforts with national expectations and standards.

- **Promote the adoption of consistent data and measurement standards among state-level reporting systems and submittal of these data to the national network of databases when the network is operational, including tracking the characteristics of state-level reporting systems over time.**

Almost half the states have implemented some form of state-level adverse-event reporting system, but these systems differ substantially in their characteristics and the types of events they capture (Beckett et al., 2006). Consequently, the data are difficult to aggregate for

tracking trends in adverse events at regional or national levels. As part of its implementation of the PSQIA, AHRQ should provide guidance to the states on ways to harmonize their reporting data standards and systems, with the goal of ultimately including data from these systems in the national patient safety data network.

CHAPTER 4. PROCESS: EPIDEMIOLOGY AND EFFECTIVE PRACTICES

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 and tools 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.

OVERVIEW

This chapter addresses two topics: the *epidemiology of patient safety risks and hazards* and the *establishment of effective patient safety practices and tools*. These system components are examined through our ongoing review of AHRQ's complete set of patient safety projects as well as the new patient safety-related grants funded in FY 2006.

The primary approach of this evaluation has been to focus on the scope of work and contributions of the projects funded by AHRQ in these areas, and to develop information on where new knowledge might be expected to emerge for ultimate use by health care providers and others. In addition, we have tracked the status of the current evidence base on patient safety practices and the potential contributions of the funded projects to expanding the evidence. Finally, we have identified the need for decisions to be made regarding the standards of evidence to be applied to research on patient safety practices. Table 4.1 presents the evaluation questions regarding patient safety epidemiology and effective practices addressed by this evaluation, as well as a brief assessment of current status for each question.

In this chapter, we update information on each of these key areas, synthesizing our findings across the full evaluation period. We also provide new information on the RHIOs, the second round of health IT implementation projects, and the PIPS grants. We conclude with a summary discussion of standards of evidence and issues related to incorporating findings from the AHRQ-funded projects into the evidence base.

EPIDEMIOLOGY OF PATIENT SAFETY

In *Evaluation Report I*, we documented the status of our knowledge as of June 2003 on the epidemiology of patient safety risks and hazards, and we examined the potential for projects funded through AHRQ's patient safety initiative to add to knowledge on patient safety epidemiology. In *Evaluation Reports II* and *III*, we updated our assessment by identifying patient safety epidemiology articles published in the literature each year and identifying the relative share that were articles supported by AHRQ funding. We update this information here by assessing contributions of AHRQ-funded projects to the published literature on epidemiology as of June 2006.

Table 4.1
Evaluation Questions and Assessments for Patient Safety Epidemiology and Practices

Evaluation Question	Summary Assessment
<i>Patient Safety Epidemiology</i>	
What information has been published over time about patient safety epidemiology, and how have the AHRQ-funded research projects contributed to this new information?	Number of articles published on patient safety epidemiology has grown steadily in the past four years. AHRQ projects have been important contributors, producing 1/3 of these articles.
To what extent has the additional research strengthened the evidence regarding epidemiology of errors?	Published research has strengthened evidence for several areas, especially medications, diagnostic or treatment errors, general patient safety, and working conditions.
What additional work is needed to strengthen the evidence regarding epidemiology and priorities for interventions to reduce adverse outcomes?	Work is needed on development of an ongoing surveillance system to identify emerging safety issues from epidemiological data.
<i>Effective Patient Safety Practices</i>	
What do we know from evidence reports about which practices are or have the potential to be effective in improving patient safety?	The original patient safety evidence report documented evidence for many practices. It led to development of the NQF list of safe practices, which offered priorities for action.
How are research and field tests on patient safety practices funded by AHRQ contributing new knowledge regarding practices for which further scientific evidence is needed?	AHRQ-funded projects addressed many practices for which additional evidence was needed, which was used in the updating of the NQF list of safe practices in 2006. More evidence synthesis is needed for other practices not addressed in the NQF update.
What health IT applications are being tested and studied by the health IT projects funded by AHRQ, and to what extent are they addressing patient safety issues specifically?	A wide range of health IT applications is being developed by AHRQ-funded projects. Virtually all the projects are addressing patient safety as well as quality issues. Evaluations of effects need to be strengthened to generate needed evidence.
What are the field tests learning about the factors and issues that need to be managed to introduce tested new practices effectively?	The same implementation issues have been identified across groups of projects. Through a literature review, RAND identified “success factors” that need to be in place to successfully implement practice improvements (see Chapter 6).
What progress has been made by the AHRQ-funded projects in documenting effects of new patient-safety practices on safety outcomes and the costs, cost effectiveness, and return on investment of the practices being tested?	Projects have examined effects on outcomes and have been publishing results. They paid limited attention to assessing costs, cost effectiveness, or return on investment. Further work is needed to make the business case for new practices.
To what extent are implementation methods and tools being developed and applied to support expanded use of tested practices across provider organizations?	Some projects have developed products or tools to support use of practices; many have not. AHRQ has packaged several tools, such as TeamSTEPSS (with DoD) and the hospital safety culture survey. More work is needed in this area.

Based on a MEDLINE database search of articles published in English between July 2005 and June 2006, Table 4.2 presents counts of articles addressing epidemiology for a number of patient safety issues.¹ A total of 101 articles on epidemiology issues, including five reviews, were published from July 2005 through June 2006. These articles addressed a total of 109 patient safety issues, providing information on the rates, types, or causes of medical errors or adverse events. This count was slightly less than the number of articles identified in *Evaluation Report III* as being published in the previous 12-month period.

Table 4.2
Patient Safety Epidemiology Information Available from Recently Published Articles and Addressed by AHRQ-Funded Patient Safety Projects, Through June 2006

Patient Safety Issue	Articles published 2000 – June 2005	New articles published July 2005 – June 2006	New articles published by AHRQ patient safety grantees
Medication ordering, administration	123	44	11
Nosocomial infections	5	2	2
Falls, pressure ulcers, restraint related	6	1	1
Nurse staffing	8	2	0
Provider fatigue, working conditions	13	9	5
Surgical or invasive procedure errors	17	6	2
Diagnostic or treatment errors	46	23	2
General patient safety	72	22	11
Other issues	12	0	0
Total number of topics addressed	302	109	34
Average number per article	1.1	1.1	1.1

Consistent with our previous findings, the largest share of recent publications focused on medication issues. Diagnostic or treatment errors were also commonly studied, with many articles focusing on errors that occur in the laboratory. However, given that diagnostic and treatment processes are central to the clinical care process, these issues are somewhat under-represented in the funded projects. As in previous years, numerous articles were on general patient safety.² The number of articles published on working conditions was the same as last year, and 8 percent of articles focused on pediatric populations. Only 4 percent of articles specifically focused on the elderly, a decrease from last year. A total of 31 articles addressing 34 patient safety issues were published by grantees in the past year, representing a slight drop from the previous year's count of 35 articles. Many grantees are still finishing their research and submitting manuscripts, so it may be several years before their full contributions can be tabulated.

¹ In the MEDLINE search, we used the subject heading *medical errors*, and limited the search to articles classified with the subheading *statistics and numerical data*.

² The term “general patient safety” is used for studies that did not limit their analysis to specific types of patient safety issues, but considered any type of issue that might be occurring.

UPDATES ON THE GROUPS OF PATIENT SAFETY PROJECTS

During the four years of this evaluation, we tracked several sets of patient safety projects funded by AHRQ, to profile the contributions the projects have the potential to make and to learn from their experiences. We briefly summarize here the status of each project group, providing a framework for our consideration of the projects' contributions to patient safety practices.

The FY 2000 and FY 2001 Patient Safety Grants

All of these grantees, with the exception of the Centers of Excellence (which were five-year projects), were to have completed their work by the end of FY 2004, but many of them received no-cost extensions to delay their completion until the end of September 2005 or later. During the intervening time, the projects continued to participate in AHRQ-sponsored patient safety activities, and they had access to technical support from the Coordinating Center for activities to disseminate their research findings and products to end users in the health care community. During 2006, we performed follow-up interviews with a subgroup of these grantees—those that included practice interventions as part of their projects—to document the impacts they estimated their projects had on stakeholders and outcomes. Results from the interviews are reported in Chapters 6 and 7.

Challenge Grants

AHRQ awarded 13 Patient Safety Challenge grants in FY 2004, six one-year projects that tested risk assessment and reduction techniques and seven two-year projects that tested implementation of safe practices. To identify early lessons learned from the challenge grants, in FY 2004, we conducted extensive telephone interviews with the risk assessment grant teams and in-person site visits with the implementation grant teams (see *Evaluation Report II*). The risk assessment grantees completed their work in September 2005, and the implementation grantees finished in September 2006. To update lessons from the implementation challenge grants, we conducted follow-up telephone interviews with the seven grantees during FY 2006, the results of which are reported later in this chapter.

Partnerships in Implementing Patient Safety Grants

In June 2005, AHRQ funded the 17 two-year PIPS grants to assist health care institutions in implementing safe practices and developing toolkits for others to use. In February and March 2006, we conducted telephone interviews with the project principal investigators to document the first year experience of the PIPS grantees, the results of which are presented later in this chapter.

The AHRQ Health Information Technology Projects

As described in Chapter 2, beginning in FY 2004, AHRQ awarded grants and contracts to advance the use of health information technology (health IT). Under three separate grant initiatives and one contract initiative, AHRQ invested resources in 40 states and 100 communities to support and stimulate investment in health IT. We interviewed these projects in their first year of operation, and interview findings are reported in *Evaluation Report III*.

Planning grants. The 38 one-year grants were intended to support community-wide planning processes to develop health IT infrastructure. AHRQ planned that the successful grantees would compete for future health IT implementation grants. In October 2005, health IT Implementation grants were awarded to 16 (50 percent) of the grantees that had planning grants.

Implementation grants. These 40 three-year grants supported implementation of health IT systems. More than 50 percent of the funding committed by AHRQ for the original health IT implementation grants was earmarked for rural and small hospitals, and most of the 16 new health IT implementation grants (funded in October 2005) also involved rural communities. The implementation grantees were to conduct evaluations of how the health IT they implemented contributed to improvements in patient safety, costs, and quality of care.

Value grants. These 26 grants have project periods of up to three years, to evaluate the value of using health IT for clinical safety or quality, financial impacts, organizational effectiveness and efficiency, or other benefits. As these grants generate findings, they could provide critical information for stakeholders to make informed clinical and purchasing decisions, develop methodology, and advance health IT adoption.

In addition, AHRQ awarded six State and Regional Demonstrations in Health Information Technology contracts. Five five-year contracts were awarded in FY 2004 to state-level organizations for Colorado, Indiana, Rhode Island, Tennessee, and Utah, and a four-year contract was awarded in FY 2005 for Maryland. We interviewed staff of the five original projects after they completed a year of their work. The results are presented later in this chapter.

CONTRIBUTIONS OF AHRQ-FUNDED GRANTS TO SAFETY PRACTICES

Profiles of the Areas and Issues Addressed by the Funded Projects

Table 4.3 provides tabulations of the number of patient safety issues addressed by four major groups of AHRQ-funded grants. Projects that addressed more than one patient safety issue were counted more than once. The FY 2000–2001 grants and challenge grants addressed the broadest range of patient safety issues. General patient safety received the most attention by the FY 2000–2001 grants, while subsequent groups of grants focused on more specific issues. Medication ordering and administration were primary focuses for all four groups. Many of the grants in each group also addressed issues for special populations. The health IT projects focused on multiple issues, with a particular emphasis on diagnostic or treatment errors, care procedures and coordination, and hand-offs. We found no clear patterns of specific relationships between IT type and issues addressed.

Table 4.4 presents the patient safety actions addressed by the four project groups. The health IT grants and PIPS grants were more focused in their actions than earlier grants, as represented by an average of 1.9 patient safety actions per project for health IT grants and 2.4 actions for PIPS grants, compared to 3.7 actions for FY 2000–2001 grants and 4.5 actions for challenge grants. The most common types of actions also varied by project group.

As Table 4.5 illustrates, the projects have taken place in a variety of settings, with hospitals and outpatient clinics or providers' offices being the most common. The knowledge generated by projects taking place in alternative settings (i.e., ambulatory care and long-term care) should serve as a useful starting point for AHRQ's future work.

Contributions to Evidence on Safety Practices

In July 2001, University of California San Francisco–Stanford University, one of the AHRQ Evidence-Based Practice Centers, published the evidence report on practices to improve patient safety (Shojania et al., 2001). A total of 79 patient safety practices were evaluated, based

on ratings of the strength of evidence regarding impact and effectiveness and whether the research is likely to be highly beneficial or beneficial.

Based on a similar analysis, we found that the AHRQ-funded projects have been addressing practices for which additional scientific evidence is needed to determine their effectiveness. Table 4.6 provides the levels of strength of evidence rated by the evidence report, and the number of AHRQ-funded projects addressing practices at that level. Across all four project groups, 102 projects are addressing practices for which there is medium strength of evidence or less, while 120 projects are addressing practices for which the evidence report indicated that further research would be beneficial or highly beneficial.

Table 4.3
Patient Safety Issues and Special Populations Addressed by the AHRQ-Funded Patient Safety Projects

Patient Safety Issue	Number of Issues by Type of Grant			
	Original Patient Safety	Challenge	Health IT*	PIPS
Medication ordering/administration	29	7	60	9
Nosocomial infections	5	2		1
Falls/pressure ulcers	7		2	
Nurse staffing	12	2		
Provider fatigue, working conditions	16	2		1
Surgical / invasive procedure errors	12	2	1	
Diagnostic/treatment errors	18		37	3
Equipment / device failure	5	1		
Ordering / administering blood		1		
Care procedures and coordination **		2	60	3
Wrong patient / procedure / test		1		
General patient safety	44	3	6	
Hand-offs	2	2	62	3
Other issues	4		2	
Total number of issues studied	154	25	230	20
Average number per project	1.8	1.9	2.2	1.2
Special Populations				
Elderly	18	3	17	4
Minority populations	19	1	16	3
Low income	16	1	25	2
Health vulnerable	11	4	34	3
Other vulnerable	7	1	13	1

* Counts for Health IT projects are for the planning, implementation, and value grants combined.

** Care procedures and coordination include errors in the admitting process, such as applying the wrong patient identification bracelet, misplaced documentation such as “lost” medical records, failure to notify patients of a positive test result, or failure to register a patient in the emergency department resulting in delayed care and adverse outcome.

Table 4.4
Patient Safety Actions Addressed by the AHRQ-Funded Patient Safety Projects

Patient Safety Action	Number Type of Projects			
	Original Patient Safety	Challenge	Health IT*	PIPS
Administrative actions to prevent error	3	1		2
Altering physical environment/infrastructure	12	3	67	1
Altering staffing/work conditions/scheduling	14	2		3
Causes of errors (root cause analysis)	43	5	2	1
Effecting change in patient safety culture	17	2	3	2
Epidemiology of medical errors	38	3	3	
Health professional education/awareness	37	1	3	3
Monitoring/reporting adverse drug events	27	4	7	1
Monitoring/reporting adverse events	24	2	4	1
Patient/consumer awareness of patient safety	4	1	1	6
Patient/family communication of errors	11			
Protocols to prevent non-medication errors	13	4	13	4
Protocols to prevent medication errors	15	6		5
Provider proficiency/training to prevent errors	27	3	4	4
Use of technology to prevent diagnostic errors	4		22	1
Use of technology to prevent medication errors	17	6	47	3
Use of technology to prevent other errors	6	2	34	3
Risk assessment – prospective		9		1
Risk assessment – retrospective		4		
Other	5			
Unclear			4	
Total number of actions	317	58	202	41
Average number per project	3.7	4.5	1.9	2.4

* Counts for Health IT projects are for the planning, implementation, and value grants combined.

Table 4.5
Health Care Settings Addressed by the AHRQ-Funded Patient Safety Projects

Health Care Setting	Number Type of Projects			
	Original Patient Safety	Challenge	Health IT*	PIPS
Outpatient clinic, provider's office	28	2	74	4
Inpatient acute care	28	6	10	9
Hospital ancillary	3	1		
Hospital outpatient diagnosis or treatment	9		8	2
Entire hospital	16	3	54	2
Community-based diagnosis or treatment	2		1	
Nursing home or inpatient rehab care	10	3	16	
Home care	3		9	
Health system	15	2	9	2
Health profession educational setting	14		2	
Behavioral health			2	
Hospice			2	
Other	1		3	
Total number of settings	129	17	190	19

* Counts for Health IT projects are for the planning, implementation, and value grants combined.

Table 4.6
AHRQ-Funded Projects Covering Evidence Report Chapters

	Number of Issues by Type of Grant			
	FY 2000-01	Challenge	Health IT*	PIPS
Evidence Report: Impact and Effectiveness				
Greatest strength of evidence	0	4	1	3
High strength of evidence	15	2	4	3
Medium strength of evidence	10	5	37	3
Lower impact or strength of evidence	15	5	8	4
Lowest impact or strength of evidence	0	1	10	4
Evidence Report: Further Research				
Likely to be highly beneficial	23	11	37	4
Likely to be beneficial	15	6	16	8
Evidence Report: not rated, but covered in projects	108	5	53	5
Practice not addressed in evidence report	7	3	2	

* Many projects are addressing health IT that falls into more than one category.

HEALTH INFORMATION TECHNOLOGY GRANTS

Conceptual Framework for Implementation of Health IT

Building on the work of Greenhalgh et al. (2004), as well as two systematic reviews on health IT conducted by RAND, we constructed a conceptual framework identifying the key components that ensure effective adoption of health IT by health care organizations. We conceptualize health IT development in any given organization as having three phases: *adoption*, *implementation*, and *sustainability* (Figure 4.1). At each phase, the *external environment* and the *internal organizational commitment and support* affect decisions about what technology to implement, the scope and timing of implementation, and the likelihood of sustainability.

The *adoption* process begins (or should begin) with an extensive planning process involving the assessment of the needs and goals of an organization, system, or community for use of health IT. *Implementation* of health IT requires detailed specifications that are most often developed by technology specialists within an organization and the health IT vendor. Once designed and built, the health IT system is installed during a field test period, and end users are trained on its use. After making workflow changes to fully integrate the health IT into the health care setting, the system is moved to the level of full-scale operation. *Sustaining* a health IT solution requires continuous effort and investment, particularly with regard to training of new and existing staff to maintain familiarity with the technology and its enhancements.

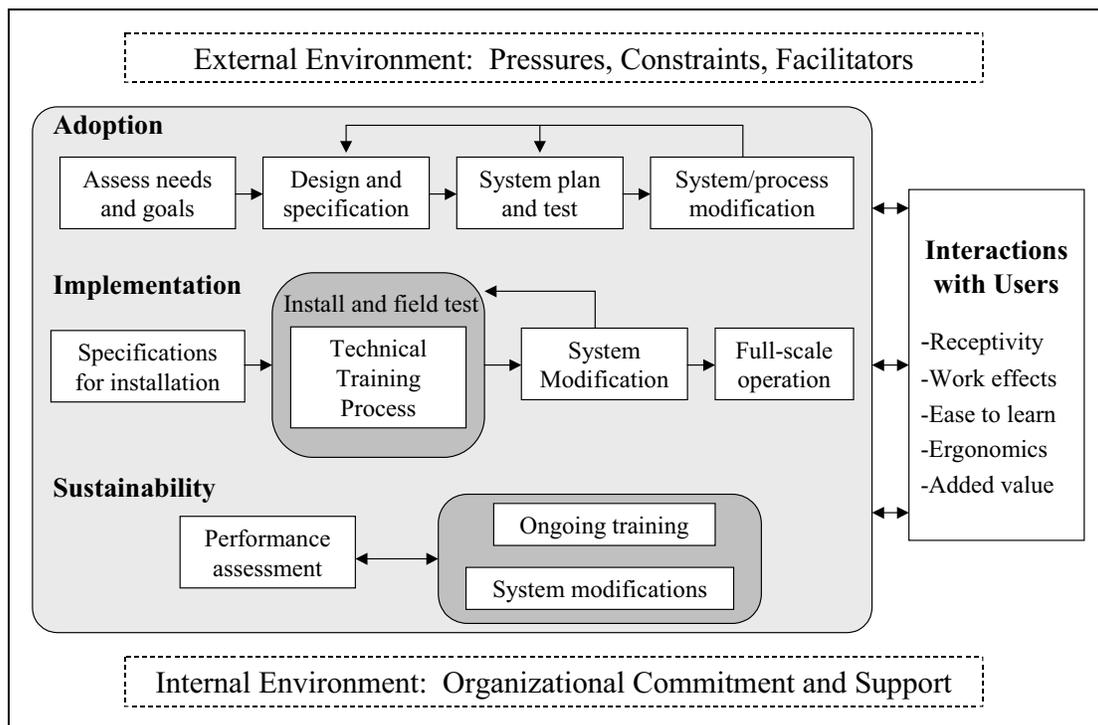


Figure 4.1 Conceptual Framework for Health IT

The involvement of end users in each phase is critical for their “ownership” of the technology. Factors that influence end users’ acceptance include their ability and willingness to learn how to use the health IT, purchasing or designing health IT that is easy to use, and, above all, implementing health IT that adds value to the individual user. Users must be willing to try new technology, but the technology also has to make their job easier.

Profile of AHRQ Projects on Health IT

Tables 4.7 through 4.9 present the number of health IT grants by their geographic setting, overall focus, numbers and types of partners, and technologies addressed. As of September 2006, all of these projects were still active, with only the original one-year planning grantees having completed their work.

Table 4.7 shows that a majority of projects are focused wholly or partly in rural areas, and address issues related to both patient safety and quality. When we compared our findings on rurality to the AHRQ designations, we found that all of the projects defined as rural by AHRQ also were coded either wholly or partly rural by our coding method. In addition, RAND identified 19 other projects with rural components that had not been identified in the AHRQ designations, which increased the projects identified as wholly or partly rural from 54 percent to 72 percent of the health IT projects. Thus, the projects exceed the 50 percent rural requirement specified in the RFAs, in large part through projects that involve both urban and rural areas and providers.

Table 4.7
Profile of the Health IT Projects Funded by AHRQ, by Group

	Planning (n=38)		Implementation (n=40)		Value (n=26)	
	Number	Percent	Number	Percent	Number	Percent
Geographic setting *						
Rural	21	55%	14	35%	1	4%
Both urban and rural	13	35	19	46	7	27
Urban	4	11	7	18	18	70
Patient safety or quality focus						
Patient safety only	0	0	2	5	1	4
Both patient safety and quality	34	87	35	88	22	85
Quality only	4	13	3	8	3	12

* A *rural-only project* had involvement only by organizations outside of a metropolitan statistical area (MSA) or outside an urbanized area within an MSA and served only a rural population. A *both urban and rural project* is one that involved a mix of urban and rural organizations or that served both urban and rural populations. An *urban-only project* had involvement only by organizations located in an urbanized area within an MSA and served only an urban population.

Table 4.8 shows that the health IT projects vary in the number of partners involved, with the implementation projects having the largest number. There is a significant representation of hospitals, physician practices or clinics, and universities, although a wide variety of other types of partners also are involved.

Table 4.8
Number and Types of Partner Organizations for the AHRQ-Funded Health IT Projects

	Number of Projects by Number and Type of Partner		
	Planning	Implementation	Value
Number of partners			
None	5	2	13
One to four	14	18	13
Five to nine	14	18	0
Ten or more	5	2	0
Type of partner			
Networks (loose affiliation)	12	8	2
Individual hospitals	26	25	6
Systems (common management)	5	15	11
Physician practices or clinics	16	22	2
University	9	18	10
Other*	27	49	7

* Includes pharmacies, membership organizations, IT companies, independent labs, community-based diagnostic centers, tribal organizations, accrediting organizations, and private research organizations.

Table 4.9 shows the types of health IT addressed by the health IT projects as well as by other patient safety projects identified as addressing health IT. The health IT projects have a heavy emphasis on planning for and implementing EHRs, decision support, computerized physician order entry, and data exchange. In addition, these projects tend to be more multi-purpose, having higher average numbers of technologies per project than do other patient safety projects. In comparison, the earlier patient safety projects did relatively more work with mobile computing and relatively less work in EHRs and data exchange and information.

LESSONS FROM INTERVIEWS FOR PROJECTS ADDRESSING PRACTICES

Over the course of this evaluation, the RAND evaluation center conducted interviews with each group of patient safety and health IT grantees to document their experiences and the insights they gained during the course of their work. We report below the results of the most recent interviews with the challenge implementation grants, the PIPS grants, the second round of health IT implementation grants, and the RHIOs. Findings from a second round of follow-up interviews with the FY 2000–2001 patient safety grants are reported in Chapters 6 and 7. (See separate Technical Appendix (Farley et al., forthcoming) for the protocols for each set of interviews.)

Challenge Implementation Grants

The seven challenge implementation projects were quite diverse, focusing on a variety of health care settings, including hospitals, ambulatory care clinics, pharmacies, and nursing homes. Four of the projects involved multiple institutions. Four projects were implementing technologies such as “smart” IV pumps and bar code systems. Although these projects were to be completed by the end of FY 2005, most had continued under no-cost extensions. We conducted one-hour interviews with the principal investigators of these grants between late December 2005 and March 2006, focusing on the results of the project activities. Six of the

seven grantees participated in the interviews. Grantees were provided with a copy of the interview questions in advance.

Table 4.9
Technologies Being Addressed by the Health IT Projects
and Other Patient Safety Projects

Type of Health IT	Technology Addressed by IT Grants			Other Patient Safety Projects
	Planning	Implementation	Value	
Computerized provider order entry	11	15	9	6
Electronic health records	21	22	2	3
Decision support	18	29	18	18
Results reporting	6	5	3	0
Electronic prescribing	4	4	1	2
Mobile Computing	1	6	2	11
Data exchange and information	32	24	3	1
Patient decision support	3	3	5	0
Communication Systems	8	7	7	1
Administrative	3	4	0	0
Knowledge retrieval systems	2	0	1	5
Data Collection and summary	9	13	4	16
Other	1	1	0	7
Not specified	1	0	1	0
Total frequency of IT types	120	133	56	70
Average number per project	3.2	3.3	2.2	1.6

The lessons learned by the challenge grantees reinforce the key factors for successful implementation of performance improvements identified in this evaluation (see Chapter 6). These include leadership support from institutional executives and physicians; effective teams and teamwork; seeking out and cultivating opinion leaders; active communication; attention to human factors when implementing technology; anticipation of unplanned events, such as leadership and staff turnover or vendor problems; and staff training.

All grantees reported positive effects on clinical care of patients, and some reported increased patient satisfaction resulting from decreased delays in receiving care and increased attention to patient needs. Most grantees reported that at least some physicians have become patient safety champions as a result of their participation, and that additional leadership development is needed at national and local levels. Most expect that the innovations they are implementing will spread across their health care organizations, although limitations in the capital to invest in technology may negatively affect this process. Community effects were mixed, and for some, there was interest from communities outside of the local area because of dissemination activities carried out by the grantees and AHRQ. These activities included publication of peer-reviewed research articles and other related communications, conference presentations, short courses, and Web-based tools.

Partnerships in Implementing Patient Safety Grants (PIPS)

The PIPS were designed to assist health care institutions in implementing safe practices that may eliminate or reduce medical errors, risks, hazards, and harms associated with health care processes. Their work focused on implementing interventions and developing toolkits to aid

their dissemination, including training modules, evaluation plans, and lessons learned. To document their implementation experiences, we conducted interviews with the principal investigators of the PIPS grants in early 2006. The interviews focused on the factors involved in the multiorganizational implementation of patient safety interventions and on experiences with toolkit development.

At the time of our interviews, the majority of grantees were in the process of implementing their interventions and developing toolkits to aid in dissemination of the PIPS interventions. All but two of the grantees foresaw being able to sustain the momentum of their work. The two less-optimistic grantees said that, to achieve sustainability, they would need to obtain additional funding after the grant period was over. The toolkit items that grantees identified most frequently were training modules, evaluation plans, and “lessons learned” materials. The majority of the 17 grantees said they actively involved end users in the selection of tools for their toolkits. Some were concerned that their tools were not generalizable enough to be useful for others; others said they were somewhat confused about what their tools should be.

The PIPS grantees identified two important keys to success: (1) strong commitment to the project by staff, partners, and people outside of the project and (2) having established relationships with key participants before implementation. Their greatest challenges were related to changing staff practices, budgetary issues, and scheduling training and project participation.

The grantees reported mixed levels of adoption and acceptance of their interventions by health care professionals, and three grantees said it was still too early to tell. Generally speaking, when interventions increased workload or involved changes in the workflow, the end users were less likely to accept them. On the other hand, when end users were involved in the design and implementation process, adoption and acceptance of the intervention was greater.

Second Round of Health IT Implementation Grants

As described above, all of the 16 second-round implementation grantees previously had been awarded health IT planning grants. Many of these grantees were implementing some form of data exchange system or health information network, several with a goal or expectation to connect with the RHIO in their area. Just over half of the grantees were conducting projects in rural settings. The target patient population for most of these projects is low-income, under- or uninsured, or medically underserved patients.

In 2006, we conducted telephone interviews with 15 of the 16 grantees (one grantee did not respond to our interview requests), when the projects were approximately seven to nine months into their three-year grant period. To maintain continuity in data collection, we used an interview protocol with this second group of grantees that was nearly identical to the one used for interviews with the first group of implementation projects in FY 2005. New questions were added to assess impacts of being a health IT planning grantee and to identify any major changes to the work plan or team or partnership composition between the two project phases.

The RFA required the grantees to have a minimum of three partners, two of which had to have also been partners in the planning grant phase. In about half of the cases, there were no changes to the partners involved in the planning and implementation phases. For the others, they either added new partners (in order to expand the reach of the health IT) or dropped existing ones (due to resource constraints).

At the time of the interview, the grantees reported experiencing relatively steady progress in implementing their work plans. More than half the grantees interviewed felt they were on schedule with the work plans they proposed in their implementation grant proposals. A few had experienced some delays, but did not think the overall progress of the project was slowed significantly. Contributors to project success included having the lead organization be a “neutral party,” with less self-interest in the project than the other partners, and the ability to sustain consensus on approach that had been developed during the project’s planning grant.

Grantees provided overwhelming positive responses about having previously received a project planning grant, which had enabled the partners to form a solid foundation for the implementation phase of their projects. Many felt that conducting the planning project provided legitimacy to the project that played a major role in garnering the support of the partner organizations and other stakeholders.

A number of challenges were also identified, such as retraction of earlier commitments by some partners regarding data access or project focus, delays associated with dealing with large university or hospital bureaucracies, and identifying vendors capable of delivering or supporting the technology that the grantees wanted to implement. Some partnerships with limited resources had to purchase off-the-shelf technologies that required little or no modifications, rather than developing home-grown applications.

The grantees identified a number of external factors that affected their implementation progress either positively or negatively. Positive factors included support from upper- and mid-level management and high levels of trust and limited competitiveness among partnering organizations, particularly for rural projects. Negative factors included competing and shifting institutional priorities among partners; drafting complex policies and regulations related to privacy, governance, and other legal issues; carrying out grant administrative requirements; and acquiring the needed funding for the project. Some grantees found it challenging to identify vendors that were capable of delivering or supporting the technology that the grantees wanted to implement.

Regional Health Information Organizations (RHIOs)

The goal of the AHRQ-funded RHIOs was to transform quality of care and patient safety through increased access to patient safety information. They were expected to develop and maintain statewide data sharing and interoperability for a wide variety of health care constituents. Expected outcomes include measurable improvements in the quality, safety, efficiency, or effectiveness of care.

We conducted interviews in early 2006 with each of the five RHIO projects funded in FY 2004, when the projects were in the second year of their contracts. We gathered information on technical factors (such as data elements, technical specifications, and privacy and security policies) as well as on their experiences in development and implementation of the RHIOs. We did not interview the sixth RHIO, which was funded in FY 2005, because it had just started its work at the time of these interviews.

All five RHIOs were exchanging or planned to exchange laboratory data, medication history, and demographic information, but they differed with respect to other planned data elements. Variations in progress were related primarily to their prior experience with data exchange activities. Most contractors were using database software that was home-grown or

legacy systems that had been in use for some time and were therefore known and trusted commodities. The most common standards used in the RHIOs were LOINC, HL7, and SNOMED. To establish patient identity, most projects were using algorithms and approaches recommended by the Connecting for Health initiative. Approaches to data storage varied widely, with a tendency toward decentralized data and exchanging information via messages only when needed.

The range and importance of privacy issues, as well as the number of stakeholders involved, have made the process more time-consuming than most grantees anticipated. Privacy concerns among the grantees centered around two issues: the consenting process and restrictions on subsequent use of the data. At the time of our interviews, it was too early in the development process to assess the robustness of the privacy and security measures being tested and adopted. All grantees were aware that these measures are vital to system success, and they were proceeding cautiously in system designs to ensure patient privacy and conformance with state and federal laws.

Although there was substantial variation among grantees' approaches to establishing state and regional health information exchange, all grantees agreed that their greatest challenge was political factors that arise when dealing with different priorities and motivations among partners and constituents. They also noted the difficulty of collaborating and building trust, even with committed partners and an established infrastructure, and that taking an incremental approach to achieve early successes in building the system helps to demonstrate value.

EVIDENCE FOR EFFECTIVE PRACTICES

In 2005, NQF updated its list of safe practices, identifying those that should be added, modified, or eliminated. Using a "preponderance of evidence" standard, the strength of current evidence on each practice's effectiveness was assessed (rather than scoring the level of evidence). Thirty safe practices were identified for which effectiveness was supported by published evidence, most of which had been on the original list. This assessment process relied heavily on published results from the AHRQ-funded patient safety projects, including papers in the *Advances in Patient Safety* compendium (AHRQ, 2005a) as well as individually published papers.

The patient safety projects have addressed a broad range of practices, however, many of which were not considered in the NQF update. To ensure that health care providers have access to the rich information becoming available on the effectiveness of various patient safety practices, comprehensive assessment of this new evidence should be performed through a systematic update of the original patient safety evidence report.

As discussed in *Evaluation Reports I and II*, criticism of the original evidence report (Shojania et al., 2001) highlighted the inability to apply traditional standards of evidence to many patient safety practices. At the Second National Summit on Patient Safety Research in November 2003, the panel addressing effective practices concluded that other types of evidence should be considered and that standards are needed that define what is required for alternative research designs and methods to ensure they generate acceptable evidence.

To establish standards of evidence for alternative research designs, it is necessary to know which designs are being used by researchers to assess the effectiveness of patient safety practices. In our most recent evaluation cycle, we asked grantees to identify the specific

elements of the study designs they used in their assessments. This information was obtained from 45 of the FY 2000–2001 grantees that had practice interventions as part of their projects, implementation challenge grants, PIPS grants, or health IT value grants.

We found that only 37 percent of the project evaluations used by these projects had designs similar to controlled trials, i.e., use of control groups and either population or randomized samples. Of the evaluations with other study designs, two-thirds used only intervention group(s), and the rest used either intervention and control groups or some other choice of grouping. All but two of the studies with only intervention groups used either population or convenience samples. These results highlight the need for standards of evidence for research designs other than controlled trials.

ISSUES AND ACTION OPPORTUNITIES

The numerous patient safety projects funded by AHRQ have addressed a diversity of patient safety issues, and they are gaining momentum in their contributions of new knowledge and scientific evidence for a range of patient safety practices. Because many of these projects involve viable partnerships across communities, AHRQ's support has enabled creation of important models that will help others implement patient safety practices and health IT to support them. To make change happen, multiple factors need to be in place, and the implementation teams need to persevere in carrying out the work. AHRQ support has helped to make these efforts credible and feasible.

Issues to Consider

In the annual reports generated from this evaluation, we offered a variety of suggestions to AHRQ for strengthening future actions in the patient safety initiative. In this final report, we are focusing on what we believe are key areas of focus for future directions in building knowledge on patient safety epidemiology and practices. In particular, a current priority for AHRQ should be to get the knowledge generated by funded projects into the hands of providers and policymakers. Many of the following suggestions reflect that priority.

Suggestions for AHRQ Action

- **Maintain an ongoing monitoring process that uses data from the national network of patient safety databases and published research, to examine shifts in trends for patient safety epidemiology in specific aspects of health care, and to identify emerging safety issues that need to be addressed to ensure the safety of health care practices.**

The availability of epidemiological information on a regular basis would support the early identification of emerging patient safety issues, or reemergence of ones previously addressed. It also could guide policy formulation, as well as AHRQ's decisions on which areas require further research or action. Patient safety trends should be monitored regularly, drawing upon available data in the published literature, existing reporting systems, and other national or state data sources. Benchmarks should be created for comparisons to baseline incidence or rates for specific safety issues. When a national patient safety data repository is established, the data in it could serve as a primary source of data for regular analyses of trends.

- **Together with the Coordinating and Resource Centers, establish structured start-up support and training for first-time grantees to help them understand their responsibilities and respond to AHRQ's expectations.**

As AHRQ shifted funding to projects focused on implementation of patient safety practices or health IT, it awarded funding to many organizations without previous experience with a federal grant or contract. Many grantees without previous experience working under a federal grant or contract have had trouble meeting AHRQ's administrative and reporting requirements. Grantees that are new to federal funding could benefit from training on both the grants management process and technical aspects of project work, and the interaction would provide a feedback mechanism for AHRQ to make refinements to the system.

- **Build upon its early success in supporting health IT development in rural areas through further development of flexible, inexpensive IT solutions, accompanied by funding support that is responsive to the needs of organizations in rural areas and other low-resource organizations.**

Health care organizations in rural areas, as well as other small or low-resource organizations, struggle to obtain the needed expertise and resources to invest successfully in health IT. Lower-cost health IT alternatives that are effective and flexible for users would be very useful for these organizations. The rural health IT grantees identified as a constraint AHRQ's cap at 20 percent of annual spending for support of purchase of IT systems and equipment. A "sliding" cap (i.e., a higher cap in the first year that decreases in subsequent years) might be a useful alternative for AHRQ to consider.

- **Continue to explore mechanisms to strengthen the evaluation component of the health IT implementation projects, including both training and technical assistance on evaluation methods, as well as alternative approaches to ensure that the impacts of these projects are effectively documented and analyzed.**

Weak evaluation designs for the implementation projects could result in loss of documentation of the effects of these projects on safety and quality. Despite AHRQ's work to help the grantees in this area, our interviews indicate that at least some grantees continue to have weak evaluation designs. Grantees should be guided toward evaluation designs that are methodologically sound and also feasible for them to implement. In the future, AHRQ might consider alternative approaches to address this issue, such as requiring that grantees partner with evaluation researchers or having the evaluation component conducted independently from the health IT implementation.

- **Using the growing volume of published results from the patient safety projects, as well as information on commonly used evaluation designs for these studies, facilitate establishment of standards of evidence for the commonly used evaluation designs, and support use of these standards to update the evidence report on patient safety practices.**

The NQF's update of evidence for a selected set of safety practices drew heavily upon published results from AHRQ-funded projects, but numerous other practices were assessed by the patient safety projects that were not considered in this review. A more comprehensive update on effective safety practices should be conducted that incorporates the newly available evidence base for this broader range of practices. To do so, new standards of evidence must be defined for

the types of research designs being used to assess effects for patient safety practices, so that these studies will be eligible for consideration in an evidence assessment.

CHAPTER 5. PROCESS: 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 (e.g., culture, information systems), hazards to safety created by the organization's structure itself (e.g., physical configurations, procedural requirements), and effects of the macro-environment on the organization's ability to act (e.g., legal and payment issues).

OVERVIEW

Building a supportive infrastructure is critical for successful adoption of improved patient safety practices throughout the United States. Infrastructure refers not only to training individuals to have the capacity to act but also to building mechanisms for dissemination of information and products so that new findings and tools can be applied in real world settings. Our overall evaluation approach has been to identify several key infrastructure elements for achieving readiness for adoption of effective safety practices by health care providers, and to assess developments for each of these elements and AHRQ's contributions to them over time. Table 5.1 presents the evaluation questions regarding patient safety infrastructure addressed by this evaluation.

In this chapter, we present our findings regarding trends in growth for national-level patient safety partnerships, the PSIC, consumer involvement, and other AHRQ initiatives designed to build infrastructure. We also provide updates on some more recent initiatives, which also are contributing to infrastructure but are still too new for assessment of development trends.

NATIONAL-LEVEL PATIENT SAFETY PARTNERSHIPS

In 2004, the evaluation team conducted interviews with a variety of organizations to examine the numbers and types of collaborative activities under way for improving patient safety practices by providers and health care organizations, including AHRQ's participation and roles in these partnerships. In 2006, we repeated those interviews to determine the current national landscape of partnerships around patient safety and how it has evolved from the 2004 baseline period. The data from these interviews were used to perform a descriptive analysis and a formal network analysis of patient safety partnerships (Scott, 2000; Wasserman and Faust, 1994).

Methodology

To help ensure consistent responses across interview participants, 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.*

This relatively narrow definition of partnership was not intended to capture all interactions between organizations on the topic of patient safety. We specifically excluded partnerships based solely on membership on another organization's board, as well as grants or other contractual relationships (e.g., between AHRQ or a foundation and its grantees) if these

were not in the context of a wider, collaborative relationship that included activities specified in our definition.³ Others that are not represented are spin-off partnerships and coalitions (e.g., the Chicago Patient Safety Forum, in which several AHRQ-funded projects played a leadership role), which are offering more subtle, qualitative benefits and by-products. Therefore, the partnership activity identified in this analysis represents a conservative estimate of partnerships taking place.

Table 5.1
Evaluation Questions and Assessments for Infrastructure for Effective Practices

Evaluation Question	Summary Assessment
How are AHRQ and its funded patient safety projects contributing to establishment of infrastructure to support patient safety in health care organizations across the country?	Significant contributions have been made in several areas, including the hospital patient safety culture survey, funding of projects to develop information systems and reporting systems, growth in partnerships at the national and local levels, training through PSIC, and measurement capability.
What have we learned from existing research and practice networks funded by AHRQ about how to establish infrastructures that stimulate and support effective practices?	Funded projects have yielded lessons regarding factors necessary for successful implementation of practice improvements, some of which involve infrastructure (e.g., safety culture, data systems), especially the health IT projects.
To what extent is there an infrastructure of inter-organization partnerships that are pursuing collaborative approaches to improving patient safety practices?	Between 2004 and 2006, the number of national-level, inter-organizational partnerships focused on patient safety grew substantially, as did AHRQ’s involvement in these partnerships. This will be important to AHRQ’s dissemination activities.
How well are payment systems structured to provide appropriate incentives for safe delivery of safe health care?	There has been growing use of financial incentives for adoption of safe practices in hospital settings, but they are largely absent in ambulatory settings, in part due to the lack of readily available measures. AHRQ can contribute to effective pay-for-performance (P4P) through measure development and guidance on their use.
What additional research or development work is needed to strengthen effective infrastructures for patient safety practices in the health care system?	Future efforts should focus on how to implement health IT to improve safety, increasing the role of leadership in establishing a strong safety culture, and supporting front-line staff in their efforts to improve safety. Additional training is still needed to greatly expand the network of individuals with safety knowledge and ability to apply that knowledge.

We designed a purposive sampling strategy for identifying leading national organizations representing a wide array of possible end users who could effect change in patient safety

³ These data represent the perceptions of interviewees of the partnerships that their organization has engaged in with other organizations. We attempted to identify interviewees knowledgeable of their organization’s range of collaborative activities, but some respondents—especially those from organizations with many partnerships—may have focused on those viewed as most important or which best exemplify their organization’s work, or may have only described specific activities within a partnership in which their organization was directly involved.

practice. To the sample of 35 organizations interviewed in 2004, we added other organizations that respondents had identified as key players in the realm of patient safety, as well as those involved in health IT work. This process resulted in a total sample of 59 leading national organizations, of which 55 organizations were interviewed (a response rate of 93 percent).

The organizations interviewed were grouped into eight major categories, as shown in Table 5.2. In both rounds of interviews, the largest number represented health care trade, industry, or professional membership associations, followed by government departments or agencies. About one-third of the interviewees in both years identified their organizations as having an extremely diverse constituent base; the other two-thirds described their organizations as having a much more narrowly targeted constituency. Patient safety was a primary or major focus for the vast majority of all of the respondents, regardless of organizational category.

Table 5.2
Organizations Interviewed for the Patient Safety Partnership Analysis,
by Type of Organization

Type of Organization	Number of Organizations		Change From 2004
	2004	2006	
Accrediting or standards-setting entity	4	4	0
Foundation	3	3	0
Government department or agency	9	9	0
Health industry or professional association	12	18	+6
Health policy or improvement organization	3	7	+4
Health IT policy or development organization	0	5	+5
Health care consumer or purchaser group	3	5	+2
Academic or research institution	1	4	+3
Total	35	55	+20

The 2006 interviews yielded 244 partnerships within the previous two-year period, of which only the 220 that were ongoing at the time of the interviews are considered here. Our analysis assumes that a partnership existed between two organizations if one was reported by a respondent in either organization.

The main limitation of our data is that an unknown number of partnerships were not captured in the sample frame or interview protocol. In addition, representatives from a large proportion of the organizations in the network analysis dataset were not interviewed, since their organizations were not part of the initial sample. Still, the overwhelming majority of such organizations (over 80 percent in both rounds) were only mentioned by one responding organization. Therefore, the data provide a reasonable representation of the main infrastructure of partnerships related to patient safety.

Network Analysis Results

Characteristics of Partners and Partnerships. As Table 5.3 illustrates, the 220 current partnerships in 2006 involved a total of 147 different organized entities. Similar to 2004, the largest numbers of organizations involved in these patient safety partnerships were health industry and professional associations, followed by government departments and agencies, with smaller numbers of organizations in other categories. In both years, there was also a large

number of group partnerships, which we defined as partnerships involving more than two individual organizations.

Of the 220 current partnerships reported in 2006, 79 percent had been in existence for more than one year, a slight increase from 61 percent in 2004, indicating some sustainability of these partnerships over time. Only 13 percent of respondents reported that the partnerships were too new to determine success (down from 40 percent in 2004). However, similar to results from 2004, when respondents were able to judge the success of a partnership, over 80 percent were deemed successful, and only two were described as not successful. Consonant with the first round, over half of the partnerships were supported solely through in-kind time and effort by staff from participating agencies. Approximately one-third received dedicated funding from either of the partner organizations, and 12 percent received dedicated funding from external sources (the latter an increase from 6 percent in 2004).

Table 5.3
All Organizations Reported as Members of Patient Safety Partnerships,*
by Type of Organization

Type of Organization	Number of Organizations		Change From 2004
	2004	2006	
Accrediting or standards-setting entity	4	5	+1
Foundation	3	3	0
Government department or agency	12	18	+6
Health industry or professional association	15	33	+18
Health policy /improvement organization	4	12	+8
Health IT policy/development organization	2	7	+5
Health care consumer or purchaser group	4	9	+5
Consulting firm	0	1	+1
Academic or research institution	5	10	+5
Group partnership	43	49	+6
Total	92	147	+55

* Includes both interviewed organizations and their reported partner organizations.

A comparison of the 35 organizations that were interviewed in both 2004 and 2006 reveals an overall expansion in their partnership activity around patient safety issues, with a 40 percent increase in the average number of partnerships per interviewed organization, and an over 50 percent increase in the average number of activities per reported partnership. As Table 5.4 illustrates, this expansion is also reflected in a relative increase in virtually all domains of partnership activity. These trends suggest that collaborative activity has shifted to a greater emphasis on dissemination and translation of patient safety knowledge into usable tools, which at the same time requires ever more extensive exchange of ideas and information.

AHRQ’s Direct Partner Network. To characterize AHRQ’s connectedness with different types of organizations, Figure 5.1 displays visual graphs of the networks formed by the partnerships among AHRQ and its direct partners for both 2004 and 2006. Each line represents a partnership relationship between two entities. A star represents AHRQ, the circles represent individual organizations, and diamonds are the “group partnerships.” The numbers are codes that represent individual organizations or group partnerships to protect their privacy. AHRQ is highly central within the overall network of partnerships. It has more patient safety partnership

links than any other organization included in the sample. Likewise, it remains the most central organization in the overall network in terms of acting as a link or connector across different parts of the network.

Table 5.4
Increases in Patient Safety Partnership Activities, 2004 to 2006

Type of Patient Safety Activity*	Percentage	Percentage for Consistent Sample**		±
	2006 (n=220)	2004 (n=117)	2006 (n=161)	
Research-related	16.4	16.2	18.6	+2.4
Dissemination	50.5	27.4	51.6	+24.2
Intellectual exchange	40.5	25.6	39.8	+14.2
Standards & guidelines development	33.2	31.6	29.8	-1.8
Tools development	32.3	14.5	35.4	+20.9
Education & training	24.1	17.9	26.7	+8.8
Policy change & advocacy	20.9	10.3	18.6	+8.3

Note: “n” represents the number of partnerships

*Categories are not mutually exclusive.

**Based on the 35 organizations interviewed in both 2004 and 2006.

Between the two rounds of interviews, AHRQ substantially expanded the number of its direct partners from 21 to 38, including the addition of two consumer groups. The additional partners added in 2006 appear to be relatively evenly distributed across organization type. We note that AHRQ is involved in numerous group partnerships, which are multifaceted activities with many participating organizations. As such, the network graphs may under represent the full extent of connectedness between AHRQ and other organizations.

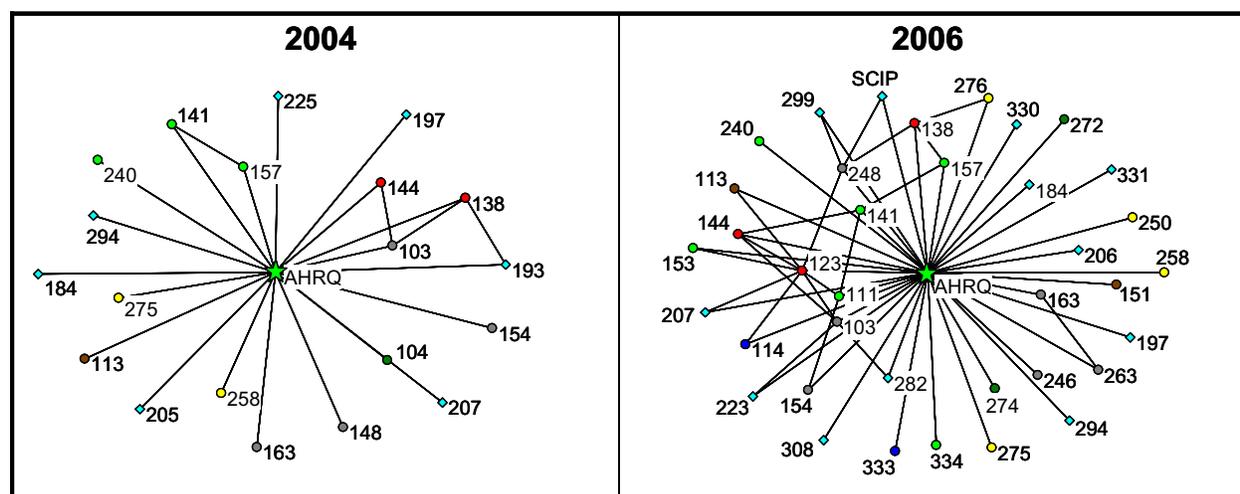


Figure 5.1 AHRQ's Direct Partners Network, 2004 and 2006

The number of partnerships formed by AHRQ's direct partners also increased through additional connections among previous partners and addition of new partners that brought their

connections. These changes signify an enhanced capacity for information flow among AHRQ and its direct partners.

Partnership Networks by Type of Activity. The panels in Figure 5.2 display networks around different types of partnership activities. Again, a star represents AHRQ, circles represent other organizations and diamonds are group partnerships.

As shown in Figure 5.2a, the number of dissemination partnerships increased from 2004 to 2006, and the network also has become less fragmented and more conducive to broad-scale spread of information. In addition, some new disconnected clusters were formed in 2006. The overall shape of a graph affects the flow of communication and interaction and the ability of the network as a whole to perform certain tasks (Burt, 1980; Guetzkow and Simon, 1955; Bavelas, 1950). Star-shaped structures, such as we find for the dissemination partnership network, tend to perform simple tasks more quickly and accurately, but they do less well with more complex tasks. This type of structure also places a burden on the central actor (in this case AHRQ) to coordinate information flows, which would require a high degree of internal cross-sharing of information and coordination regarding partnering activities.

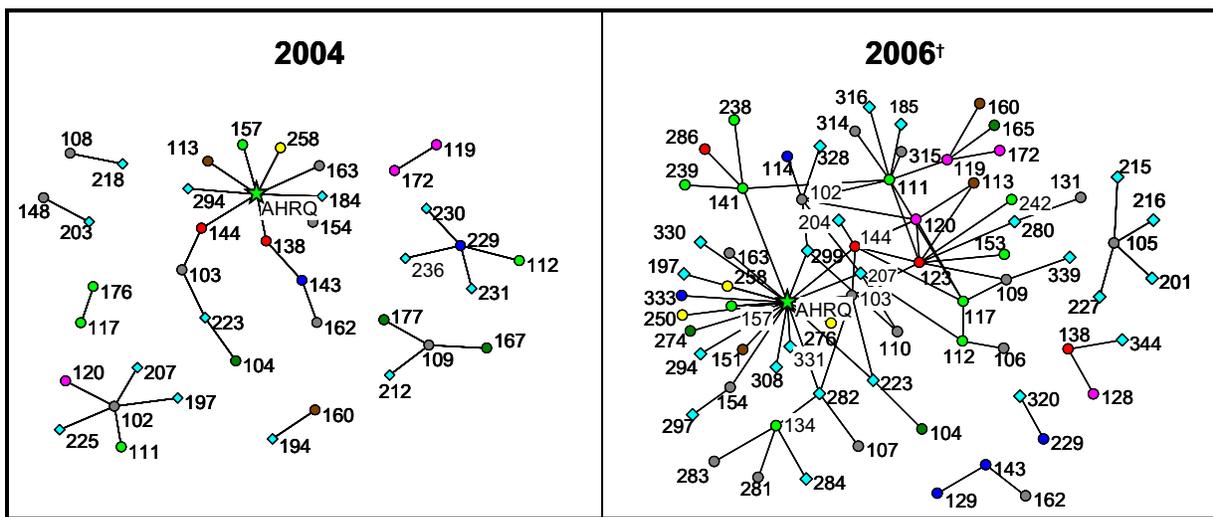


Figure 5.2a Dissemination Partnerships, 2004 and 2006

† Consistent sample based on the 35 organizations interviewed in both 2004 and 2006.

Figure 5.2b shows that accreditation and standard-setting organizations are more central to partnerships for development of standards and guidelines in patient safety (identifiers removed to protect organizations' privacy), although AHRQ is involved. Two positive changes occurred in partnerships around this activity—the sharp increase in the number of partnerships and the linking of the two main clusters of collaborative standards and guidelines activity found in 2004.

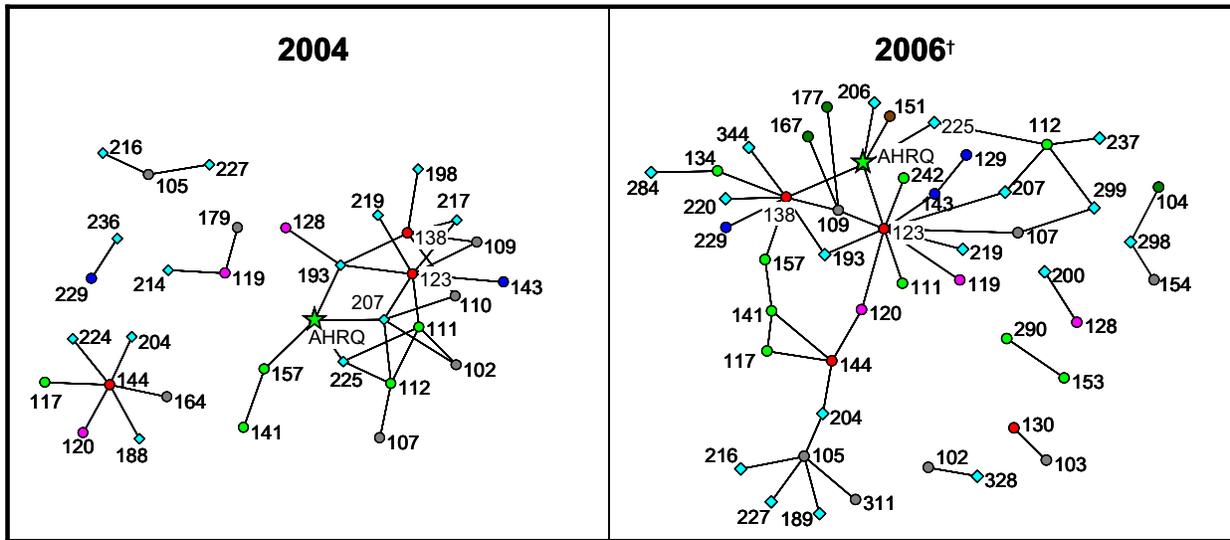


Figure 5.2b Standards and Guidelines Partnerships, 2004 and 2006

† Consistent sample based on the 35 organizations interviewed in both 2004 and 2006.

The number of AHRQ’s direct partnerships related to education and training has stayed relatively constant, and the “triangle” of collaboration between AHRQ and two major federal systems remains a salient feature of this activity, as shown in Figure 5.2c. At the same time, AHRQ’s overall cluster has been substantially enlarged. However, there were still a number of disconnected clusters of collaborative activity that could be used to build further on what has already been established in this area.

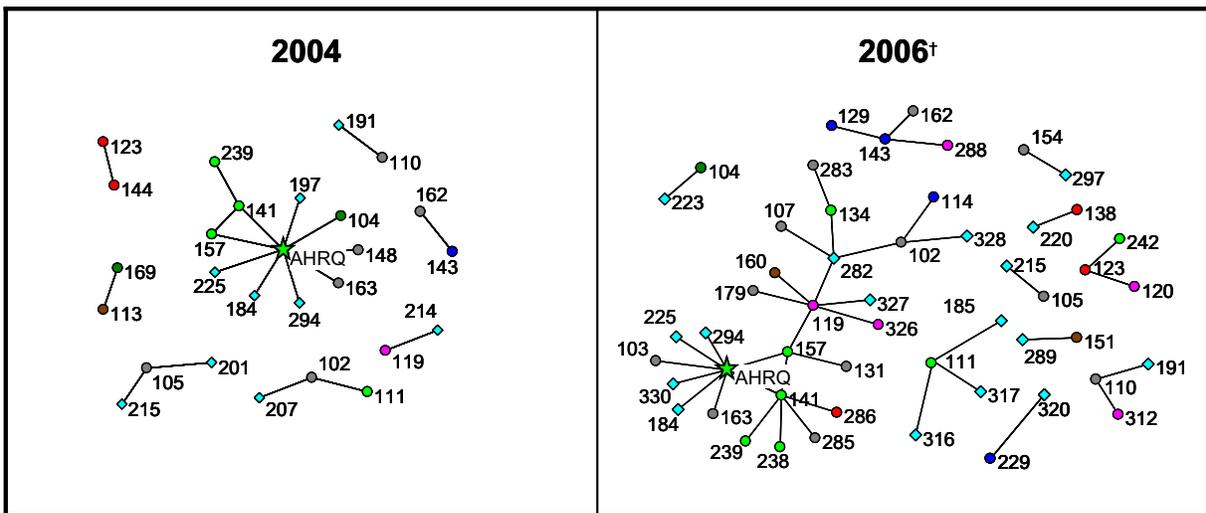


Figure 5.2c Education and Training Partnerships, 2004 and 2006

† Consistent sample based on the 35 organizations interviewed in both 2004 and 2006.

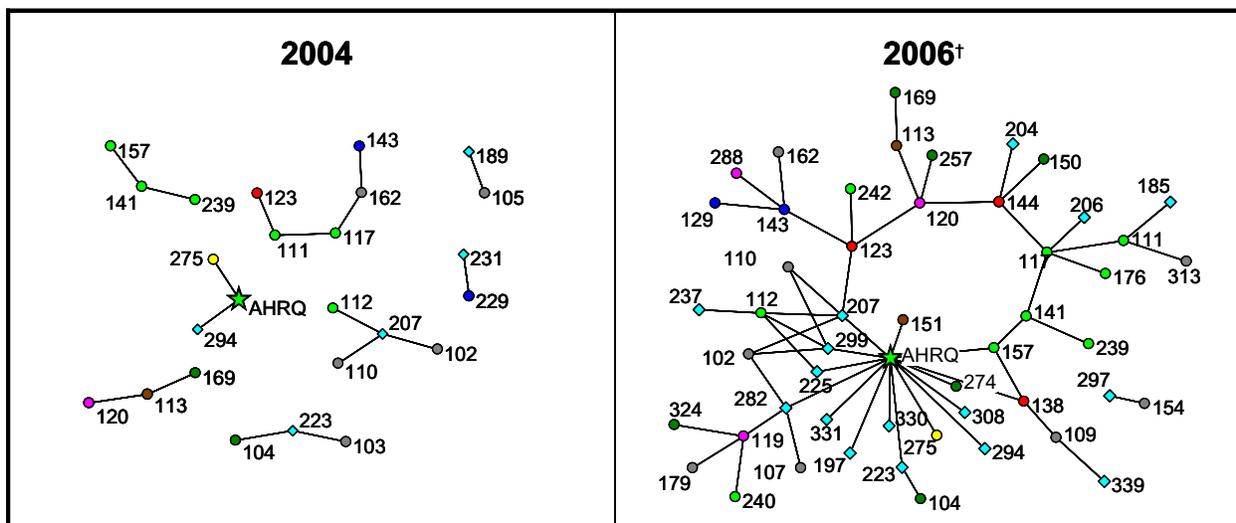


Figure 5.2d Tools Development Partnerships, 2004 and 2006

† Consistent sample based on the 35 organizations interviewed in both 2004 and 2006.

Tools development was a relatively sparse domain of activity in 2004, but it has progressed into one of the most extensive areas of collaboration, as evidenced by a fivefold increase in the number of partnerships, shown in Figure 5.2d. This growth was accompanied by a substantial decrease in fragmentation between 2004 and 2006. AHRQ considerably increased its work in tools development through a variety of partnerships, making it one of the central organizations within this network. This implies a rising emphasis for AHRQ on later steps in the implementation process.

HIGH RELIABILITY ORGANIZATIONS

As part of the overall strategy for the Office of Communication and Knowledge Transfer (OCKT) program, AHRQ contracted with the Delmarva Foundation in 2005 to manage the HRO Learning Network for patient safety. According to the learning network model, participants with shared interests come together voluntarily to increase knowledge by sharing ideas, setting standards, and building tools to strengthen the work of the member organizations (Wenger, McDermott, and Snyder, 2002; Snyder and Briggs, 2003; Bessant, Kaplinsky, and Morris, 2003).

A key purpose of the HRO learning network was to define and operationalize the concept of high reliability in patient safety, using the “learning network” model. AHRQ has been working with 19 health care systems and individual institutions to maximize their ability to interact effectively among themselves, to define what it means to be a HRO in health care, to improve the reliability of the organizations that are part of the network, and to disseminate this information to organizations outside the network. The initial goals for the HRO initiative were to increase networking by the participants, expose participants to ideas regarding what it means to be a high reliability organization drawn from other industries, and initiate bilateral “initiatives” among participants with demonstrable impact on patient safety outcomes.

To document the implementation experience of the HRO Learning Network, we interviewed the AHRQ project officer, Delmarva Foundation staff, and three of the most active members of the network. We also attended three HRO Learning Network meetings, a few

network conference calls, and accessed the HRO Learning Network Sharepoint site. Below we highlight early findings regarding the initiative's progress as of September 2006.

- The initial step of identifying the goals and approach for the work and engaging members in the Learning Network took a significant amount of time.
- Because the network was member-driven and the financial costs for participation were not overly burdensome, members' motivation to participate remained high; having the right balance of topics at network meetings is important for keeping high-level people involved.
- Face-to-face network meetings and site visits provided a useful opportunity to learn "in-depth" about best practices in patient safety from other leaders in the field and to share experiences; more opportunities for sharing best practice implementation experiences would be useful.
- The network was small enough that members have gotten to know each other well and feel comfortable to call, e-mail, and visit outside of the formal network activities.

As of September 2006, it appeared that two of the three goals established for the HRO initiative were being met. A "community of practice" had been established, with members sharing best practices at network site visits. Members also reported that they had visited or otherwise been in contact with one another outside of formal network meetings. What had not yet come to fruition was a specific collaborative project among network members. In addition, progress had been limited in defining the HRO concepts and applying them to health care.

In interviews our evaluation team conducted, the network participants reported that discussion of HRO concepts often appeared to be an afterthought at their meetings, rather than a core concept. Many felt that the participating systems were not the correct forum to develop the concept because they did not feel they really were HROs yet. They also expressed concern that the balance of topics at network meetings was not right to keep high-level people involved, and that greater clarity was needed on the goal of the meetings. Further, there was a lack of follow-up to the site visits, which precluded the opportunity for network members to share experiences in implementing the "best practices" they were learning at the meetings.

In December 2006, AHRQ announced that it was discontinuing support for the HRO learning network, as of the end of the DelMarva Contract, although the HRO concept may continue to be explored through alternative mechanisms. It is likely that three years is not a sufficient period to accomplish all of the goals set for the HRO Learning Network, given the complexity of the concept and process. The network was to be self-directed, which is appropriate for a learning network, but this approach usually requires an extended period to allow the network to establish itself and develop its own norms.

USE OF THE HOSPITAL SURVEY ON PATIENT SAFETY CULTURE

Early in the patient safety initiative, QuIC sponsored the development of the AHRQ-funded *Hospital Survey on Patient Safety Culture*, which was intended to help hospitals assess how well their cultures emphasize patient safety, facilitate open discussion of error, encourage error reporting, and create an atmosphere of continuous learning and improvement. The survey contains 51 questions that assess 12 areas or dimensions of patient safety, with three to four questions addressing each area (AHRQ, 2005b).

AHRQ partnered with the American Hospital Association (AHA) in early 2005 for dissemination of the culture survey to U.S. hospitals and health care systems through a coordinated set of informational, training, and support activities. A growing number of U.S. and other hospitals are using the culture survey. Feedback from these hospitals suggests that the dimensions measured on the survey are relevant at the operational level and are being used for quality improvement work. However, quantified data are not yet available to verify this assessment.

In the past year, AHRQ contracted with Westat to build and manage a benchmark database to which hospitals can submit their survey data and obtain information on how they compare with others. As of September 2006, several hundred hospitals had submitted their data to the database, with expectations of increasing numbers. In addition, it was known that many other hospitals were using the survey but not reporting data into the benchmark database, although estimates of the numbers of hospitals were not available. The first benchmark report, which was expected to be released in November 2006, should provide useful policy insights based on data from this large cohort of hospitals. A second report was due to be released by late 2007.

AHRQ also contracted with Westat to develop patient safety culture surveys for long-term care, ambulatory care, and individual physicians. As of September 2006, these surveys were waiting for Office of Management and Budget (OMB) approval or being pilot tested.

PATIENT SAFETY IMPROVEMENT CORPS

Under a contract to the VA National Center for Patient Safety, AHRQ has provided \$7 million over four years for the PSIC. The primary goal of the PSIC is to increase the number and capacity of health care professionals with core knowledge and skills that can be directly applied to improve patient safety. Eligible participants were teams of state staff in the field and approximately two of each state's selected hospital partners for a total of four participants maximum per state. QIOs also participated as members of some teams.

The annual PSIC training program consisted of three one-week sessions in September, January, and May. The sessions focused on the practical application of patient safety science, change management, medical errors reporting and analysis, medical/legal issues, and patient safety tools. Each team was also required to complete a team project. In total, 49 states and the District of Columbia received training, including two states that sent teams in two years. Thus, a total of 52 teams were trained: 15 in Year 1 (2003–2004), 21 in Year 2 (2004–2005), and 16 in Year 3 (2005–2006).

The patient safety evaluation center gathered information about the three annual training rounds using three methods: group interviews conducted with many of the teams during their final training session in May of each year; individual follow-up telephone interviews with graduates one year post-program completion; and updated information collected two years post-program completion from members of the Year 1 group who had participated previously in the telephone interviews. Below, we highlight key findings that emerged from this evaluation. More detailed evaluation results for the first two years may be found in a separate report entitled *Evaluation of the Patient Safety Improvement Corps: Experiences of the First Two Groups of Trainees* (Teleki et al., 2006).

Individuals Trained

Across the three years of training, state representatives tended to hold a variety of positions (e.g., director of hospital programs, assistant attorney general). The hospital representatives typically had explicit responsibilities for patient safety and quality improvement, especially in later years of the program. Due to modifications of some requirements for the Year 3 teams, many more teams than in prior years included QIO staff as state representatives.

The patient safety knowledge and experience level of individuals entering the program increased over time. In Year 1, some had used or taught about patient safety tools, designed interventions for improvement, and evaluated them, whereas others were being exposed to these concepts for the first time. By contrast, most Year 2 and 3 participants had modest-to-high levels of understanding of patient safety issues. However, most did not rank themselves high in terms of their experience with tools, interventions, and evaluation techniques.

Impact of Training

Both during training and after course completion, trainees valued the tools and skills they learned, and they used many in their day-to-day work. When asked to rate their patient safety skill levels at the end of their training, most Year 2 and Year 3 trainees reported having a high skill level in major patient safety techniques. As Table 5.5 illustrates, one year after their PSIC training ended, significant proportions of Year 1 and 2 trainees reported high levels of use of the skills and tools taught through the PSIC, especially root cause analysis, human factors engineering, and reporting of adverse events and near misses.

Reported use of tools and skills generally was similar for the Year 1 and Year 2 trainees, with three exceptions. We found statistically significant differences in use for patient safety culture survey and tools, reporting adverse events and near misses, and assessment of patient safety business case. Lower use for the Year 2 trainees was reported only for adverse event reporting. A few Year 2 trainees mentioned that they were not actively using these tools because they already had systems in place that were working well.

Two years post-training, the Year 1 trainees still were using many of those skills and tools, although usually at somewhat lower rates than their use after the first year post-training. Many trainees also said they had trained others in the use of patient safety skills and tools. The trainees noted that such activities have given increased visibility to patient safety issues throughout their states. Graduates of all three years viewed the course's networking opportunities and the broader perspective gained about patient safety as significant resources.

Table 5.5
Percentage of Skills or Tools Used by PSIC Trainees at One Year and Two Years
Post-Training, for the First and Second Year Trainees

Tool or Skill	Percent Saying Used One Year After Training		Percent Saying Used Two Years After Training *	
	Year 1 (n=38)	Year 2 (n=58)	Ever Used (n=25)	Currently Use (n=25)
Risk assessment				
Root cause analysis	79%	78%	76%	68%
Failure mode and effect analysis	58	48	76	40
Probabilistic risk assessment	13	14	32	12
VA's Safety Assessment Code	42	29	40	24
Measurement tools				
Patient safety culture survey and tools	29**	57**	56	40
Patient safety indicators	42	33	64	52
Analysis of patient safety data	42	31	52	60
Reporting adverse events and near misses	79**	55**	72	72
Safety management tools				
Human factors engineering	71	81	72	60
Tools to identify high-alert medications	50	34	48	24
Tools to assess patient safety business case	18**	48**	48	8
Tools to evaluate patient safety programs	21	26	40	28

* Responses from the first year PSIC trainings in two-year post-training update. "Ever used" signifies that a tool or skill had been used at some time since training; "currently use" signifies that it was being used at the time of the interview with the PSIC graduate.

** Year-to-year differences statistically significant at the $p < 0.05$ level.

The PSIC training also had a substantial impact on patient safety actions taken by states and hospitals. As shown in Tables 5.6 and 5.7, a variety of specific patient safety actions had been taken by states and hospitals, respectively, within the first year following their training. For both Years 1 and 2, trainees representing the states said their training most often influenced the initiation of or modifications to patient safety legislation, and modification of adverse event oversight procedures. Hospitals in both years reported that the training was an important factor in modifications they made to adverse-event oversight procedures and their use of PSIC skills and tools to promote patient safety culture. The absence of statistically significant differences between the types of actions reported by the Year 1 and Year 2 trainees, for both the state and hospital representatives, indicates that the two training cohorts did not differ in the needs or priorities for actions to which they applied their new training and skills.

Table 5.6
How the PSIC Training Influenced Patient Safety Actions by States, Reported in One-Year Follow-Up Interviews with the Year 1 and Year 2 Trainees, 2005 and 2006

Patient Safety Action	Percentage of States Responding “yes”	
	Year 1 Trainees (n=15)	Year 2 Trainees (n=18)
Initiation of or influence on regulation(s)/ legislation	47%	56%
Modification of hospital oversight procedures when an adverse event occurs (e.g., change content of root cause analysis)	47	56
Modification of an existing state reporting system to improve how it captures patient safety issues or how information is reported to others	33	22
New membership in or formation of a patient safety coalition of stakeholders	20	50
Creation of a state-wide reporting system	20	17

Notes: Entities labeled as QIOs or “other” were reclassified as either states or hospitals based on their core functions. Counts for hospital and state-specific questions vary depending on the respondent’s ability to answer the question.
 No year-to-year differences presented in this table were found to be statistically significant ($p < 0.05$).

Table 5.7
How the PSIC Training Influenced Patient Safety Actions by Hospitals, Reported in One-Year Follow-Up Interviews with Year 1 and Year 2 Trainees, 2005 and 2006

Patient Safety Action	Percentage of Hospitals Responding “yes”	
	Year 1 Trainees (n=23)	Year 2 Trainees (n=40)
Modification of processes to review/analyze adverse events or errors	83%	73%
Promotion of patient safety culture	78	83
Sharing data across organizations to better understand causes of error	52	50
Other changes in review of adverse events	48	48
Other state- or organization-wide initiatives	48	50
New membership in or formation of a patient safety group of stakeholders	35	45
Creation of institutional adverse-event reporting system	30	13

Notes: Entities labeled as QIOs or “other” were reclassified as either states or hospitals based on their core functions. Counts for hospital and state-specific questions vary depending on the respondent’s ability to answer the question.
 No year-to-year differences presented in this table were found to be statistically significant ($p < 0.05$).

Overall Assessment by Trainees

All trainees noted similar barriers to participating in the program and making changes at home. These ranged from lack of resources (e.g., time, funds, staff) to cultural obstacles within their organizations. They underscored a need for follow-up training beyond the third PSIC session, and for training of larger, more diverse teams that include front-line clinicians, high-level decisionmakers (e.g., CEOs, legislators), and senior staff (from both hospitals and states) who have the authority to effect change at higher organizational levels. To expand the reach of the program, some recommended that teams include more than one representative from each organization, and that representatives from CMS and the Joint Commission be included, given the prominent and powerful roles these entities play in national policymaking for patient safety.

Trainees across all years expressed increased confidence and a more in-depth appreciation of the complexities of patient safety as a result of the program. One year after the training ended, the overwhelming majority of Year 1 and Year 2 participants (90 and 95 percent, respectively) rated highly the helpfulness of the training in improving processes to monitor and improve patient safety, giving it ratings of seven points or higher on a ten-point scale. Two years after the training, 92 percent of Year 1 trainees continued to rate the training similarly. Those in clinical settings with more opportunities to apply PSIC-learned methods tended to voice more confidence than others. However, other trainees, such as state agencies or QIOs, said it was valuable for them to become more aware of the issues front-line staff face and the tools they use. According to many of the attendees, the PSIC has played an instrumental role in changing attitudes about patient safety within their organizations and often more broadly.

UPDATE ON AHRQ NETWORKS

AHRQ has established several networks designed specifically for accelerating development and dissemination of knowledge and practices for safety and quality, two of which we examined in *Evaluation Report III*. As of September 2006, it was too early to assess the impact of these programs on patient safety practices, but they provide an infrastructure with the potential to create collaborations for research and action. We summarize here the status of three of these networks.

Accelerating Change and Transforming Organizations and Networks (ACTION)

The ACTION program is a model for field-based research that fosters public-private collaboration in rapid-cycle, applied research. Projects are primarily demand-driven by the health care organizations and other key stakeholders within the delivery system, rather than supply-driven by the priorities and interests of funding agencies and researchers. The program places significant emphasis on developing practical approaches and tools to address problems, rapidly scaling up these products within one or more organizations, and then disseminating them widely throughout the health care system.

The 15 ACTION partnerships cover approximately one-third of the U.S population and span all 50 states. Most include more than seven partners and some have more than 30, including public and private sector providers, research organizations, safety-net providers, long-term-care facilities, credentialing organizations, QIOs, and consumer groups. The ACTION program is leveraging its approximately \$2.5 million in AHRQ funding for FY 2006 to secure additional, external funding in a targeted amount of \$4.5 million. AHRQ has secured formal commitments to sponsor ACTION projects from at least nine public and private funders. Patient safety is an

important part of the program, with four of the 19 anticipated ACTION task order requests in FY 2006 directly focusing on this area, and several others addressing issues that are relevant to patient safety.

Developing Evidence to Inform Decisions about Effectiveness (DEcIDE)

The primary focus of the DEcIDE program is to develop new knowledge and evidence. In particular, the network is designed to conduct accelerated practical studies about the outcomes, comparative clinical effectiveness, safety, and appropriateness of pharmaceuticals, devices, and health care services. As in the ACTION program, the 13 partnerships that comprise DEcIDE are eligible to bid on rapid-turn-around task orders. Each partnership generally includes at least one health care system with access to electronic health information databases as well as the capacity to conduct rapid turnaround research, and one or more research organizations. Of the 15 current DEcIDE projects, seven include a focus on patient safety.

Primary Care Practice Based Research Network (PBRN)

AHRQ has revised its existing PBRN structure to perform studies that can be conducted quickly with a broad array of partners, again with a focus on demand-driven, practical, applied topics. Research funded through this program either will address pressing questions related to the appropriateness of care delivered in primary care settings or will assess a technology, product, tool, or care delivery strategy relevant to primary care. The assumption is that findings of research conducted in community-based settings will have strong external validity and be readily implemented in primary care practice settings. AHRQ planned to award five to ten partnerships with master contracts. It is unknown how many of the research projects funded through the PBRN program will relate to patient safety.

MECHANISMS FOR CONSUMER INVOLVEMENT

In *Evaluation Report II*, we described significant roles for consumers in improving patient safety. We also offered two suggestions for AHRQ to strengthen those roles: (1) funding Centers of Excellence for Consumer Engagement to study the effect of involving patients and families in patient safety activities, and (2) disseminating best practices for consumer engagement in patient safety improvement, in partnership with consumer organizations and other organizations with expertise involving patients and families. Below, we provide a brief update based on follow-up interviews with a subset of the original informants and reviews of salient literature and Web sites.

Progress has been made on several fronts with regard to consumer involvement in patient safety. First, many patient safety and quality organizations now emphasize the role of consumers in improving care and routinely include consumers on committees or seek their input and support in other ways (Conway et al., 2006). They also have increased their efforts to educate consumers about steps they can take to help prevent errors in their medical care (AHA, 2006; McGreevey, 2006). Second, a growing number of hospitals and other provider organizations are embracing and implementing initiatives to increase consumer involvement in safety and quality initiatives. Such progress reflects, in part, the increasing sophistication and effectiveness of leading consumer organizations, such as CAPS and the Institute for Family Centered Care.

At the same time, the consumer leaders we interviewed noted that little has changed with respect to the safety of care received by the vast majority of Americans, and that consumer involvement in key patient safety decision-making processes remained limited. They

underscored that few patients are aware of the educational materials available from AHRQ and other organizations, and they are not being educated about patient safety by providers. They expressed frustration that most leaders of federal agencies, national safety and quality organizations, and health care provider organizations seemed satisfied with efforts to date and no longer had a sense of urgency or willingness to embark on aggressive outreach initiatives needed for change. These leaders also noted that, while more hospitals are successfully engaging patients and families in quality improvement efforts, many such efforts are not being sustained. Most consumer leaders agree that “less talk and research, [and] more action” is needed, and that over-emphasis on evidence-based medicine is hampering the ability of the health care system to implement common-sense safety measures.

PAYMENT FOR PATIENT SAFETY PERFORMANCE

Recognizing that many of the current provider payment policies in the United States operate as barriers to quality and safe practices, an increasing number of public and private purchasers and plans are exploring financial incentives to better align payments with improvements in quality of care. In some cases, these incentives are being used to drive patient safety improvements. The Leapfrog Group maintains the *Leapfrog Incentives and Rewards Compendium*, which contains information on national programs that offer performance incentives and rewards (Leapfrog Group, 2006). This database lists 93 incentive programs, of which 34 programs targeted hospitals. Among the programs that targeted hospitals, 26 (76 percent) included a patient safety component.

Several strategies currently are favored by purchasers, payers, and policymakers as a way to align incentives with the delivery of high-quality, safe, and efficient care. However, there is little empirical evidence at this time on the effectiveness of these strategies or on how best to structure the incentives to achieve the desired goals. Strategies being pursued include:

- Pay-for-performance (P4P)—creation of financial incentives for health care providers based on their quality performance
- Tiering—provision of financial incentives to consumers through variable cost sharing of out-of-pocket costs based on their choices of providers, as classified by tiers, in which patients pay a larger cost share for services by providers in lower-performing tiers
- Cash awards and public recognition—given to providers based on performance, to steer patients and purchasers toward those who are higher performers.

Although patient safety measures are being incorporated into hospital incentive programs, the current focus is largely on structural performance measures (i.e., staffing, systems, and policies). This may be due to the problems associated with measuring safety outcomes, including challenges in reliably and validly measuring an event. There also are policy concerns that, by rewarding providers for lower rates of errors or adverse events, P4P could suppress reporting of those events, which could have the perverse effect of compromising the effectiveness of patient safety activities that P4P was trying to encourage. Therefore, many of the current P4P programs have adopted a strategy of paying providers for reporting of errors and structural measures of safety, such as rewarding participation in the Leapfrog annual survey that collects data on safety practices.

In contrast, patient safety is largely absent from existing P4P measures sets in the ambulatory care setting. In a recent review of P4P programs that address physicians or physician

groups, we identified more than 100 P4P programs, none of which are using patient safety measures (Sorbero et al., 2006). This gap may be due to the absence of publicly available, standardized measures of patient safety standards and practices for the ambulatory care setting.

Several implications for AHRQ emerge from this review of current P4P status. For hospital P4P, the need for valid patient safety measures is a key issue, reinforcing the importance of continued work on measure development, as discussed in Chapter 3. As a national leader in patient safety and quality measurement, AHRQ can apply its strong expertise to ensure that P4P programs have credible patient safety measures available to them. In particular, the issue of perverse incentives related to outcome measures reinforces the need for valid process measures and research into effects of alternative P4P designs on provider incentives and behaviors. Measure development could start by addressing measures of the implementation of the NQF safe practices. AHRQ has a similar opportunity to fill this gap for the ambulatory care setting, working with purchasers and payers through the HQA and Ambulatory Quality Alliance.

ISSUES AND ACTION OPPORTUNITIES

AHRQ's efforts over the past four years have contributed to building a national patient safety infrastructure, which is vital to the implementation of patient safety practices across the country. This past year, it has taken steps to refine existing network programs and create new areas of investment to further support infrastructure development. In particular, the increased number of AHRQ partnerships with other national-level organizations will support its future dissemination activities, while leveraging scarce resources, and will likely be reinforced by the products of other patient safety work supported by AHRQ.

Issues to Consider

The PSIC has demonstrated the value of bringing together groups of hospitals and state regulators and providing them with intense patient safety training and support in applying tools. However, the three groups of current graduates represent a small fraction of health care personnel in the country, and further training capability is needed that can reach much larger audiences. Also providing additional opportunities to contribute to the patient safety infrastructure are the self-diagnosis capability offered to health care organizations by the patient safety culture surveys, and the models of practice being developed by the new AHRQ initiatives for HROs, ACTION, and DEcIDE. In considering future options for building infrastructure, AHRQ will need to choose strategically where its investments can achieve the maximum effect.

Suggestions for AHRQ Action

- **Sustain and build upon the success of the PSIC program by dedicating a portion of each annual patient safety budget to continued expansion of patient safety skills and knowledge through refresher courses for PSIC graduates, new training for additional individuals, and reinforcement of training for senior health care leaders.**

AHRQ should consider a variety of training models to greatly expand the pool of health care personnel who are well-versed in patient safety skills and tools. Train-the-trainer programs should be central components of the training strategy, as AHRQ has planned, to leverage its investment into training coverage that is as broad as possible. Refresher training also could be offered to PSIC graduates to help them remain engaged in patient safety issues and to update their skills and knowledge. To reach larger numbers of people, AHRQ could offer condensed regional training sessions or Web-based training modules that are tailored to specific audiences.

- **Ensure that a clear definition and explicit performance criteria for high reliability health care organizations are established and that health care organizations nationwide are provided guidance and tools to become high reliability organizations.**

As AHRQ embarked on the learning network approach for knowledge development, it identified the concept of “high reliability organization” as a central anchor for patient safety strategies. The HRO concept has the potential to make profound contributions to safer health care for our nation, by packaging patient safety culture and actions into a usable organizational and process model for health care organizations. Although its initial HRO learning network effort did not fully achieve its goals, we encourage AHRQ to continue to pursue development of a definition and criteria for HROs. By supplying health care institutions with definitions and measurement standards, AHRQ can provide guidance that will help them understand what it means to be a HRO and move toward achieving that level of performance.

- **Together with public and private entities, substantially increase education and outreach efforts to heighten consumer and provider awareness about patient safety issues and the value of collaboration among patients, families, and providers for improving the safety of care.**

AHRQ is uniquely positioned to reinforce the importance of consumer involvement in making the health care system safer and to accelerate the expansion of their actual involvement. Two suggestions we made in *Evaluation Report II* were for AHRQ to (1) fund Centers of Excellence for Consumer Engagement to study the processes and effects of involving patients and families in patient safety activities, and (2) partner with consumer organizations and organizations with expertise involving patients and families to disseminate best practices for consumer engagement in patient safety improvement. Through these activities, AHRQ could provide guidance to providers and consumers on constructive ways to work collaboratively on improving patient safety. Other options that AHRQ might consider are requiring that AHRQ-funded projects include consumers as part of the development and implementation of a project and promoting care models in which consumer involvement has led to improvements in quality and safety outcomes.

- **Working collaboratively with other public and private funders, create more opportunities for consumer organizations to obtain support for their patient safety efforts and to achieve working partnerships with provider organizations for safety and quality of care.**

To assist consumer entities in competing successfully for federal funds to support their patient safety work, AHRQ should provide them with technical assistance and/or modify the requirements for grants and contracts. Requests for proposals can also be used as a vehicle for encouraging or requiring proposed projects to consider consumer perspectives or to include consumer organizations in their safety interventions.

- **Develop guidance for the field regarding which design options and patient safety measures are most appropriate for use in incentive payment systems, such as pay-for-performance.**

With the growth of P4P programs and their increasing attention to patient safety issues, there is a clear need for evidence-based information both for implications of P4P designs on provider incentives and for safety measures to be used in these programs. AHRQ can contribute

to the science base by funding studies of P4P designs. Using the results of these studies, and drawing on its measure development expertise, AHRQ should identify measures that do not create perverse effects on safety surveillance, and it should provide clarification to end users on which measures are appropriate for incentive payment use and which are not.

CHAPTER 6. PROCESS: 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.

OVERVIEW

Five years into its patient safety initiative, AHRQ has been turning its attention to actions that support broader adoption of effective patient safety practices. A wealth of information is emerging from the AHRQ-funded patient safety projects that needs to be synthesized and packaged into products that health care providers can use to facilitate their safety improvement efforts. With diffusion of use of these practices across the health care system, effects should be seen in trends for outcome measures, as safety improvements increasingly prevent occurrence of adverse events. Table 6.1 presents the evaluation questions regarding the adoption of effective practices by health care providers addressed by this evaluation, as well as a brief assessment of current status for each question. Our overall approach in this part of the evaluation has been to examine AHRQ's progress on each of the steps involved in moving from the generation of project results to the broad adoption of safe practices proven to be effective.

In this chapter, we continue our updates on AHRQ's progress in carrying out its dissemination strategy, with a view toward the future need to achieve sustainable improvements in patient safety practices by health care providers. We also update documentation of the growing number of products generated by the patient safety projects, and we provide empirical information on the extent to which patient safety projects were able to put in place the factors for successful practice implementation. Updates also are given on the first full year of operation for three field-based initiatives for implementing safe practices in the health care system.

FRAMEWORK FOR ACHIEVING ADOPTION OF EFFECTIVE PRACTICES

As AHRQ embarks on its dissemination activities to stimulate adoption of patient safety practices by U.S. health care providers, it is important that its approach and strategy be grounded in existing evidence of what it takes to accomplish diffusion of a new practice (or other innovation). Rogers' well-tested model of diffusion of innovations states that the diffusion of an innovation (in this case, new patient safety practices or tools) will be influenced by the extent of proactive interventions to encourage its adoption (Rogers, 2003; Greenhalgh et al., 2004). According to this model, AHRQ is functioning as a change agency in carrying out its dissemination activities. A *change agency* is an organization that seeks to influence decisions by end users to adopt or reject an innovation.

A two-step strategy emerges from this theory that AHRQ, as a change agency, can use to increase the diffusion and adoption of innovations (Rogers, 2003; Valente and Davis, 1999). It also serves as a useful evaluation tool to assess the status of AHRQ's dissemination work. This model is shown in Figure 6.1.

Table 6.1
Evaluation Questions and Assessments for Broader Adoption of Effective Practices

Evaluation Question	Summary Assessment
To what extent is new evidence on effective practices and implementation methods being disseminated to the broader health care system?	Results from patient safety projects are being published in journals and compendia. The only systematic synthesis and use of this information thus far has been for the updating of the NQF safe practices. Work remains for AHRQ to update the patient safety evidence report published in 2001.
What actions has AHRQ undertaken for disseminating information and products from the patient safety grants and contracts it has funded?	AHRQ has highlighted results and products from individual projects in communications outreach using multiple media, including Web sites, press releases, newsletters, etc. More focus needs to be placed on providers, identifying important practices based on results published by patient safety projects.
What systematic programs are in place or under development by AHRQ or other organizations to provide technical support to health care providers for implementing tested patient safety practices?	Two major contributions AHRQ has made to tools have been the patient safety culture surveys and the teamwork improvement package. AHRQ has provided some technical support for the survey. The PIPS projects also have produced tool kits. The 100,000 Lives Campaign and SCIP have provided primary support for their participants. Expansion of product packaging for other practices is desirable.
How are AHRQ's dissemination strategy and activities contributing to the growing number of patient safety implementation initiatives being started by others?	AHRQ is a partner in all of the major field-based safe practices initiatives, providing a support role as needed, with other organizations taking on the lead roles. These initiatives likely will seek updated information on practices and newly developed tools from AHRQ projects.
Are patient safety practices and outcomes improving as a result of the cumulative efforts of generating knowledge, testing new practices, building an infrastructure, disseminating knowledge, and providing technical support for implementation?	Providers appear to be starting to implement safer practices, stimulated by field-based initiatives and supported by information and tools generated by AHRQ and its funded projects. The extent of actions is still too small to have detectable effects on outcomes at the national level.

Dissemination refers to the active spread of an idea by a change agency, and *diffusion* refers to the subsequent spread of the idea among adopters in the field. Adoption represents the decision to accept an innovation, and implementation entails putting it into practice. Adoption and implementation are not inevitable consequences of diffusion. Rejection, reinvention, and discontinuance of an innovation can be rational decisions and occur frequently.

The Two-Step Dissemination Model

Under the two-step dissemination model, change agencies disseminate innovations to carefully selected opinion leaders, who then diffuse the ideas to other potential adopters via interpersonal relationships. These two steps are represented by bold arrows in Figure 6.1. Importantly, scientific information alone does not persuade most people, including health care providers, to

adopt innovations. Rather, most people rely upon the subjective experiences of previous adopters whom they know and respect.

The third arrow in Figure 6.1, *Input and Feedback*, represents the importance of the perspectives of the end users about an innovation. To the extent that these perspectives are understood when an innovation is being designed, the innovation is more likely to be adopted widely by the target audience. If not fully captured early in the innovation process, this input can be provided through user feedback as the innovation is being used in the field.

Figure 6.1 emphasizes opinion leaders and followers because they represent the majority of potential adopters and are able to make diffusion a self-sustaining process. In the United States, opinion leaders are typically earlier adopters. Most other people are followers, meaning they adopt later and they prefer to obtain innovation information from local opinion leaders rather than mass media or other outside sources. Opinion leaders may lose their status among followers if they make poor adoption decisions or overuse their influence.

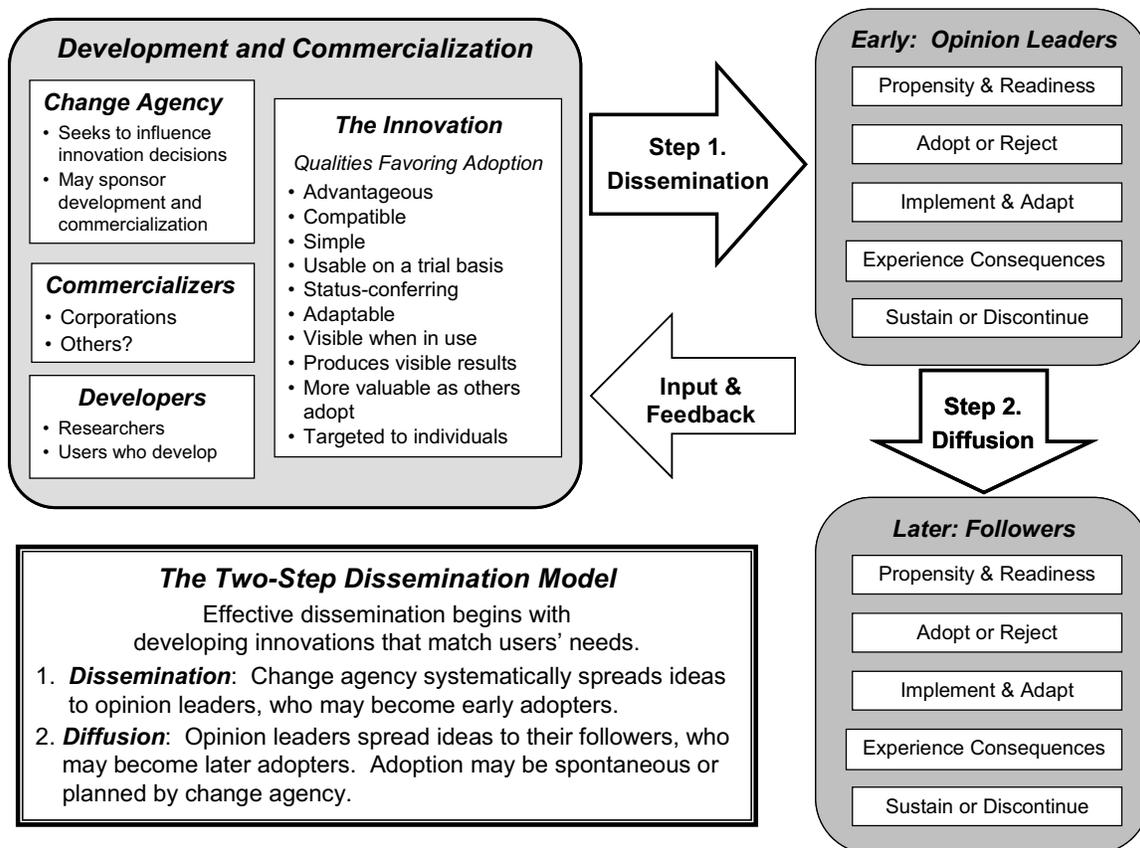


Figure 6.1 A Two-Step Model for Dissemination of Innovation

Change Agency Actions to Encourage Adoption

Working with the components of the two-step dissemination model, along with two principles on research utilization, we developed a list of actions that should be undertaken by a change agency throughout its product research, development, and dissemination process. These

actions are summarized in the left column of Table 6.2, and summaries of the current status of AHRQ’s patient safety initiative and related dissemination activities for each of these actions are listed in the right column of the table. For patient safety innovations, AHRQ is a key change agency, and the AHRQ staff performing the dissemination activities are change agents.

Table 6.2
Change Agency Actions Taken by AHRQ to Support Diffusion of
Patient Safety Practices and Products

Change Agency Action by Innovation Step	Actions Taken by AHRQ
Problem recognition and assessment <ul style="list-style-type: none"> • Sponsor research to identify problems • Seek end-user input in identifying problems • Sponsor basic and applied research on identified problems 	Funded extensive patient safety research. Input through Patient Safety Summits; less direct input into choice or execution of grants. Funded extensive research on new practices; increasing emphasis on applied work.
Development of usable innovations <ul style="list-style-type: none"> • Work with developers to ensure innovations have qualities that match users’ needs and preferences 	Information on new practices is beginning to emerge as projects publish their results.
Packaging of innovations <ul style="list-style-type: none"> • Recognize that lead users have innovations • Focus on higher priority innovations first • Package innovation to facilitate adoption • Prepare and test tailored messages for specific audiences (audience segmentation) • Develop incentives to encourage adoption 	No actions yet to identify, encourage, or coordinate with lead users. Culture survey and teamwork model were packaged as priorities; no other priorities set formally for products from funded projects. Culture survey and teamwork program were packaged. PIPS projects are developing tool kits. Mixed progress for other projects. Some messages sent to consumers on safe care; marketing of culture survey to hospitals. Quality Connect project gives states funding for quality improvement; no other actions.
Dissemination and diffusion of innovations <ul style="list-style-type: none"> • Ensure adequate resources for dissemination • Use mass media to create awareness of innovations • Identify appropriate opinion leaders • Pursue direct contact strategies to convince opinion leaders to adopt • Pursue strategies to promote diffusion from opinion leaders to their followers 	Resources allocated for Coordinating Center synthesis work; OCKT communications work. Activities on general safety issues and specific projects; formal priorities not defined. Coordinating Center working with its steering committee on project results, developing a strategy for dissemination to end users. Direct action – PSIC, Quality Connect project; also partner in SCIP, 100,000 Lives. HRO initiative began to diffuse effective practices, but no strategies have been drawn from patient safety projects.

The principles of research utilization used in Table 6.2 come from a dissemination model operated by the federal government—the Cooperative Extension Service of the U.S. Department of Agriculture (USDA), which translates research findings on new farming technology into practice by farmers across the country. A critical lesson from its experience is that any research program that has the goal of effecting changes in practices must establish *research utilization* as the foundation that guides its organization and action priorities. Several related factors influenced the success of the Cooperative Extension program, which are encompassed in the following two principles (Rogers, Eveland, and Bean, 1976): First, research is more likely to be utilized if it solves end users’ problems and addresses their needs. Second, the internal organization of the change agency should emphasize research utilization.

As the table illustrates, AHRQ has done extensive work in the problem recognition and assessment phase of change agency action through its choices of projects for funding. For the remaining phases—development and packaging of innovations and the dissemination and diffusion of those innovations—AHRQ’s activities have increased gradually as project results emerged. With a few exceptions, they tend to be focused on highlighting results of individual projects. A dissemination plan has been developed, and has been revised periodically as experience has dictated, especially time delays caused by the slow pace at which results and products have been generated by the funded patient safety projects.

PRODUCTS GENERATED FROM PATIENT SAFETY GRANTEES

In July 2006, we updated information presented in *Evaluation Reports I* through *III* on publications and reports generated by the patient safety grantees, and we added information for the 17 new PIPS grant projects funded in FY 2005. As in past years, we searched databases, PubMed, and the Coordinating Center Web site to identify relevant products. If a product was authored by a PI who led two projects or was the product of collaboration between two PIs on separate projects, we gave all possibly relevant projects “credit” for that product. Thus, the unit of analysis in this assessment is the “product-project” pair.

We merged any new products found with last year’s database of products produced between 1997 and June 2005. Across the total of 225 projects, 11 PIs had two funded projects each and four PIs had three funded projects. Thus, the 225 projects correspond to 206 unique PIs. We searched the library database, PubMed (which produced nearly all the yields in previous years’ searches), and the Coordinating Center Web site using the name of the PI. In some cases, we could identify products that pertained to the PI’s project, but which did not have the actual PI name linked to it.

Tables 6.3 and 6.4 present the results of this review. As Table 6.3 illustrates, we found a total of 1,846 documents (1,943 product-project pairs) related to patient safety, authored by AHRQ-funded patient safety grantees during the total time period covered, of which 437 (446 product-project pairs) were deemed to be related to the AHRQ projects. These project-related documents represent 23.7 percent of the total patient safety-related documents identified, increasing from 8.9 percent of the total in the last two years. For PIs of the AHRQ-funded health IT projects, we found a total of 142 documents related to health IT (164 product-project pairs), of which ten were from AHRQ-funded projects (Table 6.4).

Table 6.3
Number of Patient Safety Products Produced by AHRQ and HRSA-Funded Grantees, 1997–2006

Year	Patient Safety Project Related	Patient Safety Not Project Related	Patient Safety Not Clear if Related	Total
Year Unknown	7	0	4	11
1997	0	67	0	67
1998	0	84	3	87
1999	0	95	1	96
2000	0	130	8	138
2001	4	144	15	163
2002	41	124	67	232
2003	74	210	96	380
2004	123	140	36	299
2005	162	144	30	336
2006 (half year)	30	84	15	129
Under review	5	0	0	5
Total	446	1,222	275	1,943

Table 6.4
Number of Health IT Products Produced by AHRQ-Funded Grantees, 2002–2006

Year	Health IT Project Related	Health IT Not Project Related	Health IT Not Clear if Related	Total
2002	0	1	0	1
2003	0	0	0	0
2004	1	31	0	32
2005	8	66	25	99
2006 (half year)	2	21	10	32
Total	10	119	35	164

DISSEMINATION ACTIVITIES FOR GRANTEE PRODUCTS

The dissemination activities for the patient safety initiative are being carried out by an AHRQ team that cuts across the agency, including CQuIPS, OCKT, the Coordinating Center, and its steering committee. In the first years of this evaluation, we took an anticipatory approach to dissemination and adoption activities, offering suggestions for possible dissemination strategies. Then in the last two years, we shifted focus to more directly assess AHRQ’s dissemination actions in the context of the conceptual framework for its role as a change agency (Figure 6.1). Based on this framework, we determined that, with a well-defined dissemination strategy and action plan, AHRQ could focus its finite resources on the functions for which it is best suited, while supporting the activities of other organizations through its networks of partnerships. Specifically, from the change agent actions identified in Table 6.2, we extracted three basic steps that are necessary for successful dissemination of new knowledge and practices. We summarize here the current status of AHRQ’s activities for each of these steps.

Step 1: Synthesize the aggregate results of grantees' research and field tests across groups of projects addressing the same or similar issues to develop and update evidence for relevant safety practices.

Before promising practices can be determined to be evidence-based, a review and synthesis must be conducted of the full body of evidence on those practices, based on published papers and review of the integrity of the study designs. During 2005 and 2006, the Coordinating Center performed syntheses of results for each of the groups of patient safety projects funded in FY 2000 and FY 2001 using information collected through individual interviews with the project PIs. Data regarding outcome effects for specific practices and tools to support them have been entered into databases for future use by AHRQ and the Coordinating Center. Similar work is planned for the implementation challenge grants and PIPS grants.

Step 2: Develop packaged products and practice tool kits for practices identified as priorities for dissemination, to support end users in implementing proven practices.

In this discussion, we make a distinction between packaging products and commercializing products based on the results of AHRQ-funded patient safety projects. The work that AHRQ is doing is referred to as packaging products, in which generic products are developed to make it as easy as possible for health care providers to use and adapt them to their particular circumstances. Commercialized products, on the other hand, are developed by firms in the private market with the intent to market them for sale to health care providers.

AHRQ's product packaging activities increased during 2006, including support for products and tools from its funded patient safety projects as well as for products developed directly by AHRQ. Of the patient safety project groups, the PIPS projects are the strongest example of product orientation, with development of tools being part of their required scope of work. AHRQ staff have worked closely with both the PIPS grants and the challenge implementation grants to support packaging of products from their work. Other products developed directly by AHRQ include the patient safety culture surveys and the TeamSTEPS package for teamwork improvement.

Thus far, leaders in the health care community have not participated in the review of project results or development of products and tools. As the target audience for these products and tools, their feedback will be essential to ensure that the products are responsive to providers' needs and to encourage their use of them.

Step 3: Disseminate information about the synthesis of findings, products, and practice tool kits for the priority practices, using a strategy that combines work with opinion leaders, broad-scale communications through the media, and technical assistance to providers.

To accommodate the growing numbers of products from the AHRQ-funded projects, OCKT has a team dedicated to working on patient safety publications that communicate results to the general public and policymakers. These include program briefs on individual projects and communication of patient safety results in speeches, testimony, press releases, and other communications activities. The Coordinating Center contributes through its dissemination work with the patient safety grantees and its participation in work led by the OCKT, as well as its support for the annual patient safety conferences, which serve as important dissemination outlets. It also has been promoting work to complement OCKT's activities, such as local promotions on the news and other media to reinforce OCKT campaigns. In addition, publications and

presentations by AHRQ staff contribute directly to dissemination of information and elevating awareness.

The Web site AHRQ Patient Safety Net (AHRQ PSNet), introduced in FY 2005, is intended to be the national “go to” place for information on patient safety. This site has been a strong resource for the field, especially its WebM&M feature. However, despite its strengths, AHRQ PSNet has not yet incorporated content targeted to the variety of stakeholder groups (e.g., providers, researchers, consumers, credentialing bodies). Users often have to check multiple Web sites to find the information they seek, including several AHRQ Web sites (e.g., its main Web site, PSNet, QualityTools, and the Coordinating Center Web site) as well as Web sites of other organizations (Premier, IHI, Joint Commission, etc.). Therefore, AHRQ PSNet continues to be just one Web site among several that address patient safety, and AHRQ has the challenge of coordinating the posting of information among its various sites.

Technical assistance to the health care providers who are adopting newly proven patient safety practices is another important technique to support practice diffusion. It is not yet clear which technical assistance mechanism(s) might work best or who should provide them. In *Evaluation Report III*, we discussed the concept of a patient safety “extension service” similar to the successful Agriculture Extension Service. The QIOs have been suggested as the entities best positioned to take on this role, but such a change would require major modifications of their current scope of work and an infusion of substantial additional funding.

INTERVENTION EFFECTS FOR INITIAL PATIENT SAFETY PROJECTS

During 2006, we conducted follow-up telephone interviews with PIs for a subset of the 71 original patient safety grants funded by AHRQ in FY 2000 and FY 2001. We were specifically interested in their experiences with implementation of safe practices, so the projects targeted for the follow-up interviews were the 39 projects that tested at least one intervention to implement patient safety practices.⁴ We interviewed the leaders of these projects to obtain their retrospective assessments of the experiences and results of their practice intervention projects, at or near the completion of their work. Interviews were completed with 38 of the 39 grantees.

We present here the highlights of our findings from these interviews. We note that because these data are self-reported by the grantees, they may be positively biased, even with the best efforts of the PIs to provide objective information (which has been the case throughout our interviewing process). We gathered these data to provide early feedback for AHRQ on potential impacts of the funded projects. More objective data should become available in their published papers that present the more complete data and analyses of their results, or it could be obtained through separate data-collection processes. (If a lack of published papers is found for some projects, it may be interpreted as failures to achieve project goals or to obtain meaningful results.)

Overall assessment—Thirty-two percent (12/38) of the PIs interviewed stated that their projects completely achieved the goals and outcomes they had set for their interventions. Another 45 percent (17/38) said they had made substantial progress toward their goals, and the remainder said they had made some progress. The majority of projects that were deemed successful by their PIs had as their goal to implement actions that support use of safer practices, such as increasing

⁴ The information on interventions was obtained from the grantees in our initial interviews with them during the first year of the evaluation (Farley et al., 2005).

adherence to procedures, providing education to staff on safe practices, developing training tools for delivering safer care, and implementing technological tools for decreasing prescribing errors or facilitating error reporting.

Effects on patient outcomes—Some projects reported they achieved success in decreasing adverse events, but reductions were difficult to measure with certainty, often because of lack of measurable baseline data or unavailability of methodological tools for detecting improvements. Some projects were able to collect counts for events before and after implementation of the intervention, but they were unable to attribute changes to the intervention due to other factors that also might have influenced observed rates.

Successful intervention approaches—Regardless of their area of focus, projects deemed successful by the PIs tended to start out with dependable event reporting systems, involve a small number of implementation sites, have small-scale pilot designs, and focus on a limited set of outcomes related to achieving safer care. According to the PIs interviewed, interventions with multiple components met with mixed levels of success, in which some project components were deemed successful, while others were reported to have been less successful or even failures. A strategy identified as effective was to keep the scope of the project narrow initially, with later replication on a larger scale once promising interventions were identified and methods were refined.

Unintended or unexpected outcomes—Topics frequently mentioned included improvements in the quality and quantity of communication around safety issues; improvements in perspectives on patient safety and patient safety culture; increased emphasis on patient safety issues in the institutions more generally; learning gained through their experience of conducting the project; and knowledge diffusions extending past the intended audiences.

Perceptions of sustainability—Only 63 percent (24/38) the PIs interviewed thought that the improvements they achieved would be sustainable, and another 24 percent (9/38) thought they might be. The remaining 13 percent thought their improvements would not be sustained. The PIs felt that projects that were more likely to be sustained following implementation were those with goals of increasing knowledge and raising awareness about patient safety, integrating improvements (such as reporting) permanently into processes, or incorporating technology or information technology into the daily work flow. Other factors positively influencing sustainability included completing the implementation during the funding cycle, flexibility with respect to staff's competing obligations, and meeting existing stakeholder needs. Reasons cited for lack of sustainability included financial constraints (most frequently stated), limited leadership support, lack of staff buy-in; limited staff time, and limited commitments from staff with technical knowledge.

While these self-assessments offer useful insights into potential for sustainability and related influences, they are not objective evidence of sustainability. It would be useful to return to these grantees at least one year following project completion, to gather both interview and objective data on whether the improvements achieved at the end of the project still were in place.

FACTORS FOR SUCCESSFUL IMPLEMENTATION OF NEW PRACTICES

Because we found that our interviews with the various groups of patient safety grantees generated similar findings regarding issues related to implementing patient safety practices, we sought to establish a consistent set of factors that are well documented to be important for successful implementation. We reviewed and synthesized articles published in the health care

literature, organizing the analysis to identify factors that are part of a health care provider’s existing infrastructure as well as those that are components of the implementation process itself.

A total of 1,701 abstracts were identified and reviewed, from which a subset of 215 studies were found to report details on the factors that contributed to projects’ success. These included empirical studies, case studies, evaluations, review articles, and expert opinion papers. Presented in Table 6.5 are the sets of factors developed from our analysis of these articles as being important for successful implementation of new safety practices or products. We consider these to be “necessary but not sufficient” factors for successful implementation of safe practices; even with these factors completely in place, implementation could fail due to poor implementation techniques, insurmountable barriers, or otherwise unforeseen events.

Table 6.5
Key Factors for Successful Implementation of Safety Improvements
Identified from the Literature Review

Factor Category	Specific Factors
<i>Organizational Infrastructure</i>	
Patient safety culture	Blame-free culture Safety standards and guidelines Incentives and recognition for safety Data system for reporting
Corporate culture of excellence	(One factor)
Organizational leadership involvement	Support for the initiative Support for the team
Staff Training	(One factor)
<i>Implementation process</i>	
Project implementation team	Team Members Team Qualities and performance Stakeholders’ involvement in project plan
Financial support	(One factor)
Monitoring	Performance indicators Use of measures in monitoring Feedback to staff on performance

The data gathered on the success factors provided a structured set of measures that enabled us to compare the implementation status of the groups of grantees systematically. Reported in Table 6.6 are summaries of responses of three groups of grantees to questions addressing success factors within each of organizational infrastructure and implementation process categories. The groups are the 39 original grantees with intervention components (funded in FY 2000 and FY 2001), the challenge implementation grants, and the PIPS grants. We aggregated the index scores for the challenge and PIPS grants because separate analyses showed that they had similar scores on most of the factors, their scores tended to differ from those of the original grants, and the aggregated data provided a larger count of projects for measurement.

Using the success factor format, we could see clearly the differences between the original grants and the other two groups in their readiness to implement change, with the original grants

generally having lower scores for factors in the organizational infrastructure to support change and, to a lesser extent, the actual conduct of their intervention projects. The original grants were among the first projects undertaken in AHRQ’s patient safety initiative, and they had steeper learning curves with little previous experience by others to guide them. By the time the challenge and PIPS grants were started, patient safety had become a more visible priority and more was known about what was required to implement safe practices.

Table 6.6
Grantees’ Reports on Evidence-Informed Implementation Success Factors

Implementation Success Factor	Original Grants (n=38)	Challenge & PIPS Grants (n=21)
A. Organizational Infrastructure Scales		
	Percentage Reporting Score of 4 or 5 *	
1. Patient safety culture	9%	45%
2. Effective data system	46	42
3. Culture of excellence (quality improvement)	42	65
	Scale Average (scale maximum)	
4. Patient safety standards in place	2.1 (of 3)	2.7 (of 3)
5. Incentives for safety improvement efforts	1.3 (of 3)	1.9 (of 3)
B. Planning and Implementation Scales		
	Scale Average (scale maximum)	
1. Leadership involvement in the project	3.4 (of 10)	3.6 (of 10)
2. Resource support to project	2.3 (of 3)	2.9 (of 3)
3. Financial investment in project	1.3 (of 2)	1.5 (of 2)
4. Membership on project team	Percentage with Stakeholder on Team	
Senior management	66%	61%
Mid-level management	91	90
Physicians	89	90
Nurses	86	86
Patients	16	19
Community representatives	38	14
Information technology	71	71
Legal	44	19
	Percentage Reporting Score of 4 or 5 *	
5. Implementation Team Performance		
Defined a strategy and plan for the project	88%	95%
Persevered in implementing the project	97	100
Collaborated effectively across disciplines	91	100
Felt empowered by the organization’s leadership	81	95
6. Degree of end-user involvement	28	33
7. Monitoring of performance outcomes	70	95

* Using Likert response scale, with 1 representing “not at all” and 5 representing “a great deal.”

Organizational Infrastructure. Clear differences were found between the original grants and the other two grant groups, in particular for patient safety culture and culture of excellence. Only 9 percent of the original grants had average scores of 4 or 5 (on a 5-point scale) for patient safety culture, compared to 45 percent for the other grants. Similarly, 42 percent of the original grants and 65 percent of the other grants had scores of 4 or 5 for culture of excellence. Similar differences were found for patient safety standards and incentives to encourage safety improvement efforts.

Implementation Process. Fewer differences were found between the original grants and the other two groups for factors related to the implementation process. For example, they had similar leadership involvement in their projects (3.4 points versus 3.6 points (of 10 total) for original grants and the others, respectively), and they had similar scores for financial investments in the projects. They differed regarding the resources available to support the projects, with 2.3 points (of total of 3) for the original grants and 2.9 points for the other two groups.

The projects also had similar team memberships. For all three groups, the stakeholders most likely to be on the project team were mid-level management, physicians, and nurses. The least likely to be on the team were patients and community representative, although some of the projects did involve these stakeholders.

The grantees in all three groups reported successful team performances for developing a project plan, persevering in implementation, and cross-discipline collaboration. They differed in the extent to which they felt empowered by the organization's leadership, with 81 percent of the original grants and 95 percent of the other two groups having scores of 4 or 5 on this factor. Similar differences were found for monitoring of performance outcomes, with the original grants having lower scores than the other groups. Both groups had low scores for the degree of end-user involvement in the project.

OTHER INITIATIVES FOR PATIENT SAFETY IMPROVEMENTS

The momentum of patient safety improvement activities in the field accelerated in 2005 and 2006. Below we provide updates on three national-level initiatives being led by field-based organizations working with providers to implement proven patient safety practices. They offer excellent examples of how AHRQ has leveraged its role as a partnering organization to support patient safety improvement activities by others.

Surgical Care Improvement Project (SCIP)

SCIP was initiated as a demonstration project in 2003 by CMS and CDC. A multiyear national campaign involving more than 20 public and private participants, SCIP was launched in 2005 with the goal of reducing the national incidence of surgical complications by 25 percent by the year 2010. QIOs in each state were responsible for leading the campaign, disseminating the practice improvements, and providing technical support to the hundreds of hospitals participating. For the next phase, preparations were under way to engage consumers through communications about safety in surgery.

The number of SCIP outcome measures increased after the start of the demonstration. As of September 2006, the measures included two global outcome measures, seven infection process measures, four venous thromboembolism measures, two cardiac event measures, and one end-stage renal disease measure. Estimates of the effects the SCIP initiative on these outcome measures had not yet been published. CMS was reinforcing this work by expanding the use of

SCIP measures in the publicly reported quality measures for Medicare beneficiaries. CMS also planned to require hospitals to report on additional SCIP measures beginning in FY 2008.

The 100,000 Lives Campaign

The 100,000 Lives (now the 5 Million Lives) Campaign, led by the Institute for Healthcare Improvement (IHI) and involving more than 3,000 participating hospitals, was implementing six patient safety improvement interventions and measuring relevant outcomes. The six interventions were rapid response teams, evidence-based care for acute myocardial infarctions, medication reconciliation, five strategies for preventing central line infections, four strategies for preventing surgical site infections, and four strategies for preventing ventilator-associated pneumonia (IHI, 2006).

Based on mortality statistics reported monthly by hospitals, IHI estimated that the campaign contributed to preventing 122,342 deaths during hospitalization in the 18 months ending June 14, 2006. Acknowledging that other improvements or factors could be influencing mortality rates, IHI planned to examine trends in nonparticipating hospitals, to better understand the causal relationship between the interventions and the outcomes. Campaign leaders reported a number of contributing factors to their success: establishing bold aims; the voluntary nature of participation; maintaining a positive tone; being inclusive of everyone; setting a deadline; emphasizing the human side of the story; and employing a field infrastructure that emphasizes implementation (McCannon, 2006).

Medicare Initiative on Transformation of Hospital Cultures

The Medicare QIO Program includes a network of 53 QIOs that are supporting health care providers in reporting quality measure data to Medicare and using the data to target improvements in care processes in the provider organizations. One priority area for improvement for the period of August 2005 to July 2008 is to transform providers' organizational culture to support improvement efforts (CMS, 2006). Six hospital strategies for organizational culture change have been identified: executive leadership, board leadership, spread of improvements throughout organizations to maximize impact, education of staff on providing quality care, establishment of a culture based on quality, and empowerment of patients to manage their health. Information regarding the effects of culture change activities on hospital quality or safety outcome measures have not yet been published.

ISSUES AND ACTION OPPORTUNITIES

During 2005 and 2006, AHRQ's dissemination activities accelerated in step with the results emerging from the patient safety projects funded from FY 2000 through FY 2004. Based on the results of the FY 2000–2001 projects, the Coordinating Center has identified numerous practices for which product packaging and dissemination work can bring meaningful resources to health care providers. AHRQ itself generated toolkits to help health care organizations improve their patient safety cultures and teamwork effectiveness. The same techniques used to package and disseminate these tools were being applied to other products emerging from the patient safety projects. As the activities of other national initiatives for implementation of safe practices continue to expand the use of safe practices and providers increasingly recognize their value, AHRQ likely will experience increased pressure from the field for additional evidence on safe practices and tools to help implement them.

Issues to Consider

We have identified several areas in which AHRQ has opportunities to strengthen its dissemination activities. First, information from the Coordinating Center's synthesis reports should be used to identify candidate practices for which to conduct full evidence assessments and develop products. Second, health care leaders should be engaged actively in practice assessment and the information and tool development process to ensure that work is focusing on practices that will be of value to them, to enhance the viability of the products developed and to accelerate diffusion of practices. Third, increasing emphasis should be placed on communicating information about practices shown to be effective based on collective work by multiple projects. It will be important to maintain a balance between messages about results from individual, high-visibility projects and practices shown to be effective based on collective work by multiple projects. For sustainability, the proven safe practices will be the more important to communicate to end users. Finally, mechanisms should be strengthened for facilitating access to patient safety information for all users, as well as for ongoing technical assistance to reinforce practice sustainability.

Suggestions for AHRQ Action

- **Set priorities for specific patient safety practices to be addressed in practice dissemination activities, and collaborate with partnering organizations to ensure that end users obtain information and tools in a timely manner to support their adoption of safe practices.**

As AHRQ continues to package results from the patient safety projects for health care providers to use, it will remain challenging to identify the most important practices to address. At the same time, demand for information and tools has increased as health care providers have become more acutely aware of safety issues. Through active partnering with others, AHRQ can expand the amount of information and products available to the provider community, thus ultimately enhancing improvements in patient safety outcomes.

- **Engage health care providers actively in every phase of its processes for synthesizing research findings on practice effectiveness and subsequent product and tool development in order to ensure their value and usability.**

Health care providers have not yet been involved in the product development and dissemination process for the newly proven patient safety practices. Through the involvement of these end users, the resulting products will be more credible and the likelihood of practice adoption will increase. A variety of methods can be used to ensure that providers' needs and preferences are known and reflected in the products being developed for their use. These include basic market research methods, such as focus groups or usability testing, as well as including providers as active participants on committees responsible for product development.

- **Conduct a focused communication strategy to encourage hospitals to implement the 30 safe practices established by the National Quality Foundation.**

The safe practices endorsed by the NQF in 2006 are the result of analysis of the most recently available results of studies of their effectiveness, for which results of the AHRQ-funded studies were important sources. These practices are both evidence-based and the product of the NQF consensus process, which identified them as priority practices that should be in place in health care organizations. AHRQ can help reinforce the diffusion of these practices across providers by undertaking a proactive campaign to increase their visibility and create mechanisms

that encourage providers to implement them and sustain their use. By pursuing this strategy collaboratively with others in its partnership networks, AHRQ has the potential to achieve synergy and leverage its resources while stimulating adoption of important safe practices.

- **Establish an integrated clearinghouse on patient safety, including linkages to information provided by other organizations, that is the “go to” place for users nationwide.**

Positioning AHRQ visibly as a key national resource takes full advantage of the existing strengths of AHRQ’s research base as well as the OCKT, which has years of experience communicating with diverse stakeholders and gathering information from them on their needs and preferences. The AHRQ PSNet Web site was established as the “go to” place for patient safety information, but it still is only one of several Web sites that users must visit to find the information they need. By establishing one clearly visible entry point, together with a highly navigable Web site, AHRQ can increase ease of access to patient safety information for users. Ideally, the Web site should have clearly designated areas where each key stakeholder group can access the information most important to it.

- **Develop mechanisms to support health care providers as they continue to adopt newly proven patient safety practices to ensure their sustainability.**

Many quality improvement initiatives fail to be sustainable because new practices are not reinforced consistently. One of the most important contributors to sustainability is providers’ perceptions of value derived from using the new practices through increased efficiencies, better quality, or other benefits. An ongoing technical assistance support mechanism can enhance sustainability by improving providers’ ability to implement the practices effectively and track performance on the outcomes affected by the practices.

CHAPTER 7. PRODUCT EVALUATION OF EFFECTS

OVERVIEW

A key component of this evaluation is the identification and tracking of measures in preparation for assessing the effects of the AHRQ patient safety initiative, while simultaneously informing the development and refinement of new measures and related data capabilities. Our overall approach has been to characterize baseline trends in selected patient safety outcomes for use in assessing improvements of those outcomes as subsequent data become available.

Although AHRQ first funded patient safety projects in FY 2000 and FY 2001, we did not expect the results of these projects, and of other related activity by AHRQ and its collaborators, to have observable nationwide effects until at least three years later, and perhaps longer. Therefore, we defined the *baseline period* to be the late 1990s through 2003.

Given the time limits of the evaluation, our focus for the product evaluation has been to do the diagnostic work required to develop effective methods that can be used to estimate effects of the patient safety initiative when sufficient time has elapsed for effects to begin to be observable. Thus, we have explored a number of currently available sources of outcome measures, including measures of processes and outcomes, and we have estimated baseline national trends for selected patient outcome measures.

Among other issues, the ability to measure trends using encounter data is subject to delays due to time lags in data availability. For example, the Healthcare Cost and Utilization Project (HCUP) data we used for many of our analyses has a one-year lag, so the most recent HCUP data we could use for this report was for 2005. Not until 2008 will we begin to have enough years of data to attempt to detect early effects of patient safety activities by examining post-baseline trends in the patient-outcome measures.

We began preparation for the product evaluation in the second year of the patient safety evaluation. At that time, we developed a framework for the impact assessment, inventoried existing data sources that might be used, and began to identify issues requiring attention to ensure the effectiveness of the impact assessment. The results were presented in *Evaluation Report II*. Results from the first round of diagnostic assessments are contained in *Evaluation Report III*, including baseline trends for a number of candidate patient outcome measures through 2004. This early work led to additional diagnostic and development work performed in the most recent evaluation year. In addition, we updated the baseline trends by adding another year of data and adjusting for changes in several of the measures.

In this chapter, we first review the framework that has guided this component of the evaluation. We then discuss results of interviews with leaders of AHRQ-funded patient safety intervention projects, in which they report their perceptions of the effects their interventions had on various stakeholders. Although this subjective information is vulnerable to positive bias, the patterns they reported offer insights into the dynamics of safety improvement changes. Trends also are presented on the number of states with patient safety reporting systems, with discussion of the usability of their data to assess national-level outcomes. We then provide a summary update of the baseline trends in patient safety outcomes that were presented in *Evaluation Report III*, and we discuss some important methodological issues regarding underlying definitions and coding practices. Finally, we discuss an exploratory analysis that examined the feasibility of

examining relationships between AHRQ’s patient safety investments and changes in patient outcomes, highlighting the many issues that would challenge such an effort.

FRAMEWORK FOR THE PRODUCT EVALUATION

The model in Figure 7.1 guided our strategy for identification and analysis of outcome measures. 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 (two of the system components in Figure 1.1), which in turn should improve outcomes for patients. Both infrastructure development and practice adoption also affect other stakeholders involved in the initiative, including providers (both practitioners and organizations), states, other organizations addressing patient safety, and the federal government.

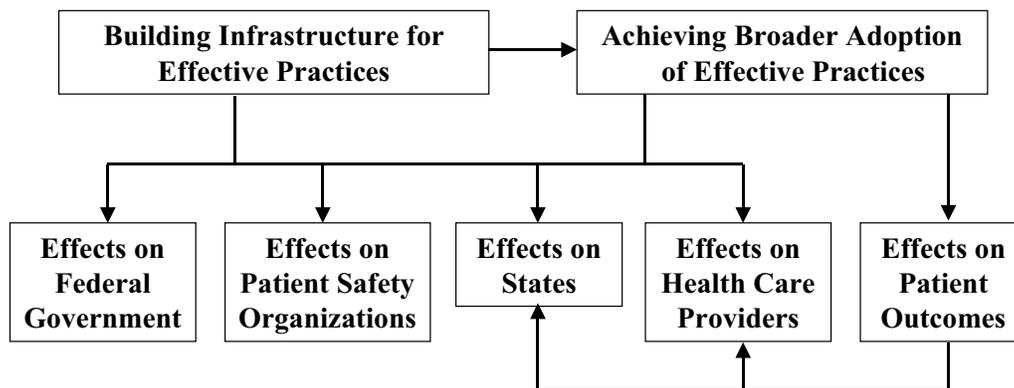


Figure 7.1 Conceptual Model of Potential Effects of the National Patient Safety Initiative

To be useful for evaluating effects of the patient safety initiative on infrastructure, practices, and various stakeholders, measures should meet the following criteria:

- Contribute to encompassing 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 on a regional or national basis.
- Be measurable 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.

To date, the focus of the product evaluation has been on exploration of baseline trends and measurement issues for patient outcome measures. For continued evaluation work in FY 2007 and FY 2008, the focus expanded to include tracking of process measures, along with continued trending of patient outcome measures, as we attempted to document progress in changing patient safety practices and outcomes in the U.S. health care system. Table 7.1 presents several potential sources of measures for addressing progress in infrastructure development and use of patient safety practices. As of September 2006, data have become available for some—but not all—of these measures.

Table 7.1
Potential Measures of Infrastructure Development and
Use of Patient Safety Practices for the Product Evaluation

Types of Measure	Potential Data Source	Availability
<i>Development of Infrastructure</i>		
Organizational collaboration on patient safety issues and strategies	RAND network analysis	Yes (data for 2004 and 2006)
Adoption of state-based reporting systems using IOM standards	State-based patient safety reporting systems	Yes (Beckett et al., 2006)
Use of NQF patient safety events in state reporting systems	State-based patient safety reporting systems	Yes (Beckett et al., 2006)
Adoption of adverse-event reporting systems by hospitals	RAND survey on Hospital-Based Adverse Event Reporting	Yes (baseline data for 2005)
Effective practices for which tools are developed for implementation	TBD	Not yet
Improved patient safety culture in hospitals	TBD	Not yet
Legal protections for reporting	Review of state laws; PSO legislation	Not yet
<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 Joint Commission patient safety practices by hospitals.	Joint Commission surveys of patient safety practices	Yes
Survey data on a variety of safe medication practice issues	Not available for multiple years	No
Use of risk assessment methods	TBD: hospitals, ambulatory care, long-term care sources	Not yet
Completed teamwork training	TBD: hospitals	Not yet (AHRQ now introducing TeamSTEPPs)
Patient safety taught in residencies	TBD: hospitals, residencies	Not yet

Note: TBD = to be determined as measurement capability develops.

EXPLORING EFFECTS ON STAKEHOLDERS AND PRACTICES

In this section, we consider some effects for stakeholders that have been identified thus far, other than the patient outcomes. We focus specifically on effects on various health care stakeholders reported in interviews by a subset of the original patient safety grantees (funded in FY 2000 and FY 2001) that carried out safe practice interventions. While these subjective estimates are vulnerable to positive bias (overestimating positive effects), they offer preliminary information on the dynamics of the implementation process. More-objective sources of this information would be surveys or focus groups with the stakeholder groups involved, which is a standard element of process evaluation for case study designs. Such work was beyond the scope of this evaluation but would be advisable to pursue in the context of a full assessment of impacts of the patient safety initiative on affected stakeholders.

As described in Chapter 6, we interviewed the leaders of 38 of the 39 patient safety grants that performed safe practice interventions as part of their projects. We identified a list of stakeholder groups and asked them to identify which of the stakeholders had been affected by the intervention they implemented, and the direction and severity of effect (negative or positive). As shown in Table 7.2, the project leaders reported that their interventions had affected a wide variety of stakeholder groups, ranging from physicians and other clinical staff to the community served by the organizations in which the interventions were carried out. Virtually all of the effects on stakeholder groups were reported to be either mixed or positive (Table 7.3). Higher percentages of mixed effects were reported for health care personnel and partnering organizations, suggesting that they experienced both positive and negative effects as they had to change their practices and interactions in response to whatever new safety standards, practices, or technologies were being introduced.

Table 7.2
Percentage of Grantees that Reported Their Intervention
Affected Various Stakeholder Groups

	Projects Having Effects (N=38)	
	Number	Percentage
Physicians	37	97.4
Nurses and other clinical staff	36	94.7
Patients receiving the health care	34	89.5
Overall health care organization	33	86.8
Other staff members	25	65.8
Any partnering organizations	21	55.3
The community served by the organization	20	52.6

Table 7.3
Strength of Effects on Stakeholder Groups for Patient Safety Intervention Projects

	Percentage Distribution of Responses				
	Very Negative	Somewhat Negative	Mixed	Somewhat Positive	Very Positive
Physicians	0	0	13.5	37.8	48.6
Nurses and other clinical staff	2.8	0	16.7	36.1	44.4
Patients receiving the health care	0	0	5.9	50.0	44.1
Overall health care organization	0	0	12.1	39.4	48.5
Other staff members	0	0	28.0	28.0	44.0
Any partnering organizations	0	0	28.6	19.0	52.4
The community served by the organization	0	0	10.0	40.0	50.0

Note: For each stakeholder group, the denominator used to calculate percentages was the number of projects for which grantees reported effects on that group, as reported in Table 7.2.

OUTCOME MEASURES FROM STATE REPORTING SYSTEMS

State-level adverse-event reporting systems provide a potentially important resource for tracking trends in patient safety outcomes, although their effectiveness has been limited by the lack of a common event taxonomy, inconsistent compliance by medical providers and facilities with reporting requirements, and limited feedback mechanisms with regard to reported data.

The operation of state-based reporting systems involves many administrative dimensions, and differences across states can make the data captured by them non-comparable and, therefore, difficult to integrate. According to a 2006 RAND study that covered the 24 state reporting systems in place at that time, some of the important administrative dimensions included (1) whether the reporting systems were mandatory or voluntary; (2) whether the states aggregated their report information in an electronic database format; and (3) whether states had formal data dictionaries or code books to standardize the way that report information is collected (Beckett et al., 2006). The same study found that, for each data element that IOM recommended be incorporated into event reporting systems, a wide array of informatics standards existed that states potentially could apply. The IOM also made recommendations regarding which informatics standards should be used. However, as of 2005, none of these standards had been widely adopted by the state systems, with the exception of several states that made use of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnostic and procedure codes (Beckett et al., 2006). State reporting systems were also far removed from using a shared set of definitions for adverse outcomes (Beckett et al., 2006; Marchev et al., 2003), and therefore, the data coming from these systems do not easily lend themselves to aggregation at the national level.

Despite the current variation in standards among state-level reporting systems, several recent developments have the potential to contribute to greater standardization of adverse event data in the future, and to increase opportunities for analysis of patient safety outcomes both within and across states. First, the Patient Safety Event Taxonomy, developed by the Joint Commission and endorsed by the NQF, establishes the first standardized classification system for medical errors and adverse events in the U.S. (Chang et al., 2005). The system provides a mechanism to begin standardizing information from disparate reporting systems, and thereby to give policymakers a more comprehensive view of patient safety issues and trends. Second, with the passage of the PSQIA in 2005, an important opportunity exists for promoting common standards in adverse-event reporting and better measurement of patient safety outcomes. Third, many of the participants in PSIC are working to refine their existing state-level reporting systems or to create such systems where they do not currently exist.

As more states implement new reporting systems and publish annual summaries of their reporting data, that data will become increasingly useful to efforts to track patient safety outcomes throughout the country. In particular, more work is needed to capture and combine outcomes data across multiple state systems and to tie differences in observed outcomes to careful specification of the characteristics of the underlying state reporting systems.

Regarding trends in implementation of state adverse-event reporting systems, Figure 7.2 reveals two major phases of system development. As of 2005, a total of 24 states had reporting systems. In the first phase (through 1999), 12 states established reporting systems over a period of more than 20 years. Most recently (2000 through 2005), the number of state reporting systems doubled. In addition, all of the reporting systems implemented since 2000 are reported to have a patient safety orientation, in comparison to only half of the systems established earlier (Beckett et al., 2006). The start of this recent phase coincides with the publication of the IOM report *To Err Is Human* (2000). Although the systems still vary widely in their contents, definitions, and technical standards, they are starting to become more similar in their specifications (Beckett et al., 2006).

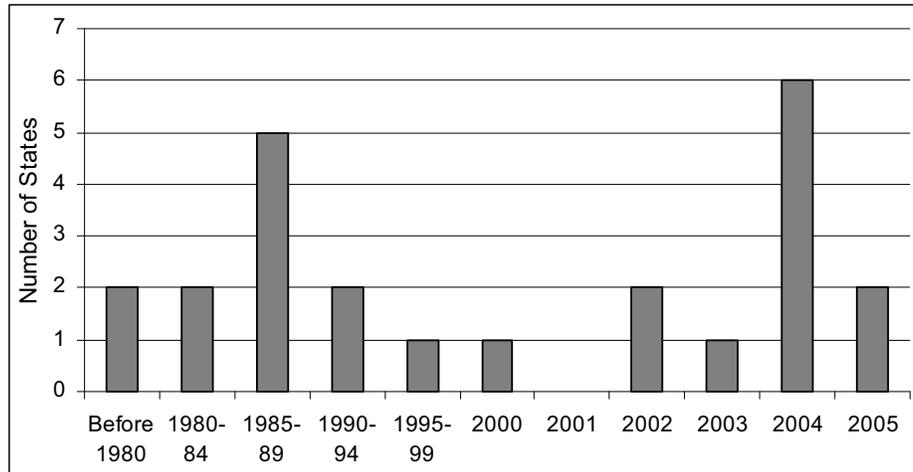


Figure 7.2 History of the Establishment of Existing State Reporting Systems

BASELINE OUTCOME TRENDS FROM EXISTING REPORTING SOURCES

To the extent that data on patient outcomes and effects on other stakeholders are currently available, valid, and usable, we have endeavored to establish methods and baseline data for measuring changes in those outcomes. Our primary focus in this chapter has been on outcomes in hospital-based care, for the simple reason that most patient safety work to date has focused on this setting, and consequently outcomes data are more readily available concerning safety in hospitals. We also present updated outcomes trends for several patient safety measures in long-term care.

During 2006, we built upon previous work to begin to identify the most important patient safety measures, conducting a modified Delphi consensus process with expert participants. As part of this process, initial steps were taken toward identifying important measures for the hospital inpatient, ambulatory care, and long-term care settings. (Refer to Chapter 3 for description of the Delphi process and its results.) In *Evaluation Report III*, we summarized the available literature on patient safety measures in ambulatory care, and described the ongoing activities of a number of organizations to promote patient safety in ambulatory settings. Future trending of patient safety outcomes in all of the key health care settings will depend on this kind of measures development work, and on building the necessary infrastructure to capture data for the new measures.

Patient Safety Outcomes in the National Health Quality Report (NHQR)

In 2003, AHRQ began annual publication of the NHQR, a resource that provides trend information on outcome measures for multiple aspects of U.S. health care quality, including patient safety. The NHQR provides summary statistics based on several data resources and measure sets. The 2005 NHQR is focused on six safety measures, a reduction from the number reported in 2004. The measures in the 2005 report are postoperative venous thromboembolic events, postoperative hip fractures, adverse events associated with central venous catheters, iatrogenic pneumothorax, hospital-acquired bloodstream infections, and inappropriate use of medications by the elderly.

Because the NHQR is publicly available through AHRQ (and can be obtained via the Internet), we do not present data here for the patient safety measures included in the 2005 report. We note, however, that the report does not list the full set of patient safety outcomes from which the six core measures were drawn, nor does it describe why these measures were selected as a focus. To be more helpful, future annual NHQRs should explain which patient safety measures are included in the print version (versus online), and should provide more technical background on the sampling, data, and methodological issues to better inform the interpretation of trends in patient safety outcomes.

MDS Measures for Nursing Home Care

CMS requires all nursing home facilities certified by Medicare or by Medicaid to report health-related data on their residents using the minimum data set (MDS) form and data elements. CMS uses that data to generate quarterly reports summarizing trends in MDS measures nationally and by state, which are published on the CMS Web site. In Figure 7.3, trends in resident falls and pressure ulcers are presented, updated with new MDS data for the quarters ending July 2004 through March 2005. These trends underscore that falls and pressure ulcers affect a very significant number of nursing home residents each year, and that no changes in the frequency of these events have been detected yet by the MDS tracking mechanism.

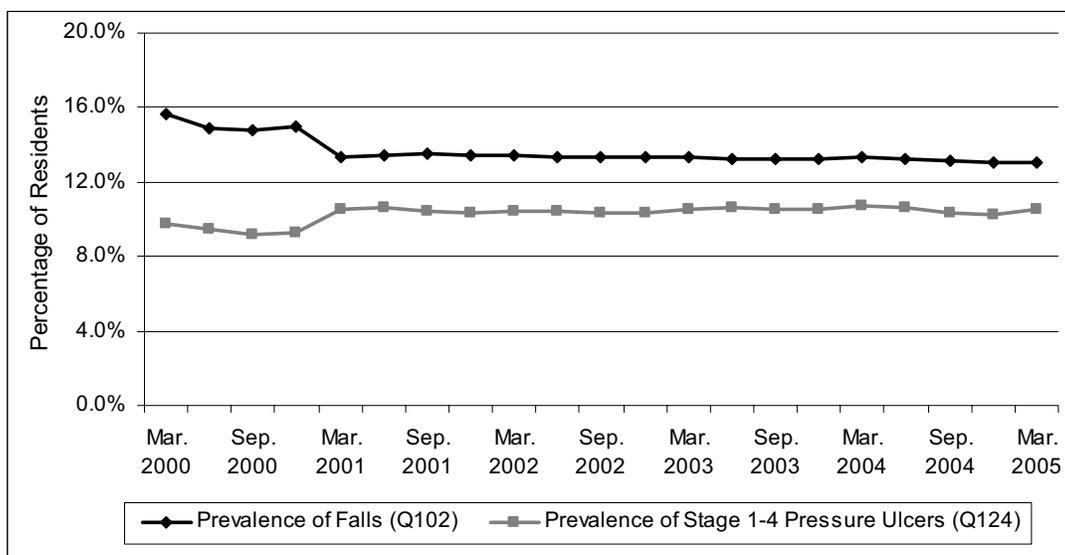


Figure 7.3 National Rates of Falls and Pressure Ulcers Among Nursing Home Residents, MDS Data, 2000-2005

Although the MDS offers some useful patient safety data for nursing home settings, as well as a unique infrastructure for collecting that data, only a limited number of patient safety measures are available that specifically cover long-term care settings. Consequently, there is a need to expand the capability for patient safety measurement in these settings. We note that the NQF endorsed a set of Nursing Home Quality Measures in 2003 that were specified using data available from the MDS dataset. About six or seven of the measures address patient safety outcomes, including measures of pressure ulcer prevalence, uncontrolled pain, and inappropriate weight loss. These additional MDS-based measures might also be used to track outcomes trends.

Joint Commission Sentinel Events

The Joint Commission has a long-established policy for the facilities it accredits regarding reporting of serious adverse events, or sentinel events. It has issued a related set of sentinel event guidelines, which individual facilities are expected to use to develop their own definitions for sentinel events and to establish local mechanisms for identifying and managing them. The Joint Commission collects information on reported sentinel events and publishes annual summary statistics on occurrences. It also tracks and reports root cause analysis findings for the sentinel events it reviews, which has been useful in helping to identify the relative importance of contributing factors for specific categories of sentinel events.

We examined the background and trends for sentinel events because they are well-known, national-level measures. Due to incomplete reporting, however, incidence statistics for the Joint Commission's sentinel events are known to be underestimates of actual rates of serious adverse events. This limitation is experienced by any system for external reporting, including the state reporting systems discussed above. In addition, because health care facilities establish their own definitions for sentinel events, there is likely to be some inconsistency in how events are classified. Given these limitations, care must be taken in how—or if—data on sentinel events can be used for tracking national trends for the most serious reported adverse events.

The frequency of reported sentinel events has generally risen over the decade that the Commission's sentinel event policy has been in effect. The reasons for the increases in reported events are not known. The Joint Commission recorded 582 total sentinel events in 2005, a modest increase from the 561 events reported in the preceding year. The Commission also publishes a more detailed breakdown of sentinel events data by type of event. Figure 7.4 shows differing trends in the occurrence of the four most frequent categories of sentinel events, collectively comprising about 50 percent of all events reported.

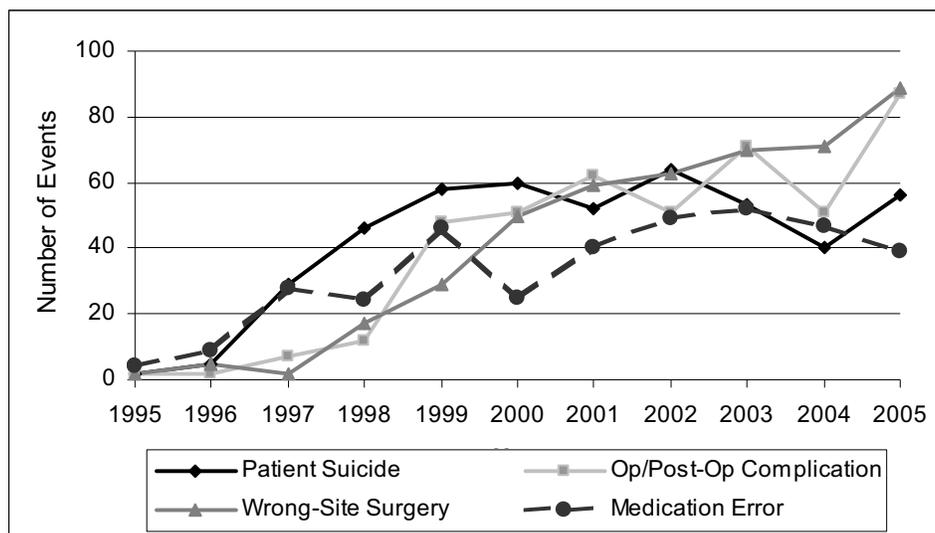


Figure 7.4 Number of Sentinel Events Reported to the Joint Commission, for Top Four Types of Events, 1995-2005

The MedMARx Reporting System for Medication Errors

MedMARx is a voluntary reporting system for adverse medication events, which is operated by the United States Pharmacopeia (USP). It is a subscription-based system in which health care facilities pay a membership fee for the reporting software and for trend analysis of their own reported data. The participating facilities are not a representative sample of U.S. health care institutions. The MedMARx reporting system originally became available in August 1998.

Medication events captured by MedMARx are classified based on the Index for Categorizing Medication Errors, a taxonomy developed by the National Coordinating Council for Medication Error Reporting and Prevention. The USP publishes annual reports with descriptive statistics on the aggregated MedMARx data. MedMARx stresses that the non-harm events provide important information for establishing patterns of medication errors in a medical facility, and for targeting interventions to prevent them.

We examined the MedMARx medication event reporting data because, like the Joint Commission sentinel events, they are well-known, national-level measures. However, they suffer from the same limitations experienced by all reporting systems, including underreporting issues and the absence of a representative sample of reporting organizations. Again, care must be taken in how—or if—MedMARx data on medication events can be used for tracking national trends for the most serious reported adverse events.

Figure 7.5 shows trends in the aggregate number of medication errors and potential errors captured by the MedMARx system from 1999 through 2004. This growth reflects a combination of growth in both the number of reporting facilities and the number of events reported per facility. The number of participating facilities increased from 56 in 1999 to 570 in 2003. The average number of events reported per facility grew from more than 100 events per facility in 1999 to more than 400 events per facility in 2003. The greatest rate of growth has been for errors not involving patient harm.

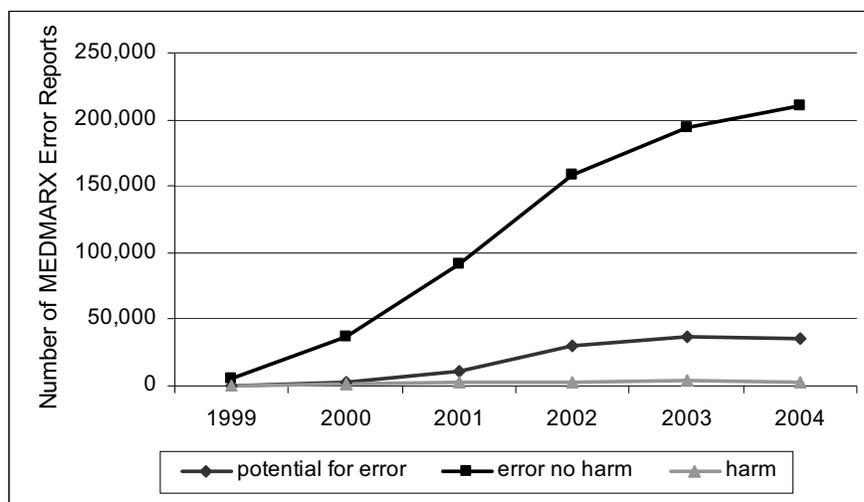


Figure 7.5 Frequency of Medication Events Reported to MedMARx by Type of Event

BASELINE TRENDS IN ENCOUNTER-BASED OUTCOME MEASURES

Below we update the analysis of outcome trends presented in *Evaluation Report III* for selected measures from AHRQ’s patient safety indicators (PSIs) and the Utah-Missouri (UT-MO) measure set by adding the newest year of claims data (2003) available through the Healthcare Cost and Utilization Project (HCUP) National Inpatient Sample (NIS) database. Table 7.4 lists the 13 specific measures for which we analyzed and updated national trends.

Table 7.4
Selected Patient Safety Outcome Measures Used in the Baseline Analysis

PSI Measures	UT-MO Measures
Postoperative Hemorrhage or Hematoma	Accidental Cut during Procedure
Death in Low-Mortality Diagnosis-Related Groups (DRGs)	Other Misadventures of Surgical and Medical Care
Postoperative Hip Fracture (NS)	Respiratory Arrest
Postoperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT)	Poisonings by Medication
Failure to Rescue	Complications Affecting Specific Body Systems
	Other Complications of Procedures
	Alternations in Mental Status
	Accidental Falls

Trends for Selected PSI Measures

In updating the PSI outcome trends for the current report, we added a new data point for calendar year 2003 to rates for each PSI measure. We also calculated the PSI measures both with the official coding algorithms used last year (the “Old Code” of 2004), as well as with the current version of the PSI coding algorithms (the “New Code,” revised in 2006). Note that AHRQ typically revises its PSI definitions and algorithms each year, in part to incorporate annual updates to the ICD-9-CM diagnostic codes and DRG codes (which define key data elements used in calculating PSI rates). Figures 7.6 and 7.7 show the updated trends in outcomes, with separate trend lines for each PSI based on either the old or new PSI coding algorithms.

For several of the PSI measures, the most recent year of HCUP data extends the existing trends from earlier years. Adjusted PSI rates for “postoperative hip fracture” and “postoperative PE or DVT” remained stable in 2003, while the rate for “failure to rescue” continued in its downward trend. Meanwhile, the rate of “postoperative hemorrhage or hematoma” appeared to be leveling out in 2003, following a five-year period of gradual decline.

The PSI measure for which significant change occurred in 2003 was “death in low mortality DRGs.” Using the “New Code” version of the measure, the rate remained stable in 2002 and 2003, but the rate spiked sharply upwards during those two years for the “Old Code” version of the measure. This spike was due in large part to changes in observed frequencies for the ICD-9-CM codes and DRGs used to calculate rates for the measure. This example points out clearly, however, that annual methodological changes have the potential to cancel out or otherwise skew trends over time, which could lead to incorrect interpretation of actual trends.

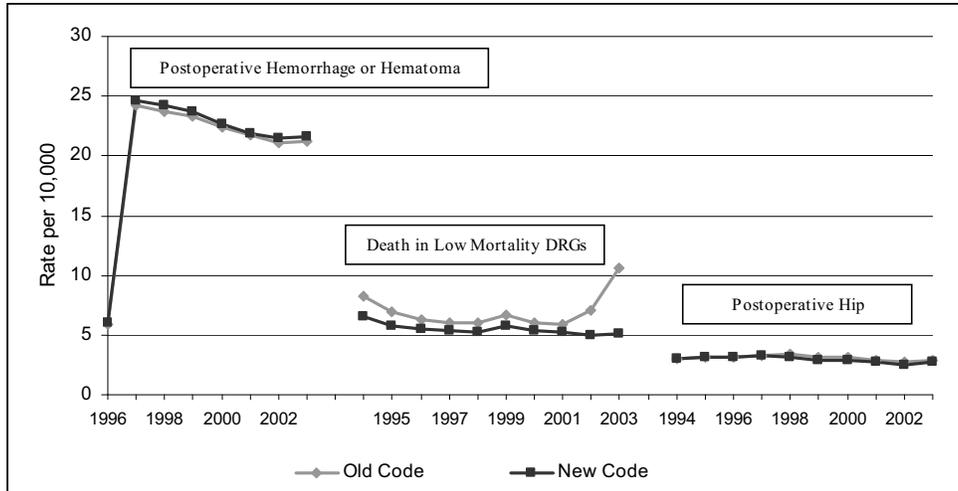


Figure 7.6 Trends for Selected PSI Measures, 1994–2003 (1)

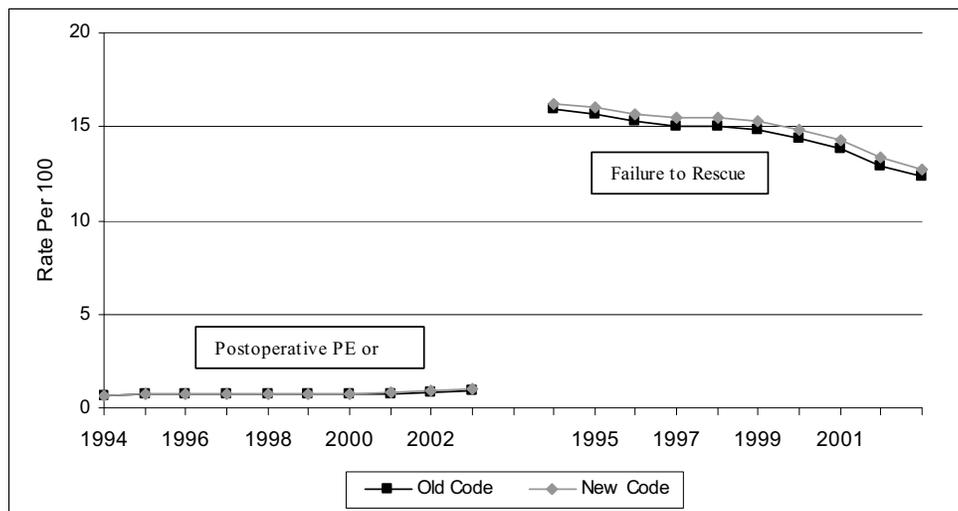


Figure 7.7 Trends for Selected PSI Measures, 1994–2003 (2)

Trends for Selected Utah-Missouri Measures

We also have updated outcome trends for the UT-MO measures by adding data for calendar year 2003 to the trend lines. In 2003, AHRQ modified the structure of the HCUP NIS by changing the way the ICD-9 E-codes (which denote external causes of injury) are incorporated in the dataset. These codes are used for computing rates for several UT-MO measures. Because the new HCUP NIS format is ambiguous regarding the primary versus secondary status of E-codes, we calculated two separate 2003 rates for each of the UT-MO measures (i.e., an upper-bound estimate and a lower-bound estimate). Figures 7.8 and 7.9 show the updated trends for the UT-MO measures, with upper-bound estimates for 2003 marked by triangles, and lower-bound estimates marked by diamonds.

For five of the eight UT-MO measures, the upper- and lower-bound estimates for 2003 are very similar, and appear to represent continuations of previous trends over time. For three of the UT-MO measures, however (accidental falls, accidental cuts, and poisonings by medication),

the upper- and lower-bound estimates are quite different. This analysis again demonstrates the vulnerability of claims-based measures to changes in the way that underlying data is structured and aggregated over time.

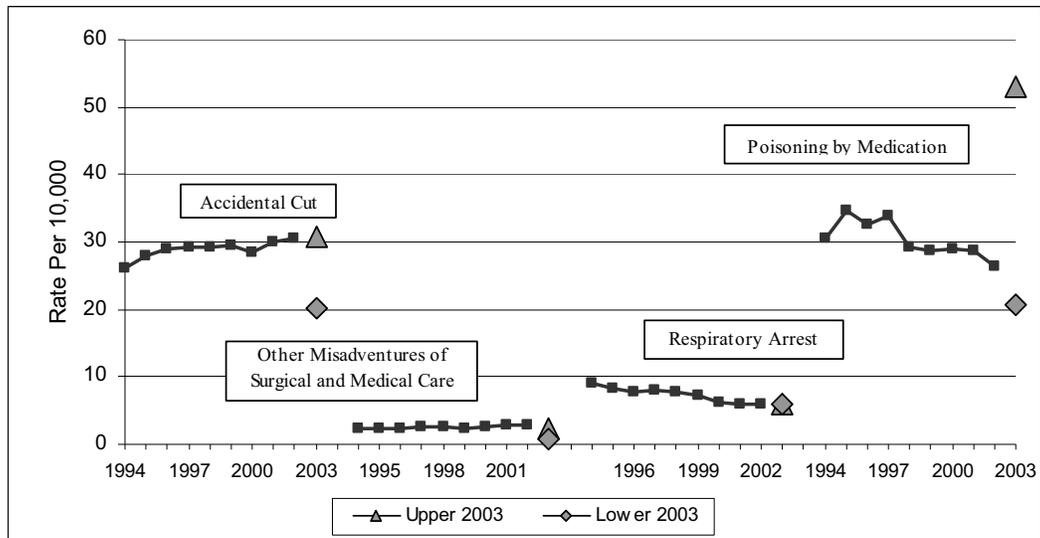


Figure 7.8 Trends for Selected UT-MO Measures, 1994–2003 (1)

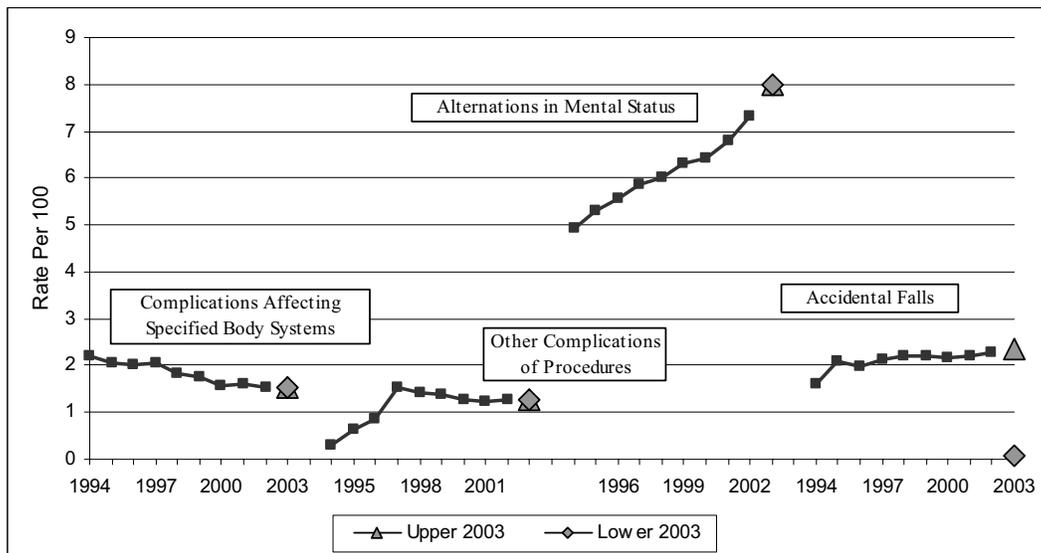


Figure 7.9 Trends for Selected UT-MO Measures, 1994–2003 (2)

FEASIBILITY OF ESTIMATING PATIENT SAFETY INITIATIVE EFFECTS

An evaluation question that interested parties can be expected to ask is whether any observed changes in patient safety practices or outcomes can be attributed to AHRQ’s patient safety initiative. Although an appropriate question from a policy perspective, it is extremely

difficult to answer with any confidence, for at least three key reasons. First, it would be necessary to observe actual improvements in practices or outcomes. No improvements on the national level have been observed yet, in large part because it is still too soon for the relatively recent momentum of practice improvements to yield detectable effects on outcomes. Second, an effective method would have to be developed for measuring the intensity of the patient safety initiative (dosage of intervention). Third, it would be necessary to disentangle the contributions of the initiative from those of other independent factors affecting any observed improvements.

While recognizing these considerable measurement challenges, we felt the evaluation center had an obligation to explore the feasibility of designing a method to assess the effects of AHRQ's investment in its patient safety initiative. We developed a geographic-based method that attempted to estimate relationships between AHRQ's investment in patient safety projects and trends in claims-based patient safety outcomes within areas representing regional markets.

We do not have reportable results from this diagnostic work, in part because we have been working with baseline data and in part due to measurement uncertainties involved. However, we believe that lessons from this attempt merit being documented here, to provide a foundation for any future methodological development efforts.

Our study design was based on identifying regional effects as practices diffuse within individual regional areas. The analysis focused on California and New York partly because full sets of standardized claims data are available for those states through HCUP, and partly because these states are large enough to include some metropolitan statistical areas (MSAs) that received AHRQ patient safety funding, and others that did not.

We identified all AHRQ-funded patient safety projects from FY 2000–2003 that operated, in whole or in part, in California or New York, and attributed the AHRQ funding to specific MSAs within the two states. Next, we divided the MSAs into three groups: those that received *high levels of patient safety investment*, those that received *medium levels of patient safety investment*, and those that received *no patient safety investment*. Finally, using state inpatient databases for New York and California, we calculated MSA-based trends in outcomes over time for six PSI measures across these three groups, and we estimated mixed statistical models. We used the mixed statistical models to identify which (if any) of the investment levels were significantly different from the others in measured outcomes, whether the outcomes over time reflected any significant trend, and whether there were any significant investment level-by-time interactions in outcomes.

Not surprisingly, a number of issues arose in this preliminary work that affected the ability to estimate with confidence any relationships between geographic variations in AHRQ patient safety investments and patient safety outcomes. A central issue was that the choice of measures to test is important and involves a high degree of uncertainty. The PSIs differed significantly in their baseline rates and trends for patient safety outcomes across groupings and states, and it is not clear which of these measures would be influenced by AHRQ's patient safety investments. Further analysis would be required to tease out some of the factors contributing to the differences. Other limitations of such analysis include the following: (1) Dependence on the availability of state-level administrative data restricts the choice of states for investigating the effects of AHRQ funding; (2) alternative statistical modeling techniques could reasonably be applied to examining the link between AHRQ investment and clinical outcomes; (3) there are difficulties in identifying whether changes in PSI rates over time reflect *true* changes in adverse

events or whether they are due to shifting coding practices or other unidentified factors; and (4) diffusion of patient-safety research findings and practices may occur through other mechanisms in addition to regional diffusion.

LESSONS FROM THE BASELINE TREND DATA

In *Evaluation Report III*, we listed several highlights that emerged from the analyses of trends in reported events and rate measures. We update those lessons here, based on the aggregate results of our analyses throughout the course of the evaluation, offering suggestions for a general approach to monitoring patient outcomes.

The preferred types of measures for monitoring changes in outcomes over time are those for which objective data are available on a national level, which can yield estimates that are reliable in completeness, validity, and reliability, both in any given year and in trends over time. Measures expressed as rates best fulfill these criteria because they control for changes in the size of the denominators over time or for differences in denominators across subsets of the population within any time period. However, these types of measures are vulnerable to other measurement challenges that must be considered.

As stated in the previous report, one of the most obvious lessons from our assessments is the large differences in the trends observed for the reported events and measures that are rates. Another lesson is the importance of carefully considering which outcomes measures should be used for assessing effects. The results of the Delphi process we conducted can guide these choices because they represent expert consensus on which measures are most important.

Measures of reported events. The incomplete reporting of events by health care providers into any external reporting system is a serious limitation for using reported-event data to monitor trends in outcomes, because of the downward bias in occurrence frequencies. Further, it usually cannot be determined which factors are affecting frequencies of reported events and therefore how accurately they represent underlying safety issues. For example, increases in reported events may reflect results of improved patient safety vigilance and reporting practices, which is a positive change for safety improvement, because the events must be identified before providers can act on them. On the other hand, an increase may reflect real increases in events, which is undesired, or it simply could be the result of improved completeness of reporting to external systems (of events already known internally).

Because of these data-validity issues, and also because lack of denominator information precludes calculation of rates, measures based on reported events are not good candidates for monitoring changes in outcomes over time. Event reports should play an important role, however, as part of the vigilance aspect of monitoring—to detect and act on new safety issues that become observable through changing frequencies of reported events.

Rate measures. Currently the only data source for calculating rate measures that comes close to meeting the criterion for objective data available on a national level (stated above) is the HCUP data, and it still has a number of limitations. Alternative sources would be data from surveys on the measures of interest (e.g., AHRQ's adverse-event reporting system survey, or other surveys fielded by federal agencies).

In addition to data source limitations, our exploratory analyses of baseline outcome trends identified the following issues that need to be addressed before effective monitoring using rate measures can be achieved:

- Differing trends observed for the PSI and UT-MO rate measures suggest that safety performance varies across measures, and patient safety activities may have differing effects on individual outcomes. Thus, measures used to monitor changes in outcome rates need to be selected carefully to ensure that, as a group, they fulfill the function of serving as proxies for larger performance trends within a health care setting.
- Variations over time in the trends for many of the rate measures highlight the importance of using data for multiple years, to establish valid estimates of baseline trend lines for the rate measures.
- Use of data from different data sources and for multiple years brings with it the challenge of adjusting estimates for changes in definitions for diagnosis codes, as well as in methods for calculating the measures using them.
- For effective interpretation of the baseline trends and any changes from them, it may be necessary to explore underlying factors that might be influencing observed trends through engagement with health care providers and further analyses of the data.

The results of these analyses lead us to conclude that, to be effective, the monitoring process for AHRQ's patient safety initiative should track trends in both patient outcome measures and the implementation of safe practices that are supported by scientific evidence as being effective in reducing harm to patients. As growth in the adoption of evidence-based safe practices is observed over time, it may be inferred that these practices are leading to improved patient outcomes, many of which may not be detectable in the outcome measures selected for national monitoring.

ISSUES AND ACTION OPPORTUNITIES

Analysis of baseline trends is a necessary initial step in exploring the effects of AHRQ's patient safety initiative, while waiting for sufficient time to pass for changes in practices to begin to affect outcomes. Our efforts to track outcomes over time using claims-based measures highlight the many issues involved and the importance of having a reliable data infrastructure and consistent definitions of measures for calculating accurate outcome rates. Validity issues associated with reported adverse events, such as the Joint Commission sentinel events and the MedMARx medication events, preclude their use for estimating rates of changes in patient safety outcomes. However, reported events remain important contributors to the vigilance aspect of monitoring because observable changes in the frequency of events being reported could signal an emerging patient safety problem.

Issues to Consider

Future actions by AHRQ can help develop the needed capability for monitoring trends in both patient safety processes and outcomes. Ambulatory and long-term care settings continue to be a priority for development of measures, and state-level reporting systems may have the potential to aggregate data on a regional or national basis. Limited data availability and lack of consensus regarding measures to be used for monitoring are issues that continue to hinder progress in developing an acceptable monitoring system and measurement methods.

Suggestions for AHRQ Action

- **Validate the integrity of the PSIs against results for measures based on data abstraction from medical records, and clearly document the methodology and**

coding for calculating the PSIs, while striving to minimize coding shifts that could lead to inappropriate interpretation of outcome trends.

Estimated rates for PSI outcome measures have been vulnerable to criticism from providers and other users, due to disagreements about codes used for defining measures as well as changing code definitions or coding practices over time. By validating PSIs against the “gold standard” of how well they match rates derived from medical chart data, AHRQ can provide validity documentation for PSIs, and identify where further development work is needed (although we note that chart data have their own limitations). For PSIs found to be valid, observed changes in the measures can be interpreted with confidence as reflecting actual outcome effects. In addition, by providing users with more clarification about the nature of periodic PSI revisions and underlying coding changes, AHRQ can improve the value of the PSI measures and interpretability of observed trends in them.

- **Place a priority on developing a set of patient safety measures for ambulatory care settings, and foster establishment of a data infrastructure that can support measurement for ambulatory care patient-safety issues.**

Currently, measurement capability for patient safety outcomes is most well developed for the hospital inpatient care setting, and even that capability is limited by validity and measurement issues for many outcome measures. However, patient safety measures and the data required to measure and monitor them are almost completely absent in the ambulatory care setting. AHRQ’s leadership in building an outcomes measurement capability for ambulatory care would make a significant contribution to the field of patient safety and advance its current focus on improving ambulatory care.

- **Work collaboratively with other organizations to establish an infrastructure and procedures for regular collection of data on the use of effective patient safety tools and practices by health care organizations, along with reports from the organizations about the effects of those tools and practices on care processes and clinical outcomes.**

As the use of evidence-based practices and tools continues to spread across the health care system, one can anticipate that improvements in patient safety outcomes will be achieved. Given that current patient safety activities are in the early phase of diffusion, baseline data on best practices should be collected as soon as possible. This task is part of the work that RAND will perform over the next two years of the evaluation, and it can best be done within the context of collaborative arrangements between AHRQ and other key organizations.

CHAPTER 8. SUMMARY ASSESSMENT

Over the course of this initiative, the patient safety evaluation center has examined actions undertaken by AHRQ to improve patient safety as well as related developments nationwide. In the process evaluation, we have documented the potential contributions of the groups of AHRQ-funded patient safety projects to expansion of knowledge for patient safety epidemiology and practices. We also have tracked activities undertaken directly by AHRQ for development of a national patient safety data network, building infrastructure to support adoption of newly proven practices, and dissemination of the knowledge and products from all this work to the end users—health care providers across the country. In the product evaluation, we have analyzed baseline trends for selected patient outcome measures for which national-level data were available, and we established a groundwork for continued assessment of the initiative’s effects on practices and stakeholders.

Given the size and decentralized nature of the U.S. health care system, and the significant patient safety problems it has been documented to have, AHRQ faces a daunting leadership challenge for effecting systems change, especially with its limited funding relative to the task at hand. One measure of progress is the gradual shift over time in the nature of activities undertaken. The initiative began with the funding of a large number of patient safety projects selected to generate new knowledge on epidemiology and practices for a diversity of patient safety issues. AHRQ’s emphasis then shifted toward testing methods to implement patient safety practices and to dissemination of project results for encouraging adoption by health care providers.

VIEWS OF NATIONAL STAKEHOLDERS ON SAFETY PROGRESS

In order to assess more broadly the initiative’s progress to date, and to understand the factors believed to be contributing to successes or challenges, the patient safety evaluation center conducted interviews with 18 representatives from a diverse set of national stakeholder organizations. These included government agencies, policymaking organizations, standards setting and accrediting organizations, purchasing groups, consumer groups, and provider organizations.

There was general agreement among all of the individuals interviewed that much work remains to be done to advance patient safety in the United States. Although awareness of patient safety issues and the need to improve has increased, progress in achieving actual safety improvements has been limited. In addition, several individuals were concerned that it is hard to know just how much progress has been made, because we lack definitive measures and data to be able to track whether improvements have occurred. Examples of specific areas where stakeholders identified gains being made include enactment of the PSQIA, an increase in the number of hospital reporting systems, enhanced attention to systems approaches for reducing medical errors and hospital-acquired infections, and training of individuals on safety concepts. Some specific project successes have also been highly visible and can serve as examples for others (e.g., the 100,000 Lives Campaign).

Some of the important drivers of the gains identified by the stakeholders include leadership by the IOM, AHRQ, and the Joint Commission; the work of the Leapfrog Group in creating national visibility for the safety issue and pushing for adoption of safe practices; and the

IHI breakthrough series on intensive care. Also cited as important drivers were the broader movements toward transparency in health care and pay-for-performance.

By contrast, numerous factors were identified as having negative effects on patient safety progress. These include, for example, lack of engagement of health care leaderships, lack of ongoing training structure, insufficient attention to systems quality, poor coordination of policies among organizations guiding standards for safety and quality, and denial of safety issues by the provider community. Interestingly, many individuals stated that they did not see funding as the key issue. Rather, what is needed is more efficient use of existing resources, along with better alignment of incentives, to ensure that resources are reallocated to improving health care. Although there was broad consensus that IT is important in efforts to improve safety, the stakeholders thought it should not be viewed as a panacea and that other solutions also are needed, such as leadership engagement and greater involvement of patients and families.

As shown in Table 8.1, the stakeholders' views regarding progress were generally negative. They gave moderately weak ratings for progress being made nationally with respect to the five components of a safer health care system, and only slightly stronger ratings for AHRQ's effectiveness in providing leadership for these efforts. The average ratings varied somewhat across the system components. The highest ratings given for both the country and AHRQ were for development of safe practices and tools and expanding knowledge of patient safety epidemiology. The lowest average rating for the country's progress was for building a national monitoring system. For AHRQ, the lowest rating given was for its contributions to adoption and diffusion of safe practices by health care providers.

Table 8.1
Assessment of Progress for the Five Patient Safety Components

System Component	Mean Scores Given by National Stakeholders Interviewed (Scale of 1 to 5 where 1 = lowest; 5 = highest)	
	Progress made nationally for each of the five components	AHRQ effectiveness in providing leadership
Building and sustaining a national monitoring system	2.1	2.7
Expanding, conducting epidemiology research	2.5	3.2
Development of safe practices and tools	2.7	3.2
Building the infrastructure for safety	2.4	2.6
Adoption and diffusion of safe practices at the community, provider, or system levels	2.4	2.3

Virtually all the stakeholders interviewed expressed solid appreciation for the work that AHRQ had done to date in the area of patient safety, particularly in light of the limited resources AHRQ had to spend on safety relative to the magnitude of the problem. AHRQ was credited with introducing effective practices and tools, developing indicators for measurement, pushing for transparency, and supporting research and development of practices and tools.

The stakeholders indicated that AHRQ needed to work more aggressively in disseminating the results from the patient safety projects, to ensure that evidence-based practices were adopted by front-line health care workers. However, for effective and quick dissemination, they felt that AHRQ needed to partner with other organizations working on safety to achieve synergy in these dissemination efforts.

SUMMARY FINDINGS

A triangulation approach was used to assess the overall progress of the patient safety initiative, which considered the combined results from three separate analyses that are presented in this report. The first was the assessment of how well the initiative was performing relative to the goals that AHRQ had established for itself, which is reported in Table 2.1 (Chapter 2). The second was the independent assessment that the evaluation center performed of the progress made for the broader set of activities that AHRQ has undertaken. This component used the collective results presented in the process evaluation chapters (Chapters 3 through 6), which addressed each of the five system components defined in the evaluation framework. The third was elicitation of the perspectives of national stakeholders regarding how much progress was being made in patient safety improvement across the country and how AHRQ was contributing to that progress, the results of which are presented above in this chapter.

Aggregating the results from these three assessments, we determined a summary finding for each of the five system components. These findings consist of a brief statement of the extent of progress, accompanied by comparison of the results of the three assessment sources, which generally were in accordance, with only a few exceptions.

Monitoring and Vigilance: Limited progress.

Two of three assessments found that AHRQ had made limited progress in monitoring and vigilance. It did not meet its targets for identifying threats to patient safety, which requires a national monitoring capability. Our evaluation found that limited progress had been made in establishing a monitoring and vigilance capability, despite several efforts made. By contrast, the stakeholders gave AHRQ a relatively high rating for this component.

Patient Safety Epidemiology: Strong progress.

Patient Safety Practices: Strong progress.

We address these two system components together because contributions to both of them have been made by the AHRQ-funded patient safety projects. All three sources identified strong progress for these components. AHRQ met its annual targets for its goal of identifying and evaluating effective practices. Our process evaluation found that AHRQ made its greatest progress in its contributions to development of knowledge of patient safety epidemiology and effective practices. The highest ratings the stakeholders gave AHRQ were for its contributions in these areas.

Infrastructure for Effective Practices: Moderate progress.

Assessments from the three sources were generally positive but mixed for this system component. Under AHRQ's goal for dissemination and implementation of practices, all of its annual targets addressed its PSIC training program, and it met those targets. The absence of targets for other aspects of infrastructure was a limitation. Our evaluation found that AHRQ had been making many contributions to building infrastructure through such activities as the health

IT projects, PSIC, patient safety partnerships, and culture surveys, although it had not addressed other aspects of this component (e.g., consumer engagement, building provider leadership commitment). The stakeholders gave AHRQ moderate ratings for this component.

Adoption of Effective Practices: Limited progress.

Because AHRQ had not developed annual targets for practice dissemination or diffusion actions, it was not possible to assess how well it was doing in this area relative to its own goals. Our assessment found that AHRQ had made limited progress in the dissemination of knowledge and products to support adoption of effective safe practices by health care providers and other end users. The stakeholders also gave AHRQ a low rating for its activities related to adoption and diffusion of safe practices by health care providers.

FUTURE DIRECTIONS AND PRIORITIES

Based on our observations of AHRQ's patient safety strategy, current activities of its grantees and field organizations, and feedback from stakeholders, we have identified the following priorities for ARHQ to consider as it moves forward with the initiative:

- Under the provisions of the Patient Safety and Quality Improvement Act of 2005, continue working toward a national patient safety data network and monitoring capability, including use of consistent data standards, and establishment of a set of national patient safety measures.
- Identify key patient safety practices and tools using information in the syntheses of results of the FY 2000–2001 patient safety projects prepared by the Coordinating Center.
- Package and disseminate patient safety products that derive from the synthesis of project results, including development of generic, “off-the-shelf” products that can be used readily by health care organizations.
- Update the patient safety evidence report to incorporate recently published results from the patient safety projects, applying standards of evidence that ensure rigorous assessment of study designs for testing patient safety practices that cannot be tested effectively using randomized control study designs.
- Assess the role of health IT in achieving safer health care practices, with a focus on its interface with the human aspects of care delivery, using results of the health IT grants as well as knowledge generated by other patient safety projects that have addressed use of technology for patient safety practices.
- Continue to engage actively in field-based partnerships that enable ARHQ to optimize its impact in building infrastructure, with a focus on training to expand patient safety expertise in the field, and in stimulating broad adoption of proven patient safety practices by health care providers, within the constraints of its finite resources.

According to Rogers' S-shaped model for diffusion of innovations (2003), the initial adoption rate for any particular innovation is slow, with only the early adopters starting to use it. Then, as a successful innovation begins to be picked up by more users, increased adoption rates are reflected in a steeper curve, after which the innovation matures and adoption levels off. After five years of the AHRQ patient safety initiative, the country appears to be standing at the threshold of the upward moving portion of the curve, as more and more health care providers begin to put proven safety practices to work (Figure 8.1).

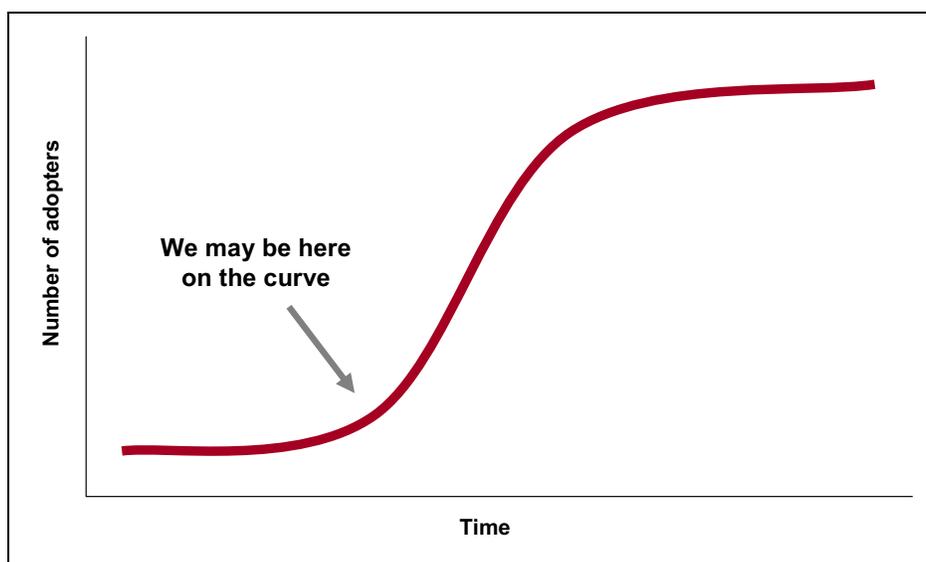


Figure 8.1 Theoretical Diffusion Curve for Adoption of Innovations (Rogers, 2003)

To advance beyond this threshold, AHRQ will need to continuously reinforce adoption activities through dissemination of information and tools to support practices and through active partnerships with organizations that are leading related initiatives in the field. At the same time, more research is needed on patient safety issues that have not yet been carefully examined, such as advancing patient safety in ambulatory and long-term care settings.

NEXT STEPS FOR THE EVALUATION

This report is the culmination of the four-year evaluation performed for AHRQ by the patient safety evaluation center. It is preceded by three annual reports, each of which documents the status of the patient safety initiative as of September of the years 2003, 2004, and 2005. In this report, we summarized evaluation results that emerged over time for each system component and presented the results of our most recent evaluation activities. Based on these findings, we offered recommendations for actions that will be important for AHRQ to carry out for successful progress in each system component and for assessing effects of the initiative.

The evaluation work for the next two years will be dedicated to documenting and analyzing the extent to which infrastructure and practices are being put into place across the nation's health care system. In the framework of the CIPP evaluation model, we will focus entirely on the product evaluation, which encompasses both effects on patient safety outcomes and effects on system structures, practices, and stakeholders participating in the system.

REFERENCES

- Agency for Healthcare Research and Quality. *Agency for Healthcare Research and Quality: Offices and Centers*. Rockville, MD, 2003. As of April 2008:
<http://www.ahrq.gov/about/offcntrs.htm>
- Agency for Healthcare Quality and Research. *2004 National Healthcare Quality Report*, AHRQ No. 05-0013, Department of Health and Human Services, Rockville, MD, 2004a.
- Agency for Healthcare Quality and Research. *Final Fiscal Year 2005 GPRA Annual Performance Plan*, Department of Health and Human Services, Rockville, MD, 2004b.
- Agency for Healthcare Research and Quality. *Hospital Survey on Patient Safety Culture*, Rockville, MD, April 2005b. As of April 2008:
<http://www.ahrq.gov/qual/hospculture/>
- Agency for Healthcare Research and Quality. *FY 2007 Budget in Brief*, Department of Health and Human Services Budget Proposal, 2006.
- Agency for Healthcare Research and Quality. *Advances in Patient Safety: From Research to Implementation*. Volumes 1–4, AHRQ Publication Nos. 050021 (1–4). February 2005a. Agency for Healthcare Research and Quality, Rockville, MD. As of April 2008:
<http://www.ahrq.gov/qual/advances/>
- American Hospital Association, Institute for Family-Centered Care. *Strategies for Leadership: Patient-and Family-Centered Care*. Chicago, IL: American Hospital Association. As of May 2006:
<http://www.aha.org/aha/issues/Communicating-With-Patients/pt-family-centered-care.html>
- Bavelas A. Communication patterns in task-oriented groups. *J. Acoustical Soc. America*, 1950, 22: 725-730.
- Beckett MK, Fossum D, Moreno CS, Galegher JR, Marken R. *A Review of Current State-Level Adverse Medical Event Reporting Practices: Toward National Standards*. Santa Monica CA: RAND Corporation, RAND TR-383-AHRQ, 2006. As of April 2008:
http://www.rand.org/pubs/technical_reports/TR383/
- Bessant J, Kaplinsky R, Morris M. “Developing Capability Through Learning Networks,” *Journal of Technology Management and Sustainable Development*, 2003, 2(1): 19-38.
- Burt RS. Models of Network Structure, *Annual Review of Sociology*, 1980, 6: 79-141.
- Centers for Medicare and Medicaid Services. *Physician Focused Quality Initiative, Overview*. As of December 2007:
<http://www.cms.hhs.gov/PhysicianFocusedQualInits/>
- Centers for Medicare and Medicaid Services. *Hospital Quality Reporting Expansion Provisions in CY 2007 Hospital Outpatient Prospective Payment System Proposed Rule*, Fact Sheet. As of August 2006:
<http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1942>
- Chang A, Schyve PM, Croteau RJ, O’Leary DS, Loeb JM. “The JCAHO Patient Safety Event Taxonomy: a Standardized Terminology and Classification Schema for Near Misses and Adverse Events,” *International Journal for Quality in Health Care*, 2005, 17(2): 95-105.

- Conway J, Johnson B, et al. *Partnering with Patients and Families to Design a Patient- and Family-Centered Health Care System: A Roadmap for the Future*. Bethesda, MD: 2006.
- Farley DO, Morton SC, Damberg C, Fremont A, Berry S, Greenberg M, Sorbero MES, Teleki S, Ricci K, Pollock N. *Assessment of the National Patient Safety Initiative: Context and Baseline. Evaluation Report I*, Santa Monica, CA: RAND Corporation, TR-203-AHRQ, 2005. As of April 2008:
http://www.rand.org/pubs/technical_reports/TR203/
- Farley DO, Morton SC, Damberg C, Ridgely S, Fremont A, Greenberg M, Sorbero M, Teleki S, Mendel P, Kaganoff-Stern R. *Assessment of the AHRQ Patient Safety Initiative: Moving from Research to Practice. Evaluation Report II*, Santa Monica, CA: RAND Corporation, TR-463-AHRQ, 2007a. As of April 2008:
http://www.rand.org/pubs/technical_reports/TR463/
- Farley DO, Damberg CL, Ridgely MS, Sorbero MES, Greenberg MD, Haviland AM, Meili RC, Teleki SS, Bradley LA, Dembosky JW, Fremont A, Nuckols TK, Shaw RN, Taylor SL, Yu H. *Assessment of the AHRQ Patient Safety Initiative: Focus on Implementation and Dissemination. Evaluation Report III*, Santa Monica, CA: RAND Corporation, TR-508-AHRQ, 2007b. As of April 2008:
http://www.rand.org/pubs/technical_reports/TR508/
- Farley DO, Damberg CL, Greenberg MD, Haviland AM, Mendel P, Ridgely MS, Sorbero ME. *Technical Appendix: Methods Used for Evaluation of the AHRQ Patient Safety Initiative*, Santa Monica, CA: RAND Corporation, forthcoming.
- Farley DO, Haviland A, Champagne S, Jain AK, Battles JB, Munier WB, Loeb JM. Adverse Event Reporting Practices by U.S. Hospitals: Results of a National Survey, under review.
- Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. "Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations," *Milbank Quarterly*, 2004, 82(4): 581-629.
- Guetzkow H, Simon HA. "The Impact of Certain Communication Nets Upon Organization and Performance in Task-Oriented Groups," *Management Science*, 1955, 1: 233-250.
- Healthcare Information and Management Systems Society. *HIMMS Declaration, Bridging the Chasm: Realizing a Universal EHR*, March 28, 2003. As of August 21, 2007:
http://www.himss.org/content/files/EHR_Declaration.pdf
- Institute of Medicine. *To Err Is Human: Building a Safer Health System*. Kohn LT, Corrigan JM, Donaldson MS, eds., Washington, DC: National Academy Press, 2000.
- Institute of Medicine. *Patient Safety: Achieving a New Standard of Care*, Aspden P, Corrigan JM, Wolcott J, Erickson SM, eds., Washington, DC: National Academy Press, 2004.
- Institute for Healthcare Improvement. *The 100,000 Lives Campaign*, 2006. As of April 2008:
<http://www.ihl.org/IHI/Programs/Campaign/>
- Joint Commission on Accreditation of Healthcare Organizations. *Patient Safety Goals*, 2005. As of April 2008:
<http://www.jcaho.org/accredited+organizations/patient+safety/05+npsg/intro.htm>

- Joint Commission International Center for Patient Safety. *WHO Collaborating Centre for Patient Safety Solutions*. As of 2006:
<http://www.jcipatientsafety.org/24971/>
- The Joint Commission International Center for Patient Safety. *Fact Sheet*, 2007. As of April 2008:
<http://www.jcipatientsafety.org/fpdf/ICPS/FactsAboutICPS.pdf>
- Leapfrog Group. *Leapfrog Incentives and Rewards Compendium*. As of 2006:
<http://www.leapfroggroup.org/compendium2>.
- The Lewin Group, Inc. *Health Information Technology Leadership Panel, Final Report*, March 2005.
- McCannon CJ, Schall MW, Calkins DR, Nazem AG. Saving 100,000 lives in US hospitals. *BMJ*, 332:1328-1330 (3 June), 2006.
- McGreevey M. *Patients as Partners: How to Involve Patients and Families in Their Own Care*. Oakbrook Terrace, IL: Joint Commission Resources, 2006.
- Public Law 109-41, Patient Safety and Quality Improvement Act of 2005, July 29, 2005. As of April 2008:
<http://web.lexis-nexis.com/congcomp/>
- Quality Improvement Coordination Task Force. *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and their Impact*. Report of the Quality Interagency Coordination Task Force (QuIC) to the President, 2000.
- Rogers EM. *Diffusion of Innovations*, 5th ed., New York: Free Press, 2003.
- Rogers EM, Eveland JD, Bean AS. *Extending the Agricultural Extension Model*, Stanford, CA: Institute for Communication Research, Stanford University, 1976.
- Marchev M, Rosenthal J, Booth M. *How States Report Medical Errors to the Public: Issues and Barriers*, National Academy for State Health Policy, Portland, ME: National Academy for State Health Policy, 2001.
- Office of the National Coordinator of Health IT (ONC) Web site. As of September 2007:
<http://www.hhs.gov/healthit/onc/mission>
- Scott, J. *Social Network Analysis. A Handbook*. 2nd edition. London: Sage, 2000.
- Shojania KG, Duncan BW, McDonald KM, Wachter RM. *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*, Evidence Report/Technology Assessment No. 43. AHRQ Publication No. 01-E058 (prepared by University of California at San Francisco-Stanford Evidence-based Practice Center, under Contract No 290-97-0013), Rockville, MD: Agency for Healthcare Research and Quality, 2001.
- Snyder WM, Briggs X. *Communities of Practice: A New Tool for Government Managers*, IBM Center for the Business of Government, 2003.
- Sorbero, MES, Damberg CL, Shaw R, Teleki S, Lovejoy S, Decristofaro A, Dembosky J, Schuster C. *Assessment of Pay-for-Performance Options for Medicare Physician Services: Final Report*. WR-391-ASPE. Prepared for the Assistant Secretary for Planning and Evaluation, US Department of Health and Human Services, May 2006.

- Stufflebeam D, Gephart WJ, Guba EG, Hammond RL, Merriman HO, Provus MM. *Educational Evaluation and Decision Making*, Itasca, IL: F.E. Peacock Publishers, Inc., 1971.
- Stufflebeam DL, Madaus GF, Kellaghan T. *Evaluation Models: Viewpoints on Educational and Human Services Evaluation*. Norwell, MA: Kluwer Academic Publishers, 2000.
- Teleki SS, Damberg CL, Sorbero MS, Fremont AM, Bradley L, Farley DO. *Evaluation of the Patient Safety Improvement Corps: Experiences of the First Two Groups of Trainees*, Santa Monica, CA: RAND Corporation, TR-407-AHRQ, 2006. As of April 2008:
http://www.rand.org/pubs/technical_reports/TR407/
- Valente TW, Davis RL. "Accelerating the Diffusion of Innovations Using Opinion Leaders," *The Annals of the American Academy of Political and Social Science*, 566, November 1999, pp. 55-67.
- Wasserman S. and K. Faust. *Social Network Analysis. Methods and Applications*. Cambridge: Cambridge University Press, 1994.
- Wenger E, McDermott R, Snyder WM. "Seven Principles for Cultivating Communities of Practice," *Cultivating Communities of Practice: A Guide to Managing Knowledge*, Harvard Business School Press, 2002.
- White House. *Executive Order: Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs*, Washington DC, August 22, 2006. As of April 2008:
<http://www.whitehouse.gov/news/releases/2006/08/20060822-2.html>