CHAPTER 1.
INTRODUCTION

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

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

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

EVALUATING THE PATIENT SAFETY INITIATIVE

The Policy Context

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

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

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

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

The Evaluation Model Used

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

- ***Context evaluation*** assesses the circumstances stimulating the creation or operation of a program as a basis for defining goals and priorities and for judging the significance of outcomes.
- ***Input evaluation*** examines alternatives for goals and approaches for either guiding choice of a strategy or assessing an existing strategy against the alternatives, including congressional priorities and mandates, as well as agency goals and strategies. Stakeholders also are identified and their perspectives on the patient safety initiative are assessed.
- ***Process evaluation*** assesses progress in implementation of plans relative to the stated goals for future activities and outcomes. Activities undertaken to implement the patient safety initiative are documented, including any changes made that might alter the initiative's effects, positively or negatively. Three questions are addressed in this evaluation phase: (1) Is the initiative reaching the target population(s)? (2) Are delivery and support functions consistent with program design? and (3) Are positive changes occurring as a result of these activities?
- ***Product evaluation*** identifies consequences of the program for various stakeholders, intended or otherwise, to determine effectiveness and provide information for future program modifications.

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

Table 1.1.
Time Line for Reporting Results from the Longitudinal Evaluation of the National Patient Safety Initiative

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

Major Stakeholder Groups Addressed

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

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

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

A Framework for the Process Evaluation

For AHRQ's patient safety initiative, the process evaluation is the largest and most complex component of the evaluation because many aspects of the health system are affected by AHRQ's work and that of numerous other organizations involved in patient safety. We identified five system components that are essential to bringing about improved practices and a safer health care system for patients; together, these components provide a cohesive framework for the process evaluation, as shown in Figure 1.1. Our process evaluation examined progress in strengthening each of these five system components. For each component, it addressed the three questions identified above: (1) Is the initiative reaching the target population(s)? (2) Are delivery and support functions consistent with program design? and (3) Are positive changes occurring as a result of these activities?

This system framework can represent the components of an effective system at either the national level or a more local level. At the national level, AHRQ is engaged in all of these system components, as are numerous other key organizations. The system components are defined as follows:

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

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

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

Building Infrastructure for Effective Practices. Establishment of the health care structural and environmental elements needed for successful implementation of effective patient safety practices, including an organization's commitment and readiness to improve patient safety,

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

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

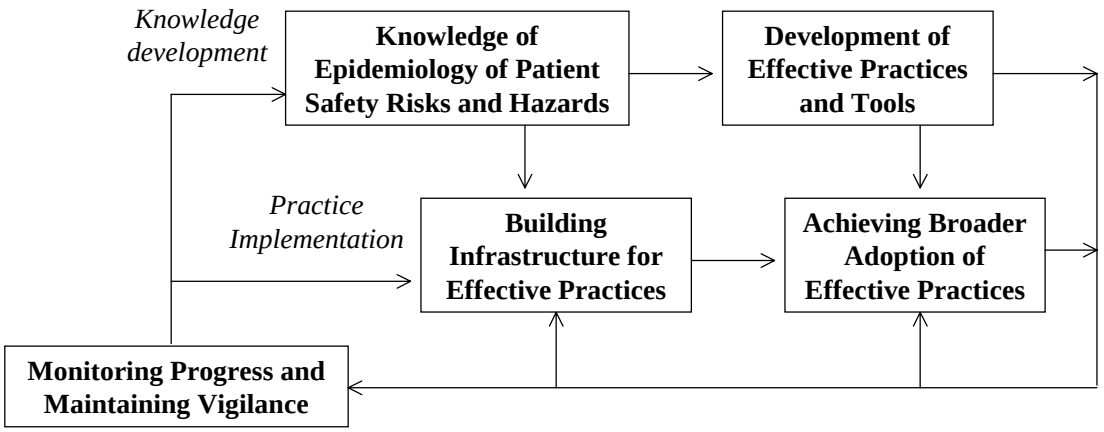

Figure 1.1 The Components of an Effective Patient Safety System

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

EVALUATION APPROACH AND METHODS

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

At the local level, AHRQ projects are generating new knowledge on patient safety epidemiology or developing new practices to prevent errors and adverse events. Others are testing new practices under field conditions, in preparation for adoption of successful practices by health care providers. The Patient Safety Research Coordinating Center (hereafter called the Coordinating Center) is funded by AHRQ to serve as an administrative extension of the agency staff to help achieve the synergy to make "the whole initiative greater than the sum of its parts."

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

ABOUT THIS REPORT

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

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

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

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