CHAPTER 1. INTRODUCTION

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

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

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

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

EVALUATING THE PATIENT SAFETY INITIATIVE

The Policy Context

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

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

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

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

The CIPP Evaluation Model

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

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

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

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

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

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

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

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

Major Stakeholder Groups Addressed

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

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

A Framework for the Process Evaluation

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

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

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

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

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

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

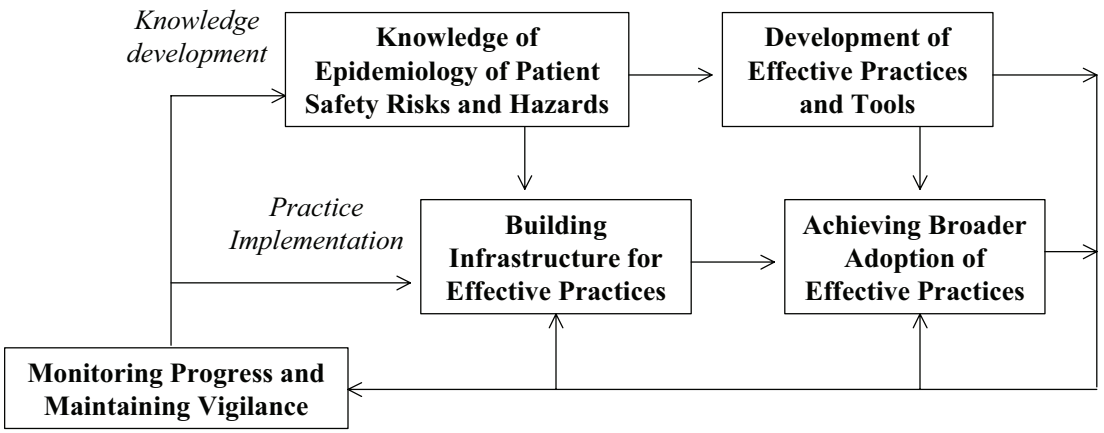

Figure 1.1 A Framework for an Effective Patient Safety System

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

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

EVALUATION APPROACH AND METHODS

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

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

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

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

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

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

ABOUT THIS REPORT

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

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

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

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