Chapter Title: INTRODUCTION

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CHAPTER 1. INTRODUCTION

As of October 2005, it has been four 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 Corporation in September 2002 to serve as the evaluation center for its patient safety initiative. The evaluation center is responsible for performing a longitudinal evaluation of the full scope of AHRQ's patient safety activities and for providing regular feedback to support the continuing improvement of this initiative. This report—*Evaluation Report III*—is the third of four annual evaluation reports to be prepared by the evaluation center. The report covers the period October 2004 through September 2005.

THE POLICY CONTEXT

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 identifying 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).

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

EVALUATING THE PATIENT SAFETY INITIATIVE

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 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 development, operation, and outcomes 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.

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- ***Input evaluation*** examines alternatives for goals and approaches for either guiding the 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.
- ***Product evaluation*** identifies consequences of the program, intended or otherwise, for various stakeholders 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 third evaluation report are shown in the shaded column. They include updates on the context and input evaluations, and continued assessment of patient-safety-initiative activities through the process evaluation. The product evaluation consists of an initial assessment of baseline data related to outcomes of the initiative, which will serve as the basis of the product-evaluation results, to be presented in the fourth and final report.

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 brunt 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* – 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* – organizations that are working to promote best practices, education, and technology adoption in patient safety, and that have a stake in building collaborations to achieve those ends.
- *Federal government* – agencies in the federal government involved in patient safety activities—in particular, AHRQ and other 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, which together 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, addressing for each component 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?

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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 impacts			X	X

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.

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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.

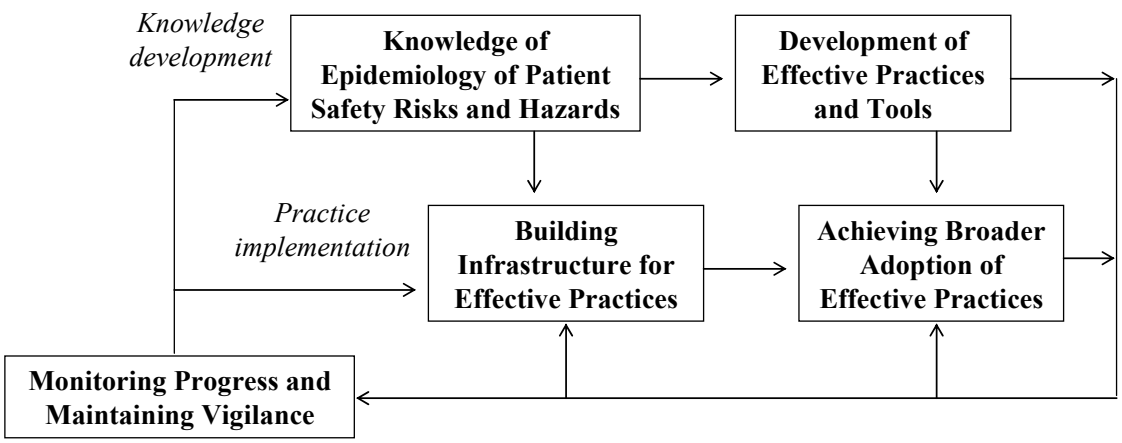

Figure 1.1 The Components of an Effective Patient Safety System

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 (in the second row of the figure) that contribute to practice implementation—building infrastructure and achieving adoption of effective practices.

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

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funded by AHRQ. At the national level, AHRQ is building a coordinated initiative from which the collective activities and knowledge generated across the country can be applied to improve patient safety epidemiology and practices. At the local level, our evaluation focuses on the work of the AHRQ-funded projects, which are working at various local and regional levels to generate new knowledge on patient safety epidemiology, develop new practices for preventing errors and adverse events, or test new practices or infrastructures to support practices under field conditions. The Patient Safety Research Coordinating Center (hereafter called the Coordinating Center) is funded by AHRQ 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 are used for the evaluation and are tailored to each specific aspect of the patient safety initiative being addressed. We use existing information from written reports and documents, Web sites, and proposals written for the patient safety projects that were awarded AHRQ funding. We also conduct 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 *Evaluation Reports I* and *II* (Farley et al., 2005; Farley et al., 2007). 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 Reports I* and *II*; in other cases, we offer new recommendations or expansions of previous ones based on our most recent findings. (See the Appendix for suggestions for AHRQ action presented in the previous two reports.)

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 components of the evaluation, 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, which 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 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 addresses the product evaluation component of the CIPP model and presents baseline trends for selected patient safety outcome measures. Chapter 8 concludes with a summary of the current status of the AHRQ patient safety initiative, and it describes the steps to be completed in the fourth and final year of this evaluation.

Unless stated otherwise, the information presented in this report is current as of September 2005. Assessment of the additional activities related to AHRQ's national patient safety initiative undertaken since that time will be included in *Evaluation Report IV*.

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