



Chapter Title: INTRODUCTION

Book Title: Assessment of the AHRQ Patient Safety Initiative

Book Subtitle: Final Report—Evaluation Report IV

Book Author(s): Donna O. Farley, Cheryl L. Damberg, M. Susan Ridgely, Melony E. Sorbero, Michael D. Greenberg, Amelia M. Haviland, Stephanie S. Teleki, Peter Mendel, Lily Bradley, Jacob W. Dembosky, Allen Fremont, Teryl K. Nuckols, Rebecca Shaw, Susan G. Straus, Stephanie L. Taylor, Hao Yu and Shannah Tharp-Taylor

Published by: RAND Corporation

Stable URL: <https://www.jstor.org/stable/10.7249/tr563ahrq.9>

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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.

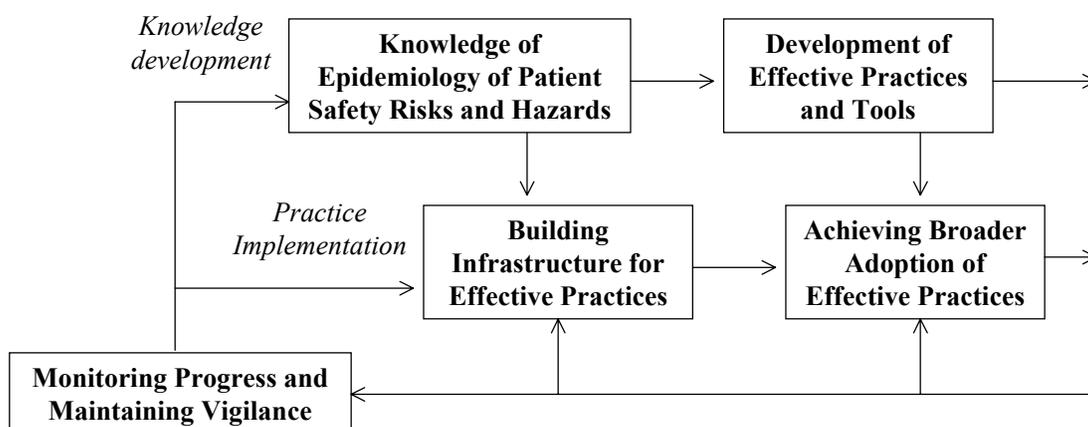


Figure 1.1 The Components of an Effective Patient Safety System

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.

