CHAPTER 1.
INTRODUCTION AND BACKGROUND

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 the Agency for Healthcare Research and Quality (AHRQ) as the lead agency for patient safety research and practice improvement (IOM, 2000). Soon thereafter, the U.S. Congress funded AHRQ, in the Department of Health and Human Services, to establish a national patient safety initiative. This initiative represents one of numerous, important patient safety efforts being undertaken by organizations across the country in which AHRQ has played a leadership role. It has done so by funding a portfolio of patient safety research and implementation projects to expand knowledge in this area, providing motivation and guidance for the activities of others, and integrating its work with that of other public and private organizations to achieve synergy through collaboration.

AHRQ contracted with RAND in September 2002 to serve as the Patient Safety Evaluation Center (evaluation center). The evaluation center was 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 evaluation was completed in September 2006, culminating in a final report that presents evaluation findings over the full four-year evaluation period (Farley et al., 2008b). The final report was preceded by three annual reports, each of which documents the status of the patient safety initiative as of September 2003, 2004, and 2005 (Farley et al., 2005; Farley et al., 2007a; Farley et al., 2007b).

The evaluation center then undertook another two years of work in 2007 and 2008 to document and analyze the extent to which patient safety infrastructure and practices were being put into place across the nation's health care system, and the effects they were having on involved stakeholders. The goal of the work was to begin to assess progress in effecting changes in patient safety practices and outcomes. This report presents the results of that work, consisting of four specific assessments that developed information on the country's progress in adoption of safe practices and improving patient safety. In this chapter, we present the framework used to guide the product evaluation, and we introduce these assessments. Subsequent chapters present the results of each assessment.

FRAMEWORK FOR THE PATIENT SAFETY EVALUATION

The study results presented in this report are products of the final phase of work for the Patient Safety Evaluation Center. These analyses focus on one component of the overall framework within which the overall evaluation was performed. Called the product evaluation, this component is the assessment of the effects of the AHRQ patient safety initiative on safety activities and outcomes in the U.S. health care system. We describe here the overall framework for the evaluation and how the product evaluation fits within it.

Overall Framework

The overall evaluation design was based on the Context-Input-Process-Product (CIPP) evaluation model, 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

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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.

A Nested Process-Evaluation Framework

Because of the size and complexity of the patient safety initiative, we identified the need to develop a second logic model within the larger CIPP framework to guide the process evaluation. Such a model enabled the evaluation to "tell the story" of the implementation of the AHRQ patient safety initiative in a way that was intuitively accessible to AHRQ staff and other policymakers who would use the evaluation results. Specifically, the model helped the evaluation (1) track a changing mix of activities over time and assess their contributions to the overall initiative, (2) summarize the overall effects of the initiative through the collective contributions of its multiple activities, and (3) examine how AHRQ's initiative contributed to the larger set of patient safety activities undertaken across the country, with AHRQ both as leader and partner.

As shown in Figure 1.1, the framework consists of five key system components that work together to bring about improved practices and safer health care for patients. AHRQ is engaged in all of these system components at the national level, as are numerous other key organizations. In the process evaluation, we organized our evaluation results by these five components and examined the collective contributions of AHRQ-sponsored activities in strengthening each component. 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.

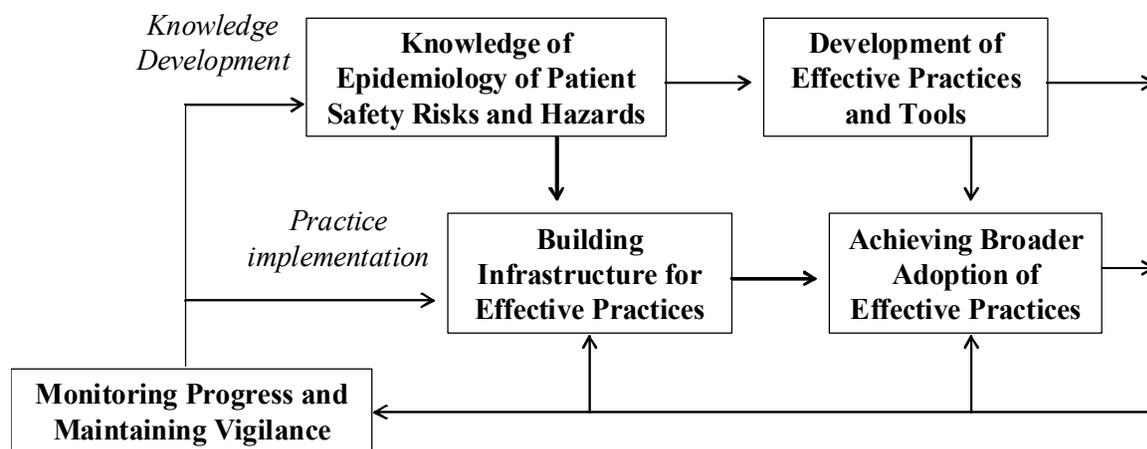_**Knowledge of Epidemiology of Patient Safety Risks and Hazards.**_ Identification of medical errors and causes of patient injury in health care delivery, with a focus on vulnerable populations.

**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

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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 (e.g., culture, information systems) 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 (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.

Knowledge Development

| Knowledge of Epidemiology of Patient Safety Risks and Hazards | → | Development of Effective Practices and Tools | → |

Practice implementation

| Building Infrastructure for Effective Practices | → | Achieving Broader Adoption of Effective Practices | → |

| Monitoring Progress and Maintaining Vigilance |

Figure 1.1 The Components of an Effective Patient Safety System

The system 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, which contribute to *practice implementation*—building infrastructure and adopting effective practices (in the second row of the figure).

Product Evaluation Framework

As described above, the fourth component of the CIPP program evaluation model is the product evaluation, within which we assessed the consequences of the patient safety initiative for various stakeholder groups. Our focus is on stakeholder effects that arise from actions taken for the *practice implementation* aspect of the system framework identified in Figure 1.1—the two components of infrastructure development and adoption of effective practices (see also Farley et al., 2008b). Successful implementation of actions in these areas should lead to outcomes of improved practices by providers, fewer adverse events, and reduced harm to patients.

To guide our product evaluation work, we built upon the framework in Figure 1.1 to define the logic model for patient safety effects shown in Figure 1.2. According to this model,

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actions taken in the health care system for development of infrastructure should lead to adoption of effective patient safety practices by providers (both from Figure 1.1) and these, in turn, should achieve improved outcomes for patients. Both infrastructure development and practice adoption also affect other stakeholders involved in the initiative to create a safer health care system, including providers, states, organizations involved in patient safety, and the federal government.

This model is a simplified representation of the actual dynamics involved in moving from actions to effects, which are complex and inter-related, with often interacting effects of the various stakeholders involved. While we recognize these limitations, the framework enables us to explicitly identify the key components of these dynamic processes for consideration in the evaluation as well as in future work by AHRQ.
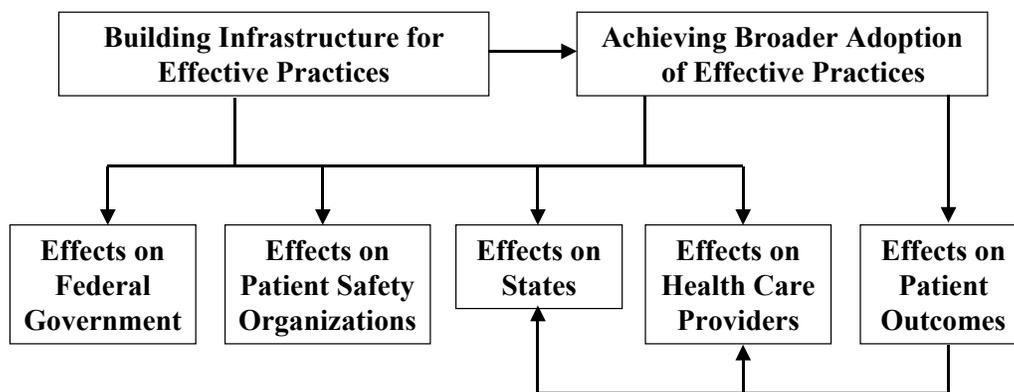
Figure 1.2 Conceptual Framework of Potential Effects of National Patient Safety Activities

To track effects of national patient safety activities on patient outcomes and effects on other stakeholders, identifying measures to be tracked, drawing from sets of already-developed measures, is one of the first steps required. We established the following criteria that should be met by selected measures, to be useful for evaluating changes in patient outcomes and other effects on infrastructure, practices, and various stakeholders:

- Contribute to covering 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
- Can be measured 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.

Presented in Table 1.1 are several types of measures that we identified that could be used to track progress in infrastructure development and use of patient safety practices. These measures reflect the activities currently under way by AHRQ and other organizations to establish reliable data on patient safety practices and outcomes.

Table 1.1
Potential Measures of Infrastructure Development and
Use of Patient Safety Practices for the Product Evaluation

Types of Measure	Potential Data Source	Availability
Development of Infrastructure		
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	AHRQ Survey on Hospital-Based Adverse Event Reporting	Yes (survey-data for 2005; again in 2009) (Farley et al., 2008a)
Safe practices for which tools are developed for implementation	Use of TeamSTEPPS (AHRQ, 2007); toolkits developed by AHRQ grantees	No data yet on usage of tools
Improved patient safety culture in hospitals	AHRQ Hospital Survey on Patient Safety Culture (SOPS) (2005b)	Yes (SOPS database)
Legal protections for reporting	Review of state laws; PSO legislation	Yes (2005 legislation)
Use of Effective Patient Safety Practices		
Adoption of NQF safe practices by hospitals	1. Leapfrog surveys of patient safety practices	Leapfrog data reported
	2. AHRQ Survey on Hospital Adoption of NQF Safe Practices (developed by RAND as described in Chapter 4)	AHRQ survey not yet fielded
Adoption of patient safety practices defined in Joint Commission (2007)	Some are NQF safe practices, so data from Leapfrog survey or AHRQ survey	Leapfrog-reported data
Survey data on a variety of safe medication practice issues	Some are NQF safe practices, so data from Leapfrog survey or AHRQ survey	Leapfrog-reported data
Use of risk-assessment methods	TBD: hospitals, ambulatory care, long-term care sources	Not yet
Completed teamwork training	Use of TeamSTEPPS	No data yet on usage of TeamSTEPPS
Patient safety taught in residencies	TBD: hospitals, residencies	Not yet

TBD = to be determined as measurement capability develops
NQF=National Quality Forum; PSO=Patient Safety Organization

One identified measure is the AHRQ Hospital Survey on Patient Safety Culture (HSOPS), which is now being used by hospitals across the country, many of which are reporting data into the HSOPS database (see Chapter 3). Another is the TeamSTEPPS package, developed by AHRQ and the Department of Defense, which has been made available to providers for implementation, and AHRQ also has implemented the Patient Safety Organization (PSO) program under provisions of the Patient Safety and Quality Improvement Act of 2005 (Public

Law 109-41, 2005). The measures also include some that were developed as part of the patient safety evaluation. These include the RAND network analysis (Farley et al., 2008b; Mendel et al., 2009), and the fielding of the AHRQ Survey on Hospital-Based Adverse Event Reporting Systems in 2005 (Farley, Haviland, et al., 2008a).

In our product evaluation work during the four-year evaluation, we specifically focused on patient outcome effects while starting to identify effects on other stakeholders, specifically on organizations involved in the AHRQ-funded patient safety projects (Farley et al., 2008b; Greenberg et al., 2009). Our continued product evaluation work in 2007 and 2008 has expanded to include assessment of practice adoption, and we also continued trend analyses for patient outcomes.

ANALYSES PRESENTED IN THIS REPORT

A product evaluation (the final component of the CIPP evaluation model) should consider effects of the national patient safety initiative on health system structures, practices, and stakeholders participating in the system, including effects on patient outcomes. Thus, our product evaluation included analysis of the extent of both adoption of patient safety practices and trends in related outcomes across the United States. We strategically selected our most recent analyses to address the following priority information needs for AHRQ:

- **Provide AHRQ with timely information on what health care providers are doing with adoption of safe practices.**

What we did. We performed case studies of four communities across the country, using qualitative data-collection and analytic methods to examine the extent of use of safe practices at the community level (presented in Chapter 2). The case-study approach was chosen because it could generate the most timely data, given that no instrument was available yet for collecting quantitative data on safe practice use rates by providers. We selected four communities that have been studied by the Center for Studying Health System Change (HSC) and also are part of the patient safety initiative operated by the Leapfrog Group. We collected information on how local communities are moving forward with adoption of patient safety practices among health care providers, and identified the dynamics and issues that might guide future data collection on practice diffusion for a broader number of providers. We conducted telephone interviews with health care leaders in those communities, and performed site visits with 15 hospitals in the communities.

The data obtained were analyzed to characterize the extent to which the communities had implemented initiatives to improve patient safety practices, including use of tools developed by AHRQ. This approach enabled us to draw upon information already collected by the HSC on the community environments and providers, and to relate choices and progress in practice adoption to characteristics of the providers and the environments in which they deliver care.

- **Provide AHRQ with useful feedback on the experiences of providers in using at least one of the major tools AHRQ has developed to support their patient safety practices.**

What we did. We examined the experiences of hospitals that used the AHRQ Hospital Survey on Patient Safety Culture (presented in Chapter 3). We also considered examining use of the TeamSTEPPS package, but we determined that it was too early because AHRQ still was introducing TeamSTEPPS to the field at the time of this evaluation work.

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We worked with a sample of 17 hospitals that had submitted their culture-survey data to the HSOPS benchmarking database, which is managed by Westat under contract to AHRQ. Through interviews with representatives from these hospitals and two other related organizations, we gathered information on the hospitals' experiences in using the survey and documented the actions or changes that occurred in their organizations as a result of their use of information generated by the survey. We also drew upon information from Westat's analysis of survey data to help inform the interpretation of the interview results. Because of our collaboration with Westat in carrying out this work, our results will be useful for its technical support work, as well as for policy considerations.

- **Develop measurement capability to enable AHRQ to collect trend data on the extent to which safe practices are being used by health care providers.**

    What we did. We developed and performed preliminary testing of a questionnaire to use in a national survey of hospitals on adoption of the safe practices endorsed by the National Quality Forum (NQF), from which adoption rates for the various practices could be estimated (presented in Chapter 4). The greatest challenge in developing data on the diffusion of patient safety practices in the U.S. health care system is the inability to estimate national adoption rates of safe practices by health care providers. Therefore, we saw development of data-collection instruments as an important first step to take. The Leapfrog Group has fielded a survey on hospital use of these safe practices, but because its primary purpose is for public reporting of hospital performance and information support for hospital quality-improvement efforts, its results are not nationally representative and it does not generate adoption-rate estimates.

    We developed a questionnaire that can be used in a national survey to obtain information from hospitals about their implementation of many of the NQF safe practices released in late 2006. We performed cognitive testing of the draft questionnaire, and we also validated it by comparing the questions in the survey to actual practices by 15 hospitals that participated in our community-based study of safe-practice diffusion. The next step would be to pilot-test the survey, in preparation for AHRQ to perform regular surveys to gather trend data on use of safe practices by hospitals.

- **Update trend information for patient outcomes for use by AHRQ in monitoring progress in improving safety outcomes, including exploration of methods that AHRQ might use to examine underlying patterns of changes in outcomes.**

    What we did. Much of the outcome trend analysis performed during the third and fourth years of the patient safety evaluation was continued during these subsequent two years, adding data for the years 2004 and 2005 to the outcome trends (presented in Chapter 5). Any effects of the patient safety initiative on outcomes might begin to be seen in these two years. Additional geographic analyses were performed, continuing the analysis started in 2006 to identify possible patterns of outcome differences or changes in outcomes related to possible patterns of diffusion of safe practices in the health care system (e.g., in multihospital systems).

- **Develop a suggested approach that AHRQ could use to regularly monitor progress being made by the U.S. health care system in improving patient safety practices and outcomes.**

    What we did. Drawing upon the full body of work during the evaluation, including the four analyses presented in this report, we have developed a suggested approach for ongoing

monitoring by AHRQ of progress in the various aspects of effects on stakeholders (presented in Chapter 6). This approach includes tracking trends in practice-adoption rates, assessing effects on various stakeholders, and tracking trends in patient outcomes (the ultimate outcome of patient safety improvements) (see Figure 1.2). We also have identified a number of relevant measurement issues that require attention. Much more work remains to be done to achieve effective measurement of effects on the various stakeholders identified in the evaluation framework.