Assessing Patient Safety Practices and Outcomes in the U.S. Health Care System

Donna O. Farley, M. Susan Ridgely, Peter Mendel,
Stephanie S. Teleki, Cheryl L. Damberg, Rebecca Shaw,
Michael D. Greenberg, Amelia M. Haviland,
Peter Hussey, Jacob W. Dembosky, Hao Yu,
Julie A. Brown, Chau Pham, J. Scott Ashwood

RAND HEALTH

The RAND Corporation is a nonprofit research organization providing objective analysis and effective solutions that address the challenges facing the public and private sectors around the world. RAND's publications do not necessarily reflect the opinions of its research clients and sponsors.

RAND® is a registered trademark.

EXECUTIVE SUMMARY

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). Soon thereafter, the U.S. Congress funded the Agency for Healthcare Research and Quality (AHRQ), in the Department of Health and Human Services, to establish a national patient safety initiative. In its patient safety initiative, AHRQ has funded a portfolio of patient safety research and implementation projects to expand knowledge in this area, provided motivation and guidance for the activities of others, and integrated 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 its Patient Safety Evaluation Center (evaluation center) and evaluate AHRQ's patient safety 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 designed to document and analyze the extent to which patient safety infrastructure and practices are being put into place across the nation's health care system. This report presents the results of that work.

FRAMEWORK AND APPROACH FOR PRACTICE-ADOPTION ASSESSMENT

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. See Chapter 1 for a full description of how the analyses presented in this report fit into our overall evaluation framework and approach.

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, 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

Due to 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. As shown in Figure S.1, the framework consists of five key system components that work together to bring about improved practices and safer health care for patients. We organized our process-evaluation results by these five components and examined the collective contributions of AHRQ-sponsored activities to progress 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 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 (e.g., legal and payment issues) 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.

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).
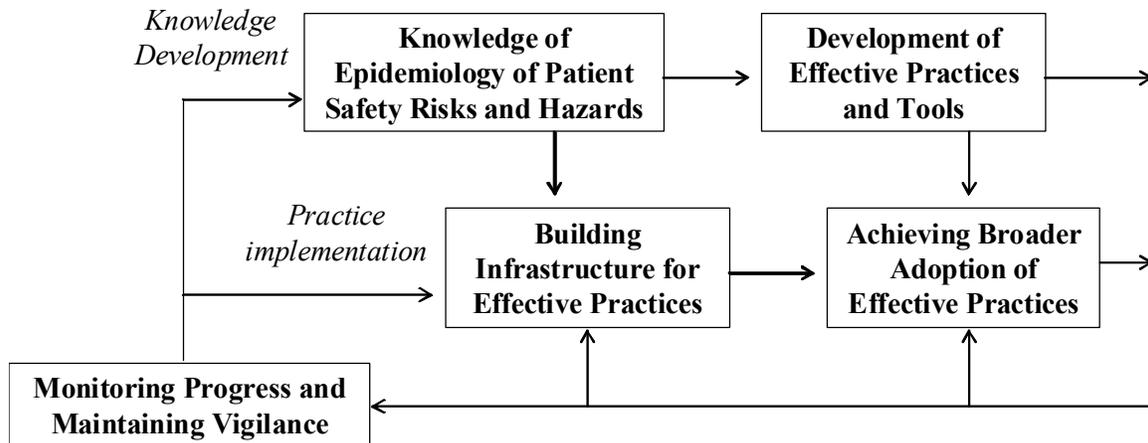
Figure S.1 The Components of an Effective Patient Safety System

Product-Evaluation Framework

In performing the product evaluation, our focus was on stakeholder effects that arise from actions taken for the *practice implementation* aspect of the system framework identified in Figure S.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 S.1 to define the logic model for patient safety effects that is shown in Figure S.2. According to this model, 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 S.1) and these, in turn, should achieve improved outcomes for patients. Both infrastructure development and practice adoption also affect other stakeholders involved in creating a safer health care system, including providers, states, patient safety organizations, 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 interrelated, with often-interacting effects of the various stakeholders involved. While recognizing these limitations, the framework enables us to explicitly identify the key components of these dynamic processes for consideration in the evaluation and in future work by AHRQ.

```
┌─────────────────────────┐          ┌─────────────────────────┐
│ Building Infrastructure │─────────▶│ Achieving Broader       │
│ for Effective Practices │          │ Adoption of Effective   │
│                         │          │ Practices               │
└─────────────────────────┘          └─────────────────────────┘
```
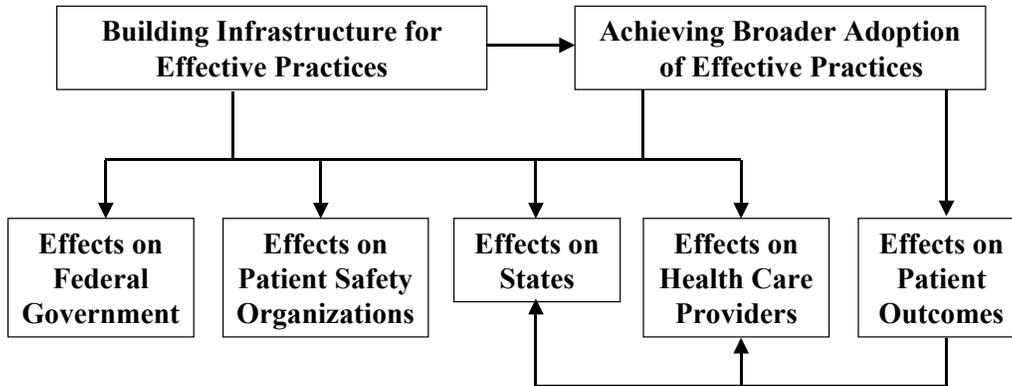
Figure S.2 Conceptual Framework of Potential Effects of National Patient Safety Activities

Analyses Presented in This Report

A product evaluation 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. The case-study approach was chosen because it could generate the most timely data, given that no instrument was available for collecting quantitative data on safe-practice use by providers (presented in Chapter 2).

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

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

- **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 their adoption of the safe practices endorsed by the National Quality Forum (NQF). 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 (presented in Chapter 4).

- **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 two years, adding data for the years 2004 and 2005 to the outcome trends (presented in Chapter 5). These results address outcomes for patients, which is one of the stakeholder groups identified in the framework.

- **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 developed a suggested approach for ongoing monitoring by AHRQ of progress in the various aspects of effects on stakeholders, including practice-adoption rates and effects on various stakeholders, including patients (presented in Chapter 6). We also identified a number of relevant measurement issues that require attention.

This report presents the results of each of these five specific assessments designed to develop information on progress in adoption of safe practices in the field, each of which is the topic of a chapter. The results of the assessments are summarized below.

UPTAKE OF SAFE PRACTICES IN FOUR U. S. COMMUNITIES (Chapter 2)

Specific Aims

1. To trace the evolution of patient safety efforts in four U.S. communities that are typical of local health care markets in various regions of the United States. The unit of analysis was the community. The focus of the study was to document patient safety initiatives and trends over time across three specific sectors within each community—hospitals, ambulatory settings, and long-term care facilities.

2. To understand, in particular, how hospitals in those communities made decisions about adoption of safe practices and how they implemented them within their institutions. The unit of analysis was the individual hospital. The focus of the study was to understand how hospitals are implementing the set of Safe Practices established by the National Quality Forum (NQF, 2007).

Using case study methods, we assessed the uptake of patient safety practices in four U.S. communities, selecting communities from those in the *Community Tracking Study* (CTS) led by the Center for Studying Health System Change (HSC) (HCS, 2009). Since 1996, the HSC has conducted biannual site visits to 12 nationally representative metropolitan areas, to study how the interactions of providers, insurers, and other stakeholders help to shape the accessibility, cost, and quality of health care in local communities. At the time of our study, eight of these communities were also communities in the 2007–2008 regional rollout of voluntary patient safety and quality improvement initiatives by the Leapfrog Group.

We selected four communities for our study that were both study sites in the HSC *Community Tracking Study* and the Leapfrog Group rollout communities. We studied patient safety activities in the following sites:

Indianapolis, Indiana   Cleveland, Ohio
Seattle, Washington   Greenville, South Carolina

We performed the community-level study to allow us to examine activities across health care settings. Then we did the hospital-level study so that we could obtain more-detailed information on the dynamics of patient safety activities by hospitals, which we already were aware was the setting where most patient safety activity was taking place.

Our data collection was performed using telephone interviews with 76 health care leaders in those communities, as well as site visits with 15 hospitals in the communities. In each hospital site visit, we conducted a series of interviews with hospital leaders knowledgeable about the evolution of the hospital's history and strategy related to patient safety, and we conducted two roundtable discussions about specific safe practices that had been implemented by each hospital. The data were analyzed to characterize the extent to which initiatives to improve patient safety practices have been implemented in the communities, including their use of tools developed by AHRQ.

Key Results—Community Level

The IOM report, *To Err Is Human* (2000), brought attention to patient safety, sparked discussion across the local communities, and stimulated actions by health care providers. The pace at which providers and others built momentum, however, varied widely across communities, in some cases taking years before actions began. Although the communities varied widely in their approaches and experiences, we found a number of common themes that could also be relevant for many other communities across the country.

Patient safety can be "evolutionary" as well as "revolutionary" in nature. It is not always a high-profile adverse event that starts a community or a hospital on the road to change. Even after some progress has been made, there may be tragic events, but they can provide an opportunity to rally around the hospital where the event occurred, reminding everyone that "the job isn't yet done." It also was clear that there is no single "best" approach to addressing patient safety and making local health care safer. In some communities, action was collaborative; in others, the hospitals or hospital systems looked inward.

For all of the communities studied, patient safety activities in the ambulatory care and long-term care (LTC) sectors were much less developed than those in the hospital sector. The ambulatory care or LTC organizations that were part of larger, consolidated health care systems were more likely to have undertaken some actions, compared with independent organizations.

Specific key findings are presented in Chapter 2, addressing the following topic areas:

- Use of community patient-safety coalitions
- Lessons from providers' patient-safety experiences
- Perspectives regarding other stakeholders.

Perhaps the most consistent and urgent message conveyed by providers across these four communities was the immense burden being placed on hospitals by the current state of measurement initiatives by national and state organizations. These reporting requirements have been interfering with the ability of hospitals to focus their attention on improving patient safety issues identified as their own priorities. They saw a need for national and state organizations to coalesce around measures, definitions, and goals for measurement and reporting activities.

Key Results—Hospital Activities

Our findings across 15 hospitals[1] in the four communities focused on their experiences in adoption of patient safety practices. Our review addresses the following dimensions:

- How hospitals set their goals and priorities around patients safety
- How they organize and structure their patient safety efforts
- How the process of implementing safe practices plays out in terms of challenges and facilitators
- Their perspective on the role that wider system-level players and forces (including AHRQ) played in promoting patient safety efforts within their institutions.

Goals and priorities. When asked how patient safety became a priority for their institutions, hospital leaders identified a wide variety of reasons, including a catalyzing event (e.g., a very public death from a medical error), an evolutionary process stimulated by outside influences, a natural outgrowth of decades of work on quality improvement, and stimulus by a new chief executive officer (CEO). After 2000, most hospitals began to develop a more strategic structure around patient safety improvement.

Hospitals also used a variety of processes for determining priorities. For some, there was a strong sense that priorities were based on "doing what is good for the patient"—whether that was the result of a sense of a public mission (e.g., safety-net hospitals) or a faith-based mission. Others described formal priority-setting processes that involved the hospital leadership, and often the Board. It was clear that for some hospitals the process of priority setting was a top-down endeavor—with more emphasis coming from the hospital leadership—while leaders in other hospitals emphasized the role of one or two physicians or nurse champions who had attended either AHRQ or Institute for Healthcare Improvement (IHI) meetings and came back with enthusiasm for change that they then spread to their colleagues.

Organization and structure. Hospital leaders described a variety of organizational structures (e.g., various types and levels of committees and staffing schemes) that were mostly idiosyncratic to their hospitals. There were, however, common themes about leadership, including the imperative for committed CEO involvement, a relatively new emphasis on Board of Director involvement in patient safety endeavors, and designation of a Patient Safety Officer (or someone clearly identified to handle that role) as part of (or reporting directly to) hospital senior management. Interviewees also discussed issues about infrastructure, such as incident-reporting systems and the benefits and challenges of health information technology (health IT).

Implementation process. Leaders from the hospitals pointed to a number of challenges they faced in the process of implementing patient safety practices, some of which already were identified in the case studies. The following key observations were made by the interviewees (in their words):

---

[1] Although we identified and recruited 16 hospitals to participate in the site visits, after repeated attempts we were unable to come to a mutually agreeable date for the site visit for the final hospital. By that point, there was not sufficient time to recruit an alternative hospital, so we report here on the experience of 15 hospitals.

- You can figure out what changes need to be made, but getting people at the bedside to adopt the changes can be a challenge.
- Perceptions of a punitive environment linger, despite assurances to the contrary.
- Counteracting physician skepticism to adopting new patient safety practices is one of the most difficult challenges to overcome.
- Simplify the safety message and focus on a few areas, or risk doing nothing well.
- Health IT can be both a challenge and a facilitator.
- For an effort to work, it takes support of the team to gather reliable data.
- Academic medical centers face some particular issues.
- Leverage community resources to supplement those in the hospital.
- Involving front-line staff in patient safety initiatives is empowering.

Role of systemwide players and forces. Every hospital leader mentioned the importance of external forces to their patient safety efforts. Hospital leaders pointed to AHRQ, the Institute of Medicine, the Institute for Healthcare Improvement, the Leapfrog Group, the Centers for Medicare and Medicaid Services, the Joint Commission, and others as critical to raising awareness and providing tools that have been instrumental in stimulating or supporting their own patient safety work.

Yet hospitals feel that they have no option but to respond to the various regulatory and mandatory programs and other private-sector initiatives. At least some of the leaders are skeptical about the value of some of these reporting initiatives to consumers, purchasers, or the hospitals themselves. Staff at the hospitals complained about conflicting standards, fragmented and duplicative reporting and lack of consideration of the effect of measurement on clinical behaviors, and questionable data.

They saw the need for a lead organization to fill the role of bringing the organizations together to prioritize initiatives in order to focus money, time, and effort on the most significant opportunities for improvement. Many of them named AHRQ as the agency best positioned to serve as a lead organization to bring the organizations together, as well as potentially to develop a national data repository for patient safety data. Hospital leaders thought that AHRQ could fulfill this important role by

- Bringing uniformity to safety and quality measures so that health care organizations would have only one set of measure to report
- Ensuring that all indicators have been tested and actually improve outcomes in order to cut down on meaningless or less effective markers, freeing up energy and resources to focus attention on the most meaningful patient safety activities
- Acting as a clearinghouse to facilitate real-time dissemination of patient safety ideas and innovations.

Summary of Community-Study Findings

Taken together, our findings from the community-level case studies and the interviews with hospital leader suggest that real progress has been made in average communities and average hospitals over the past eight years. Hospitals are building organizational infrastructure to support patient safety work, using data from their incident-reporting systems to determine

specific areas for process improvements, and assessing their own progress toward achieving practice sustainability. However, little action was found in ambulatory care or long-term care settings, at least in part due to lack of existing science and tools. Pockets of formal community-wide collaboration can be found, even in very competitive health care markets. Perhaps the most important caution was in the area of measurement. Most respondents reported that current measurement efforts are imperfect and, as "unfunded mandates," may be actually putting patient safety practice at risk by siphoning off resources that could be better spent on addressing safety issues identified as priorities in each hospital. Opportunities for AHRQ leadership are suggested in many of these findings.

USE OF THE HOSPITAL SURVEY ON PATIENT SAFETY CULTURE (Chapter 3)

Specific Aims

1. To develop information on hospitals' motivation and experiences in using the Hospital Survey on Patient Safety Culture (HSOPS).

2. To understand the extent to which the HSOPS has contributed to hospitals' patient safety efforts.

3. To provide feedback to AHRQ on how it might modify the survey questionnaire or offer technical support to enhance the usefulness of HSOPS to hospitals and other users.

One of the major tools that AHRQ developed to help health care providers improve their patient safety culture and practices is the set of Surveys on Patient Safety Culture (SOPS). The first survey developed was the HSOPS. AHRQ also has established a benchmarking database for SOPS data, which is being managed by Westat. Since 2007, annual HSOPS comparative database reports have been published that provide data on HSOPS scores for participating hospitals (Sorra et al., 2007, 2008).

We worked with a sample of 17 hospitals from across the country that had submitted their culture survey data to the HSOPS benchmarking database. We conducted telephone interviews with representatives from these hospitals and two other related organizations, through which we gathered information on the hospitals' experiences in using the survey. We documented the actions or changes that occurred in their organizations as a result of their use of survey information. We also drew upon information from Westat's analysis of survey data to help inform the interpretation of the interview results. As a result 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.

Key Results

In general, the hospitals we interviewed were pleased with the AHRQ Hospital Survey on Patient Safety Culture: the contents of the survey, ease of administration, usefulness to their patient safety strategies and activities, and availability of the national benchmarking data. Not surprisingly, the hospitals varied in how they administered the survey and used the data, as well as in the extent to which they needed and sought assistance in working with it from Westat and other external organizations. From the perspective of patient-safety strategy, hospitals reported that they used HSOPS as a key measurement and monitoring tool in their patient safety initiatives. These findings suggest that the survey was being put to good use in the field.

The interviews also yielded valuable insights regarding possible actions that AHRQ and Westat could take to enhance the value of HSOPS and the benchmarking database for hospitals. We also identified that an increasing number of hospitals were working with external organizations for survey administration and related technical support, which could reduce future demand for benchmarking and technical assistance from Westat, despite hospitals' positive feedback about the support provided by Westat. This information needs to be considered carefully in planning future roles for national-level technical assistance roles, to find creative approaches for gaining synergy between what is provided nationally with what other support organizations are providing.

NATIONAL SURVEY ON ADOPTION OF NQF SAFE PRACTICES (Chapter 4)

Specific Aims

1. To support efforts to monitor and assess the extent to which safe practices are being adopted in the national health care community by creating a national-level survey on hospitals' use of safe practices.

2. To provide AHRQ with supportive information about the survey that it can use as it adinisters and updates the survey in the future.

The greatest challenge in developing data on the diffusion of patient safety practices in the U.S. health care system has been the inability to measure effectively the extent to which each practice actually is being used by providers. Therefore, we saw development of data collection instruments as the first important step to take in this area. We have developed a survey questionnaire that addresses the majority of the set of safe practices endorsed by the NQF (NQF, 2007), which can be administered to a national sample of U.S. hospitals.[2]

Survey Development and Testing

A 93-item questionnaire was developed, tested through cognitive interviews with four hospitals, and then validated by comparing the survey items for each practice to information from the 15 hospitals interviewed in the community study on how hospitals actually implemented that practice. We first determined which of the 30 NQF safe practices were amenable to assessment with a standardized, self-administered survey of hospitals. We used the standard that a safe practice was not amenable to assessment through a hospital survey if the central component of the practice necessitates observation or chart data to ensure that implementation has occurred. Through a detailed review of each practice, we concluded that 22 of the 30 safe practices could be assessed using an organization survey.

We then created seven groupings of these 22 safe practices based on similarity of topic and hospital function that would use them. This was done for the twofold purpose of providing a framework for organizing the safe practices in the survey and for exploring a modular sampling strategy to reduce data collection burden on hospitals. These groupings were patient safety culture, communication with patients or families, transparency across continuum of care, surgery procedures, medical evaluation and prevention, medication safety management, and workforce.

---

[2] The National Quality Forum is a national organization that reviews and approves health-quality measures, using a consensus process, with the goal of establishing national standards of measurement.

For each safe practice included in the survey, we drafted a set of survey items. Our primary goal was to stay true to the intention, and—as much as possible—to the actual language of each safe practice, as outlined in the Safe Practice Update document (2007). Our core survey-development team consisted of two health services researchers and two staff from the RAND Survey Research Group. Throughout this process, we consulted with clinicians and other RAND researchers with expertise in patient safety, hospitals, and organization surveys.

We conducted cognitive-testing interviews with teams of staff at four hospitals—two in the Los Angeles area and two in the Pittsburgh area. In advance of the interview, each hospital was sent a subset of the draft survey items to be addressed in the interview, which represented approximately two-thirds of the survey. All hospitals received the patient safety culture group, and we divided the remaining practice groups in the survey among the four hospitals.

After revising the draft survey based on cognitive-testing results, we then validated the survey items using data collected in the roundtable discussions with the 15 hospitals that participated in our community study, as discussed above. The goals were to (1) assess how well the survey questions "fit" how hospitals actually implement and use each practice, and (2) solicit specific comments on individual survey items. The written notes from the roundtable discussions were reviewed in detail by a researcher on our survey development team, to identify themes and issues regarding implementation of each safe practice and assess the extent to which the survey questions were consistent with hospitals' actual practice. The core survey-development team then discussed these validation findings as a group.

This questionnaire is now ready for updating and pilot testing before use in a full national survey. The results of this work, presented in Chapter 4, include suggestions for pilot tests and fielding of the survey.

Key Results

Our findings from the cognitive interviews and validation process suggest that, in general, respondents understood the questions and that the questions obtained the desired information about the hospital's patient-safety activities. Hospital responses also identified weak or unclear areas of the survey, which we addressed in subsequent revisions. The pilot test should be used to further examine interpretation of key phrases, definitions, and item intent (e.g., Do terms and phrases have consistent meaning across respondents? Do respondents have uniform understanding of item content?).

Hospitals frequently are asked to complete surveys, and in our discussions with them, many expressed significant resistance to completing yet another survey. Through the testing we conducted, we found that completion of the entire survey requires approximately 2 to 3 hours. However, this preliminary estimate was extrapolated based on hospitals' completion of only parts of the survey, not the entire survey. The pilot study also should test overall hospital and individual respondent burden to complete the survey in its entirety, and determine the survey administration cost per completed survey.

NQF periodically updates its set of safe practices, and indeed it published a revised set of safe practices in March 2009. Therefore, careful consideration should be given to revising the current survey version. It is important to ensure that the survey reflects up-to-date evidence and recommendations; nevertheless, any proposed changes will need to be weighed against the ability to estimate trends, given the importance of being able to conduct longitudinal analyses.

TRENDS FOR PATIENT SAFETY OUTCOMES (Chapter 5)

Specific Aims

1. Continue much of the outcome trend analysis performed during the third and fourth years of the patient safety evaluation, adding data for the years 2004 and 2005 to the trends. Any effects of the patient safety initiative on outcomes might begin to be seen in these two years.

2. Perform additional geographic analyses to identify possible patterns of outcome differences or changes in relation to possible patterns of diffusion of safe practices in the health care system (e.g., in multihospital systems).

Our work in evaluating patient safety outcomes followed two tracks during the two-year assessment focusing on practice adoption. These analyses for patient safety outcomes complement other analyses of changes in uses of safe practices and event-reporting activities, by addressing another key dimension of effects related to patient safety activities.

First, we continued to estimate trends on several patient outcomes measures based on inpatient-encounter or reporting-system data. For the first time in our outcome analyses, this year we also sought to identify changes in the trend lines for the measures used, because we had two years of post-baseline data to examine. We have used 2003 as the end of the baseline period (the earliest time at which we estimate the patient safety activities across the country might begin to show effects on patient outcomes). Second, we pursued several analytic projects, including an investigation of patterns by which changes in patient safety outcomes might diffuse across organizations in the health care system, and an analysis of differences among hospitals in trajectories of change for their patient safety measures.

Key Results

Results of our most recent trend analyses for the AHRQ Patient Safety Indicators (PSIs) as measures of patient outcomes, offer some hope for potentially being able to observe, within a few years, statistically significant reductions in rates for some of the PSIs we have tracked. Our analyses presented in this report now include data for two years following 2003 (the last year in the baseline period we defined). We observed slight downward changes in national rates for four of the PSIs, relative to their baseline trends, but because of the small sizes of changes and limited number of years of post-baseline data, it is too early to tell if those changes are real. Additional years of data will be needed to detect statistically significant changes.

The preferred types of measures for monitoring changes in outcomes over time are those for which objective data are available on a national level, and which can yield estimates that are robust in completeness, validity, and reliability, both in any given year and in trends over time. As we have worked with currently available outcome measures, however, we have found that many of these measures are vulnerable to measurement challenges.

This finding leads us to conclude that, to be effective, the monitoring process for AHRQ's patient safety initiative should track trends in both patient-outcome measures and the implementation of safe practices that are supported by scientific evidence as being effective in reducing harm to patients. As adoption of such evidence-based practices grows over time, it may be inferred that the practices are leading to improved patient outcomes, many of which may not be detectable in the outcome measures selected for national monitoring.

Some important opportunities remain for future action by AHRQ. Ambulatory and long-term care settings continue to be a high priority for measure-development efforts. State-level

reporting systems also present a priority for refining and harmonizing adverse-event measures, ultimately in support of the ability to aggregate reported data on a regional or national basis. Inconsistency in coding of administrative data and lack of continuity in measurement definitions for the PSIs remain serious concerns in ongoing efforts to use these data.

SUGGESTED APPROACH FOR MONITORING EFFECTS OF THE PATIENT SAFETY INITIATIVE (Chapter 6)

Specific Aim

1. To provide suggestions to AHRQ regarding the structure and processes for a program of ongoing monitoring of patient safety outcomes, performed either by itself or through an external contractor, after the work of the Patient Safety Evaluation Center is completed.

We anticipate that AHRQ will continue its own monitoring efforts after our evaluation effort ends. Such national monitoring would provide policymakers and the public with transparency regarding the status of patient safety in the U.S. health care system. It also would enable AHRQ to assess effects of its own investments in patient safety and develop a better understanding of which initiatives are most effective in promoting patient safety.

Components of a Suggested Monitoring Program

As a result of our work on the product evaluation, one of our key conclusions is that the monitoring process for AHRQ's patient safety initiative should continually assess

- Implementation of safe practices
- Patient-outcome measures
- Effects on other stakeholders.

The safe practices of interest are those that are supported by scientific evidence as being effective in reducing patient harm. As growth in the adoption of evidence-based safe practices is observed over time, it may be inferred that these practices are improving patient outcomes, many of which may not be detectable in the outcomes measures selected for national monitoring.

A monitoring program should examine, at a minimum, how the nation's patient safety activities are affecting the range of stakeholders involved, in addition to patients. If such an examination is not done, important effects that merit attention could be missed. Further, by tracking trends in adoption of key patient safety practices, it is possible to infer that progress is being made in the right direction, which, eventually, should be manifested in improved patient outcomes (if the practices are evidence-based).

The monitoring program we are suggesting consists of four components: tracking trends in patient safety-practice adoption, tracking trends in relevant patient outcomes, assessing effects on other stakeholders, and assessing how the AHRQ patient safety initiative has been contributing to these three types of effects.

Capabilities Needed for Effective Monitoring

Through our exploratory analyses of effects of national patient safety activities on relevant outcomes, we identified a number of issues that are barriers to achieving valid and reliable measures that can be monitored with confidence. In our discussion of needed monitoring-system capabilities, we examine these issues and possible ways to address them:

Establishing appropriate patient-outcomes measures

- The need for measures for other settings, beyond hospital inpatient care
- Improving measures of adverse events from event reporting systems
- Adding measures of patient and family safety experiences on Consumer Assessment of Healthcare Providers and Systems (CAHPS®) surveys
- Establishing measures of practice adoption.

Establishing valid measures

- Validating existing patient-outcomes rate measures
- Validating event-reporting measures

Consistent definitions and calculation of measures

- Defining *patient safety event* to eliminate conflicting approaches
- Correcting coding issues for the PSIs
- Developing additional data sources, especially in ambulatory care and long-term care.
- Improving measurement consistency across state event-reporting systems.

Appropriate trending methods for the PSIs

We suggest that AHRQ take the following related steps to achieve credible estimates for outcomes trends for the PSIs:

- Any publication of updated PSI definitions or algorithms should include not only a full version history, describing all updates and changes, but also the rationale behind those changes.
- Any longitudinal-tracking effort (e.g, annual *National Health Quality Report*) should state explicitly which version of the indicators is being used, and the effect of any minor updates to the indicators should be examined and published as well.
- When major revisions are made to the PSIs, retrospective analyses may be needed to see how new definitions affect old years of data: major measurement changes may make old years of published summary statistics noncomparable to more-recent years of data.

Transparency in Public Reporting of Trends

From our analyses of trends in the PSI measures, we identified several issues regarding the public reporting that AHRQ has performed for these measures. We believe these issues merit attention. AHRQ has been reporting publicly on health care quality for a number of years through its annual *National Health Quality Report* (NHQR), including trends for some PSIs and other measures of patient safety outcomes. However, recent NHQRs have moved away from providing explanations of how their small set of reported measures have been drawn from the many available measures. In addition, for the patient-safety outcome measures it does cover, the NHQR has not discussed the methods used and limitations for sampling, data, or measure computation. We suggest that future NHQRs could be made more helpful by

- Providing a clearer explanation of which patient safety measures are included in the print version versus online version
- Providing additional technical background information on the sampling, data, and methodological issues that qualify the interpretation of trends in patient safety outcomes

- Presenting more than a few years of data on each measure, to provide a more-accurate perspective regarding patterns of safety outcomes over time.

DISCUSSION

Although it is important for AHRQ to measure effects of its initiative on patient safety activities and outcomes in the U.S. health care system, such measurement has been shown to be difficult for several reasons. One challenge is the limited availability of tools to measure many of the salient effects at a national level—in particular, the adoption of safe practices and effects on a variety of stakeholder groups. The most developed measures are for patient outcomes, but even these are available primarily for hospital inpatient care, with few measures available for ambulatory care or long-term care settings. Further, measurement of patient outcomes remains fraught with issues related to changes over time in measure definitions and coding.

Another challenge is AHRQ's limited funding relative to the magnitude of the patient safety problem, which has limited AHRQ's ability to have a strong influence on outcomes measured at the national level. AHRQ has taken a collaborative approach of working in partnership with many other organizations to effect patient safety improvements. This strategy effectively leverages its limited funding, but it also makes it difficult to attribute any observed changes in outcomes specifically to AHRQ's efforts. Such attribution might be most feasible for effects from the AHRQ-funded patient safety projects; many of these projects would not have happened without AHRQ funding.

AHRQ showed foresight in providing for an analysis on the diffusion of safe-practice adoption at the end of the Patient Safety Evaluation Center contract. The results of this two-year analysis, which are presented in this report, serve as a good "first step" in this assessment process. From the community study, we know that average U.S. communities have indeed been making progress in adopting safe practices, using a variety of approaches, and we have extended the evidence that most of the activity has been in the hospital inpatient sector. Most of this activity has occurred in only the most recent 3 to 5 years, however, and as the providers readily attest, they are still some distance from achieving sustainable safety practices and outcomes. We also have learned that many hospitals across the country are successfully using one of the major tools that AHRQ has developed and supported—the HSOPS—and that this survey is contributing to their patient safety strategies as both a diagnostic and monitoring tool.

Despite this observed progress, our work here has reconfirmed that much remains to be done. More work is needed to develop tools and measures for patient safety in the ambulatory care and long-term care sectors, as well as to establish a national capability to monitor changes in patient safety infrastructure, practices, and effects on a variety of involved stakeholders. Moving forward on future monitoring activities, we encourage AHRQ to use the product-evaluation model to guide its work on tracking practice-adoption activities and their effects on various stakeholder groups. Over time, AHRQ can use the model to ensure that its assessments have considered all of the key system components and stakeholder groups.