

Developing Best Practices for Patient Safety

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1. Structured Abstract

Purpose: To improve the national evidence base for measuring and predicting potential patient safety problems, and to investigate cost-effective strategies for improving patient safety practices at individual hospitals.

Scope: Patient safety is an important national goal, but the determinants of safety, particularly safety culture, are not fully understood. New culture survey work under the project took place in a Consortium of 26 California and Nevada hospitals. Analysis of potential patient safety indicators (PSIs) was conducted using broader groups of hospitals.

Methods: Working from previous surveys and theoretical constructs, we developed a survey tool for assessing culture: the Patient Safety Climate in Healthcare Organizations (PSCHO) tool. In 2001 and 2002, Consortium hospitals were surveyed using the tool. Data were analyzed to study the performance of the instrument and patterns in safety climate scores. PSI measures were computed for many hospitals, and some analyses of relationships between PSIs, PSCHO survey scores, and other measures were conducted.

Results: The survey was implemented in Consortium hospitals, and results were reported back to hospitals. Overall, approximately 18% of responses to survey questions were “problematic,” in that they indicated absence of safety culture---much higher than in at least one comparison setting (naval aviation). Hospitals exhibited a range of responses to the data and are engaged in a number of new activities around safety. Analysis of PSI measures suggests some relationships with hospital characteristics, with additional analysis ongoing.

Key Words: patient safety, culture, quality

2. Purpose

This project had two overall goals. One goal was to develop a more comprehensive evidence base on the impact of major recent patient safety initiatives in hospitals throughout the country. Some evidence exists on the impact of specific innovations in computerized drug ordering systems in reducing medication error rates.¹ Even in this case, evidence exists primarily on the impact of interventions on inappropriate use of medications. Evidence on the impact on costs of care and on patient outcomes,² some of which has been developed by project investigators,³ is quite limited; much of it is based on simulations or assumptions about what costs would have been in the absence of a patient safety initiative rather than on empirical evidence on the actual resource use of affected patients. Moreover, experts on quality and patient safety widely believe that the most effective approach to minimizing errors must go well beyond specific changes in computerized information and order entry systems.^{4,5,6} Evidence from other industries, in which errors also may have catastrophic consequences, including airlines and submarines, suggests that a “culture of safety” is required to minimize serious errors.⁷ The limited evidence from the hospital industry that exists on the impact of systematic efforts to change institutional culture and adverse event outcomes has made it more difficult to identify cost-effective approaches for improving patient safety, which in turn has probably hampered the implementation of effective patient safety reforms in hospitals.

Our second, closely related goal was to contribute to the development of effective strategies for improving patient safety at a diverse range of individual hospitals. Perhaps because of both the relatively recent attention directed to patient safety and the limited evidence on effective approaches, many different approaches to promoting patient safety are under development. Although many of these initiatives focus on medication safety,^{8,9} patient safety initiatives range from anesthesia¹⁰ to patient restraint systems and procedures for preventing cardiac arrests.¹¹ A number of the hospitals, hospital associations, and investigators participating in our consortium have played leading roles in developing these patient safety initiatives. Despite their diversity in details, virtually all these systems emphasize the importance of organizational culture---a fundamental orientation of each organization---to achieving safety goals.

The overall purpose of this project was to approach our two main goals by working with a group of hospitals to better measure and improve safety culture. Previous studies suggest that an effective strategy for changing organizational culture should include ongoing, high-level management attention; regular meetings and opportunities for communication about obstacles and opportunities for implementing safety initiatives; specific targets for interventions that are regarded as important and achievable goals; and specific, ideally quantitative feedback on the impact of safety initiatives.^{12,13} We integrated these features into our efforts to measure and improve safety culture in a group of hospitals.

We focused particularly on the development of a tool for measuring patient safety, the implementation of that tool in a group of hospitals, reporting results from the project back to hospitals, and engaging hospitals in conversations about culture and their efforts to improve safety. Furthermore, we worked to develop a range of other measures of patient safety (called “patient safety indicators” or “PSIs”) from administrative or similar data and to analyze them and their relationship to safety culture and other hospital characteristics.

The specific aims of the project included the following:

1. For the majority of US hospitals, to construct a broad range of potential patient safety indicators (PSIs) that can be used on a routine basis to provide empirical evidence on possible patient safety problems.

2. Describe recent trends in important patient safety practices at most US hospitals, and use supplemental surveys to describe patient safety practices and “safety cultures” in detail at Consortium hospitals.
3. Examine the empirical relationship between patient safety practices, PSIs, and hospital resource use with statistical methods that recognize the limitations of available measures and potential reporting biases.
4. Conduct an ongoing initiative to help Consortium hospitals share, assess, and improve their patient safety practices, including presentations of our empirical analysis tailored to the individual hospitals.
5. Prepare manuscripts and present major findings on effective interventions for improving hospital patient safety, and incorporate our findings into the ongoing strategies of the participating organizations to promote patient safety in their member hospitals.

3. Scope

Background and Context

Patient safety problems appear to be far too common in the delivery of hospital care.^{14 15 16 17 18 19} By some estimates, as many as a half million preventable injuries and 98,000 preventable deaths may occur each year, at a cost estimated to exceed \$30 billion per year.²⁰ Most of these injuries and deaths arise from errors in the course of inpatient care and could be prevented by more effective institutional programs to promote patient safety.²¹²² As a result of considerable recent attention to patient safety problems, many institutions and collaborative organizations, including the hospitals and associations participating in the Patient Safety Consortium, have begun to implement patient safety initiatives. However, effective implementation of patient safety programs is hampered by the paucity of evidence on the effectiveness and cost of comprehensive patient safety programs for reducing avoidable injuries. This project aimed to fill critical gaps both in the effective implementation of patient safety initiatives and in the development of evidence on their effectiveness.

In particular, improving safety culture appears to be an important element of improvements in safety. Ongoing efforts have begun to examine culture, but much remains to be done to fully understand it. Moreover, tools for measuring patient safety more broadly continue to require development, refinement, and examination.

Settings and Participants

Activities of this project were largely conducted in the context of a Patient Safety Consortium, which consisted of a partnership between 26 diverse California and Nevada hospitals, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Institute for Safe Medication Practices (ISMP), the California Healthcare Association (CHA), and the Patient Safety Center of Inquiry (PSCI) at the Department of Veterans Affairs. The project built on activities related to quality of care and medical errors underway in all the participating organizations.

Efforts to compute and study broader PSIs typically focused on larger sets of hospitals, including hospitals represented by the AHRQ HCUP data sets, hospitals surveyed by JCAHO, and other generally broad groups of hospitals.

3. Methods

Initial analyses and work on the project suggested the importance of focusing on safety culture, and so many of the efforts of the project were directed to developing a tool for measuring culture and implementing it with consortium hospitals.

Patient Safety Climate in Healthcare Organizations Survey

Due to perceived deficiencies of available instruments for measuring safety climate, Stanford University's Center for Health Policy and Center for Primary Care and Outcomes Research (CHP/PCOR) and the Patient Safety Culture Institute (PSCI) at the VA Palo Alto Health Care System developed the Patient Safety Climate in Healthcare Organizations (PSCHO) survey, a tool that includes aggregated concepts and questions from existing instruments. This tool assesses attitudes and experiences of hospital personnel about the safety climate as enacted in their organizations.

Survey Instrument. The survey instrument, initially constructed by PSCI, was adapted with permission from five existing surveys.²³ Review of these instruments demonstrated partially overlapping questions covering 16 topics plus demographic information. Many of these topics have been identified as important to a culture of safety.^{24,25,26,27}

The preliminary survey instrument was tested extensively in pilot studies at VA facilities prior to the implementation at the Consortium hospitals. After modification based on feedback about specific questions in the pilot studies, a revised instrument (94 questions plus demographics) was distributed to Consortium hospitals in two mailing waves. The final instrument used in the last wave in 2001 and in all waves of 2002 was an abridged version (32 questions plus demographics) that was created by eliminating overlapping questions through factor analysis. All questions were close ended. A five-point Likert scale was used.

Human subjects approval to conduct this survey was granted in advance by the relevant Institutional Review Boards of all of the participating institutions.

Survey Sample. At each participating hospital, the target sample was 100% of the hospital's attending physicians, 100% of senior executives (defined as department head or above), and a 10% random sample of all other employees (designed to be different groups of employees in each year). Logistical issues required small variations to this sampling strategy in some hospitals.²⁸ Excluding undeliverable surveys, the total survey sample size in the 12 hospitals was 5,685 in 2001 and 6,090 in 2002. The response rate was 46% (2,643 respondents) in 2001 and 45% (2,753 respondents) in 2002.

Survey Administration. We surveyed 15 hospitals in 2001. Approximately 13 months after the first survey implementation, we surveyed a group of 18 Consortium hospitals, including 12 hospitals that participated previously. Survey recipients received packets via US or inter-office mail, which included a cover letter co-signed by an investigator and a senior executive from the applicable hospital, a paper survey instrument, a business-reply return envelope, and a separate questionnaire completion notification (QCN) postcard (first two mailing waves only). The QCN postcard allowed us to track nonresponders to each of the first two waves without compromising the anonymity of the survey responses. We examined survey results to determine which attitudes and experiences varied by hospital, job class, clinical status, and over time among these hospitals as measured by the PSCHO instrument. Because the participating hospitals made patient safety a high priority and implemented a variety of initiatives to improve safety culture, we hypothesized that the rate of problematic responses to the same set of questions would be lower in 2002 than in 2001.

Weighting of Data. We applied two weights multiplicatively to the raw data to allow accurate comparison across participating hospitals and job types and to correct in part for subject nonresponse. To correct for the different sampling strategy for executives and physicians (100% sampling) versus other employees (10% sampling), we weighted responses of other employees by a factor of 10 relative to executives and physicians. For hospitals that surveyed fewer than 100% of physicians or senior managers, we adjusted sampling weights accordingly. This weighting was applied whenever responses from different job types were aggregated together. To correct for the different rate of nonresponse to the survey from employees of different job types, we created our primary data set by weighting the respondents for each of three job types by the inverse of the (all-waves) nonresponse rate for that job type. For example, if the overall response rate across all waves of management, physicians, and other employees was 66%, 33%, and 50%, respectively, the relevant respondents would be weighted by factors of approximately 1.5, 3, and 2, respectively, to account for nonresponders. We also created alternate data sets that accounted for the nonresponders by weighting the waves separately. Responses to waves 1 and 2 were significantly more likely to suggest the absence of a culture of safety (i.e., they were more “problematic” about safety culture than were those to wave 3). Weighting respondents only from wave 1 and 2 to account for those who never responded to any wave yielded a data set that gives a relatively pessimistic estimate of safety culture by the nonresponders. Weighting only the wave 3 data to account for nonresponders created a more optimistic estimate of nonresponder attitudes.

Analysis. To allow aggregation across the different survey questions and comparison across hospitals and job types, we compared “problematic responses” for each question. The answer choice that constituted a “problematic” response varies by question, depending on how the question was phrased. For example, in response to “I will suffer negative consequences if I report a patient safety problem,” to agree or strongly agree was considered problematic. In contrast, in response to “I am rewarded for taking quick action to identify a serious mistake,” to disagree or strongly disagree was problematic. We also examined the frequency of neutral responses, as these might also imply a lack of safety culture (Kearney L, PhD, Vice President, Professional Services, Summit Leadership Solutions, Colorado Springs, CO, personal communication). “Neutral” responses were neutral on questions using a five-point Likert scale.

Communication with Patient Safety Consortium Hospitals

In addition to developing and implementing the survey, an important goal of the project was to work with hospitals to improve their culture and safety overall. Personnel at the Consortium hospitals were aware of survey results and were engaged in a variety of other patient safety activities during the study period. Following each implementation of the PSCHO survey, we presented hospital-specific and aggregated results from the surveys to senior management groups from each hospital, asking standardized questions designed to elicit interpretation and reaction to the results and to promote discussion of past and current patient safety activities. In addition, teams of hospital executives conducted annual self-assessments of current safe medication practices using the Institute for Safe Medication Practices (ISMP) tool, and hospitals shared and discussed results with investigators.²⁹ Participating hospitals received ongoing information about patient safety activities nationally through a Patient Safety Consortium list-serve and project website (<http://healthpolicy.stanford.edu/PtSafety>). They participated in conference calls to discuss survey results as well as specific topics of interest, including implementation of computerized physician order entry systems. Hospitals also participated in annual Patient Safety Consortium conferences, at which hospital representatives and experts discussed

and shared documentation of recommended practices on topics such as building a business case for safety, the role of senior management in creating safe cultures, and designing and implementing safe medication plans. These activities suggest the possibility of change between the two surveys.

These activities also provided strong opportunities to gather qualitative information, based on hospital experiences, about the areas of greatest progress as well as those of greatest continuing difficulty and about some of the critical factors considered necessary to improve safety culture and patient safety more generally.

Cross-Industry Comparison of Safety Culture

Evidence from other industries is important in providing a comparison for safety culture in hospitals. In collaboration with Tony Ciavarelli, PhD, and colleagues at the Naval Postgraduate School, Stanford investigators are now analyzing data from a 61-question Command Safety Assessment Survey (CSA), created by Ciavarelli. Many questions from the CSA were adopted for use in the PSC Culture Survey. For these questions, we compared the Navy results against the Patient Safety Cultures in Healthcare Organizations survey results. The CSA data includes 6,901 respondents from participating squadrons in the US Navy.

Patient Safety Indicators

Beyond culture, there are a number of other potentially useful measures of safety outcomes and related issues in hospitals. We worked to compile additional measures and conduct analysis of them. First, we sought to improve the evidence base on the effects of patient safety practices by determining the relationship between practices and a variety of safety-related outcome measures. The major set of measures captures adverse events in hospitals using hospital discharge data. Originally pioneered in the early work under this grant, these measures have since been incorporated into a much broader framework of quality measures developed and studied by AHRQ. In this context, the measures envisioned and originally developed in this project are the precursors for what are now the “Patient Safety Indicators,” or PSIs, in the AHRQ Quality Initiatives project. Thus, much of the analysis of PSIs under this grant contributed insights used in the related work; conversely, this project benefited from the extensive development of PSIs in the larger AHRQ project. The PSIs we ultimately used here were constructed following the protocols in the AHRQ PSI set.

Using multivariate signal extraction methods (MSX), investigators compared a set of outcomes-related measures of potentially preventable safety events to a variety of potential determinants of patient safety. The PSIs are measured using HCUP discharge abstract data, Medicare claims data, and Death Record Index data on a national basis.

In addition to the PSIs and climate survey, we collected data on a range of factors that may influence patient safety practices. These include accreditation survey data from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO); hospital financing and organization characteristics from the American Hospital Association, Medicare Cost Reports, and Dun and Bradstreet; nurse staffing ratios; and safety climate and medication practices from CHP/PCOR-PSCI and ISMP, respectively. We also collected data on state laws and policies related to patient safety and event reporting.

With these data, we performed descriptive comparisons and formal statistical analyses of the relationship between various potential determinants of patient safety and the PSIs and related measures. Essentially, we used statistical modeling to examine the relationships between hospital characteristics and PSIs or related measures. We typically used regression models, controlling for a range of factors.

Results

PSCHO Findings

The implementation of the PSCHO survey in Consortium hospitals produced data that we used both to report back to the individual hospitals and in other analyses of culture. Some of the main findings are reported below. Others are in manuscripts that were produced, which are included in the bibliography.

Response rates from administration of the survey were generally quite good, and administration of the survey was generally viewed as successful.

Survey implementation	Overall	Excluding Physicians	Total Surveys Returned
2001	47%	62%	2,643
2002	45%	65%	2,753

Other than the slight decline in the proportion of physicians among respondents overall, the demographics of respondents changed little between 2001 and 2002. Women made up a slight majority of respondents overall. Although women represented almost half of senior managers, they constituted less than 30% of physicians. More than 60% of the sample was between 40 and 60 years old, and more than 60% were physicians, nurses, or pharmacists.

2001 Demographics-12 PSC Hospitals				2002 Demographics-12 PSC Hospitals			
	Female	Male	Overall		Female	Male	Overall
Overall	54%	46%	100%	Overall	53%	47%	100%
Job Class				Job Class			
Senior Manager	7.2	7.3	14.5	Senior Manager	7.1	7.8	14.9
Physician	10.0	25.1	35.1	Physician	8.3	25.2	33.5
Other Employee	36.5	13.9	50.4	Other Employee	37.9	13.7	51.7
Age				Age			
18-25	1.1	0.3	1.3	18-25	1.1	0.3	1.4
26-30	4.1	0.6	4.6	26-30	3.6	1.1	4.7
31-40	12.3	8.6	20.9	31-40	12.1	10.3	22.4
41-50	20.3	15.8	36.1	41-50	19.3	15.5	34.7
51-60	13.1	14.2	27.2	51-60	14.3	13.1	27.3
>60	3.0	6.9	9.9	>60	3.0	6.5	9.5
Clinician Status*				Clinician Status*			
Physician	11.5	30.1	41.6	Physician	9.6	30.4	39.9
Nurse	16.4	1.6	18.0	Nurse	18.3	1.4	19.7
Pharmacist	0.9	0.4	1.2	Pharmacist	0.4	0.7	1.1
Other Clinician	5.4	2.4	7.8	Other Clinician	5.1	2.1	7.2
Nonclinician	19.5	11.9	31.4	Nonclinician	19.7	12.4	32.1

*Physicians include Staff Physicians, Residents, Interns, and Fellows. Nurses include RNs and RNP's. Other Clinicians are LVNs, Nursing Assistants, Physician Assistants, Physical Therapists, Respiratory Therapists, Audiologists, Psychologists, Occupational Therapists, and Speech Pathologists. Nonclinicians are Housekeeping Aides, Food Technicians, Clinical Lab Technicians, Ward/Clinic Clerks, Patient Travel/Escorts, Radiology Technicians, and Other.

We found that, although the majority of survey respondents answered in ways indicating a strong safety climate, a substantial minority of respondents (18% on average) gave problematic responses. A similar percentage provided neutral responses. Average problematic responses among hospitals in 2002 ranged from 13.0% to 20.9%, approximately the same as in 2001. In 2001 and 2002, we also found that senior managers, especially nonclinician senior managers, were significantly *less* likely to give problematic responses than frontline workers, and clinicians were *more* likely to give problematic responses than nonclinicians.³⁰ We compared responses among hospital personnel against responses among personnel from another high-reliability organization, naval aviation. This analysis showed that problematic responses among hospital personnel were three times higher than those among naval aviators and up to 12 times greater on individual questions.³¹

Although the overall share of problematic responses remained similar between the 2 years, there were some areas in which significant improvement was noted. In particular, the rate of problematic response declined by almost 2% among questions that focused on organization and management issues. Employees reported significant improvement on questions that asked about whether patient safety decisions were made at an appropriate administrative level, whether employees had enough resources to provide safe patient care, and whether they had observed a coworker do something that appeared unsafe for a patient. Problematic responses also increased significantly in some areas between 2001 and 2002: a larger percentage of personnel felt that they lacked time to safely complete tasks, that asking for help is a sign of incompetence, and that it was easy for clinicians to hide mistakes.

The difference between senior managers and frontline personnel in percentage of problematic responses increased significantly from 2001 to 2002. Frontline workers had a rate of problematic response that was 4.7 percentage points higher than that of senior managers in 2002, compared with 3.3 percentage points in 2001. Attitudes among physicians also changed, frequently becoming more negative.

In all, these results point to the potential for meaningful changes over time, but a longer time series and probably a larger sample of hospitals will be necessary to determine whether true changes have occurred.

Feedback from Hospitals

In discussions, hospitals reported a wide range and mix of patient safety improvement activities, including adoption of error-reducing technologies, patient safety committees, educational programs, self-assessments, and other organization-wide initiatives. However, hospital reports on the results of these activities appeared to be mixed and most often dependent on success in the implementation phase. Overall, we found that leadership, creativity, and established reporting processes and communication channels, combined with meaningful data on the effectiveness of improvement initiatives and attention to implementation issues, were essential to improving patient safety in participating hospitals.³²

Patient Safety Consortium (PSC) hospitals rated themselves better on the ISMP self-assessment in 2002 than in 2001 (73% v 65%). In addition, PSC hospitals (2002) scored themselves higher than the US average (2000) (73% v 57%).

PSIs

We conducted work in several areas with PSIs and other related data. 1) We computed the PSIs for all hospitals for which we could get data from the AHRQ HCUP project through the central distributor. This process included keeping up with revisions to the measure specifications over time. This effort was generally successful and provided a basis for more exploration. There were

some delays in getting the PSIs computed due to a delayed start in the release of the patient safety indicators (not publicly available until March 2003 and revised in October 2004); thus, some of the subsequent analyses were delayed as well. In the end, we were able to make progress on many important analyses, though some of this work remains in preliminary draft stage, and results are not ready for submission yet. 2) We worked with JCAHO to define a set of standards for analysis. This proved to be time consuming, as there are a large number of JCAHO standards, and the standards change every year. We analyzed the complete set of standards from multiple years and selected a group of standards that are appropriate for comparison with the PSI data. We were able to conduct basic analysis of this data, though initial results did not reveal strong associations. We have a manuscript in progress that describes these analyses, though it is not ready for release yet. 3) We computed measures of nurse staffing ratios at hospitals. We worked to develop a theoretical framework for studying nurse staffing and PSIs, because previous work does not offer a strong multifaceted theoretical structure for understanding linkages between nurse staffing, patient volume, organization size, and other key variables. We also conducted some analyses of empirical relationships between nurse staffing and PSIs. Due to the need to circle back and work on theoretical frameworks, the full empirical analysis is not complete. We anticipate producing a manuscript on these analyses in the next several months. 4) We collected data on the financial status of hospitals and conducted analysis of the relationship between financial status and patient safety measures. This work is nearing completion and suggests that hospitals with better financial performance do better on patient safety. We are in the process of submitting abstracts of this work to professional meetings and completing the paper reporting these results. 5) We worked with hospitals that had completed the ISMP self assessment to study relationships between self assessments, PSIs, and culture scores. This analysis proved disappointing due to small samples and empirical difficulties, so it was not pursued. 6) We studied the relationship between state adverse event reporting laws and PSIs. Initial analysis did not reveal statistically significant relationships, but we continue to pursue more refined models and anticipate being able to produce a manuscript describing these analyses over the next year or so.

Future work

Over the past 2 years, our research team was contacted by 37 researchers in nine countries who were interested in implementing the PSCHO at their facilities. At least four of the researchers are implementing the survey in its entirety; others used pieces of the tool in their own research. We routinely provide researchers and students the tool and implementation guidelines, and we hope to complete some comparisons in the future.

We are currently implementing the survey in a diverse group of hospitals across the United States. This research, which is also supported by AHRQ, will provide additional information on safety culture nationally and will examine regional differences that may exist.

List of Publications

Singer SJ, Gaba DM, et al, "The Culture of Safety in California Hospitals," *Quality and Safety in Healthcare*, April 2003, 12:112-8.

Gaba DM, Singer SJ, et al, "Safety Culture Differences Between Hospitals and Navy Aviators," *Human Factors*, Summer 2003.

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²⁸ In 2001, three of the 12 hospitals employed different sampling strategies. Two hospitals surveyed less than 100% of physicians (one, large hospital sampled 250 of their top-admitting physicians, and the other hospital randomly sampled 20% of their physicians). In a third hospital, we received too few responses from physicians to analyze them as a separate category. In 2002, three of the 12 hospitals employed different sampling strategies. Two large hospitals sampled their 200 highest physician admitters plus all hospitalists, and another large hospital excluded volunteer and contract physicians. Also in 2002, 8 of the 12 hospitals conduct some teaching. Four of these elected to survey house staff physicians and four did not.

²⁹ Institute for Safe Medication Practices. 2000 ISMP Medication Safety Self Assessment [Internet]. Huntingdon Valley, PA: ISMP, 2000. Available from: <http://www.ismp.org/Survey/>.

³⁰ Singer SJ, Gaba DM, Geppert JJ, et al. The culture of safety: results of an organization-wide survey in 15 California hospitals. *Qual Saf Health Care* 2003 12(2):112-118.

³¹ Gaba DM, Singer SJ, Sinaiko J, et al. Differences in safety climate between hospital personnel and naval aviators. *Human Factors* 2003;45(2):173-185.

³² Singer SJ, Dunham KM, Bowen JD, et al. "Lessons from a California Hospital Consortium About Safety Climate and Safety Practices." In: Henriksen K, Battles JB, Lewin DI, Marks E, editors. *Advances in patient safety: From research to implementation*. Vol. 3, Implementation Issues. Rockville, MD: Agency for Healthcare Research and Quality; 2005. [In press]