Implementing a Program of Patient Safety in Small, Rural Hospitals

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Structured Abstract

Purpose: To implement the patient safety practices of voluntary medication error reporting and organizational learning to improve the safety of medication use in 35 Critical Access Hospitals (CAHs).

Scope: Medication errors are the most common source of risk to hospitalized patients. In the 1,283 CAHs in the nation, limited resources, low patient volume, and lack of accreditation by The Joint Commission are associated with not fully implementing safe medication practices.

Methods: We used community-based participatory research to implement a program of voluntary medication error reporting and to engage, educate, and execute the organizational practices needed to support a safe, informed culture in 35 CAHs. We used the AHRQ Hospital Survey on Patient Safety Culture (HSOPSC) to evaluate the effectiveness of these interventions.

Results: The HSOPSC can identify components of culture in need of improvement, raise awareness of safety culture, evaluate the effectiveness of patient safety interventions, and create benchmarks. A safe, informed culture requires a foundation of reporting using standardized taxonomies and systematic analysis. CAHs will have to collaborate with rural advocacy organizations to obtain the educational and technical resources necessary to understand and execute the practices that support reporting and just, flexible, and learning cultures.

Key Words: Medication errors, voluntary reporting, safety culture, Critical Access Hospitals, community-based participatory research

PURPOSE

The purpose of this project was to implement the patient safety practices of voluntary medication error reporting[1] and organizational learning to improve the safety of medication use in 35 small, rural hospitals. The Institute of Medicine (IOM) identified voluntary reporting systems as an integral part of patient safety programs because of their ability to contribute to an understanding of the system sources of errors.[2] Effective error reporting systems provide timely feedback and analysis to educate providers about the system causes of errors so that data collection results in system changes that produce safer care.[3,4,5] A voluntary reporting system that emphasizes learning from errors and improving systems of care is the foundation of an informed, safe culture.[6] Consequently, our primary aim was to develop the organizational infrastructure for reporting, providing timely feedback and analyzing medication errors within small, rural hospitals to identify evidence-based practices that minimize the latent system causes of these errors. Secondary aims were to develop and evaluate the effectiveness and sustainability of a medication safety toolkit within participating hospitals and to disseminate the results of the project, in collaboration with AHRQ, to policymakers and those responsible for quality improvement and patient safety in small, rural hospitals.

SCOPE

Medication errors are the most common source of risk to hospitalized patients.[2] On average, a hospitalized patient experiences one medication error a day.[7] This lack of reliability in hospitals' medication use practices results in 400,000 preventable medication-related injuries that cost $3.5 billion annually.[7] The vast majority of research regarding medication errors has been conducted in large, tertiary-care centers. Critical Access Hospitals are a category of limited-service hospitals created in 1997 as part of the Balanced Budget Act to maintain access to care in rural areas by providing cost-based reimbursement—CAHs are the nation's smallest hospitals.[8] CAHs are limited to 25 inpatient beds for acute care and have an average inpatient length of stay of 96 hours. As of May 2007, there were 1,283 CAHs,[9] representing approximately one fourth of the community hospitals in the nation.[10]

Background

In CAHs, limited resources, low patient volume, and lack of accreditation by The Joint Commission are associated with not fully implementing safe medication practices and with having limited onsite pharmacy support.[11,12] For example, our 2005 survey of a random sample of CAHs found that 20% were accredited by The Joint Commission, 52% had conducted a root cause analysis in the previous year, 79% dispensed the majority of oral medications in unit-dose form, 73% read back verbal orders, 76% obtained a pharmacist's review of medication orders within 24 hours, and 43% had a pharmacist onsite fewer than 20 hours a week.[12] Limited onsite presence of pharmacists in CAHs restricts pharmacists' active participation in medication use and medication error reporting.[13]

Context

Lack of reliability in systems of care is the problem that all healthcare providers face in crossing the chasm from the care we currently provide to the care we could provide.[2] Solving this problem requires changing the culture of healthcare from one in which errors are viewed as the result of individual failure to one in which errors are viewed as opportunities to improve the system.[14] A voluntary reporting system that emphasizes learning from errors and improving systems of care is the foundation of an informed, safe culture.[6] The IOM recommends mandatory reporting of adverse events and voluntary reporting of nonharmful errors to facilitate learning about and preventing systems-level sources of errors.[2]

Successful voluntary reporting programs allow organizations to learn from their experience by providing independent, expert analysis focused on systems rather than individuals.[3] In 1998, the United States Pharmacopeia (USP) established MEDMARX, the nation's first internet-accessible voluntary medication error reporting program. Over 870 hospitals and health systems have submitted more than 1.3 million medication error records to MEDMARX. MEDMARX is an anonymous medication error reporting program that subscribing hospitals and health systems participate in as part of their ongoing quality improvement initiatives. MEDMARX uses standardized taxonomies of the severity, type, cause(s), and phases of medication use in which the error originated.[15] MEDMARX uses the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) *Index for Categorizing Medication Errors* to assess the severity of the error. This index assigns an alphabetical ranking, A through I, based on the severity of the outcome to the patient.[16] Given the limited technological and human resources in CAHs, we used MEDMARX as the tool for 35 small, rural hospitals to report and analyze medication errors to support a reporting culture, which is the foundation of a safe, informed culture.

Safety culture is the enduring and shared attitudes and practices of organization members regarding the organization's willingness to detect and learn from errors.[17,18] The IOM[4] states that a culture of safety in healthcare requires three elements: (1) the belief that, although healthcare processes are high risk, they can be designed to prevent failure, (2) a commitment at the organizational level to detect and learn from errors, and (3) an environment that is just, because managers discipline only when an employee knowingly increases risk to patients and peers.[19] A culture of safety is present in high-reliability organizations that are characterized by complex, risky processes but very low error rates. Such organizations achieve high reliability because they are preoccupied with failure and are sensitive to how each team member affects a process; they allow those who are most knowledgeable about a process to make decisions, and they resist the temptation to blame individuals for errors within complex processes.[20]

Efforts to assess safety culture are based on the organizational psychology perspective, which views safety culture as shared beliefs and practices that can be categorized, measured, and changed.[17] Reason categorizes a culture of safety into four components, which reflect his assertion that an informed culture is a safe culture.[6] These components identify the practices and beliefs present in an organization that is informed about risks and hazards and takes action to become safe. Fundamentally, a safe organization is dependent on the willingness of frontline workers to report their errors and near-misses—organizational practices support a *reporting culture*. This willingness of workers to report depends on their belief that management will support and reward reporting and that discipline occurs based on risk taking[19]—organizational practices support a *just culture*. The willingness of workers to report also depends on their belief that authority patterns relax when safety information is exchanged, because those with authority respect the knowledge of frontline workers—organizational practices support a *flexible culture*. Ultimately, the willingness of workers to report depends on their belief that the organization will analyze reported information and then implement appropriate change—organizational practices support a *learning culture*. The interaction of these four components produces an informed, safe organization that is highly reliable. The organizational beliefs and practices associated with these components of culture are assessed by the Agency for Healthcare Research and Quality (AHRQ) Hospital Survey on Patient Safety Culture (HSOPSC).[21]

Achieving a safe, informed culture is dependent on how leaders at all levels of an organization obtain, use, and disseminate information.[22,23] Consequently, organizations must assess safety culture at the unit/department level and at the organizational level to (1) identify areas of culture in need of improvement and increase awareness of patient safety concepts, (2) evaluate the effectiveness of patient safety interventions over time, and (3) conduct internal and external benchmarking.[24] Internal comparisons require assessment using the unit/department and position as the unit of analysis and allow organizations to prioritize interventions within units and departments. External comparisons allow organizations to identify how their culture may differ from that of others and to prioritize organization-wide improvement efforts.[25] AHRQ established the HSOPSC Comparative Database to enable hospitals that administer this survey to conduct valid external comparisons by using standardized data.[26] The biggest challenge in assessing culture is establishing a link between safety culture and patient outcomes.[24,27,28]

When assessing culture, an organization must follow specific processes to obtain valid results. These processes include selecting an appropriate survey instrument, using effective and unbiased data collection procedures, and using the survey results to plan targeted interventions. All healthcare organizations face challenges when independently administering a safety culture survey. Inappropriate sampling, bias in data collection procedures (such as administering the survey in a group setting), and respondent concerns about confidentiality that result in poor response rates can all lead to useless results.[24] The limited resources in CAHs make it especially difficult for these hospitals to independently administer and analyze a safety culture survey and take action to improve components of culture.

Settings

This intervention took place in 35 CAHs located in 34 different counties across three Midwestern states. Twenty-four of the CAHs are located in 24 different counties in Nebraska, one is located in Wyoming, and the remaining 10 are located in nine counties in North Dakota.

These 34 counties had a median 2006 population of 5,509 (range 1,544 to 27,094).[29] Of the 34 counties, 26 are considered "frontier," with extremes of low population density (0 to 20 people per square mile) and distance (30 to 90+ miles) or travel time (30 to 90+ minutes) to a service market.[30]

Participants

The characteristics of the 35 participating CAHs are summarized in Table 1. These 35 CAHs can be categorized into three groups based on their length of participation in the project. Specifically, Group 1 consists of the14 CAHs—13 from Nebraska and 1 from Wyoming—that participated in the pilot phase of the project prior to July 2005. Group 2 consists of the 11 additional Nebraska CAHs that joined the project in July 2005, when funding from the grant became available. Group 3 consists of 10 CAHs from North Dakota that joined the project in July 2006 to test the replicability of the intervention.

Incidence and Prevalence of Medication Errors and Medication Error Reporting

Due to the variety of terminology and reporting, the exact incidence of medication errors is unknown. A study of medication errors in 36 healthcare facilities that directly observed administration of 50 doses of medication per nursing unit found that 19% of all doses were given in error. No significant differences in error rates were found between large hospitals of more than 100 beds, small hospitals of 100 and fewer beds, and skilled nursing facilities.[31] MEDMARX annual reports[32] and data from the pilot phase of our study[13] indicate that, regardless of hospital size or the structures and processes of medication use, the incidence of harm in voluntary medication error reporting programs is approximately 1 to 2% of reports. However, voluntary reporting systems capture just 1% to 10% of all actual errors[33,34] and just 1% to 5% of adverse drug events.[35] In addition to this low capture rate, comparisons of error rates generated from voluntary reporting systems are likely to be invalid due to differences in culture, differences in the definitions of medication errors, differences in patient populations, and differences in reporting systems across organizations. Consequently, comparing error rates across hospitals has no value and may actually be counterproductive, because an emphasis on a rate is likely to decrease reporting and prevent learning from the latent conditions revealed by analysis of error reports.[36,37] Facilities reporting higher numbers of medication errors may encourage reporting and may be leaders in quality improvement efforts.[38,23] As organizations engineer a culture of safety, overall reporting rates should not decrease, but the severity of reported errors should decrease, reflecting the effectiveness of quality improvement efforts.[38]

A safe, informed culture is built on a foundation of systematic analysis of reported errors. Our 2005 national survey of a representative sample of CAHs found that approximately half of these hospitals had practices in place that would support systematic analysis of medication errors. Specifically, 56% used a reporting form specific to medication errors, 6% placed error reports in the personnel files of those making the error, and 73% routinely reported near-misses. Furthermore, 63% categorized errors by severity; 57%, by phase of the medication use process; 85%, by type of error; 50%, by cause of error; and 20%, by therapeutic class of the drugs involved in an error.

METHODS

Study Design

This project is an example of action research, which is a collaborative form of social science research. Action research consists of collaboration between community or organizational stakeholders and researchers to describe and interpret events in order to solve problems and produce change in organizations.[39,40] Action research is also referred to as community-based participatory research (CBPR). Improving medication safety in the nation's smallest hospitals within the context of engineering a culture of safety is a real-world problem that requires researchers to collaborate with local providers and cross the boundary between academia and society. Action research is intended to solve real-world problems within and between groups through action research cycles that include periods of planning, action, and evaluation. Action research has two objectives: first, to produce information that is useful to groups and, second, to educate and enable individuals within groups to apply the knowledge produced by the research.[41] Within 35 CAHs, our action research project produced information about the extent to which current medication use processes were consistent with evidence-based practices and a baseline assessment of the culture of safety. Through action research cycles, we used the change model proposed by Pronovost and colleagues of engage, educate, execute, and evaluate.[42] We educated participants and provided tools they could use to execute a voluntary medication error reporting program, evidence-based safe medication practices, and practices that support the components of a safe, informed culture. We evaluated the effectiveness of these interventions using data from MEDMARX, the HSOPSC, and an outcomes survey.

Within the action research methodology, we used a time-series design to assess four outcomes of interest: (1) changes in the patterns of medication error reporting due to use of MEDMARX, (2) changes in the medication use process within hospitals during the project, (3) extent of implementation of practices that support a safe, informed culture, and (4) changes in the AHRQ HSOPSC from baseline assessment in 2005 to the reassessment in 2007.

In addition, we sought to answer specific research questions through two studies that were submitted on September 10, 2007, to AHRQ's call for papers, "Advances in Patient Safety: New Directions and Alternative Approaches." The purpose of the first study was to compare the medication errors reported to MEDMARX by the 35 CAHs that participated in our patient safety project with those reported to MEDMARX by 147 nonfederal community hospitals (NFCHs) with 24-hour pharmacist support. The amount of pharmacist support was used as an indicator of differences in the structure and process of the medication use system. We sought to determine whether the proportion of errors classified as near-misses is associated with the structures and process of medication use, as represented by the amount of pharmacist support. Reports submitted to MEDMARX are clustered by hospital, which means that the reports submitted by each hospital are correlated and cannot be treated as independent outcomes. Generalized estimating equations (GEEs) are typically used to account for the correlation of data within clusters. However, the GEE methods assume that cluster size is not related to the outcomes of interest.[43] Cluster size—the number of reports submitted by a hospital—was significantly associated with our outcomes of interest. Specifically, reporting greater numbers of medication errors was significantly associated with reporting errors of severity category B ($p < 0.0001$). Because the CAHs tended to submit fewer error reports than the NFCHs, we could not ignore the differences in cluster size in our analysis. To achieve a valid estimate of the standard error in the presence of this difference in cluster size, we used a within-cluster resampling method to account for the nesting of error reports within hospitals. This method remains valid when cluster size is informative.[43, 44] We excluded one CAH and four NFCHs that submitted fewer than 10 error reports during the reporting period from this analysis. One error report was randomly drawn from each of the 177 hospitals included in the analysis. Because the 177 error reports from each sample were independent, a logistic regression was used to estimate the association between pharmacist support and the likelihood of reporting category B errors. This sampling procedure was repeated 1,000 times with replacement, and logistic regression was conducted for each sample. The odds ratio and 95% confidence interval for the odds ratio were estimated from the results of the 1,000 samples using the method provided by Hoffman.[43]

The primary purpose of the second study was to demonstrate how the AHRQ HSOPSC can be used as a tool to plan and evaluate patient safety interventions within multiple CAHs.

A secondary aim was to demonstrate that safety culture varies by work area and position across this sample of the nation's smallest hospitals. In the fall of 2005, we conducted the AHRQ HSOPSC in 24 CAHs to obtain a baseline assessment of their culture of safety and raise awareness about safety culture (one CAH in Group 1 opted not to participate in the baseline culture assessment). We used the results to create benchmarks and plan educational activities regarding tools to address components of culture in need of improvement. In the spring of 2007, 21 of the 24 CAHs chose to participate in a reassessment using the HSOPSC. In both years, we conducted a mailed, self-administered survey of all eligible staff in the participating CAHs. Eligible staff were those employees for whom the survey was intended: those with direct patient contact; those whose work directly affects patient care; physicians and mid-level providers; and those who identified themselves as supervisors, managers, or administrators.[21] This study focused on the HSOPSC results for the 21 CAHs that participated in the baseline and reassessment. We modified the demographic sections of the survey to fit the CAH environment and protect the anonymity of survey respondents in these small organizations. The details of this adaptation are available from the authors. We also modified the Customized Excel™ Data Tool [45] available for entering and analyzing the survey data to incorporate these adaptations. We shared our adaptations of the survey and data tool with Quality Improvement Organizations (QIOs) that used the HSOPSC in their work with rural hospitals.

We followed the same process to administer the survey in 2005 and 2007. Our key contact at each hospital provided a list of names and positions of staff potentially eligible to participate in the survey. We reviewed the list to verify each participant's eligibility according to the categories described above. We assigned a unique identification number to each participant to track response rate and hospital affiliation and to prevent duplicate entries. We assigned each participant the same identification number in both years to track change at the respondent level. Following the Dillman tailored-design methodology,[46] each survey participant received four contacts at 2-week intervals. The first contact was a personalized letter from the hospital administrator explaining the purpose of the survey and the importance of participation. The second contact was a personalized envelope that contained a cover letter, the survey, and a postage-paid envelope addressed to a post office box at UNMC. The third contact was a personalized postcard thanking participants for their response and reminding them to return the survey if they had not already done so. The fourth contact was tailored to response status: respondents received a personalized envelope that contained a thank you letter; nonrespondents received a cover letter encouraging response, the survey, and the postage-paid return envelope. All survey materials were mailed in bulk at 2-week intervals to our key contact for internal distribution within each CAH. Upon receiving a survey, we electronically scanned it into an Access™ table. We exported this data to the Customized Excel™ Data Tool for reporting to each CAH.

Data Sources/Collection

There were four sources of data in this project. First, the 25 Group 1 and Group 2 CAHs voluntarily reported 10,081 errors to MEMARX from July 2005 through June 2007, and the 10 Group 3 CAHs reported 812 errors from August 2006 through June 2007 (Table 3). The second source of data was the 2005 baseline and 2007 reassessment with the HSOPSC for 21 of the Group 1 and 2 CAHs. The third source of data was a mailed, self-administered outcomes survey that key contacts within 30 (86%) of the 35 CAHs completed. This survey collected information about the number of medication errors and near-misses reported in the year prior to joining the project, the extent to which safe medication practices and practices that support components of a safe, informed culture had been implemented, and the relative importance of our project in implementing these practices. The fourth source of data was a qualitative exit interview completed in 20 of the 25 Group 1 and Group 2 CAHs during site visits in June 2007.

Interventions
The interventions were provided in the form of workshops, regular conference calls, and onsite education. They are organized in the context of the practices required to support and evaluate a safe, informed culture.

- Practices to support a reporting culture
  - Subscription to MEDMARX reporting program
  - Workshops to educate CAH personnel regarding data entry and report generation using MEDMARX
- Practices to support a just culture
  - Education regarding the concept of just culture based on the work of David Marx
  - Adapted Unsafe Acts Algorithm from work of James Reason
- Practices to support a flexible culture
  - Education regarding teamwork knowledge, skills (leadership, communication, situation monitoring, and mutual support), and attitudes[47]
  - Tools: team huddles, team briefs, team debriefs, Patient Safety Leadership WalkRounds™ and Safety Briefings[47,48]
- Practices to support a learning culture
  - Education regarding individual RCA and aggregate RCA[49]
  - Education regarding use of MEDMARX charts and graphs to analyze errors
  - Education regarding evidence-based safe medication practices using resources from the Institute for Safe Medication Practice and workshop to share best practices and implement change
  - Tool: Map of medication use process highlighting deviations from evidence-based safe practices
  - Quarterly medication error reports based on data entered into MEDMARX
  - Instructed facilities how to use quarterly MEDMARX reports and data to identify deficiencies in their medication use process and prioritize implementation of best practices
- Practices to evaluate a safe, informed culture
  - Adapted survey to fit CAH environment by collapsing work area and job title
  - Conducted a baseline assessment of safety culture in 13 Group 1 and 11 Group 2 CAHs in the fall of 2005 and in six Group 3 CAHs in the fall of 2006
  - Reassessed safety culture in 10 Group 1 and 11 Group 2 CAHs in the spring of 2007
  - Analyzed survey results and presented results with suggested action plans and tools for implementation in the form of an executive summary
  - Provided peer benchmarks for the range of responses within each survey dimension

Measures
Our primary outcome measures were (1) changes in medication error reporting due to use of MEDMARX, (2) changes in the medication use process within hospitals during the project, (3) extent of implementation of practices that support a safe, informed culture, and (4) changes in the AHRQ HSOPSC from baseline assessment in 2005 to the reassessment in 2007.

Limitations and Barriers
There are major limitations to the generalizability of these findings. First, these 35 CAHs were located in three Midwestern states and were self-selected for participation in the project. Second, the extent of their participation varied. Three Group 1 CAHs did not participate in project activities or in the 2007 HSOPSC reassessment. Of the 21 Group 1 and Group 2 CAHs that participated in the 2007 HSOPSC reassessment, four did not participate in project activities.

The barriers to implementing project activities included the limited human and technological resources within the CAHs. Specifically, lack of computer skills was a barrier to implementing MEDMARX in all of the CAHs; only one third of the CAHs had a full-time position dedicated to quality improvement, and only three had previous experience with mapping of processes. In addition, the distances across the three states were a barrier to face-face contact. Finally, as university-based researchers, it was difficult to meet the human resources needed to support the participatory nature of this project in 35 CAHs across three states.

RESULTS

Principal Findings from the Analysis of MEDMARX Data Study

The 35 CAHs from the UNMC PIPS grant and the 147 NFCHs reported 167,632 medication errors to MEDMARX in calendar years 2005 and 2006. After excluding the five hospitals that reported 10 or fewer errors in this period, there were 34 CAHs that reported 8,087 medication errors and 143 NFCHs that reported 159,519 errors. The number of error reports submitted by the 177 hospitals varied from 11 to 8,309. There were varying levels of pharmacist support among the CAHs: 18 (53%) had a pharmacist available 15 or fewer hours a week and reported 2,586 medication errors. The remaining 16 CAHs (47%) had a pharmacist available 32 to 76 hours a week and reported 5,501 medication errors.

The severity of medication errors varied by the availability of pharmacist support. Specifically, the CAHs reported a higher proportion of circumstances that have the capacity to cause an error (category A) (28% and 23% vs. 6%). When actual medication errors (categories B through I) are considered, the CAHs reported a lower proportion of near-misses (category B) (21% and 31% vs. 43%) and a higher proportion of errors that reached the patient but did not cause harm (categories C or D) than did the NFCHs (79% and 69% vs. 55%). Harmful errors (categories E through I) accounted for approximately 2% of reported errors from the NFCHs and less than 1% of reported errors from the CAHs. After accounting for the clustering of error reports within hospitals using the within-cluster resampling technique, we found that the CAHs with 15 or fewer hours of pharmacist support were significantly less likely to report category B errors than were hospitals with 24-hour pharmacist support (odds ratio [OR] 0.64; $p = 0.048$, two-tailed test). No significant difference in the likelihood of reporting near-misses was found between CAHs with 32 to 76 hours of pharmacist support and NFCHs (OR 0.98; $p = 0.91$).

Principal Findings from the AHRQ HSOPSC Study

In the 2005 baseline assessment, there were 1,995 eligible employees in the 21 CAHs, and we obtained an aggregate response rate of 70.4%. In the 2007 reassessment, there were 1,963 eligible employees, and we obtained an aggregate response rate of 70.0%. The range of the number of respondents from the 21 hospitals was 29 to 160 in 2005 and 28 to 144 in 2007. The range of response rates across the 21 hospitals was 51% to 92% in 2005 and 58% to 95% in 2007. The pattern of percent-positive responses by dimension and item across hospitals was similar in 2005 and 2007. The most positively perceived dimensions were teamwork within departments (80% and 81%) and hospital management support for patient safety (73% and 74%) as well as organizational learning (72% and 75%), and supervisor/manager expectations and actions promoting patient safety (72% and 75%). The least positively perceived dimensions were nonpunitive response to error (50% and 52%), hospital handoffs and transitions (57% and 58%), communication openness (58% and 62%), and feedback and communication about error (59% and 62%). The least positively perceived items were the same in both years: from the communication openness dimension—staff feel free to question the decisions and actions of those with more authority (41% and 46%)—and from the nonpunitive response to error dimension—staff worry that mistakes they make are kept in their personnel file (41% and 46%).

After adjusting for repeated assessment of respondents and the correlation of respondents within the same hospital, the odds of respondents from the 21 CAHs reacting positively to the five survey items that represent the four components of a safety culture were greater at reassessment in 2007 than at the baseline in 2005. This difference was statistically significant for the three attitudes and practices that support a reporting culture, a just culture, and a flexible culture but not for the attitudes and behaviors that support a learning culture.

- The odds of a respondent indicating in 2007 that *a mistake that is caught and corrected before affecting the patient* is reported “most of the time” or “always” were 1.30 times the odds of responding similarly in 2005.
- The odds of a respondent disagreeing in 2007 that they *worry that mistakes they make are kept in their personnel file* were 1.24 times the odds of responding similarly in 2005.
- The odds of a respondent agreeing in 2007 that *they feel free to question the decisions or actions of those with more authority* were 1.23 times the odds of responding similarly in 2005.

We used the same five survey items that represent the four components of an informed, safe culture to test for differences in beliefs and practices by work area and position while adjusting for the correlation of respondents within the same hospital. Perceptions of organizational beliefs and practices that support a just culture, a flexible culture, and a learning culture varied significantly by work area and position. Beliefs and practices supporting a reporting culture did not vary significantly by work area or position.

Outcomes

Aim 1: Develop the organizational infrastructure for reporting, providing timely feedback and analyzing medication errors within participating small, rural hospitals necessary to identify and implement evidence-based practices that minimize the latent system causes of these errors.

We received an outcomes survey from 22 of the 25 Group 1 and Group 2 CAHs and from eight of the 10 Group 3 CAHs. We used this survey to determine the influence of our project on the organizational infrastructure for reporting and analyzing medication errors in 35 CAHs. Compared with the year prior to participating in the project, there was approximately a three-fold increase in the number of medication errors reported by the 35 CAHs in the first full year of participation in the project (Table 2). Specifically, the 30 CAHs that completed the outcomes survey reported 1,407 errors in the year prior to entering the project, and all 35 CAHs reported 4,638 errors in their first full year participating in the project. In addition, just four of the 30 CAHs completing the outcomes survey reported collecting 47 near-misses in the year prior to entering the project. In comparison, in 2006 the 35 CAHs reported 965 potential errors (category A) and 924 near-misses (category B) (Table 3). The proportions of category B reports increased each year in Group 2 and Group 3 CAHs but declined in Group 1 CAHs. Changes in the systematic collection of information through voluntary medication error reporting are summarized in Table 4. Prior to using MEDMARX, 22 of the 30 CAHs returning an outcomes survey categorized reported errors by type and reported the drug(s) involved in the error, 14 collected information about the cause of the error, 13 categorized reported errors by severity, 11 categorized errors by phase of the medication use process in which the error originated, and 12 collected information about the actions taken in response to a reported error. Five of the CAHs reported using the NCC MERP taxonomy of medication error severity prior to entering the project. During the project, all 35 CAHs systematically collected this information.

The following are representative quotes from our key contacts regarding the impact of the use of MEDMARX on collecting and analyzing information:

- “Before the project, we just counted errors. We never went past the type of error.”
- “Using MEDMARX increased reporting because people had more knowledge that what we are doing is intended to make the system safer.”
- “Without the language of errors associated with MEDMARX, all we could talk about was who did it and not what happened and why. MEDMARX created a standardized process that allowed us to collect more information. The use of MEDMARX and its graphs and charts contributes to the perception of errors as having a system source.”
- “Using the lingo of MEDMARX, errors got broken down into categories that even the board could understand, so they were more open to thinking about allocating money for an automated dispensing system.”
- “Because we were able to visualize the system through the graphs and charts, we could communicate to staff and take action.”

The extent to which these CAHs implemented evidence-based practices to minimize the latent system sources of medication errors varied (Table 5). The majority of CAHs in Groups 1 and 2 implemented approximately one half of the safe medication practices during the project. The majority of CAHs in Group 3 implemented over one third of the safe medication practices during the project. The 30 CAHs that completed the outcomes survey were most likely to have partially or fully implement the following safe medication practices as written policies during the project (these numbers do not include those CAHs that implemented the practice prior to the project):

- 24 implemented a list of inappropriate abbreviations not to be used in medication orders
- 22 implemented independent double checks of insulin prior to administration
- 20 implemented writing down and reading back verbal orders
- 20 implemented the use of two identifiers to verify patient identify prior to administering medications
- 19 implemented verification of the 5 Rights by nurses at the bedside using a unit dose or unit of use and the MAR
- 19 implemented documentation of medications given on the MAR at the bedside
- 18 implemented independent double checks of anticoagulants prior to administration

As a result of conducting the AHRQ HSOPSC, we identified specific practices that support the components of a safe, informed culture. The extent to which these CAHs implemented practices to support a safe, informed culture varied (Table 6). Five of the 30 CAHs completing the outcomes survey indicated that they had conducted an RCA prior to participating in the project. However, we did not verify the thoroughness and credibility of these RCAs. Thirteen CAHs reported conducting 40 RCAs during the project, and 12 CAHs had designated a specific individual to facilitate RCAs within their organization. Twenty-eight of the 30 CAHs that returned an outcomes survey indicated that they had implemented a nonpunitive, anonymous, voluntary medication error reporting program; 25 of these 28 CAHs indicated that our project had been very or somewhat important in establishing this program. The eight CAHs that indicated they had implemented a nonpunitive reporting program prior to beginning the project had all participated in the pilot phase of the project from 2002 through 2004. Fewer than half of the CAHs implemented the following practices:

- 13 implemented the SBAR structured communication tool to support a flexible culture
- 12 implemented regular patient safety culture surveys to guide implementation and evaluation of the practices that support a safe, informed culture
- 10 implemented the Leadership WalkRounds tool, which supports all four components of a safe, informed culture
- 9 implemented the Unsafe Acts Algorithm to support just culture

- o 9 implemented the Patient Safety Briefings tool, which supports all four components of a safe, informed culture

Aim 2: Evaluate the effectiveness and sustainability of the small, rural hospital medication safety toolkit within participating hospitals.

We used the extent to which the CAHs opted to continue to subscribe to MEDMARX after support from the grant ended as a measure of the sustainability of the intervention. Specifically, 27 (77%) of the 35 CAHs continued to subscribe to MEDMARX after support from the grant ended. This 27 included 10 of the 14 Group 1 CAHs, all 11 of the Group 2 CAHs, and six of the 10 Group 3 CAHs. Group 2 and 3 CAHs opted to use grant funds from the Medicare Rural Hospital Flexibility (Flex) Program to pay for their subscriptions.

Aim 3: Disseminate the results of the project, in collaboration with AHRQ, to audiences positioned to modify policies and/or implement the intervention.

Results of this project have been disseminated at presentations in state, regional, and national meetings. As a result of our experience conducting the AHRQ HSOPSC, we have developed a reputation for conducting and interpreting the survey in rural hospitals. Through the Rural QIO Support Center at Stratis Health, we disseminated our modifications of the demographic section and the Excel™ Data Tool and our graphic tools to interpret the survey to the QIOs working with rural hospitals as part of their 8th Scope of Work. Dr. Jones conducted a webinar to assist QIOs to interpret the survey and create action plans to implement tools to address areas of culture in need of improvement. Over 800 people across the nation listened to this webinar. The community-based participatory design of this project and dissemination of our work resulted in a demand for administering and interpreting the AHRQ HSOPSC in CAHs. Specifically, we administered the HSOPSC in six CAHs on a fee-for-service basis and plan to do so in three CAHs in October 2007. We are developing a business plan with the National Rural Health Association to create a Rural Safety Culture Service that will provide an infrastructure for administering and interpreting the survey using our standardized methods in rural hospitals across the country.

Discussion

Our results and outcomes demonstrate that health services researchers can use action research to assist small, rural hospitals to implement evidence-based patient safety practices using Reason's components of a safe, informed culture as a framework. More specifically, these results demonstrate that CAHs can learn to use MEDMARX, the national medication error reporting program, to overcome resource deficiencies and systematically collect and analyze information about medication errors that supports just, flexible, and learning cultures. By using standardized taxonomies of error severity, type, phase, and cause, personnel in the majority of theses CAHs learned to analyze errors in the context of their medication use processes. The standardized taxonomy and emphasis on systems associated with using MEDMARX resulted in an increase in the volume of all medication error reports by over three-fold (from 1,407 annually to 4,638). In addition, the use of the NCC MERP taxonomy introduced these CAHs to the importance of using potential and near-miss error reports to identify system sources of error. The proportion of errors reported as category B increased during each year of the project in Groups 2 and 3. (We monitored the accuracy of reporting error severity for Groups 2 and 3 throughout the project. We did so for Group 1 through July 2006. This lack of monitoring in Group 1 may explain the increase in category A errors in 2006 and 2007.)

However, there appears to be a floor effect to intercepting errors before they reach the patient in CAHs that is due to the limited availability of pharmacist support. Specifically, our study of MEDMARX data demonstrated that, after accounting for the correlation of reports within a hospital, CAHs with 15 or fewer hours of pharmacist support a week were significantly less likely to report intercepting errors before they reach a patient than were hospitals that have pharmacists available 24 hours a day. As a result of the project, 11 CAHs have either added or are exploring options to add hours of onsite pharmacist support, telepharmacy, automated dispensing machines, and barcoding (Table 7).

Our results and outcomes also demonstrate that the AHRQ HSOPSC can be used to identify components of culture in need of improvement, raise awareness of safety culture, evaluate the effectiveness of patient safety interventions over time, and create benchmarks for CAHs. These results also demonstrate that 21 of the nation's smallest hospitals can make improvements in safety culture by implementing practices that support the components of an informed, safe culture. These practices must include (1) a voluntary error reporting system that uses a standardized taxonomy to support a reporting culture; (2) Reason's algorithm for determining the blameworthiness of unsafe acts to support Marx's concept of a just culture; (3) teamwork training that emphasizes the knowledge, skills, and attitudes necessary to function as a team within and across departments to support a flexible culture; and (4) multiple approaches to communicate about and learn from errors (Leadership WalkRounds, Safety Briefings at the unit/department level, aggregate RCA of nonharmful errors, and individual RCA of harmful errors) to support a learning culture.

Conclusions

Our focus on CAHs reflects the IOM's belief that the healthcare environment should be safe for all patients.[14] We used support from AHRQ to develop a sound methodology for conducting and analyzing the HSOPSC in the nation's smallest hospitals. This methodology produces valid results, which we linked to the practices required to achieve a safe, informed culture. Reason asserts that an informed, safe culture must be socially engineered by executing these interacting practices.[6] Hospital leaders impact beliefs about organizational culture by supporting frontline workers as they execute these practices. Reporting practices provide a common language for describing error in terms of a system and provide the foundation of a safe culture. Using the taxonomies associated with the MEDMARX voluntary medication error reporting program resulted in improvements in reporting culture across 21 CAHs. However, safety culture emerges gradually from sustained attention to engineering the interactions between reporting practices and practices that support just, flexible, and learning cultures. In CAHs, directors of nursing and quality improvement must engineer these interactions. Consequently, they require support from their senior leaders and education and tools from network hospitals, QIOs, and other organizations that advocate for rural hospitals. This project exemplifies the type of field-based, mixed-methods research that is necessary to understand how patient safety interventions can change the behaviors and beliefs that define an organization's culture.[25]

Significance

This study can inform policymakers, network hospitals, QIOs, and other organizations that advocate for rural hospitals about resources and practices that 1,283 CAHs in the nation can use to improve medication safety and create a safe, informed culture that supports patient safety and quality improvement efforts.

Implications

A high-reliability organization requires a systems approach to error prevention that results from engineering the interactions between the practices that support reporting, just, flexible, and learning cultures. Consequently, a healthcare organization must evaluate its culture to identify those areas in need of improvement. In the context of teaching CAHs to use a medication error reporting program, we linked the reporting, just, flexible, and learning components of a safety culture with organizational practices that support those components. The limited resources in CAHs make it especially difficult for these hospitals to independently administer and analyze a safety culture survey and take action to improve components of culture. Consequently, network hospitals, QIOs, and other organizations that advocate for rural hospitals must collaborate to ensure that CAHs have the resources necessary to validly assess and improve their cultures. One outcome of this project is the incorporation of our service to conduct and interpret the AHRQ HSOPSC into the National Rural Health Association's quality improvement initiative.

List of Publications and Products

Jones KJ, Skinner AM, Leo CE, Cochran GL. Implementing a program of patient safety in small rural hospitals: findings and trends in medication error reporting from 25 Critical Access Hospitals. Nebraska Center for Rural Health Research. Agency for Health Care Research and Quality. October 2005 Data Report PR 06-08.

Cochran GL, Jones KJ, Brockman J, Skinner A, Hicks RW. Errors prevented by and associated with bar-code medication administration systems. The Joint Commission Journal on Quality and Patient Safety; 2007,33(5):203-301.

Jones KJ, Cochran GL, Xu L, Skinner AM, Knudson A, Hicks RW. The association between pharmacist support and voluntary reporting of medication errors: an analysis of MEDMARX® data. Submitted September 10, 2007, to AHRQ Advances in Patient Safety: New Directions and Alternative Approaches.

Jones KJ, Skinner A, Xu L, Sun J, Mueller K. The AHRQ Hospital Survey on Patient Safety Culture: a tool to plan and evaluate patient safety programs. Submitted September 10, 2007, to AHRQ Advances in Patient Safety: New Directions and Alternative Approaches.

A toolbox of practices to support medication error reporting and a safe, informed culture, posted at http://www.unmc.edu/rural/patient-safety/

Rural Safety Culture Service Products

- AHRQ HSOPSC adapted so that the demographic sections reflect the environment of small rural hospitals
- Customized Excel™ Data Tool adapted to incorporate our changes to the HSOPSC that allow sorting by work area or position when there are five or more employees
- Graphical comparison of a hospitals results on the HSOPSC to the minimum and maximum percent-positive scores of a peer group to engage, educate, and plan change
- Spreadsheet comparison of management versus nonmanagement results on the HSOPSC to engage, educate, and plan change
- A generic executive summary of results from the HSOPSC that links components of culture to tools that execute the practices that support the components of a safe, informed culture
- Power point presentation and DVD that engages and educates about the principles of patient safety

Medication Safety Products

- Medication Error Reporting Form (integrates taxonomies used in MEDMARX and reflects the CAH environment)
- Excel report templates use data from MEDMARX to facilitate analysis of medication errors
- Patient Safety Process Change form for documenting changes in systems

- Medication Error Data Entry Feedback Report (provides feedback about the accuracy of classification of the severity, phase, type, and cause of medication errors reported to MEDMARX)

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Table 1. Characteristics of 35 Critical Access Hospitals

Characteristic	n (%)
Pharmacist Availability	
0 – 15 hours a week	19 (54%)
32 – 76 hours a week	16 (46%)
Average occupied bed size	
1 – 10	18 (51%)
11 – 24	17 (49%)
Owner/operator of facility	
Government, nonfederal (state/city/country)	14 (40%)
Nongovernment, nonprofit	21 (60%)
Average doses dispensed per month	
<9,999	31 (89%)
10,000 – 19,999	3 (9%)
20,000 – 29,999	1 (3%)
Computerized prescriber order entry	
In use in all clinical areas	1 (3%)
In use in some clinical areas	4 (11%)
Not in use	30 (86%)
Computer-generated medication administration record	9 (26%)
Automated dispensing system in use	
Both centralized and decentralized systems	2 (6%)
Centralized system	3 (9%)
Decentralized system	3 (9%)
Not in use	27 (77%)
Inpatient intravenous admixtures prepared primarily by pharmacist	8 (23%)

Source: United States Pharmacopeia, 2005, 2006.
Note: No facility had a pharmacist available 16 - 31 hours a week.

Table 2. Medication error reports one year prior to project compared to first full year of project

	Self-reported number of error reports one year prior to project*	Error reports submitted to MEDMARX during first full year of project**	Self-reported near-miss reports one year prior to project*	Near-miss reports submitted to MEDMARX during first full year of project**
Groups 1 & 2 (n = 25 CAHs)	1,206 from 16 CAHs	3,826 from 25 CAHs	41 from 3 CAHs	809 from 25 CAHs
Group 3 (n = 10 CAHs)	201 from 8 CAHs	812 from 10 CAHs†	6 from 1 CAH	286 from 10 CAHs†

*Source: Outcomes survey
**Source: United States Pharmacopeia, 2005, 2006, 2007.
†From 08/01/2006 – 06/30/2007

Table 4. Medication error information collected prior to project

Medication error information collected	CAHs (n = 30)
Severity of error	13
Type of error	22
Phase (node) of medication use process in which error originated	11
Cause of the error	14
Drugs involved in the error	22
Actions taken in response to an error report to prevent error from recurring	12

Source: Outcomes survey

Table 3. Severity and phase of origination of voluntarily reported medication errors for three groups of Critical Access Hospitals 2005 – 2007

	Group 1 (14 CAHs)			**Group 2 (11 CAHs)**			**Group 3 (10 CAHs)**	
Severity Category	2005 n = 3,414 (%)	2006 n = 2,509 (%)	2007* n = 1,744 (%)	2005** n = 483 (%)	2006 n =1,317 (%)	2007* n = 614 (%)	2006** n = 371 (%)	2007* n = 441 (%)
A (potential error)	847 (24.8%)	485 (19.3%)	613 (35.2%)	164 (34.0%)	442 (33.6%)	124 (20.2%)	38 (10.2%)	41 (9.3%)
B (near miss)	720 (21.1%)	607 (24.2%)	252 (14.5%)	57 (11.8%)	202 (15.3%)	139 (22.6%)	115 (31.0%)	171 (38.8%)
C (reached patient, no harm)	1,688 (49.4%)	1,352 (53.9%)	846 (48.5%)	238 (49.3%)	644 (48.9%)	338 (55.1%)	205 (55.3%)	210 (47.6%)
D (required monitoring or intervention)	147 (4.3%)	56 (2.2%)	31 (1.8%)	21 (4.4%)	21 (1.6%)	11 (1.8%)	12 (3.2%)	19 (4.3%)
E (temporary harm)	6 (0.2%)	7 (0.3%)	2 (0.1%)	3 (0.6%)	8 (0.6%)	2 (0.3%)	1 (0.3%)	0
F (temporary harm, hospitalization)	6 (0.2%)	2 (0.1%)	0	0	0	0	0	0
G (permanent harm)	0	0	0	0	0	0	0	0
H (intervention to sustain life)	0	0	0	0	0	0	0	0
I (death)	0	0	0	0	0	0	0	0
Phase of Medication Use Process†	2005 n = 2,567 reports	2006 n =2,024 reports	2007 n = 1,131 reports	2005 n = 319 reports	2006 n = 875 reports	2007 n = 490 reports	2006 n = 333 reports	2007 n = 400 reports
Prescribing	217 (8.5%)	193 (9.5%)	35 (3.1%)	29 (9.1%)	33 (3.8%)	37 (7.6%)	11 (3.3%)	23 (5.8%)
Documenting	725 (28.2%)	580 (28.7%)	257 (22.7%)	82 (25.7%)	317 (36.2%)	152 (31.0%)	94 (28.2%)	110 (27.5%)
Dispensing	246 (9.6%)	174 (8.6%)	104 (9.2%)	17 (5.3%)	42 (4.8%)	12 (2.5%)	72 (21.6%)	90 (22.5%)
Administering	1,344 (52.4%)	1,051 (51.9%)	723 (63.9%)	185 (58.0%)	470 (53.2%)	284 (58.0%)	150 (45.1%)	174 (43.5%)
Monitoring	22 (0.9%)	16 (0.8%)	9 (0.8%)	2 (0.6%)	3 (0.3%)	0	5 (1.5%)	0
Procurement	13 (0.5%)	10 (0.5%)	3 (0.3%)	4 (1.3%)	10 (1.1%)	5 (1.0%)	1 (0.3%)	3 (0.8%)

*Reports for 01/01/2007 – 06/30/2007. **Reports for August – December of the year. †Does not include category A error reports.

Source: United States Pharmacopeia, 2005, 2006, 2007.

Table 5. Progress in implementing safe medication practices

Safe Medication Practice	Groups 1 and 2 (n = 22)				Group 3 (n = 8)			
	Implementation		Role of UNMC		Implementation		Role of UNMC	
	Prior to project	Partially/ fully during project	Very important	Somewhat important	Prior to project	Partially/ fully during project	Very important	Somewhat important
Written policy to write down and read back verbal orders	5	14	9	9	1	6	4	0
Written "no huddle" policy to clarify confusing or illegible orders	2	4	9	4	0	3	2	3
Written policy to reconcile newly ordered medications with a list of usual home medications	0	18	12	7	0	6	2	4
Written policy not to use inappropriate abbreviations in medication orders	7	11	9	5	2	4	3	1
Written policy to double check transcription to the MAR before a newly ordered medication is obtained for administration.	5	10	11	6	0	3	2	2
Written policy for 24-hour chart check to verify MAR against original order	6	14	8	7	0	5	4	2
Pharmacist routinely uses a software program to verify appropriateness of ordered drug	3	5	3	3	1	3	1	1
In absence of onsite pharmacist, nurses routinely use a software program to verify appropriateness of ordered drug.	3	5	6	4	0	2	2	2
High-alert medications stored in a specific area of the pharmacy	6	10	8	3	0	5	2	3
High-alert medications within pharmacy have a high-alert label	1	12	7	3	0	4	3	1
Pharmacy "key" provides a cross reference for brand/generic names and location of drug within pharmacy	6	8	4	5	1	6	2	0
Pharmacist reviews all medication orders for appropriateness within 24 hours	5	5	10	3	1	2	1	0
Majority of oral medications packaged as a "unit dose" or "unit of use"	5	14	5	5	2	5	2	2
Written policy for nurses to double check insulin prior to administration	4	18	8	5	2	4	1	3
Written policy to double check anticoagulants prior to administration	3	15	8	5	0	3	0	5
Written policy to double check opioids prior to administration	0	7	9	3	1	2	0	5
Written policy to double check chemotherapy drugs prior to administration	5	13	8	2	0	3	1	2
Written policy to double check pediatric medications prior to administration	3	10	10	3	0	2	2	3
Written policy for nurses to use two identifiers to verify patient identification before medications are administered	4	15	11	1	0	5	4	3
Written policy for nurses to verify 5 Rights at the bedside using a "unit dose" and the MAR	5	16	14	1	2	3	2	3
Written policy for nurses to document medications given on the MAR at the bedside	4	13	13	1	1	6	5	2

Source: Outcomes survey

Table 6. Progress in implementing practices that support a safe, informed culture

	Groups 1 and 2 (n = 22)				Group 3 (n = 8)			
	Implementation		Role of UNMC		Implementation		Role of UNMC	
Practice to support a safe informed, culture	Prior to project	Partially/ fully during project	Very important	Somewhat important	Prior to project	Partially/ fully during project	Very important	Somewhat important
Nonpunitive and anonymous approach to voluntary medication error reporting	8	13	16	2	1	6	5	2
Unsafe Acts Algorithm (Decision Tree for Unsafe Acts)	0	7	8	2	1	2	3	2
SBAR Structured Communication Tool	0	9	6	6	1	4	3	3
Patient Safety Briefings Tool	0	6	6	2	0	3	2	2
Leadership WalkRounds Tool	0	8	5	5	2	2	1	3
TeamSTEPPS: Team Strategies and Tools to Enhance Performance and Patient Safety	0	2	3	5	0	1	2	3
Individual Root Cause Analysis	4	9	NA	NA	1	1	NA	NA
Regularly conduct survey of patient safety culture	2	9	10	2	1	3	2	3

Source: Outcomes survey

Table 7. Progress in increasing pharmacy support

	All hospitals responding to Outcomes Survey Addendum (n = 11 CAHs)	
	Increased during project	Planning to increase
Number of hours a pharmacist is onsite	3	2
Telepharmacy services	1	5
Technological support in pharmacy (i.e., automated dispensing system)	2	5

Source: Addendum to Outcomes Survey