FINAL PROGRESS REPORT

Systems Approach for Improving Region-Wide Patient Safety

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September 1, 2002-August 31, 2005

Federal Project Officer: Eileen Hogan, PhD

We wish to acknowledge AHRQ for providing support via this cooperative agreement.

Grant Award Number: 5U18HS011926-03

Abstract

Purpose: Adverse events are among the nation's most pervasive patient safety problems. Establishing effective reporting systems capable of compiling useful information on these events is a necessary condition for improving outcomes. Creating the capacity for sustainable change requires region-wide exploration and evaluation of inter-related systems that transform that information into knowledge and learning.

Scope: Pittsburgh Regional Healthcare Initiative (PRHI) was created to achieve the best patient outcomes solving systemic problems at the point of patient care. PRHI was a collaboration of leaders from all major healthcare stakeholder groups in a six-county region.

Methods: Our 38-hospital system implemented MedMARx and components of the National Nosocomial Infection Surveillance System. Based on this shared analysis of regional outcomes data, prevention strategies and interventions were developed. We achieved variable success through a variety of mechanisms, including PRHI's existing Center for Shared Learning. Using multiple metrics, we explored three sets of study aims to understand how well the *Reporting Systems* succeed in creating usable information; how well the *Feedback Review Systems* function; and the *Problem-Solving Systems* through which knowledge is translated into organizational learning.

Results: The results were inconsistent, as we learned of the difficulties in linking feedback and reporting. Institutional uptake of patient safety priorities was variable. There were inherent difficulties in creating a collaborative platform between competing institutions and a coordinating body whose goals and objectives were not closely coordinated. Voluntary, regional approaches to systems-based models for goal-directed changes to improve patient safety remain difficult to sustain.

Key Words: patient, safety, outcomes.

Purpose

We had three sets of study aims based on the conceptual framework articulated in the Section Scope below:

Objectives of the Study. 1) To understand how well the **Reporting Systems** associated with nosocomial infections and medical errors succeed in creating usable information. The Reporting System is the process of analysis, formatting, and reporting that turns data into information. Data refers to the inputs to the reporting system and ways in which these are coded and presented (e.g., reliability, adequacy, accuracy, validity, format, and user-friendliness). Although data quality can be standardized across all hospitals, differences in users and characteristics of healthcare settings mean that data interpretations are not necessarily the same across all settings. Information refers to facts derived from data (e.g., relative standing of unit compared to others). How data is coded and presented impacts the degree to which they yield information, as does the capability of users to interpret them.

2) To understand how well the **Feedback Review System** functions. The Feedback Review System turns information into knowledge by putting the information in the hands of those who can interpret it. Knowledge refers to the implications for action derived from information (e.g., increased attention to specific procedures, follow up). Given the decision-making structure in most healthcare organizations, the Feedback Review System needs to involve administrators, physicians, nurses, and other clinicians (e.g., pharmacists), because lack of support by any one of these could prevent effectively moving to the next step, namely, the Problem-Solving System. In a supportive organizational context, the Feedback Review System launches an organizational search for solutions to improve performance.

3) To understand the **Problem-Solving Systems** through which knowledge is translated into organizational learning. Learning, or the use of knowledge to change practices, is evident in the creation and use of new standards, procedures and routines, and mechanisms for ongoing monitoring of changes in patient safety standards and procedures in response to performance feedback. Effective Problem-Solving Systems, in which experiments can be conducted to enhance learning, are characterized by cultural norms supporting care quality rather than bureaucratic formality, positive consequences to dissemination of safety-related information, and a focus on problem-solving rather than blame. Organizations learn not only from their own experiences but also from those of other organizations. Learning can occur not only at the level of individuals, units, and hospitals but between and among participating organizations themselves. Indeed, previous research on implementation of complex organizational change indicates that improved outcomes seldom have a single cause. Rather, it is the co-occurrence of multiple forms of learning (e.g., improved practices, enhanced feedback mechanisms, and organizational supports) that promote successful change.

Feedback mechanisms exist from the Problem-Solving System such that, over time, learning should enhance the capability of both individual users and organizational settings to use the Reporting systems and the Feedback Review Systems, thereby enhancing subsequent Problem-Solving Systems and a sustained reduction in errors and infections.

Scope

Preventable adverse patient events, including nosocomial or hospital-acquired infections and medication errors, are among the nation's most pervasive patient safety problems. The Institute of Medicine reports that adverse patient events are responsible for 44,000-98,000 deaths annually at a cost of $17-$29 billion. The underlying causes of such events are known to be systemic and not necessarily related to individual practitioners. Types of system failures that have been identified include inadequate adverse outcome reporting systems, ineffective analysis and dissemination of findings from the data reported, and unsustainable efforts to identify process changes for reducing adverse patient events. Although the establishment of effective reporting systems capable of compiling credible data is a necessary condition for creating the capacity for change, it is not sufficient. How well and with whom the information is shared are equally crucial for sustaining the system of learning required for long-term improvement of patient safety and overall healthcare delivery.

Background/Context/Settings/Participants. In 1997, members of the Pittsburgh Regional Alliance (PRA), a civic organization composed of influential business leaders, was charged with devising a new regional economic development strategy. To address the region's mounting healthcare problems, the PRA supported the creation of the Pittsburgh Regional Healthcare Initiative (PRHI)—a collaboration of leaders from all major healthcare stakeholder groups in the region. PRHI's diverse membership—38 hospitals, four major insurers, 32 major and small-business healthcare purchasers, hundreds of physicians, dozens of corporate and civic leaders, organized labor, and state government—makes this community effort, to our knowledge, unique among the nation's reinvention efforts. The extraordinary focus and commitment of our members, even in the context of a very competitive healthcare environment, was evidenced by the formal endorsement of PRHI's "Charter Documents" by all major healthcare institutions in Southwestern Pennsylvania as well as by the executives of the region's largest employers.

After a year of study (calendar year 1998), participants agreed upon PRHI's goal: "To achieve the world's best patient outcomes, through superior health system performance, by identifying and solving problems at the point of patient care." PRHI partners identified the following indicators as entry points for the pursuit of patient focused system change.

<u>Perfect Patient Safety</u>:

- The elimination of medication errors
- The elimination of preventable hospital-acquired nosocomial infections.

Incidence/Prevalence. In our view, the operative word in this research demonstration is *system.* Systems are interdependent sets of elements whose qualities influence each other and the larger whole.

Error reduction in organizations involves exploration and evaluation of multiple interrelated systems (Moray, 1994). This study is designed to explore three of the most important systems in organizational learning: Reporting Systems, Feedback Review Systems, and Problem-Solving Systems. Taken together, these systems inform and shape the conventional learning model:

Data → Information → Knowledge → Learning.

Methods

Study Design/Data Sources/Collection/Interventions/Measures/Limitations.

Nosocomial Infections and NNIS. Nosocomial infections (NIs) are neither present nor incubating at the time a patient is admitted to the hospital. NIs have been long recognized as a critical problem affecting the quality of healthcare and a principal source of adverse patient events. NIs occur in 5-10% of patients admitted to acute care facilities in the United States, affecting over 2 million patients annually at a cost in excess of $4.5 billion. In 1995, NIs were responsible for 88,000 deaths in the United States, or one death every 6 minutes. Among all major complications of hospitalization, NIs account for 50%; the remaining are medication errors, patient falls, and other noninfectious adverse events. National NI rates have been systematically collected since 1970 and since then have remained remarkably stable (approximately 5.5 infections per 100 admissions). However, because length of stay of hospitalized patients has significantly decreased over the past 20 years, the rate of NIs per 1,000 patient days has actually increased by over 35% from 1975 to 1995.

PRHI formalized a close working partnership with the Center for Disease Control and Prevention (CDC) to establish a region-wide nosocomial reporting system in Western Pennsylvania. This system was based on the National Nosocomial Infection Surveillance System (NNIS) that has been reporting data on NIs to hospital infection control divisions since its inception in 1970. The 300 participating hospitals of NNIS conduct infection surveillance to (1) determine the frequency and types of NIs in their institutions; (2) identify clusters of infections or single infections of epidemiological significance; (3) identify infections that merit special attention regarding isolation or precaution procedures and/or notification of hospital staff; and (4) identify community-acquired communicable diseases that are required to be reported to the Health Department. CDC uses the data reported to them voluntarily by these hospitals to estimate the magnitude of the healthcare-associated infections problem in the United States and to monitor trends in infections and their related risk factors. Data on risk factors are collected on the entire population of monitored patients. Prior to CDC involvement, only three PRHI participating hospitals used the NNIS system. Despite interest in this system, most hospitals did not meet the CDC's rigid enrollment criteria that disallows most small-sized hospitals. Through a collaborative effort between PRHI and CDC, special arrangements were made to allow participating PRHI facilities of all sizes to report data to the NNIS system. Central Line-Associated Blood Stream Infections (CLABs) in Intensive Care Units (ICUs) represented the initial focus of this evaluation.

Medication Errors and MedMARx. Over 7,000 people in the United States died in 1993 as a result of a medication error, a 2.6 fold increase since 1983. This rise in death rate cannot be completely accounted for by the increase in the frequency of medication use, which rose only 1.4 fold during this period. Adverse Drug Events (ADEs), which can result from a medication error, occur at a rate of 2.4% to 4.6% of admissions.

In October 1999, PRHI completed an extensive evaluative process of reporting systems capable of recording, classifying, and providing evaluative information regarding medication errors. Experts from the region representing physicians, pharmacists, nurses, and information systems assisted PRHI in developing the functional requirements of the "ideal" reporting system. These include (1) reporting systems that incorporate standard definitions for errors; (2) reporting systems that are easy to use; (3) results that can be de-identified to promote the "no blame" philosophy for reporting; and (4) report formats that can represent the aggregate results for each hospital and all hospitals across the region. MedMARx, developed by the United States Pharmacopeia (USP), met the requirements of the evaluation group and was selected as the region-wide reporting tool.

The purpose of MedMARx is to allow hospitals to report, track, and share medication error data in a standardized format, thus providing the foundation for understanding the causes of medication errors and for developing systems-based solutions. To quantify the extent and nature of medication errors, an effective nonpunitive, nonthreatening data collection mechanism is necessary. The MedMARx system is based on the definition of medication error of the National Coordinating Council on Medication Error Reporting and Prevention (NCCMERP). It is clear, inclusive, and credible with healthcare leaders. In this research demonstration, 38 member hospitals used the MedMARx database to collect information on medication errors.

Data Collection for Evaluating the Learning System. In addition to ongoing monitoring of the primary data obtained via the NNIS and MedMARx reporting systems, we used a series of focus groups, key informant Background and Structure Interviews (B/SIs), and unit member surveys to determine whether or not the types of intended actions have been taken and what their impact has been.

To support our goal of working more closely with hospital CEOs in championing the cause of patient safety in their institutions and across the region, the project team completed a series of in-depth hospital case studies designed to enhance our understanding of the role of hospital leadership in patient safety and to develop a leadership model for improving patient safety. Three participating facilities were selected based on their public commitment to patient safety as well as the representative characteristics of their institutions. Data collection was carried out over an ensuing 12-month period.

The project team conducted focus groups with ***MedMARx*** and NNIS report and system users in participating PRHI hospitals. Data collection focused on users' opinions, attitudes, and experiences with the reporting systems as well as the reports.

The focus groups attempted to answer several questions, including (1) how the users interpret the reports; (2) how useful the quarterly reports are to each hospital; (3) how the reports can be improved or changed; and (4) whether the reports are being used effectively at each facility (e.g., translating the information/data contained in the reports into knowledge and learning).

A regional survey to evaluate the patient safety culture at each participating hospital was administered. All 38 hospital partners participated in this survey, which included 10 subscales for assessing the manner in which hospitals were addressing patient safety as well as how influential the Initiative was in each hospital's patient safety culture.

Results

Principal Findings. Prior to the launch of PRHI's nosocomial infection and medication error programs, no shared reporting structure existed among the region's providers. Accordingly, the first focus of PRHI's patient safety programs was the implementation of the most credible data collection platforms available. These capacities were essential, serving as the common foundation to continuously improve work processes, change industry culture, and reach patient outcome goals. In addition, the ability to review data on a region-wide basis enabled PRHI to benchmark progress relative to the rest of the country. Based on shared analysis of regional outcomes data, prevention strategies and interventions were developed for both nosocomial infections and medication errors.

The implementation of both a modified version of the CDC NNIS was implemented. USP ***MedMARx*** was also implemented throughout the region. With the addition of AHRQ supplemental funds, the initial cohort of hospitals engaged in this work was expanded from 30 to 38.

Region-Wide Reporting

Outcomes.

Infections: Twenty-five of 38 hospitals in the region (66%) reported Central Line-Associated Bloodstream (CLAB) infections. The number of CLAB infections in ICUs across the region dropped from a high of 119 infections in the third quarter of 2001 to a low of 98 infections at the time of the last report. This translates to a decrease in the CLAB rate from 4.2 per 1000 central line days to 3.7 per 1000 central line days. The overall Central Line Utilization Ratios (CLUR) rate remained relatively stable during this same period (between 0.45 and 0.50 per central line days).

Additionally, 25 hospitals in the region were reporting hospital-acquired Methicillin-Resistant Staph Aureus (MRSA) infections for ventilator-associated pneumonias (VAPs), primary bloodstream infections (PBSIs), and surgical site infections (SSIs) associated with coronary bypass graft (CABG) and hip and knee replacement surgeries. At the conclusion of the demonstration project, a Pennsylvania state law was enacted that superseded this work, requiring hospitals to report to the Pennsylvania Health Care Cost Containment Council specific hospital infections.

At the conclusion of the demonstration, PRHI was working selectively in the region with hospitals deeply committed to decreasing infection rates.

Medication Errors: At the conclusion of the demonstration, 33 of 38 hospitals in the region (87%) reported errors through the USP's ***MedMARx*** system. Between July 2001 and the conclusion, errors reported to this system by PRHI hospitals consistently increased. Total errors reported approached 20,000 and represented over 6.0% of all reported errors in the Medmarx database nationally.

In 2003, PRHI and the Data Coordinating Center (DCC) deployed the ***MedMARx*** multifacility module among those hospital partners reporting errors through ***MedMARx***. This new system allowed the DCC to retrieve data and give feedback to the hospitals in a more timely and less intrusive manner.

In August and September 2002, the operations field managers at PRHI began pioneering the application of a Real-Time Safety System (RTSS, designed by Paul O'Neill, former Alcoa CEO) in participating hospitals using ***MedMARx***.

Region-Wide Information Sharing

Discussion.

DCC Data Collection and Quarterly Reports: Drawing on data provided voluntarily by hospital partners through the NNIS and ***MedMARx*** reporting systems, PRHI developed and distributed quarterly reports to each participating hospital. These reports included data specific to the facility as well as regional and national data. In addition, the evaluation team developed and administered a survey designed to examine the penetration of the reporting systems within the hospitals. Results indicated that medication error reports were received by 60.9% of respondents, read and reviewed by 69.8% of respondents, and shared with other colleagues by 60% of respondents; nosocomial infection reports were received by 42.9% of respondents, read and reviewed by 43.6% of respondents, and shared with other colleagues by 38.9% of respondents.

Regional Advisory Committees and Working Groups: PRHI had two advisory committees to help promote region-wide information sharing based on the reporting systems: the Infection Control Advisory Committee (ICAC) and the Medication Safety Advisory Committee (MSAC). Advisory committee meetings, which were held monthly, included representatives from all 38 participating hospitals (e.g., infection control professionals or directors of pharmacy and clinical pharmacists, health system representatives, nurses, physicians, risk and quality managers). Meeting formats improved over time such that a significant amount of time was devoted specifically to shared learning.

Additionally, both committees organized into smaller work groups to foster the formation of strong collegial connections and to allow members to review evidence, create consensus, and make recommendations for region-wide improvement initiatives, which were then implemented with the support of the full committee. The evaluation team regularly surveyed the members of ICAC, MSAC, and their related working groups to assess how useful the participants found these meetings and determined what specific shared learning regarding patient safety issues occurred during the meetings.

Of the persons surveyed, 95% reported that they learned something related to patient safety in the meetings. All participants (100%) reported that the policy decisions of the advisory committee and working groups were helpful to their institution.

Region-Wide Problem Solving

Initiatives to Eliminate Infections: PRHI facilitated implementation of an evidence-based initiative to reduce CLABs. The initiative focused on practice targets around IV access, CVC insertion, and catheter site care. The practice targets developed for insertion of central lines were accepted by all participating hospitals. As part of this initiative, all hospitals were expected to train 100% of clinicians who insert central lines. A referenced education module was created and distributed for this purpose. To ensure compliance with recommended practices, the bundling of all necessary items used to safely place central lines (e.g., a chlorhexidine-containing antiseptic product) was recommended.

A second initiative that was developed as the demonstration came to closure sought to reduce MRSA colonizations and infections. This initiative focused on practice targets around identification using active surveillance culturing, appropriate isolation precautions, decolonization protocols (if indicated), and antibiotic control to prevent MRSA.

Initiatives to Eliminate Medication Errors: PRHI developed two evidence-based initiatives for improving medication patient safety practice as a region: safe prescribing and use of fentanyl transdermal patches, and preventing use of unsafe abbreviations. The abbreviation initiative was broad in scope and impacted a large number of patients in Western Pennsylvania. The use of fentanyl was narrow in scope and affected a smaller number of patients. The selection of these two contrasting initiatives enabled PRHI to determine the impact of region-wide reporting, information sharing, and problem solving on the process of medication use (safe abbreviations) and physician behavior related to the safe use of medications (safe fentanyl prescribing).

A third initiative focused on the correct use of PCA pumps.

Case studies

Our case study work yielded important insights into the difficult in improving patient safety: 1) even in organizations seemingly committed to improvement, there is often an absence of specific organizational objectives for patient safety; 2) reliance on ambiguous, inconsistent metrics to assess improvements in patient safety; 3) inefficiencies in structures and processes for learning, and 4) limited role of senior leaders in incident reporting. Viewed as a whole, our observations suggest that current organizational designs do not adequately facilitate the use of data from increased medication error reporting for improving patient safety in the four hospitals studied and, by extension, other similar healthcare organizations. This is not to say that these organizational deficiencies indicate a lack of progress in improving patient safety; rather the potential benefits of increased reporting have not yet been fully realized.

Implementing a design for continuous organizational learning based on incident reporting will remain difficult unless patient safety enters the strategic agenda of the organization and specific change management capabilities are developed. In sum, though patient safety is viewed as an important organizational priority in the hospitals studied, it is not an urgent one. The lack of urgency about patient safety can be inferred from the infrequency of critical learning activities and the time lags between them. Elevating the importance of patient safety would enable the benefits of increased reporting to drive continuous learning, at least partially, but long-term success depends on continued senior management attention and resources.

Conclusions/Significance/Implications. Region-wide reporting of medication errors and nosocomial infections enhanced our region's focus on patient safety as a high-priority issue in healthcare. As described above, these data were used to link processes to outcomes regionwide, with associated shared learning and problem-solving strategies across the region's providers intended to eliminate medication errors and nosocomial infections. Penetration of shared learning and dissemination to new areas of focus was somewhat limited despite high rates of reporting and compliance with reporting efforts by pharmacy and infection control leadership in the region. The healthcare participants of an entire region did learn to work together across competitive barriers to form a unique learning laboratory, but the sustainability of this effort was in question as the program drew to a close, given conflicting priorities and interests for both PRHI and institutional participants.

As described above, redesigning the organizational elements of hospitals to facilitate continuous learning from incident reporting will require the elevation of patient safety to the level of strategic significance and the development of the change management capabilities that are necessary for implementing improvements. In turn, these requirements point to several implications for health care organizations and policy.

Patient safety initiatives must be conceived and implemented using a systems approach where the interdependencies among the various elements of organizational learning are taken into account. Objectives for patient safety must be better specified and challenging so that they spur organizational search for improvements. Patient safety must be assessed using multiple metrics that capture not just a few outcomes and that provide information about learning activities. In particular, metrics must go beyond the reported number of incidents and consider the level of participation (e.g., % of employees reporting incidents during a month), time (e.g., lag between when an incident is reported and when it is resolved), and learning processes (e.g., % errors reported that were resolved). Only by monitoring these metrics can organizations achieve continuous learning. Time required for reporting must be reduced even as the frequency and duration of problem-solving activities must be increased to enable more sophisticated understanding of underlying causes.

Patient safety policies must focus primarily on making the pursuit of patient safety strategically significant to organizations. The specific form this may take remains an open question, with options such as offering lower insurance premiums to healthcare organizations that demonstrably improve patient safety or making data incident reporting public.

In addition, policies must shift their emphasis from data to learning by requiring organizations to review their internal context for data collection, information sharing, problem solving, and process improvement.

CEOs and senior leaders must take on expanded roles in providing a vision for patient safety, creating guiding coalitions of powerful stakeholders in driving the organizational change necessary, and above all participating directly in the learning processes linked to patient safety.

Finally, education and training of healthcare professionals must provide them with knowledge and skills about effective change management.

As documented in the original proposal, the success of PRHI activities was dependent upon fostering an atmosphere of trust, collaboration, and mutual support while at the same time defining and maintaining accountability for the Initiative's objectives. Maintaining a trusting and collaborative atmosphere between competing organizations and PRHI proved to be difficult. A major resulting finding of this effort is that voluntary community-based organizations attempting to draw together multiple institutions cannot get too far ahead of their audience and constituents. PRHI was unable to balance its zeal for rapid improvement with an understanding of the cultural impediments that must be overcome within healthcare to drive rapid improvement. Furthermore, despite early enthusiasm by the purchasing community for this undertaking, an overall inability to remain engaged and focused was an important lost catalyst to the effort. These became major stumbling blocks to sustainability and serve as major lessons for others who may attempt similar future efforts.

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Four additional manuscripts are in preparation at the time of this report.